MERIT MEDICAL SYSTEMS INC
Form 10-K
February 29, 2012
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K
(Mark One)
x Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
for the fiscal year ended December 31, 2011,

or

o 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	0-18592	87-0447695
(State or other jurisdiction of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

1600 West Merit Parkway
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 o No x
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No x
Indicate by check mark whether the registrant (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 x No o
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 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 x No o
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. o
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 x	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant, on June 30, 2011, 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, 2011), was approximately $711,681,890. 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 February 21, 2012, the registrant had 41,999,063 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 23, 2012.

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PART I

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

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This report includes “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). All statements other than statements of historical fact are “forward-looking statements” for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning proposed new products or services, any statements regarding future economic conditions or performance, and any statements of assumptions underlying any of the foregoing. All forward-looking statements included in this report are made as of the date hereof and are based on information available to us as of such date. We assume no obligation to update any forward-looking statement. In some cases, forward-looking statements can be identified by the use of terminology such as “may,” “will,” “expects,” “plans,” “anticipates,” “intends,” “believes,” “estimates,” “potential,” or “continue,” or the negative 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 compliance (or the failure to comply) with federal, state, local or international laws or regulations; product recalls or product liability claims; infringement of our technology or the assertion that our technology infringes the rights of other parties; recent health care reform legislation; the consequences of debt obligations, including the effect of any breach of our credit documents or other agreements; 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; potential reforms or other changes of the regulations administered by the U.S. Food and Drug Administration (the “FDA”); limits on reimbursement imposed by governmental and other programs; laws targeting fraud and abuse in the healthcare industry; violations of the U.S. Foreign Corrupt Practices Act or anti-bribery laws; 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; current domestic and international economic conditions; failure to comply with environmental laws and regulations; 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.

Our operations are divided in the following markets: diagnostic and interventional cardiology, interventional radiology, interventional gastroenterology, interventional pulmonology, thoracic surgery, interventional nephrology, 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.

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.

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PRODUCTS

We design, 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. We have devoted our attention to four primary areas: cardiology, radiology, pulmonology, and gastroenterology. Our products are also used in other clinical areas such as pain management, ear nose and throat physicians ("ENTs"), interventional nephrology, endovascular surgery, and thoracic surgery.

The success of our products is 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, trays and procedural packs at the request of our customers, and our dedication to offering facility-unique solutions in the markets we serve worldwide.

Cardiology and Radiology Products

Interventional cardiology and interventional radiology are specialty disciplines that use many common visualization techniques and therapeutic approaches to treat vascular disease. The common aspect of these two disciplines affords us the opportunity to gain product line efficiencies by serving two distinct therapeutic needs with very similar product platforms. We also recognize the unique aspects of the two disciplines and provide very specific products to serve the unique product needs of physicians practicing in the two disciplines.

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 that can be performed by catheterization involve the insertion of a sheath into the femoral, radial, or brachial artery. Fluoroscopy (real-time moving X-ray images) and computed tomography ("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. In 2011, we introduced the ASAP® Aspiration Catheter, a single extrusion wire braided catheter with a large aspiration lumen to facilitate quick aspiration of emboli and thrombi from tortuous anatomy.

Interventional radiology is related to the minimally invasive treatment of disease in peripheral vessels and organs of the body. Percutaneous peripheral interventions ("PPI") are used to treat peripheral vascular 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. The Blue Diamond™ Digital Inflation Device features a new angled gauge for better viewing. Products like our IntelliSystem® and Monarch® inflation systems (state-of-the-art digital inflation systems), as well as the BasixCOMPAK™ 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 MBA Plus™, and the Passage®.

Vascular Retrieval Devices. The EN Snare® Endovascular Snare System is intended for use in the cardiovascular system or hollow viscous to retrieve and manipulate foreign objects. The EN Snare® is designed with three interlaced loops to increase the probability of foreign body capture and is offered in seven sizes to accommodate a broad range of vessels throughout the body.

Vascular Access Products. We offer a broad line of devices used to gain and maintain vascular access while protecting the clinician from accidental cuts and needle sticks during procedures. 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™ Introducer 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. We offer diagnostic catheters for use during both cardiology and radiology angiographic procedures. Our diagnostic catheter offering includes our Impress® line of peripheral catheters and the Performa® line of cardiology catheters. These catheters offer interventional radiologists and cardiologists superior performance during a variety of angiography procedures.

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Guide Wires and Torque Devices. Our diagnostic guide wires are used to traverse vascular anatomy and aid in placing catheters and other devices. Our pre-coated, high performance InQwire® diagnostic guide wires are lubricious and are available in a wide range of configurations to meet clinicians' diagnostic needs. 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.

Angiography and Angioplasty Accessories. In 2011, we introduced the Flow Control Switch™, an integrated, one-handed, single-channel switch designed with clinician and patient safety in mind. Since the introduction of the CCS™, our 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 VacLok® negative pressure syringe. The most recent line extensions to our syringe product family are frosted and sword-handled Medallion® syringes. Additionally, we offer an extensive line of kits containing fluid management products such as syringes, manifolds, stopcocks, tubing, and disposable pressure transducers (Meritrans®) for measurement of pressures within the vessels and chambers of the heart. The TRAM™ and TRAM-P™ Integrated Transducers 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™ pen and label medication labeling system (which complies with the latest patient safety initiatives of The Joint Commission (formerly known as "JCAHO") are designed to help minimize mix-ups in administering medication. We also offer waste management products to help avoid accidental exposure to contaminated fluids. These include our Occupational Safety and Health Administration ("OSHA") compliant waste disposal basins: the BackStop®, BackStop+™, 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.

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®.

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 Securement 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, Thoracentesis and Pericardiocentesis Catheters. Paracentesis is a procedure to remove fluid that has accumulated in the abdominal cavity (peritoneal fluid). Our One-Step™ Centesis Catheter, Safety Paracentesis

Procedure Tray (“SPPT”) and Thoracentesis and Paracentesis Set (“TAPS”) are designed to provide clinicians with a safe, convenient, and cost-effective method for removing this fluid accumulation. Thoracentesis is a procedure to remove fluid that has accumulated in the pleural space. Our One-Step™ product line includes a valved version of the device. The valved One-Step™ Centesis Catheter and TAPS may also be used to remove the excess fluid in the pleural space during a thoracentesis. Pericardiocentesis is a procedure in which fluid is aspirated from the pericardial sac (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 System and the Mistique® Infusion Catheter. 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.

Embolic Microspheres. In September 2010 we acquired BioSphere Medical, Inc. (“BioSphere”) in a merger transaction. With the acquisition of BioSphere, we now offer embolic microspheres and microsphere delivery systems. Microspheres are precisely-calibrated, spherical, hydrophilic, microporous beads made with acrylic copolymer cross-linked with gelatin. We also

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offer microcatheters and small ("mini") guide wires which are used as delivery systems for the embolic particles. These products include the following:

Embosphere® Microspheres and EmboGold® Microspheres, which are marketed for symptomatic uterine fibroids, 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.

Multipurpose Microcatheters. With our acquisition of BioSphere, we expanded our multi-purpose 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 (through the skin) treatment of uterine fibroids.

Dialysis and Interventional Nephrology. In 2011, we added the Centros® and the CentrosFLO™ split-tipped dialysis catheters to our chronic dialysis line. 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® 30 cm 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.

Interventional Gastroenterology and Pulmonology Products

Airway Stents. Through our Merit Endotek division, we sell a variety of non-vascular stents. Our AERO® and AERO DV® Fully Covered Tracheobronchial Stents are used by interventional pulmonologists, ENTs, and thoracic surgeons. These products offer our customers patented, fully covered, self-expanding metal stents used to improve patency of patient airways-both tracheal and bronchial-and to offer palliation to patients suffering from strictures caused by cancer.

Esophageal and Biliary Stents. The Alimaxx-ES® Fully Covered Esophageal Stent System and the Alimaxx-B® Biliary Stent System are used by interventional gastroenterologists to palliate symptoms associated with malignant tumors affecting the esophagus and the biliary duct. Additionally, we sell a plastic biliary stent that is used 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.

Stent Sizing Device. Merit Endotek also sells the AEROSIZER® tracheobronchial stent sizing device which is used in interventional pulmonology procedures. This proprietary product allows length and diameter measurement accuracy, thus minimizing the possibility of stent mis-sizing and associated cost and complications.

Guide Wires for Non-Vascular Procedures. MAXXWIRE® is a line of specialty guide wires that have pulmonology and gastroenterology applications.

Bipolar Coagulation Probes. Bipolar probes are used by physicians as one means of controlling bleeding within the gastrointestinal tract. Our Brighton™ Bipolar Probe is now sold directly by our Merit Endotek division and our original bipolar probe is sold on an original equipment manufacturer (“OEM”) basis to customers who market them to a large number of gastroenterologists.

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Inflation Devices. Merit Endotek's BIG60™ Inflation Device is a 60ml device designed to inflate and deflate non-vascular balloon dilators while monitoring and displaying inflation pressures up to 12 atmospheres. Merit Endotek also offers Endotek-labeled versions of the BasixCOMPAK™ and Monarch® inflation devices to customers in pulmonology, gastroenterology, and thoracic surgery.

Cholangiography Rapid Refill Continuous Injection Kits. Merit Endotek's BiliQuick™ incorporates a convenient all-in-one kit that is used in gastroenterology to deliver contrast media both quickly and efficiently while eliminating unnecessary time spent refilling the injection syringe. Our Inject10n™ syringe is included in the kit.

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 systems ("MEMS") pressure 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, interventional gastroenterology, interventional pulmonology, ENT, vascular surgery, interventional nephrology, pain management, and thoracic surgery.

According to government statistics, cardiovascular disease continues to be a leading cause of death and a significant health problem in the United States. Treatment options range from dietary changes to surgery, depending on the nature of the specific disease or disorder. Endovascular techniques, including angioplasty, stenting, and endoluminal stent grafts, continue to represent important therapeutic options for the treatment of vascular disease. We derive a large percentage of our revenues from sales of products used during percutaneous 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. Currently, 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.

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.

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We believe our recently-created Endotek division and the move into the areas of interventional gastroenterology, pulmonology, ENT, and thoracic surgery will open up new opportunities to sell, 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 and guide wire 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 and to address the increasing demands of these 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 65%, 68% and 66% of our total sales for the years ended December 31, 2011, 2010 and 2009, respectively. Our direct sales force currently consists of an Executive Vice President of Marketing and Sales, a Vice President of U. S. Sales, 12 regional sales managers and 87 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 division President, Vice President of Sales, Vice President of Marketing, three regional sales managers, and 15 direct sales representatives.

Approximately 400 independent dealer organizations and custom procedure tray manufacturers distribute our products worldwide, including territories in Europe, Africa, the Middle East, Asia, South and Central America, Australia and Canada. We have a President of our Technology Group, based in South Jordan, Utah, who directs our international sales efforts in Asia, South and Central America, Australia and Canada. We have an Executive Vice President 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 30 direct sales representatives, country managers and clinical specialists presently sell our products in Germany, France, the United Kingdom, Belgium, The Netherlands, Denmark, Sweden, Finland, Ireland, Italy and Austria. We employ approximately 30 individuals who support the distribution and sale of our products in China. In 2011, our international sales grew approximately 32% over our 2010 international sales, and accounted for approximately $125.9 million or 35% 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 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. Our worldwide OEM division sells molded components, sub-assembled goods, custom kits, 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. Our OEM division consists of an Executive President of Global OEM, a Vice President of OEM Sales, a staff of regional sales representatives based in the US and Europe, and a dedicated OEM Engineering and Customer Service Group.

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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, and custom procedure tray manufacturers 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 2011, our U.S. sales force made approximately 45% of our sales directly to U.S. hospitals (including 3% for our Merit Endotek division) and approximately 11% of our sales through other channels such as U.S. custom procedure tray manufacturers and distributors. We also sell products to other medical device companies through our U.S. OEM sales force, which accounted for approximately 9% of our 2011 sales. Approximately 35% of our 2011 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 largest customer accounted for approximately four percent of total sales during the year ended December 31, 2011.

RESEARCH AND DEVELOPMENT

We remain committed to new product development by advancing leadership in all of our market segments. In 2011, we launched the ASAP® Aspiration Catheter in the United States which addresses a clinical need in cardiology for improved clot extraction. We also released the Blue Diamond™ Inflation Device for cardiology and radiology with an enhanced visual display and more information for clinicians performing angioplasty procedures. Inflation devices remain an important area in which we continue to innovate for our customers. We also launched the Big60™ Inflation Device for our Merit Endotek division which has a larger volume to facilitate stenting in the gastrointestinal and airway tracts. We anticipate that our research and development growth will continue into 2012 with the initiation of additional projects.

Our research and development expenses were approximately $21.9 million, $15.3 million, and $11.2 million in 2011, 2010 and 2009, respectively. Our research and development activities continue 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; Jackson Township, New Jersey; Galway, Ireland; Paris, France and Venlo, The Netherlands.

During the year ended December 31, 2011, we entered into several asset acquisitions related to research and development projects, which resulted in aggregate expenses of approximately $4.9 million. Since technological feasibility of the underlying research and development projects had not been reached as of December 31, 2011 and such technology had no future alternative to us as of that date, the charge of approximately $4.9 million has been included in the accompanying consolidated statements of operations for the year ended December 31, 2011. We may enter into additional acquisition transactions in future periods.

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 International Standards Organization (“ISO”) 13485:2003

certification for our facilities in Utah, Texas, Virginia, Massachusetts, Ireland and France. We have also received ISO 9001:2008 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 Sensors"), develops and markets silicon pressure sensors. Merit Sensors 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.

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 have also contracted with a third-party manufacturer to produce some of our products at a contract manufacturing facility in

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Mexico.

We have distribution centers located in South Jordan, Utah; Angleton, Texas; Chester, Virginia; Beijing, China; Hong Kong 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 Laboratories, Teleflex, Cook Incorporated, and Terumo Corporation. Medium-size companies we compete with include AngioDynamics, Vascular Solutions, B. Braun, Olympus, Navilyst Medical, Edwards Lifesciences, and ICU Medical.

Our 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, BTG 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 uterine fibroid embolization (“UFE”) are BTG, Boston Scientific, Cook, Cordis Corporation (Johnson & Johnson), 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.

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 market leaders in the United States 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 procedures. Medical professionals are starting to use new 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.

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PROPRIETARY RIGHTS AND PATENT LITIGATION

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, 2011, we owned more than 400 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 for registration of 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 200 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.

A third party has asserted that certain of our product offerings infringe their patents. Monetary judgments, remedies or restitution are often not determined until the conclusion of trial court proceedings, which can be modified on appeal, and are difficult to predict or quantify. While our pending litigation is in its preliminary stages and it is not possible to assess damages or predict an outcome, an adverse outcome could limit our ability to sell certain products or reduce our operating margin on the sale of these products and could have a material adverse effect on our financial position, results of operations or liquidity. We have established defenses and intend to vigorously defend our position.

REGULATION

FDA Regulation. The 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, require a recall, 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 Premarket Review. Subject to certain specific exemptions issued by the FDA, we cannot introduce a new medical device into the market until we obtain market clearance through a 510(k) premarket notification or approval through a pre-market approval (“PMA”) application.

The FDA’s 510(k) clearance procedure is less rigorous than the PMA approval procedure, but is available only to sponsors who 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. 510(k) clearance usually takes between three months and one year from the date a 510(k) notification is submitted, but it may take longer. The FDA may find that substantial equivalence has not been shown and, as a result, require additional clinical or non-clinical testing to support a 510(k) or require a PMA application.

PMA applications must be supported by valid scientific evidence to demonstrate the safety and effectiveness of the subject device. Such evidence typically includes 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 manufacturing process and controls for the device. As part of the PMA application review, the FDA will inspect the manufacturer's facilities for compliance with the FDA's Quality System Regulations ("QSR"). If the FDA approves the PMA, it may place restrictions on the device. 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

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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.

If human clinical trials of a medical device are required for FDA clearance or approval and the device presents a significant risk, the sponsor of the trial must file an investigational device exemption ("IDE") application with the FDA 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 regulations, including the requirement that informed consent 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. On November 29, 2010, the FDA approved a phase 3 clinical trial protocol to treat primary liver cancer with QuadraSphere® Microspheres combined with the chemotherapeutic agent doxorubicin compared to conventional transarterial chemoembolization, or cTACE, with doxorubicin. Enrollment has begun both in Europe and in the United States. Our inability to complete this trial or 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 supplemental 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 certain manufacturing changes, 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 Quality System Regulation ("QSR") and Good Manufacturing Practice ("GMP") 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 the event the malfunction were to recur.

Labeling and Promotion. 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 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. FTC enforcement can result in orders requiring, among other things, limits on advertising, corrective advertising, consumer redress, rescission of contracts and such

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other relief as may be deemed necessary.

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 the 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.

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 Economic Area ("EEA") is subject to compliance with European Medical Device Directives. Under this regime, a medical device may be placed on the market within the EEA if it conforms to certain "essential requirements" and bears the European Conformity ("CE") mark. The most fundamental essential requirement is that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in a suitable manner.

Manufacturers must demonstrate that their devices conform to the relevant essential requirements through a conformity assessment procedure. The nature of the assessment depends upon the classification of the device. The classification rules are mainly based on three criteria: the length of time the device is in contact with the body, the degree of invasiveness and the extent to which the device affects the anatomy. Conformity assessment procedures for all but the lowest risk classification of device involve a notified body. Notified bodies are often private entities and are authorized or licensed to perform such assessments by government authorities. Manufacturers usually have some flexibility to select conformity assessment procedures for a particular class of device and to reflect their circumstances, e.g., the likelihood that the manufacturer will make frequent modifications to its products. Conformity assessment procedures require an assessment of available clinical evidence, literature data for the product and post-market experience in respect of similar products already marketed. Notified bodies also may review the manufacturer's quality systems. If satisfied that the product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity and application of the CE mark. Application of the CE mark allows the product to be distributed throughout the EEA.

Failure to materially comply with applicable EEA and other foreign medical device laws and regulations would likely have a material adverse effect on our business. In addition, the European Commission is currently considering revising the legal framework for medical evidence in the EEA and has announced its intention to proposed new legislation during the course of 2012. If the current EEA and other foreign regulations regarding the manufacture and sale of medical devices change, the new regulations may impose additional obligations on medical device manufactures or otherwise have a material adverse effect on our business.

Reimbursement. Our products are used in medical procedures generally covered by government or private health plans. In general, a third-party payer covers a medical device or procedure only when the plan administrator is satisfied that the product or procedure is reasonable and necessary to the treatment of the patient. Some private payers in the U.S. and government payers in foreign countries may also condition payment on the cost-effectiveness of the treatment. 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 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.

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Patient Protection and Affordable Care Act. In March 2010, the U.S. Congress enacted legislation known as the Patient Protection and Affordable Care Act ("PPACA"), which we anticipate will substantially change the way that health care in the United States is financed by both governmental and private insurers and will 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 PPACA may adversely affect our net revenue for our marketed products and any future products. The new legislation, 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.

The PPACA also includes new reporting and disclosure requirements for device manufacturers with regard to payments or other transfers of value made to health care providers. Reporting under these provisions is scheduled to commence in March 2013, and the first report will relate to payments or other transfers of value made in 2012. Reports submitted under these new requirements will be placed in 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.

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. Certain exceptions, including payments to bona fide employees, certain discounts and certain payments to group purchasing organizations, are provided in the statute and/or have been promulgated through regulation. 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.

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 ("OIG") issued a series of regulations, generally known as "safe harbors." 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 an 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 the sales and marketing activities of pharmaceutical, medical device, and other health-care companies, and recently have brought cases against individuals or entities that 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 adopted statutes or regulations similar to the federal false claims laws, which apply to items and services reimbursed under Medicaid and other state

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programs, or, in several states, apply regardless of the payer. 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.

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 (including most health care providers and health plans), to comply with established standards, including standards regarding the privacy and security of protected health information ("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 associate agreements to which we are a party. Moreover, if we fail to meet our contractual obligations under such agreements, we may incur significant liability.

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. Those state laws that are more protective of individually identifiable health information are not preempted by 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.

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 public and worker health and safety. In the course of our business, we are involved in the handling, storage and disposal of certain chemicals. The laws and regulations applicable to our operations include provisions that regulate the release or discharge of hazardous or other regulated 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. Our operations are also subject to various laws and regulations relating to occupational health and safety. We maintain safety, training and maintenance programs as part of our ongoing efforts to ensure compliance with applicable laws and regulations. Compliance with applicable health and safety laws and regulations has required and continues to require substantial expenditures. Environmental, health and safety legislation and regulations change frequently.

EMPLOYEES

As of December 31, 2011, we employed 2,400 people.

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.

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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:

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

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 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 facilities with respect to compliance with the FDCA, QSRs and similar requirements of foreign countries. Some physicians may be using our products in procedures that are not included in the clearance or approval of the products. If the FDA or any other foreign, federal or state enforcement agency were to conclude that we have improperly promoted our products for uncleared or 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.

On February 1, 2012, Merit Medical Ireland Ltd., one of our wholly-owned subsidiaries ("Merit Ireland"), received a warning letter from the FDA (the "Warning Letter") regarding modifications to the coating process for our Laureate® Hydrophilic Guidewire (the "Guidewire"). In the Warning Letter, the FDA alleged that recent modifications to the Guidewire's coating process constitute a significant change or modification that could significantly affect the safety or effectiveness of the Guidewire. The FDA claimed that the Guidewire is adulterated because we do not have an approved application for premarket approval in effect pursuant to Section 515(a) of the FDCA or an approved application for an investigational device exemption under Section 520(g) of the Act. The Warning Letter also sets forth the FDA's position that the Guidewire is misbranded under Section 502(o) of the FDCA, because we did not notify the FDA of our intent to introduce the modified Guidewire into commercial distribution, as required by Section 510(k) of the Act. The Warning Letter requested that we provide certain information to the FDA regarding modifications to the Guidewire. We have responded to the Warning Letter; however, there can be no assurance that the FDA will accept our response and approve the actions we have taken with respect to the Guidewire or permit us to manufacture, sell, market or distribute the Guidewire in the United States as currently offered and packaged. There can be no assurances regarding the length of time or cost required to resolve these issues to our satisfaction and to the satisfaction of the FDA. Our inability to resolve these issues in a timely manner may further delay Guidewire launch schedules within and to the United States, which may weaken our competitive position in the market for guidewires or other products. If we are unable to favorably resolve the concerns expressed in the Warning Letter, or if we fail to satisfy any other requirements established by the FDA or one or more foreign regulatory authorities, our sales of the Guidewire or other products could be restricted, which could adversely affect our business, operations or financial condition. Furthermore, we may need to devote additional financial and human resources to our efforts to resolve regulatory issues or concerns, and the FDA may elect to take additional regulatory actions.

In addition, we are subject to certain export control restrictions administered by the U.S. Department of the Treasury and may be subject to regulations administered 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.

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

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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 operations or financial condition; however, patients or customers may bring claims in a number of circumstances, including if our products were misused, if our products' 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.

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.

We have been named as a party to a patent infringement lawsuit and are, from time to time, involved in other litigation, regulatory proceedings or other disputes. The outcomes of pending litigation are difficult to predict or quantify. The pending litigation is in its preliminary stages and it is not possible to assess damages or predict an outcome; however, an adverse outcome could limit our ability to sell certain products or reduce our operating margin on the sale of these products. The expense of defending such litigation may be costly and divert our management's attention from the day-to-day operations of our business, which could adversely affect our business, results of operations or cash flows. In addition, an unfavorable outcome in such litigation could negatively impact our business, results of operations or cash flows. Similar infringement claims may be asserted against us in the future related to events not presently known to our management. Because we are self-insured with respect to intellectual property infringement claims, a significant claim against us could have a material adverse effect on our financial position or results of operations.

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 an adverse effect on our business, operations, or financial condition:

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

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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.
- All of our patents will eventually expire, and some of our patents, including patents protecting significant elements of our technology, will expire within the next several years.

Recent 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 was 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% 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. In addition, the costs of compliance with the Patient Protection and Affordable Care Act's new reporting and disclosure requirements with regard to payments or other transfers of value made to health care providers 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.

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 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.

Our breach of any covenants in the Credit Agreement, not otherwise cured, 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 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.

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 currently conducting a clinical trial in an effort to obtain approval from the FDA to claim the use of the QuadraSphere® microspheres for the treatment of a specific disease or condition, such as the treatment of liver cancer in the United States. European Union regulations do not currently require such an application for this class of medical device. In order for us to obtain FDA approval or clearance to promote the use of QuadraSphere® microspheres for the treatment of liver cancer through embolization, we will need to complete our ongoing clinical trial and submit positive clinical data to the FDA. If we cannot enroll study subjects in sufficient numbers to complete the necessary studies, if there is a disruption in the supply of materials for the trial or if any other factors preclude us from completing the trial in a timely manner we will likely not be able to complete our ongoing clinical trial. Even if we complete our current clinical trial, the FDA may require us to undertake additional testing, or the trial results may not be sufficient to obtain FDA approval for other reasons. If we do not obtain FDA approval, we will not be able to promote our QuadraSphere® microspheres for the treatment of specific diseases or conditions (including liver cancer) in the United States.

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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. 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. On January 19, 2011, the FDA announced its "Plan of Action" for implementing these recommendations. The Plan of Action included 25 action items, including revising existing guidance or developing guidance to clarify various aspects of the 510(k) process and to streamline the review process for innovative, lower risk products (the "de novo" process); improving training for the Center for Devices and Radiological Health ("CDRH") staff and industry; increasing reliance on external experts; and addressing and improving internal processes. FDA has already begun implementing many of these reforms, and may implement other reforms in the future, which could have the effect of making it more difficult and expensive for us to obtain 510(k) clearance.

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, and other third-party 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 our business.

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, any of which could adversely affect our business or financial results.

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 experience 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. The FCPA generally prohibits companies and their intermediaries from illegally offering things of value to non-U.S. officials for the purpose of obtaining or retaining business. As we continue to expand our business activities internationally, compliance with the FCPA and other anti-bribery laws presents greater challengers to our operations. If our employees or agents violate the provisions of the FCPA or other anti-bribery laws, we may incur fines or penalties, which could have a material adverse effect on our operating results 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

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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 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 foreign currency exchange rates may negatively impact our financial results.

Our principal market risk relates to changes in the value of the Euro and Great Britain Pound ("GBP") relative to the value of the U.S. Dollar. As our operations have grown outside the United States, we have also become subject to market risk relating to the Chinese Yuan, Hong Kong Dollar and the Swedish and Danish Kroner. Those fluctuations could have a negative impact on our margins and financial results. For example, during 2011, the exchange rate between all applicable foreign currencies and the U.S. Dollar resulted in a decrease in our gross revenues of approximately $1.9 million.

For the year ended December 31, 2011, approximately $59.5 million, or 16.6%, of our sales, were denominated in foreign currencies. If the rate of exchange between the Euro, GBP, Chinese Yuan, Hong Kong Dollar or Swedish or Danish Kroner declines against the U.S. Dollar, we may not be able to increase the prices we charge our customers for products whose prices are denominated

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in Euros, GBP, Chinese Yuan, Hong Kong Dollars or Swedish or Danish Kroner. 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, GBP, Chinese Yuan, Hong Kong Dollars or Swedish or Danish Kroner 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.

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, 2011, sales of our inflation devices (including inflation devices sold in custom kits and through OEM channels) accounted for approximately 19% of our total revenues. Sales of our inflation devices to a single OEM customer, representing our largest customer, were approximately 16% of our total inflation device sales for the year ended December 31, 2011. 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 natural disasters.

Our operations could be affected by many factors beyond our control, including severe weather conditions and natural disasters, including hurricanes and tornadoes. 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

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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 key management personnel, could have a materially adverse effect on 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.

Domestic and international economic conditions could adversely affect our business and results of operations.

We are subject to risks arising from adverse changes in general domestic and global economic conditions, including the current global economic slowdown, European sovereign debt crisis, and disruption of credit markets. There can be no assurance that there will not be further deterioration in global or regional economies. Our customers may experience financial difficulties or be unable to borrow money to fund their operations which may adversely impact their ability or decision to purchase or pay for our products. For example, our customers, particularly in the European region, may extend or delay payments for products already provided, which may lead to collectability concerns with respect to our accounts receivable. The strength and timing of any economic recovery remains uncertain, and we cannot predict to what extent the global economic slowdown and European sovereign debt crisis may negatively impact our average selling prices, our net sales and profit margins, procedural volumes and reimbursement rates from third party payors.

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

We manufacture and assemble certain products that require the use of hazardous materials that are subject to various national, federal, state and local laws and regulations governing the protection of the environment, health and safety. 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. Additionally, because we use hazardous and other regulated materials in our manufacturing processes, we are subject to certain risks of future liabilities, lawsuits and claims resulting from any substances we manufactured, disposed of or released. Any accidental release may have an adverse effect on our business and results of operations. We cannot predict what

additional environmental, health and safety legislation or regulations will be enacted or become effective in the future or how existing or future laws or regulations will be administered or interpreted with respect to our operations, capital expenditures, results of operations or competitive position. Compliance with more stringent laws or regulations or adverse changes in the interpretation of existing laws or regulations by government agencies could have a material adverse effect on our financial position and the results of our operations and could require substantial expenditures.

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 distribution and customer service facility located in Maastricht, The Netherlands. In addition, we lease office space in Washington D.C.; Jackson Township,

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New Jersey; Beijing, Hong Kong and Shanghai, China 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. Our research and development activities are conducted principally at facilities located in South Jordan, Utah; Paris, France; and Galway, Republic of Ireland. The following is an approximate summary of our facilities as of December 31, 2011 (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 August 2010, we acquired approximately five acres of real property located in the Parkmore East Business Park in Galway, Ireland. 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. We anticipate that construction of the new building will be completed during the first quarter of 2012.

In late 2010, we commenced construction of a production, warehouse and administration office building, which will total approximately 253,000 square feet, at our world headquarters in South Jordan, Utah. We anticipate that construction of the new building will be completed in late 2012. In 2011, we completed construction of a parking structure totaling approximately 244,000 square feet located at our world headquarters in South Jordan, Utah.

In August 2011, we acquired approximately twelve acres of property in Pearland, Texas. In December 2011, we commenced construction of a production, clean room, warehouse and administrative office building on the acquired property. The new building will total approximately 117,000 square feet. The new building will be used to relocate our Angleton, Texas, manufacturing facility and is designed to provide better protection from natural disasters, modernized facilities and room for future expansion.

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.

See Note 9 “Commitments and Contingencies” set forth in the notes to our consolidated financial statements included in Item 8 of this Annual Report.

Item 4. Mine Safety Disclosures.

The disclosure required by this item is not applicable.

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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, after giving effect to a stock dividend of one share of our Common Stock that we distributed for every four shares of Common Stock outstanding on May 2, 2011.

For the year ended December 31, 2011	High	Low
First Quarter	$20.10	$14.23
Second Quarter	$24.20	$17.03
Third Quarter	$19.23	$12.52
Fourth Quarter	$14.24	$12.32

For the year ended December 31, 2010	High	Low
First Quarter	$15.88	$11.02
Second Quarter	$13.62	$11.42
Third Quarter	$14.20	$12.38
Fourth Quarter	$13.28	$11.71

As of February 21, 2012, the number of shares of Common Stock outstanding was 41,999,063 held by approximately 140 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 the Credit Agreement.

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PERFORMANCE GRAPH

The following graph compares the performance of the Common Stock with the performance of the NASDAQ Stock Market (U.S. Companies) and NASDAQ Stocks (SIC 3840-3849 U.S. Companies - Surgical, Medical and Dental Instruments and Supplies) for a five-year period by measuring the changes in Common Stock prices from December 31, 2006 to December 31, 2011.

Comparison of 5 Year Cumulative Total Return
Among Merit Medical Systems, Inc., NASDAQ Stock Market (U.S.)
and NASDAQ Stocks (SIC 3840-3849)

	12/2006	12/2007	12/2008	12/2009	12/2010	12/2011
Merit Medical Systems, Inc.	$100	$88	$113	$121	$100	$106
NASDAQ Stock Market (U.S. Companies)	100	108	66	95	113	114
NASDAQ Stocks (SIC 3840-3849 U.S. Companies)	100	135	74	100	107	120

The stock performance graph assumes for comparison that the value of the Common Stock and of each index was $100 on December 31, 2006 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), Center for Research in Security Prices (CRSP®), Graduate School of Business, The University of Chicago. Copyright 2012. Used with permission. All rights reserved.

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SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

The following table contains information regarding our equity compensation plans as of December 31, 2011 (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	4,077(1),(3)	$11.96	1,786(2),(3)

(1) Consists of 4,076,806 shares of Common Stock subject to the options granted under the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan.

(2) Consists of 359,227 shares available to be issued under the Merit Medical Systems, Inc. Qualified and Non-Qualified Employee Stock Purchase Plan and 1,427,000 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.

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Item 6. Selected Financial Data (in thousands, except per share amounts).

	Years Ended December 31,				
	2011	2010	2009	2008	2007
OPERATING DATA:					
Net Sales	$359,449	$296,755	$257,462	$227,143	$207,768
Cost of Sales	193,981	168,257	148,660	133,872	127,977
Gross Profit	165,468	128,498	108,802	93,271	79,791
Operating Expenses:					
Selling, general, and administrative	104,502	87,615	64,787	53,127	48,133
Research and development	21,938	15,335	11,168	9,160	8,688
Acquired in-process research and development	5,838	—	—	—	—
Goodwill impairment charge	—	8,344	—	—	—
Total operating expenses	132,278	111,294	75,955	62,287	56,821
Income From Operations	33,190	17,204	32,847	30,984	22,970
Other Income (Expense):					
Interest income	129	34	178	781	393
Interest expense	(789)	(596)	(28)	(17)	(3)
Other income	345	146	97	97	39
Other income (expense)—net	(315)	(416)	247	861	429
Income Before Income Taxes	32,875	16,788	33,094	31,845	23,399
Income Tax Expense	9,831	4,328	10,564	11,118	7,811
Net Income	$23,044	$12,460	$22,530	$20,727	$15,588
Earnings Per Common Share:					
Diluted	$0.58	$0.35	$0.63	$0.58	$0.44
Average Common Shares:					
Diluted	39,733	35,976	35,758	35,688	35,255
BALANCE SHEET DATA:					
Working capital	$89,857	$72,125	$57,706	$84,283	$60,194
Total assets	447,017	369,480	271,513	231,776	200,420
Line of credit	—	—	7,000	—	—
Long-term debt	30,737	81,538	—	—	—
Stockholders' equity	357,089	235,615	218,809	194,305	164,368

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, Inc. ("Alveolus") acquisition in March of 2009, uncertainty regarding acceptance of new products and continued operating losses for our endoscopy business segment.

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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 Item 8 of this report. Although our financial statements are prepared in accordance with accounting principles which are generally accepted in the United States of America ("GAAP"), our management believes that certain non-GAAP financial measures provide investors with useful information regarding the underlying business trends and performance of our ongoing operations, and can be useful for period-over-period comparisons of such operations. Included in our management's discussion and analysis of our financial condition and results of operation are references to some non-GAAP financial measures. Readers should consider these non-GAAP measures in addition to, not as a substitute for, financial reporting measures prepared in accordance with GAAP. These non-GAAP financial measures exclude some, but not all, items that may affect our net income. Additionally, these financial measures s may not be comparable with similarly-titled measures of other companies.

OVERVIEW

We design, develop, manufacture and market 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. 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.

For the year ended December 31, 2011, we reported record sales of approximately $359.4 million, up approximately $62.7 million or 21.1%, over 2010 sales of approximately $296.8 million. Our base business sales (which exclude BioSphere's embolization device sales) increased 13.5% or approximately $40.5 million for the year ended December 31, 2011, compared to the year ended December 31, 2010. Sales of BioSphere embolization devices accounted for an increase in total sales of 7.5%, or approximately $22.2 million, for the year ended December 31, 2011, compared to the year ended December 31, 2010.

Gross profits as a percentage of sales was 46.0% for the year ended December 31, 2011, compared to 43.3% for the year ended December 31, 2010. The improvement in gross profits was primarily due to an increase in sales of higher-margin BioSphere products and higher prices and unit sales through our distribution system in China.

Net income for the year ended December 31, 2011 was approximately $23.0 million, up 85%, or $.58 per share, compared to approximately $12.5 million or $.35 per share, for the year ended December 31, 2010. Our net income results for 2011 included acquired in-process research and development and stepped-up inventory cost charges of approximately $4.0 million, net of tax, while our 2010 net income results included a goodwill impairment charge of approximately $5.2 million, net of tax, and non-recurring BioSphere acquisition costs including legal, accounting, investment banking, severance and stepped-up inventory costs, net of tax, of approximately $4.3 million. Excluding these items, net income for the years ended December 31, 2011 and 2010 would have been approximately $27.0 million and $22.0 million, respectively.

On June 22, 2011, we completed our first equity offering since 1992 of 5,520,000 shares of Common Stock (the "Equity Offering") and received proceeds of approximately $87.7 million, which is net of approximately $4.6 million in underwriting discounts and commissions and approximately $127,000 in other direct costs incurred and paid by us in connection with this equity offering. In the short term, we used the proceeds of the Equity Offering to pay down

amounts owing under our Credit Agreement and reduce interest costs. In the longer term, we intend to use the portion of our Wells Fargo credit facility that was repaid with the proceeds of the Equity Offering to invest in additional capacity and expansion, new products, and other business development opportunities.

During 2011, we began enrollment of patients into our Hi-Quality Clinical Trial Protocol for the Treatment of Primary Liver Cancer. In 2011, we incurred costs of approximately $553,000 in connection with the trial protocol. We plan to spend a total of approximately $10.0 million over four years to complete this trial. We anticipate that we will spend approximately $3.5 million during 2012 towards this trial.

Our business continues to grow in most of our geographic regions and product groups. As our sales continue to grow in international markets, we plan to continue to expand our product offerings in strategic foreign markets. Our international sales for the year ended December 31, 2011 represented 35% of our total sales, compared to 32% of our total sales for the year ended December 31, 2010. We believe the investments we have made over the past few years in acquisitions and internally-developed

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products are paying off. Our acquisitions are providing best-in-class products, as well as the pull-through of other core products we sell, which has helped accelerate our sales growth.

RESULTS OF OPERATIONS

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

	2011	2010	2009
Net sales	100%	100%	100%
Gross profit	46.0	43.3	42.3
Selling, general, and administrative expenses	29.1	29.5	25.2
Research and development expenses	6.1	5.2	4.3
Acquired in-process research and development	1.6	—	—
Goodwill impairment charge	—	2.8	—
Income from operations	9.2	5.8	12.8
Income before income taxes	9.1	5.7	12.9
Net income	6.4	4.2	8.8

Listed below are the sales by business segment for the years ended December 31, 2011, 2010 and 2009 (in thousands):

	% Change	2011	% Change	2010	% Change	2009
Cardiovascular						
Stand-alone devices	15%	$101,959	16%	$88,586	12%	$76,075
Custom kits and procedure trays	11%	91,532	11%	82,799	12%	74,541
Inflation devices	8%	67,353	2%	62,495	(1)%	61,058
Catheters	23%	55,357	18%	44,824	23%	38,126
Embolization devices	247%	31,229	—	9,003	—	—
Total	21%	347,430	15%	287,707	10%	249,800
Endoscopy						
Endoscopy devices	33%	12,019	18%	9,048	—	7,662
Total	21%	$359,449	15%	$296,755	13%	$257,462

Cardiovascular Sales. Our cardiovascular sales for the year ended December 31, 2011 were approximately $347.4 million, up 20.8%, when compared to the comparable period for 2010 of approximately $287.7 million. Sales were favorably affected by an increase in sales of our embolization devices of approximately $22.2 million, or 7.7%; an increase in sales of our stand-alone devices (particularly our Merit Laureate® Hydrophilic guide wire, hemostasis valves and manifolds) of approximately $13.4 million, or 4.7%; and increased sales of catheter devices (particularly our Prelude® sheath product line, aspiration catheter product line and diagnostic catheter product line) of approximately $10.5 million, or 3.6%. 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 approximately $9.0 million, or 3.6% of sales; and approximately $6.7 million, or 2.7% of sales, related to the EN Snare® products we acquired from Hatch Medical, L.L.C., a Georgia limited liability company, (“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 approximately $6.7 million in EN Snare® sales). Our sales increased during 2011, 2010, and 2009 notwithstanding the fact that the markets for many of our products experienced slight pricing declines as our customers tried to

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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 0.5% in 2011 compared to 2010; decreased sales by 0.3% in 2010 compared to 2009; and decreased sales by 1.0% in 2009 compared to 2008. New products are another source of revenue growth. In 2011, 2010 and 2009, our sales of new products represented 14%, 10%, and 6% of sales, respectively. Included in those sales are revenues from recent acquisitions of 0%, 3% and 3% for 2011, 2010 and 2009, respectively. The third main source of revenue increases came from market share gains in our existing product lines.

Endoscopy Sales. Our endoscopy sales for the year ended December 31, 2011 were approximately $12.0 million, up 33%, when compared to sales in the corresponding period of 2010 of approximately $9.0 million. This increase was due primarily to an increase in sales of approximately $2.4 million of our Aero® Tracheobronchial stent, in large part, accelerated by a competitor's withdrawal from the airway stent market. 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.

International sales for the year ended December 31, 2011 were approximately $125.9 million, or 35% of total sales; international sales for the year ended December 31, 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. The increase in our international sales during 2011 was primarily related to increased sales in Europe Direct of approximately $9.7 million, up 31%, China sales of approximately $8.1 million, up 66%, EMEA distributor sales of approximately $5.6 million, up 46%, and Pacific Rim sales (excluding China) of approximately $4.8 million, up 21%. The increase in our international sales during 2010 was primarily related to increased sales in China, Japan, Germany and the U.K. The previous increase in 2009 over 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 European direct sales were approximately $39.9 million, $29.7 million, and $26.3 million in 2011, 2010, and 2009, respectively.

Our gross profit as a percentage of sales was 46.0%, 43.3%, and 42.3% in 2011, 2010 and 2009, respectively. The increase in gross profit in 2011 was attributable to an increase in sales of higher-margin BioSphere products of approximately 1.9% of sales and higher prices and unit sales through our distribution system in China of approximately .60% of sales. The improvement in gross profit in 2010 was primarily the result of the addition of higher-margin EN Snare® and embolization devices (offset by $1.7 million in costs related to mark-up on finished goods) acquired from Hatch and BioSphere, respectively. 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.

Our selling, general and administrative expenses increased approximately $16.9 million, or 19%, in 2011 compared to 2010; approximately $22.8 million, or 35%, in 2010 compared to 2009; and approximately $11.7 million, or 22%, in 2009 compared to 2008. The increase in selling, general and administrative expenses in 2011 was primarily related to the addition of sales and marketing employees, trade shows, commissions and amortization of intangibles relating to the BioSphere acquisition and starting up our Chinese distribution system. The increase in selling, general and administrative expenses in 2010 was largely the result of our acquisition of BioSphere in September 2010 and subsequent integration expenses (including additional sales representatives, marketing support and advertising costs). In connection with the BioSphere acquisition, we had approximately $2.8 million in non-recurring severance costs and approximately $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 approximately $5.7 million

and the hiring of additional domestic and international sales representatives. Selling, general and administrative expenses as a percentage of sales was 29.1%, 29.5% (27.8% without non-recurring BioSphere acquisition costs), and 25.2% in 2011, 2010 and 2009, respectively.

Research and development expenses increased by 43.1% to approximately $21.9 million in 2011, compared to approximately $15.3 million in 2010. This increase was primarily related to headcount additions to support various new product launches, regulatory costs for seeking product approvals from the U.S. Food and Drug Administration (the “FDA”) and international regulatory agencies, additional regulatory costs incurred for the start-up of our Hi-Quality clinical trial and the development of several new products for our endoscopy product line. Research and development expenses increased 37% to approximately $15.3 million in 2010, compared to approximately $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 approximately $11.2 million in 2009, compared to approximately $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 in March 2009 and to growth in our traditional organic research and development projects, some of which are nearing completion. Our research and development expenses as a percentage of sales were 6.1% for 2011, 5.2% for 2010, and 4.3% for 2009. We have a pipeline of new products

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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 average gross margins that are higher than our historical gross margins.

During 2011, we incurred in-process research and development charges of approximately $5.8 million related to the purchase of several new product technologies. These technologies included the acquisition of intellectual property for a vena cava filter for $1.0 million, flexible sheath technology for approximately $1.9 million, and support guide catheter technology for $2.0 million. In addition to these acquisitions, we abandoned our Vysera biomaterial technology and our Alveolus covered biliary acquired in-process research and development, resulting in a charge of $500,000 and $400,000, respectively.

Our operating profits by business segment for the years ended December 31, 2011, 2010 and 2009 were as follows (in thousands):

	2011	2010	2009
Operating Income (Loss)			
Cardiovascular	$38,010	$30,176	$35,836
Endoscopy	(4,820)	(12,972)	(2,989)
Total operating income	$33,190	$17,204	$32,847

Cardiovascular Operating Income. Our cardiovascular operating income for the year ended December 31, 2011 was approximately $38.0 million, compared to operating income of approximately $30.2 million for the year ended December 31, 2010. This increase was favorably affected by higher sales and gross margins, and was negatively affected by higher selling, general and administrative expenses, research and development expenses and acquired in-process research and development expenses. Our cardiovascular operating income for 2010 was approximately $30.2 million, compared to operating income of approximately $35.8 million for 2009. This decrease in operating income was primarily related to the non-recurring acquisition costs of approximately $6.9 million related to the acquisition of BioSphere.

Endoscopy Operating Loss. Our endoscopy net operating loss from operations for the year ended December 31, 2011 was approximately $4.8 million, compared to an operating loss of approximately $13.0 million for the year ended December 31, 2010. Excluding the abandonment of Vysera biomaterial technology of $500,000 and $400,000 related to our Alveolus covered biliary acquired in-process research and development, our net operating loss for the year ended December 31, 2011 would have been $3.9 million. Excluding a goodwill impairment charge of approximately $8.3 million that we recognized during 2010, our net operating loss for 2010 would have been approximately $4.6 million. Excluding these charges one time charges, the decrease in our 2011 operating loss was favorably affected by higher sales and gross margins, which were partially offset by higher research and development expenses and selling, general and administrative expenses. Our endoscopy net operating loss from operations for 2010 was approximately $13.0 million, compared to an operating loss of approximately $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 continue to invest heavily in expanding our product offering in this business segment in an effort to continue to reduce our operating losses.

Our effective income tax rates for the years ended December 31, 2011, 2010 and 2009 were 30%, 26%, and 32%, respectively. The increase in the effective income tax rate for 2011 compared to 2010 is primarily related to the increased profit of our U.S. operations which are taxed at a higher rate than our foreign operations income (primarily our Irish operations). 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 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.

Our other income (expense) for the years ended December 2011, 2010, and 2009 was approximately ($315,000), ($416,000), and $247,000, respectively. The decrease in other expenses for 2011 over 2010 was primarily the result of cash balances maintained in China which resulted in increased interest income and foreign exchange gains recognized with the appreciation in the Chinese Yuan, all of which was partially offset by higher interest expenses. The increase in other expenses for 2010 over 2009 was principally the result of interest expense of approximately $451,000 on our long-term debt incurred in connection with the

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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.

Our net income for 2011, 2010, and 2009 was approximately $23.0 million, $12.5 million, and $22.5 million respectively. Our 2011 net income included charges related to acquired in-process research and development of approximately $5.8 million, or approximately $3.6 million net of tax, and an increase in the cost of goods sold related to BioSphere's mark-up on finished goods of approximately $724,000, or approximately $442,000 net of tax. Excluding these charges, our 2011 net income would have been approximately $27.0 million, compared to net income for 2010 of approximately $22.0 million, adjusted for non-recurring charges related to goodwill impairment of approximately $5.2 million, net of tax and BioSphere acquisition costs including legal, accounting investment banking, severance and stepped-up inventory costs, net of tax of approximately $4.3 million. This increase in net income was primarily related to 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 and acquired in-process research and development expenses. 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 2009.

LIQUIDITY AND CAPITAL RESOURCES

Capital Commitments and Contractual Obligations

The following table summarizes our capital commitments and contractual obligations as of December 31, 2011, as well as the future periods in which such payments are currently anticipated to become due:

	Payment due by period (in thousands)				
Contractual Obligations	Total	Less than 1 Year	1-3 Years	4-5 Years	After 5 Years
Long-term debt	$30,737	$—	$—	$30,737	$—
Interest on long-term debt (1)	2,066	483	1,134	449	—
Operating leases	19,378	3,444	7,391	2,165	6,378
Royalty obligations	698	100	158	100	340
Total contractual cash	$52,879	$4,027	$8,683	$33,451	$6,718

(1) Interest payments on our variable long-term debt were forecasted using the LIBOR forward curves plus a base of 1.25 percent.

As of December 31, 2011, we had approximately $3.5 million of unrecognized tax positions and $4.6 million of deferred compensation payable 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

At December 31, 2011 and 2010, we had cash and cash equivalents of approximately $10.1 million and $3.7 million respectively, of which $9.0 million and $2.7 million, respectively, were held by foreign subsidiaries. For each of our foreign subsidiaries, we make an assertion as to whether the earnings are intended to be repatriated to the United States or held by the foreign subsidiary for permanent reinvestment. The cash held by our foreign subsidiaries for permanent reinvestment is used to fund the operating activities of our foreign subsidiaries and for further investment in foreign operations. A deferred tax liability has been accrued for the earnings that are available to be repatriated to the United States.

In addition, cash held by our subsidiary in China is subject to local laws and regulations that require government approval for the transfer of such funds to entities located outside of China. As of December 31, 2011 and 2010, we had cash and cash

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equivalents of approximately $5.9 million and $1.6 million, respectively, held by our subsidiary in China.

Our cash flow from operations was approximately $34.0 million in 2011, a decrease of approximately $745,000 over 2010. Our working capital for the years ended December 31, 2011, 2010 and 2009 was approximately $89.9 million, $72.1 million, and $57.7 million respectively. The increase in working capital for 2011 from 2010 was favorably affected by an increase in our cash and inventory balances. 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).

During the year ended December 31, 2011 our inventory balances increased approximately $9.3 million, from approximately $60.6 million at December 31, 2010 to approximately $69.9 million at December 31, 2011. The increase in inventory was largely the result of higher inventory levels of approximately $8.2 million attributable to a 13.5% increase in our base business and an increase in raw materials related to maintaining a one-year supply of resins.

During the year ended December 31, 2010, our inventory balances increased approximately $13.4 million, from approximately $47.2 million at December 31, 2009 to approximately $60.6 million at December 31, 2010. The increase in inventory was primarily related to our acquisition of 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 approximately $38.4 million at December 31, 2008 to approximately $47.2 million at December 31, 2009. The increase resulted from a combination of factors, including the following principal elements: an approximate $3.2 million increase in raw materials, work in 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.

On September 10, 2010, we entered into the Credit Agreement. As of December 31, 2011, Wells Fargo was 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 principal amount of $125 million. Wells Fargo has also agreed to make swing line 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. 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, an earnings before interest, taxes, depreciation and amortization ("EBITDA") ratio, a minimum adjusted consolidated net income, and limits the amount of annual capital expenditures we can incur. Additionally, the Credit Agreement contains various negative covenants with which we must comply, a prohibition on the payment of dividends and limitations respecting: the incurrence of indebtedness, the creation of liens on our property, mergers or similar combinations or liquidations, asset dispositions, investments in subsidiaries, and other provisions customary in similar types of agreements. As of December 31 2011, we were in compliance with all financial covenants set forth in the Credit Agreement.

As of December 31, 2011, we had outstanding borrowings of approximately $30.7 million under the Credit Agreement, with available borrowings of approximately $94.3 million, based on the leverage ratio in the terms of the Credit Agreement. Our interest rate under the Credit Agreement as of December 31, 2011 was a fixed rate of 1.54% on $24.0 million, a fixed rate of 1.55% on $5.0 million and a variable floating rate of 1.84% on approximately $1.7 million. In July 2011, we used $55.0 million of the proceeds from the Equity Offering to pay down the outstanding balance on the Credit Agreement, and we terminated our interest rate swap agreement, which resulted in a cash receipt

of and gain of approximately $28,000 upon final settlement.

Capital expenditures for property and equipment were approximately $59.2 million, $23.6 million, and $18.5 million for the years ended December 31, 2011, 2010 and 2009, respectively. During 2011 and 2010, we spent approximately $36.9 million and $2.0 million, respectively, for the construction of buildings and a parking lot as discussed below. We anticipate that we will spend approximately $54 million in 2012 for property and equipment, of which $34 million will be spent on building construction.

On June 22, 2011, we completed the Equity Offering of 5,520,000 shares of Common Stock and received proceeds of approximately $87.7 million, which is net of approximately $4.6 million in underwriting discounts and commissions. In the short term, we used the proceeds of the Equity Offering to pay down amounts owing under our Credit Agreement and reduce interest costs. In the longer term, we intend to use the portion of our Wells Fargo credit facility that was repaid with the proceeds of the

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Equity Offering to invest in additional capacity and expansion, new products and other business development opportunities. In addition to the proceeds of the Equity Offering, we received approximately $7.2 million in cash related to the exercise of options to acquire approximately 1.1 million shares of common stock and approximately $3.1 million in tax benefits attributable to appreciation of the options exercised during the year ended December 31, 2011.

Historically, we have incurred significant expenses in connection with new facilities, production automation, product development and the introduction of new products. Over the last three years, we spent a substantial amount of cash in connection with our acquisition of certain assets and product lines ($10.3 million to acquire the assets of Ash Access Technology, Inc., and AAT Catheter Technologies, LLC, among other transactions, during 2011, approximately $96.0 million to acquire BioSphere in September 2010, and $46.2 million to acquire the assets of Alveolus and Hatch, among other transactions, during 2009). We are in the process of constructing three new production facilities in South Jordan, Utah, Galway, Ireland, and Pearland, Texas. During 2011, we also finished construction of a parking terrace in South Jordan, Utah. The total anticipated cost of these construction projects is approximately $78 million. As of December 31, 2011, we had incurred total costs of approximately $38.9 million with respect to those construction projects. In the event we pursue and complete significant 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:

Inventory Obsolescence. 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 adjustments 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, 2011, 2010 and 2009, we recorded obsolescence expense of approximately $1.5 million, $1.9 million and $1.5 million, respectively, and wrote off approximately $1.1 million, $1.1 million and $1.3 million, respectively. Based on this historical trend, we believe that our inventory balances as of December 31, 2011 had been accurately adjusted for any 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. custom procedure tray manufacturers 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.

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Stock-Based Compensation. We measure stock-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 and Contingent Consideration. 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 of goodwill balances in 2010, which was completed during the third quarter, 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 our annual test of goodwill balances in 2011, which was completed during the third quarter, we determined that the fair value of each reporting unit with goodwill exceeded the carrying amount by at least 40%.

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.

Contingent consideration is an obligation by the buyer to transfer additional assets or equity interests to the former owner upon reaching certain milestone payments. We have entered into asset purchase agreements which will require us to pay additional purchase consideration upon reaching certain revenue-based milestones and/or future royalties based on a percentage of related product sales. In connection with a business combination, any contingent consideration is recorded on the acquisition date based upon the consideration expected to be transferred in the future. We utilize a probability-weighted discounted cash flow method in valuing the contingent consideration. We re-measure this liability each quarter and record changes in the estimated fair value through operating expense in our consolidated statements of income. Significant increases or decreases could result in the estimated fair value of our contingent consideration liability, as the result of changes in the timing and amount of revenue estimates, as well as changes in the discount rate or periods.

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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. We also have a limited market risk relating to the Chinese Yuan, Hong Kong Dollar and the Swedish and Danish Kroner. Our consolidated financial statements are denominated in, and our principal currency is, the U.S. Dollar. For the year ended December 31, 2011, a portion of our revenues (approximately $59.5 million, representing approximately 16.6% of our aggregate revenues), was attributable to sales that were denominated in foreign currencies. All other international sales were denominated in U.S. Dollars. Certain of our expenses for the year ended December 31, 2011 were also denominated in foreign currencies, which partially offset risks associated with fluctuations of exchange rates between foreign currencies on the one hand, and the U.S. Dollar on the other hand. During the year ended December 31, 2011, the exchange rate between our foreign currencies against the U.S. Dollar resulted in an increase in our gross revenues of approximately $1.9 million, or .53%, and a decrease of .15% in gross profit, as result of our increase in Irish manufacturing operation cost which are denominated in Euro.

On November 30, 2011, we forecasted a net exposure for December 31, 2011 (representing the difference between Euro and GBP-denominated receivables and Euro-denominated payables) of approximately 12,000 Euros and 328,000 GBPs. In order to partially offset such risks at November 30, 2011, we entered into a 30-day forward contract for the Euro and GBP with a notional amount of approximately 12,000 Euros and notional amount of 328,000 GBPs. 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 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. 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, 2011, 2010 and 2009, we recorded a net gain on all forward contracts of approximately $221,000, $126,000 and $83,000, respectively, which is included in other income in the accompanying consolidated statements of income. The fair value of our open positions at December 31, 2011 and 2010 was not material.

As discussed in Note 7 to our consolidated financial statements, as of December 31, 2011, we had outstanding borrowings of approximately $30.7 million under the Credit Agreement. Accordingly, our earnings and after-tax cash flow are affected by changes in interest rates. 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 $307,000 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 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.

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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, 2011 and 2010, and the related consolidated statements of income, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2011. 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, 2011 and 2010, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, 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.

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, 2011, 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 February 29, 2012, expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Salt Lake City, Utah
February 29, 2012

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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2011 AND 2010
(In thousands)

	2011	2010
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$10,128	$3,735
Trade receivables — net of allowance for uncollectible accounts — 2011 — $464 and 2010 — $593	40,550	37,362
Employee receivables	154	110
Other receivables	1,750	1,242
Inventories	69,911	60,597
Prepaid expenses	3,775	2,089
Prepaid income taxes	883	452
Deferred income tax assets	3,704	4,647
Income tax refund receivable	2,797	2,067
Total current assets	133,652	112,301
PROPERTY AND EQUIPMENT:		
Land and land improvements	16,288	12,586
Buildings	59,905	50,274
Manufacturing equipment	103,629	92,839
Furniture and fixtures	22,559	18,313
Leasehold improvements	12,659	12,121
Construction-in-progress	47,534	13,775
Total property and equipment	262,574	199,908
Less accumulated depreciation	(83,434)	(71,853)
Property and equipment — net	179,140	128,055
OTHER ASSETS:		
Intangible assets:		
Developed technology — net of accumulated amortization — 2011 — $4,759 and 2010 — $2,301	35,415	34,273
Other — net of accumulated amortization — 2011 — $10,215 and 2010 — $6,695	21,254	22,911
Goodwill	61,144	58,675
Deferred income tax assets	5,366	4,140
Marketable securities	2,798	—
Other assets	8,248	9,125
Total other assets	134,225	129,124
TOTAL	$447,017	$369,480

See notes to consolidated financial statements. (Continued)

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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2011 AND 2010
(In thousands)

	2011	2010
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$22,727	$20,092
Accrued expenses	20,197	18,890
Advances from employees	225	307
Income taxes payable	646	887
Total current liabilities	43,795	40,176
LONG-TERM DEBT	30,737	81,538
DEFERRED INCOME TAX LIABILITIES	2,112	1,267
LIABILITIES RELATED TO UNRECOGNIZED TAX BENEFITS	3,489	3,527
DEFERRED COMPENSATION PAYABLE	4,585	4,258
DEFERRED CREDITS	1,984	1,763
OTHER LONG-TERM OBLIGATIONS	3,226	1,336
Total liabilities	89,928	133,865
COMMITMENTS AND CONTINGENCIES (Notes 2, 7, 8, 9 and 13)		
STOCKHOLDERS' EQUITY:		
Preferred stock — 5,000 shares authorized as of December 31, 2011 and 2010; no shares issued		
Common stock, no par value; shares authorized — 2011 and 2010 - 100,000; issued and outstanding as of December 31, 2011 - 42,008 and December 31, 2010 - 35,496	166,231	67,091
Retained earnings	190,708	167,664
Accumulated other comprehensive income	150	860
Total stockholders' equity	357,089	235,615
TOTAL	$447,017	$369,480

See notes to consolidated financial statements. (Concluded)

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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF INCOME
YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009
(In thousands, except per share amounts)

	2011	2010	2009
NET SALES	$359,449	$296,755	$257,462
COST OF SALES	193,981	168,257	148,660
GROSS PROFIT	165,468	128,498	108,802
OPERATING EXPENSES:			
Selling, general, and administrative	104,502	87,615	64,787
Research and development	21,938	15,335	11,168
Acquired in-process research and development	5,838	—	—
Goodwill impairment charge	—	8,344	—
Total operating expenses	132,278	111,294	75,955
INCOME FROM OPERATIONS	33,190	17,204	32,847
OTHER INCOME (EXPENSE):			
Interest income	129	34	178
Interest expense	(789)	(596)	(28)
Other income	345	146	97
Other income (expense) — net	(315)	(416)	247
INCOME BEFORE INCOME TAXES	32,875	16,788	33,094
INCOME TAX EXPENSE	9,831	4,328	10,564
NET INCOME	$23,044	$12,460	$22,530
EARNINGS PER COMMON SHARE:			
Basic	$0.59	$0.35	$0.64
Diluted	$0.58	$0.35	$0.63
AVERAGE COMMON SHARES:			
Basic	39,086	35,290	35,014
Diluted	39,733	35,976	35,758

See notes to consolidated financial statements.

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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009
(In thousands)

	Total	Common Stock Shares	Common Stock Amount	Retained Earnings	Accumulated Other Comprehensive Income (Loss)
BALANCE — January 1, 2009	$194,305	35,116	$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	30	353		
Warrants exercised	517	64	517		
Options exercised	1,920	385	1,920		
Stock repurchased and retired	(2,474)	(313)	(2,474)		
Shares surrendered in exchange for payment of payroll tax liabilities	(254)	(29)	(254)		
Shares surrendered in exchange for the exercise of stock options	(230)	(27)	(230)		
BALANCE — December 31, 2009	$218,809	35,226	$63,690	$155,204	$ (85)
Comprehensive income:					
Net income	12,460			12,460	
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	31	378		
Options exercised	1,330	239	1,330		
BALANCE — December 31, 2010	$235,615	35,496	$67,091	$167,664	$ 860
Comprehensive income:					
Net income	23,044			23,044	
Interest rate swap, net of tax of $451	(708)				(708)
Unrealized gain on marketable securities, net of tax of $115	180				180

Foreign currency translation adjustment	(182)				(182)
Total comprehensive income	22,334				
Tax benefit attributable to appreciation of common stock options exercised	3,122		3,122		
Stock-based compensation expense	1,644		1,644		
Issuance of common stock, net of offering costs	87,700	5,520	87,700		
Options exercised	8,449	1,099	8,449		
Issuance of common stock under Employee Stock Purchase Plans	430	31	430		
Shares surrendered in exchange for payment of payroll tax liabilities	(953)	(60)	(953)		
Shares surrendered in exchange for exercise of stock options	(1,252)	(78)	(1,252)		
BALANCE — December 31, 2011	$357,089	42,008	$166,231	$190,708	$ 150

See notes to consolidated financial statements.

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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009
(In thousands)

	2011	2010	2009
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	$23,044	$12,460	$22,530
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	19,194	14,856	12,271
Losses on sales and/or abandonment of property and equipment	31	533	271
Write-off of patents and license agreement	103	134	154
Goodwill impairment charge	—	8,344	—
Acquired in-process research and development	5,838	—	—
Amortization of deferred credits	(106)	(111)	(120)
Purchase of trading investments	—	(644)	(458)
Unrealized gains on trading investments	—	(382)	(561)
Deferred income taxes	1,677	(554)	1,791
Tax benefit attributable to appreciation of common stock options exercised	(3,122)	(399)	(987)
Stock-based compensation expense	1,644	1,294	1,182
Changes in operating assets and liabilities, net of effects from acquisitions:			
Trade receivables	(3,323)	(2,088)	(2,131)
Employee receivables	(62)	29	(16)
Other receivables	(245)	223	(13)
Inventories	(9,314)	(7,614)	(6,882)
Prepaid expenses	(1,726)	(192)	(571)
Prepaid income taxes	(431)	(60)	—
Income tax refund receivable	(733)	(1,573)	319
Other assets	(283)	(43)	(568)
Trade payables	(2,129)	5,643	296
Accrued expenses	1,334	3,090	1,628
Advances from employees	(65)	99	—
Income taxes payable	2,658	1,037	825
Liabilities related to unrecognized tax benefits	(226)	(372)	114
Deferred compensation payable	327	876	1,034
Other long-term obligations	(70)	174	(38)
Total adjustments	10,971	22,300	7,540
Net cash provided by operating activities	34,015	34,760	30,070
CASH FLOWS FROM INVESTING ACTIVITIES:			
Capital expenditures for:			
Property and equipment	(59,195)	(23,648)	(18,478)
Patents and trademarks	(2,077)	(1,083)	(1,191)

Purchase of marketable securities	(2,503)	—	—
Proceeds from the sale of marketable securities	—	9,673	—
Proceeds from the sale of property and equipment	5	17	27
Cash paid in acquisitions, net of cash acquired	(10,250)	(97,785)	(46,150)
Net cash used in investing activities	(74,020)	(112,826)	(65,792)

See notes to consolidated financial statements.

(Continued)

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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009
(In thousands)

	2011	2010	2009
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock	$95,454	$1,708	$2,560
Payment of offering costs related to issuance of common stock	(127)	—	—
Proceeds from issuance of long-term debt	104,585	108,491	—
Payments on long-term debt	(155,386)	(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	3,122	399	987
Long-term debt issuance costs	—	(522)	—
Payment of taxes related to an exchange of common stock	(953)	—	(254)
Common stock repurchased and retired	—	—	(2,474)
Net cash provided by financing activities	46,695	76,123	7,819
EFFECT OF EXCHANGE RATES ON CASH	(297)	(455)	6
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	6,393	(2,398)	(27,897)
CASH AND CASH EQUIVALENTS:			
Beginning of year	3,735	6,133	34,030
End of year	$10,128	$3,735	$6,133
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION			
Cash paid during the year for:			
Interest (net of capitalized interest of $299, $13 and $0, respectively)	$509	$512	$26
Income taxes	$7,023	$6,050	$8,215
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES			
Property and equipment purchases in accounts payable	$8,849	$3,778	$2,724
Acquisition purchases in other long term obligations	$1,270	$250	$—
Merit common stock surrendered (78, 0 and 27 shares, respectively) in exchange for exercise of stock options	$1,252	$—	$230

See notes to consolidated financial statements. (Concluded)

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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2011, 2010 and 2009

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization. Merit Medical Systems, Inc. ("Merit," "we" or "us,") 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.

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:

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Customer lists	5 - 15 years
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, 2011, 2010 and 2009.

Property and Equipment. Property and equipment is stated at the historical cost of construction or purchase. Construction costs include 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 new buildings and 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 is computed using the straight-line method over estimated useful lives as follows:

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

Depreciation expense related to property and equipment for the years ended December 31, 2011, 2010 and 2009 was approximately $13.2 million, $11.4 million, and $10.0 million, respectively.

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 $4.8 million and $4.3 million at December 31, 2011 and 2010, respectively, which is included in other assets in our consolidated balance sheets. We have recorded a deferred compensation payable of approximately $4.6 million and $4.3 million at December 31, 2011 and 2010, respectively, to reflect the liability to our employees under this plan.

Marketable Securities. Marketable securities consist entirely of available-for-sale equity securities. As of December 31, 2011, these equity securities had a cost basis of approximately $2.5 million, fair value of approximately $2.8 million, and gross unrealized gains that are included in accumulated other comprehensive income of approximately $295,000. There were no gross unrealized losses as of December 31, 2011.

Other Assets. As of December 31, 2011, other assets consisted 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, unamortized debt issuance costs and a long-term income tax refund receivable. As of December 31, 2010, other assets also included the fair value of an interest rate swap.

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 procedure tray manufacturers 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

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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, 2011, 2010 and 2009. 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 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, 2011, 2010 and 2009 was approximately $1.6 million, $1.3 million and $1.2 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 custom procedure tray manufacturers 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%, 4% and 6% of total sales for the years ended December 31, 2011, 2010 and 2009, 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

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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 used 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 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). As of December 31, 2011, accumulated other comprehensive income (loss) included approximately $180,000 (net of tax of $115,000) related to unrealized gains on marketable securities and $(30,000) related to foreign currency translation. As of December 31, 2010, accumulated other comprehensive income included approximately $708,000 (net of tax of $451,000) related to an interest rate swap and $152,000 related to foreign currency translation.

Recently Issued Financial Accounting Standards. In September 2011, the Financial Accounting Standards Board ("FASB") issued authoritative guidance related to testing goodwill for impairment. This guidance provides that entities may first assess qualitative factors to determine whether it is necessary to perform the two-step goodwill impairment test. If the qualitative assessment results in a more than 50% likely result that the fair value of a reporting unit is less than the carrying amount, then the entity must continue to apply the two-step impairment test. If the entity concludes the fair value exceeds the carrying amount, then neither of the two steps in the goodwill impairment test is required. This guidance is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011 with early adoption permitted. We are currently evaluating the impact of adopting this guidance on our consolidated financial statements.

In June 2011, the FASB issued authoritative guidance on the presentation of comprehensive income. This guidance specifies that an entity has the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both choices, an entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. This guidance does not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. It also does not change the presentation of related tax effects, before related tax effects, or the portrayal or calculation of earnings per share. This guidance is to be applied retrospectively and is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. We are currently evaluating the impact of adopting this guidance on our consolidated financial statements.

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. We adopted this guidance during the year ended December 31, 2011, the adoption of which did not have a material effect on our consolidated financial statements.

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 nor third-party evidence is available. We adopted this guidance prospectively for revenue arrangements entered into or materially modified after January 1, 2011, the adoption of which did not have a material effect on our consolidated financial statements.

2. ACQUISITIONS

On September 2, 2011, we entered into an Asset Purchase Agreement with Ash Access Technology, Inc. (“Ash Access”), an Indiana corporation, and AAT Catheter Technologies, LLC (“AAT”), an Indiana limited liability corporation (collectively “Ash”), to purchase intellectual property rights with respect to various dialysis catheters. We made an initial payment of $5.0 million to Ash in September 2011. We are obligated to pay an additional $1.0 million upon reaching a certain milestone set forth in the purchase agreement and future royalties based on a percentage of related product sales. We accounted for this acquisition as a business combination. The acquisition-date fair value of these contingent liabilities has been included as part of the purchase consideration. Acquisition-related costs during the year ended December 31, 2011, respectively, which are included in selling, general and administrative expense in the accompanying consolidated statements of operations, were not material. During the year

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ended December 31, 2011, sales subsequent to the acquisition date related to our dialysis catheter acquired were not material. The purchase price was preliminarily allocated as follows (in thousands):

Assets Acquired	
Property and equipment	$73
Intangibles	
Developed technology	3,200
Customer lists	300
Goodwill	2,697
Total assets acquired	6,270
Liabilities Assumed	
Contingent liabilities	1,270
Net assets acquired	$5,000

With respect to the assets we acquired from Ash, we intend to amortize developed technology over 15 years and customer lists on an accelerated basis over two years. The total weighted-average amortization period for these acquired intangible assets is nine years. The assets and liabilities related to this acquisition are included in our cardiovascular segment.

Pro forma consolidated financial results for the Ash acquisition discussed above have not been included in our consolidated financial results because we believe their effects would not be material.

On June 20, 2011, we acquired the intellectual property rights to certain vena cava filter technology. We made an initial payment of $1.0 million in June 2011, and we are obligated to pay up to an additional $3.5 million if certain milestones set forth in the agreement are reached related to further research and development activities and regulatory approval of the vena cava filter.

On July 18, 2011, we acquired the intellectual property rights to certain introducer sheath technology. We made an initial payment of $1.0 million in July 2011, and we are obligated to pay an additional $1.0 million upon the earlier of the commercialization of the product or the third anniversary of the effective date of the agreement. The discounted liability of $948,000 has been reflected in our consolidated balance sheets as a long-term liability as of December 31, 2011.

On December 15, 2011, we acquired the intellectual property rights to certain support guide catheter technology. We made an initial payment of $2.0 million in December 2011, and we are obligated to pay up to an additional $3.0 million if certain obligations and milestones set forth in the agreement are performed or reached related to further research and development activities and regulatory approval of the support guide catheter.

Each of these three transactions discussed above represented an asset acquisition related to a research and development project and a not business combinations. A total charge of approximately $4.9 million related to these acquired in-process research and development assets has been included in the accompanying consolidated statements of operations for the year ended December 31, 2011, since technological feasibility of the underlying research and development projects had not yet been reached and such technology had no future alternative use.

On September 10, 2010, we completed our acquisition of BioSphere in an all-cash merger transaction valued at approximately $95.7 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 the acquisition of BioSphere gives us a platform technology applicable to

multiple therapeutic areas with significant market potential while leveraging existing interventional radiology call points. The gross amount of trade receivables we acquired from BioSphere was approximately $4.6 million, of which $51,000 was 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 the BioSphere acquisition in our cardiovascular segment. It is not practical to separately report the earnings related to the BioSphere acquisition, as we cannot split out sales costs related to Biosphere's products, principally because our sales representatives are selling multiple products (including BioSphere products) in the cardiovascular business segment. As of December 31, 2010, the BioSphere purchase price was allocated as follows (in thousands):

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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

During the year ended December 31, 2011, the goodwill related to the BioSphere acquisition was decreased by approximately $228,000. The change was primarily due to BioSphere tax adjustments including items related to the BioSphere 2010 income tax return, which was finalized during the third quarter of 2011.

With respect to the BioSphere assets, we intend to amortize developed technology over 15 years, 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 primarily of loan origination fees and legal costs that we intend to amortize over five years, which is the contract term of our unsecured Credit Agreement, dated September 10, 2010 with Lenders who are or may become party thereto and Wells Fargo, as administrative agent for the Lenders. We also incurred approximately $86,000 and $2.5 million of acquisition-related costs during the years ended December 31, 2011 and 2010, respectively, which are included in selling, general and administrative expense in the accompanying consolidated statements of operations.

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 intend to amortize the customer lists on an accelerated basis over 10 years.

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 2010, a second payment of $250,000 in May 2010, a third payment of $250,000 in November 2010 and a final payment of $250,000 in August 2011. We have included the $1.0 million intangible asset in developed technology and intend to amortize the asset over an estimated life of 10 years.

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The following table summarizes our consolidated results of operations for the years ended December 31, 2010 and 2009, as well as the 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	$0.35	$0.21	$0.64	$0.49
Diluted	$0.35	$0.20	$0.63	$0.48

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 entered into an Exclusive License, Development and Supply Agreement with Vysera Biomedical Limited ("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, which we intend to amortize over 15 years. During 2011, we abandoned our Vysera coating technology of $500,000, which has been included in the accompanying consolidated statements of operations in acquired in-process research and development. On April 6, 2011, we supplemented and amended our Exclusive License, Development and Supply Agreement with Vysera to include the manufacturing rights for Vysera's valve technology. We made an initial payment of $500,000 in April 2011 and a final payment of $500,000 in August of 2011. We have recorded the $1.0 million intangible asset as developed technology for purposes of our consolidated balance sheet and we intend to amortize it over an estimated life of 10 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	—

Net assets acquired	$21,000

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.

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On February 18, 2009, we entered into an Asset Purchase Agreement with 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 was expected to be uncollectible. Our consolidated financial statements for the year ended December 31, 2009 reflect sales subsequent to the acquisition date 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