

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



13003341

FORM SE

FORM FOR SUBMISSION OF PAPER FORMAT EXHIBITS  
BY EDGAR ELECTRONIC FILERS

Merit Medical Systems, Inc.  
Exact name of registrant as specified in charter

0000856982  
Registrant CIK Number

Annual Report to Shareholders for fiscal year ended Dec. 31, 2012  
Electronic report, schedule or registration statement  
of which the documents are a part (give period of report)

000-18592  
SEC file number, if available

S- \_\_\_\_\_  
(Series identifier(s) and names(s), if applicable; add more lines as needed)

SEC  
Mail Processing  
Section

C- \_\_\_\_\_  
(Class (contract) identifier(s) and names(s), if applicable; add more lines as needed)

APR 12 2013

Fiscal year ended Dec. 31, 2012  
Report period (if applicable)

Washington DC  
401

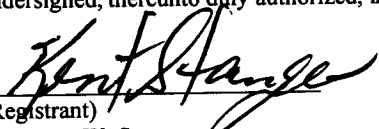
\_\_\_\_\_  
Name of person filing this exhibit (if other than the registrant)

Identify the provision of Regulation S-T (§232 of this chapter) under which this exhibit is being filed in paper (check only one):  
 Rule 201 (Temporary Hardship Exemption)  
 Rule 202 (Continuing Hardship Exemption)  
 Rule 311 (Permitted Paper Exhibit)

SIGNATURES

*Filings Made By the Registrant:*

The Registrant has duly caused this form to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of South Jordan, State of Utah, on April 11, 2013.

  
(Registrant)  
By: Kent W. Stanger,  
Chief Financial Officer, Secretary and Treasurer

*Filings Made by Person Other Than the Registrant:*

After reasonable inquiry and to the best of my knowledge and belief, I certify on \_\_\_\_\_, 20\_\_\_\_, that the information set forth in this statement is true and complete.

By: \_\_\_\_\_

Title: \_\_\_\_\_

SEC 2082 (11-11)

Persons who respond to the collection of information contained  
in this form are not required to respond unless the form displays  
a currently valid OMB control number.

SEC  
Mail Processing  
Section

APR 12 2013

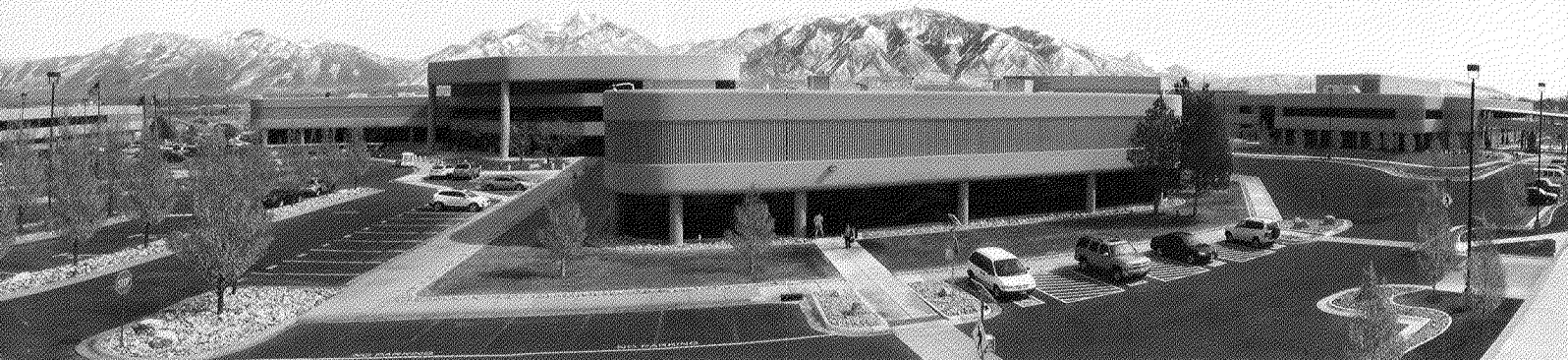
Washington DC  
401

opening  
new doors to  
innovation



**MERTMEDICA™**

2012 ANNUAL REPORT



Dear Shareholders,

The year 2012 was a busy one for Merit as we laid the groundwork for continued growth, innovation, productivity and capacity in 2013.

During 2012, we achieved record revenues of \$394.3 million, with growth in all areas of our business. As many companies in our sector are struggling to grow, our sales grew 10%, with our core business up 9% for the year.

A substantial portion of our growth came from international markets. This was primarily a result of the investments we have made over the last several years in China, Brazil, India, Russia, the Gulf States and other emerging markets.

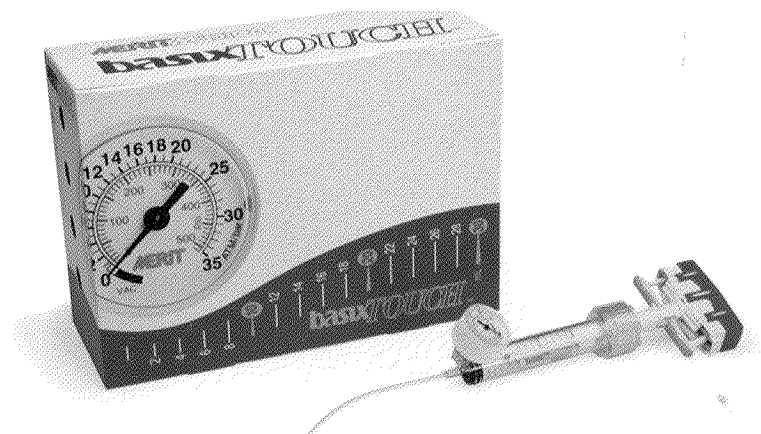
During 2012, we acquired the assets of Ostial Solutions, LLC, a privately-held company based in Kalamazoo, Michigan. The primary asset we acquired from Ostial Solutions is the patented Ostial Pro Stent Positioning System®, which facilitates precise stent implantation in coronary and renal aorto-ostial lesions and reduces guesswork when deploying a stent at the “true” ostium of the vessel. We believe this product will complement many of our existing products, as well as anticipated future products.

We also acquired substantially all of the assets of Medigroup, Inc., a manufacturer of peritoneal dialysis catheters based in Illinois. The Medigroup assets represent a broad product line of catheters and implantation devices, and we believe this opportunity will enhance our overall dialysis business.

Additionally, we acquired Thomas Medical, Inc., formerly a unit of GE Healthcare, which designs and manufactures catheter-based vascular access delivery devices for diagnostic and therapeutic procedures in electrophysiology (“EP”), cardiac rhythm management (“CRM”), interventional cardiology and interventional radiology applications, primarily on an OEM basis. We believe Thomas Medical’s products are recognized as “gold standard” by many of the leading CRM and EP market participants.

We have identified substantial growth and pull-through opportunities from the Thomas Medical acquisition, and we believe the transaction will help expand our market presence into new product categories, particularly in interventional cardiology.

We expect to launch a number of internally developed products this year, including the basixTOUCH™ inflation device, the PHD™ Hemostasis Valve, the ConcierGE® Guiding Excellence Catheter, the PreludeEASE™ Hydrophilic Radial Sheath, the ASAP LP™ Aspiration Catheter, the Bearing™ NS PVA Embolization Particles and the EndoMAXX EVT™ Esophageal Stent.



continued on back page

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

FORM 10-K

(Mark One)

- Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2012,  
or  
 Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

**MERIT MEDICAL SYSTEMS, INC.**

(Exact name of registrant as specified in its charter)

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

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

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

**1600 West Merit Parkway**  
**South Jordan, Utah 84095**

(Address of principal executive offices, including zip code)  
Registrant's telephone number, including area code: **(801) 253-1600**

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

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant, on June 30, 2012, 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, 2012), was approximately \$548,850,112. 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 26, 2013, the registrant had 42,530,822 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 22, 2013.

## TABLE OF CONTENTS

PART I		
Item 1.	Business	2
Item 1A.	Risk Factors	18
Item 1B.	Unresolved Staff Comments	26
Item 2.	Properties	26
Item 3.	Legal Proceedings	26
Item 4.	Mine Safety Disclosures	26
PART II		
Item 5.	Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	27
Item 6.	Selected Financial Data	30
Item 7.	Management’s Discussion and Analysis of Financial Condition and Results of Operations	31
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	42
Item 8.	Financial Statements and Supplementary Data	43
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	81
Item 9A.	Controls and Procedures	81
Item 9B.	Other Information	83
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	83
Item 11.	Executive Compensation	83
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	83
Item 13.	Certain Relationships and Related Transactions, and Director Independence	83
Item 14.	Principal Accountant Fees and Services	83
PART IV		
Item 15.	Exhibits and Financial Statement Schedules	83
SIGNATURES		88

## 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 in this report, 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 our management for future operations, any statements concerning proposed new products or services, any statements regarding the integration, development or commercialization of the business or any assets acquired from other parties, 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 product recalls or product liability claims; potential restrictions on our liquidity or our ability to operate our business by our current debt agreements; possible infringement of our technology or the assertion that our technology infringes the rights of other parties; the potential imposition of fines, penalties, or other adverse consequences if our employees or agents violate the U.S. Foreign Corrupt Practices Act or other laws or regulations; expenditures relating to research, development, testing and regulatory approval or clearance of our products and the risk that such products may not be developed successfully or approved for commercial use; greater governmental scrutiny and increasing regulation of the medical device industry; reforms to the 510(k) process administered by the U.S. Food and Drug Administration (the “FDA”); laws targeting fraud and abuse in the healthcare industry; potential for significant adverse changes in, or our failure to comply with, governing regulations; increases in the price of commodity components; negative changes in economic and industry conditions in the United States and other countries; termination or interruption of relationships with our suppliers or failure of such suppliers to perform; our potential inability to successfully manage growth through acquisitions, including the inability to commercialize technology acquired through recent, proposed, or future acquisitions; fluctuations in Euro and GBP exchange rates; our need to generate sufficient cash flow to fund our debt obligations, capital expenditures, and ongoing operations; concentration of our revenues among a few products and procedures; development of new products and technology that could render our existing products obsolete; market acceptance of new products; volatility in the market price of our common stock (the “Common Stock”); modification or limitation of governmental or private insurance reimbursement policies; changes in healthcare markets related to healthcare reform initiatives; failures to comply with applicable environmental laws; changes in key personnel; work stoppage or transportation risks; uncertainties associated with potential healthcare policy changes which may have a material adverse effect on Merit; introduction of products in a timely fashion; price and product competition; availability of labor and materials; cost increases; fluctuations in and obsolescence of inventory; 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. Actual results will differ, and may differ materially, from anticipated results. Financial estimates are subject to change and are not intended to be relied upon as predictions of future operating results, and we assume no obligation to update or disclose revisions to those estimates. Additional factors that may have a direct bearing on our operating results are described under Item 1A “Risk Factors” beginning on page 18.

**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 healthcare professionals to enhance patient care and enable them to perform procedures safely and effectively.

Our operations are divided into 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.

In December 2012, we completed the acquisition of Thomas Medical Products, Inc. ("Thomas Medical") from a subsidiary of GE Healthcare. Thomas Medical, based in Malvern, Pennsylvania, designs and manufactures catheter-based vascular access delivery devices for diagnostic and therapeutic procedures in electrophysiology ("EP"), cardiac rhythm management ("CRM"), interventional cardiology and interventional radiology applications, primarily on an OEM basis.

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](http://www.merit.com).

**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, otolaryngology (ear, nose and throat care), interventional nephrology, endovascular surgery, thoracic surgery and oncology.

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. These shared techniques give us the opportunity to gain product line efficiencies by serving two distinct therapeutic needs with very similar product platforms. We recognize the unique demands of the two disciplines and provide very specific products to serve the unique product needs of physicians practicing in the two fields.

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.

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 an angled gauge for better viewing. Our IntelliSystem® and Monarch® Inflation Devices (state-of-the-art digital inflation systems), as well as the BasixCOMPAK™ Inflation Syringe, offer the clinician a wide range of features and prices.

**Hemostasis Valves.** We have developed a broad line of technically sophisticated, clinically acclaimed, hemostasis valves, MAP™ Merit Angioplasty Packs 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 valve line includes the Honor®, AccessPLUS™, Access-9™, DoublePlay™, MBA™ and MBA Plus™, and the Passage®.

**Vascular Retrieval Devices.** During 2012 we added the ONE Snare™ Endovascular Snare System to our product offerings. The ONE Snare is a single-loop snare designed for foreign body manipulation and retrieval. The ONE Snare can be used to retrieve inferior vena cava filters, reposition indwelling venous catheters, strip fibrin sheath formation, or assist in central venal access venipuncture. We also offer the EN Snare® Endovascular Snare System, which has 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 such as the Merit Advance® and the SecureLoc™ Safety 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.

The acquisition of Thomas Medical added the ClassicSheath™ Splittable Hemostatic Introducer System, the HeartSpan® Braided Transseptal Sheath and HeartSpan Transseptal Needle to our list of vascular access products. The ClassicSheath allows for insertion of cardiac pacer leads for pacemakers or implantable cardiac defibrillators. The robust valve design reduces the risk of air embolism and backbleed. The HeartSpan products provide access to the atrial septum allowing the physician, generally an electrophysiologist, to study the heart for cardiac arrhythmias.

**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.

**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. The Merit Laureate® Hydrophilic Guide Wire has a consistent, lubricious coating to promote rapid catheter exchanges and to minimize friction. The Merit Laureate was designed with one-to-one torque to reduce wire whipping. We introduced the BowTie™ Guide Wire Insertion Device during 2012. The BowTie is used to facilitate alignment of the proximal end of a micro guide wire into the tip of a device such as a dilator, introducer, or catheter. The BowTie has two funneled ends and a tear-away slit for easy removal. We also offer a line of torque devices (SeaDragon™ and H2O Torq™), which are 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 2012, we acquired the assets of Ostial Solutions, LLC, which included the Ostial PRO® Stent Positioning System, a medical grade disposable guide wire system designed to provide consistent and precise stent implantation in aorto-ostial lesions during coronary or peripheral interventional procedures. The Ostial PRO® can be used to introduce and position stents and other interventional devices within the coronary and peripheral vasculature and function as an alignment tool. Additional angiographic accessories include 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™ 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® Vacuum 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™ Manifolds with Integral Transducers combine a low torque manifold with the transducer. We also provide devices, kits, and procedure trays to effectively and safely manage fluids, contrast media, and waste during angiography and interventional procedures. The Miser® 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® Syringes and the PAL™ Pen and Label Medication Labeling System comply with the latest patient safety initiatives of The Joint Commission (formerly known as “JCAHO”) and 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. Vascular closure devices are used to achieve hemostasis after a diagnostic or interventional procedure. In 2012, we entered into a long-term distribution agreement with Scion Cardio-Vascular, Inc. to sell its Clo-Sur<sup>PLUS</sup> P.A.D.™ The Clo-Sur<sup>PLUS</sup> P.A.D is intended for the local management of bleeding wounds and to provide a barrier to bacterial penetration. Noninvasive devices, including topically applied hemostatic dressings, are used primarily in diagnostic procedures; however, radial access sites use compression devices on both diagnostic and interventional procedures. As a result, we have developed and offer two independent, highly differentiated radial compression systems, including the Finale® Compression Device and the RADStat® Radial Artery Compression Device.

**Drainage Catheters and Accessories.** We have a broad line of catheters for nephrostomy, abscess, and other drainage procedures. Our ReSolve® Locking and Non-Locking Drainage Catheter line has been expanded every year since the product family was introduced in 2006. The unique, convenient locking mechanism is 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 save time, enhance patient comfort, and improve cost-effectiveness. 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™ Drainage 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. Our ASAP® Aspiration Catheter is a safe and efficient method for the removal of fresh, soft emboli and thrombi from the vessels of the arterial system.

**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 spherical, hydrophilic, microporous beads made with acrylic copolymer cross linked with gelatin. We also offer microcatheters and micro guide wires, which are used as delivery systems for the embolic particles. These products include:

*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 and other emerging markets for drug delivery in the treatment of primary and metastatic liver cancer. We received regulatory approval in Canada in 2012 to sell HepaSphere Microspheres in a smaller size (30-60 µm), giving physicians the ability to achieve more distal occlusions when embolizing hypervascular tumors and arteriovenous malformations; and

*QuadraSphere® Microspheres*, which are marketed for the treatment of hypervascularized tumors and arteriovenous malformations in the United States. In 2012 we received FDA approval to sell a smaller size QuadraSphere Microsphere (30-60 µm) in the United States.

**Multipurpose Microcatheters.** With our acquisition of BioSphere, we expanded our multipurpose microcatheter offering to include the EmboCath® Plus Infusion Microcatheter for the controlled and selected infusion of diagnostic media or the delivery of interventional devices or therapeutic pharmaceuticals into selected blood vessels. The Merit Maestro® Microcatheter has a swan neck design to seat catheters in the vessel and to reduce the recoiling effect of the embolic agent as it is introduced. These specialty catheters are used to deliver various embolic agents, including microspheres, alcohol, coils, polyvinyl alcohol particles, Onyx, n-butyl cyanoacrylate, 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 2012, we added peritoneal dialysis catheters and accessories to our dialysis and interventional nephrology product line through our acquisition of substantially all of the assets of Medigroup, Inc. The acquisition included the Flex-Neck® and ExxTended™ Peritoneal Dialysis Catheters and Y-TEC® Implantation Kits. The Centros® and CentrosFLO® Long-Term Hemodialysis Catheters anchor our chronic dialysis line. The ProGuide™ is considered a “workhorse” catheter for chronic dialysis and provides a platform for the development of 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 Fistula 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.

## **Endoscopy Products for Gastroenterology, Pulmonology, and Thoracic Surgery**

**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, otolaryngologists (commonly referred to as 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 Stents.** The Alimaxx-ES® and the new EndoMAXX® Fully Covered Esophageal Stents are used by interventional gastroenterologists, ENTs and thoracic surgeons to palliate symptoms associated with malignant tumors and strictures affecting the esophagus, as well as to treat concomitant tracheoesophageal fistulae.

**Biliary Stents.** The Alimaxx-B® Biliary Stent System is used by interventional gastroenterologists to palliate symptoms associated with malignant tumors affecting the bile 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.

**Inflation Devices.** Merit Endotek's BIG60® Inflation Device is a 60 mL 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™ Cholangiography Rapid Refill Continuous Injection Kit 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 Inject10™ Coronary Control 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, otolaryngology, 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 secretions) 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. The kidneys remove excess water and chemical wastes from blood, permitting clean blood to return to the circulatory system. When the kidneys malfunction, waste substances are not properly excreted, creating an abnormal buildup of wastes in the bloodstream. Dialysis machines are used to treat this condition. Dialysis catheters, which connect the patient to the dialysis machine, are used at various stages in the treatment of dialysis patients. In the past few years, we have added catheters and other accessories to our dialysis-related product offering.

We believe our Endotek division and the move into the areas of interventional gastroenterology, pulmonology, otolaryngology, 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.

**Marketing 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 personnel working in cardiology, radiology, 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 U.S. accounted for 63%, 65% and 68% of our total sales for the years ended December 31, 2012, 2011 and 2010, respectively. Our U.S. direct sales force currently consists of an Executive Vice President of Marketing and Sales, a Vice President of U. S. Sales, a Director of Sales, 12 regional sales managers and 88 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 18 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. In Europe, the Middle East and Africa, our sales and marketing organization is led by a Europe-based Executive Vice President, a Vice President of Direct Sales, a Vice President of Dealer Sales, seven regional directors, and approximately 40 sales representatives and clinical specialists that presently sell our products in Germany, France, the United Kingdom, Belgium, The Netherlands, Denmark, Sweden, Norway, Finland, Ireland, Italy, Russia, the Middle East and Austria. We employ approximately 30 individuals who support the distribution and sale of our products in China. In 2012, our international sales grew approximately 16% over our 2011 international sales, and accounted for approximately \$146.3 million, or 37% of our total sales. Our 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 global 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 Vice President of Global OEM, a Vice President of Global OEM Sales, a staff of regional sales representatives based in the U.S. and Europe, and a dedicated OEM Engineering and Customer Service Group.

## **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 force, 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 2012, our U.S. sales force made approximately 46% of our sales directly to U.S. hospitals (including 3% for our Merit Endotek division) and approximately 9% 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 11% of our 2012 sales. Approximately 37% of our 2012 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, 2012.

## **RESEARCH AND DEVELOPMENT**

Merit continues to lead the industry in innovation by striving to meet the needs of skilled physicians. We have launched several new industry leading products. During the first quarter of 2012 we acquired and began marketing the Ostial Pro® Stent Positioning System, designed to help accurately place stents. It is a nitinol device with gold-plated feet to ensure accurate placement of stents at the junction of arterial vessels within the aorta.

We developed the ONE Snare™ Endovascular Snare System for planned situations such as the removal of an inferior vena cava ("IVC") filter, dialysis catheter fibrin sheath stripping, or stent placement. The ONE Snare System can also be used for unplanned circumstances such as the removal of a sheared catheter tip, a broken guide wire or a defective stent.

During 2012, we introduced the BowTie™ Guide Wire Insertion Device, our innovative solution to the problem of aligning devices with micro guide wires. During 2012, we also launched the Blue Diamond™ Digital Inflation Device, and the EndoMAXX® Fully Covered Esophageal Stent. We also added two new improvements to our ReSolve® Locking Drainage Catheters. Additionally, we obtained Section 510(k) clearance for improvements to one of our existing products, the Merit Laureate® Hydrophilic Guide Wire.

Our research and development expenses were approximately \$27.8 million, \$21.9 million, and \$15.3 million in 2012, 2011 and 2010, respectively. We develop our product ideas through a collaborative effort that includes several physicians with whom we have established long-term relationships, our Chief Executive Officer, our Vice President of Research and Development and valuable input from our research and development and sales and marketing teams.

In May 2012, we completed construction of a new research and development facility in Galway, Ireland, which added to our existing research and development capabilities in South Jordan, Utah; Angleton and Dallas, Texas; Jackson Township, New Jersey; Paris, France; and Venlo, The Netherlands. Additionally, through the Thomas Medical acquisition, which we completed in December 2012, we acquired another facility in Malvern, Pennsylvania that we intend to utilize to broaden our line of introducer sheaths and catheters.

During the years ended December 31, 2012 and 2011, we entered into multiple asset acquisitions related to research and development projects. Of the acquisitions we completed during those years, there were several which had not reached technological feasibility as of the acquisition date, and we had no future alternative use of the underlying technology as of that date. For such technology, we have included charges of approximately \$2.5 million and \$4.9 million in the accompanying consolidated statements of operations for the years ended December 31, 2012 and 2011, respectively. 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, Pennsylvania, Ireland and France. We have also received ISO 9001:2008 certification for our Merit Sensor Systems, Inc. ("Merit Sensors") 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 Sensors, one of our wholly-owned subsidiaries, 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; Malvern, Pennsylvania; 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 Mexico.

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

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

## **COMPETITION**

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

In the interventional cardiology and radiology markets, as well as the gastroenterology and pulmonology markets, we compete with large international, multi-divisional medical supply companies such as Cordis Corporation (Johnson & Johnson), Boston Scientific Corporation, Medtronic, C.R. Bard, Abbott Laboratories, Teleflex, Cook Incorporated, and Terumo Corporation. Medium-size companies we compete with include AngioDynamics, Vascular Solutions, B. Braun, Olympus, 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, 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. We believe 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.

## **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, 2012, we owned more than 400 U.S. and international patents and patent applications. We also operate under licenses from owners of certain other 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.

On November 18, 2011, a third party filed suit for patent infringement against us in the United States District Court, District of Massachusetts, alleging that we infringed certain patents. The patents generally related to fluid management systems. On August 27, 2012, we entered into a Settlement and License Agreement with the third party, and the case was dismissed on August 29, 2012.

## **REGULATION**

**U.S. Regulation.** The FDA and other federal, state and local authorities regulate our products and product-related activities. Pursuant to the Federal 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.** In general, 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. Some devices, typically lower-risk devices, are subject to specific exemptions from premarket review. In addition, in limited cases devices may come to the market through alternative procedures, such as a humanitarian device exemption (“HDE”), which applies only to devices that are intended to treat or diagnose diseases or conditions affecting fewer than 4,000 people in the United States each year.

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 (i) was on the market prior to the enactment of the Medical Device Amendments of 1976, (ii) has been reclassified from Class III to Class II, or (iii) has been cleared through the 510(k) procedure. The 510(k) clearance procedure 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 several years to complete. There is also a substantial “user fee” that must be paid to FDA in connection with the submission of each PMA application. 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. PMA supplements often must be approved by FDA before the modification to the device, the labeling, or the manufacturing process may be implemented.

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. Clinical trials are subject to extensive recordkeeping and reporting requirements. Our clinical trials must be conducted under the oversight of an IRB for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices. We are also required to obtain each patient's written informed consent in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. We, the FDA or the IRB may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. 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 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 in the clinical trial 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 Practices and Quality System Regulation.** 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. These requirements are complex and technical and require substantial resources to remain compliant. Our failure or the failure of our suppliers to maintain compliance with the QSR requirements could result in the shutdown of our manufacturing operations or the recall of our products, which would have a material adverse effect on our business. In the event that one of our suppliers fails to maintain compliance with our quality requirements, we may have to qualify a new supplier and could experience manufacturing delays as a result. We also could be subject to injunctions, product seizures, or civil or criminal penalties.

**Medical Device Reporting.** Medical Device Reporting (“MDR”) regulations 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 other relief as may be deemed necessary.

**Import Requirements.** To import a medical device into the United States, 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 and we may not be able to export such products.

Foreign countries often require, among other things, an FDA certificate for products for export, also called a Certificate to 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 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 devices in the EEA and proposed new legislation in September 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 generally used in medical procedures 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.

**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 healthcare 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 healthcare programs, reimbursement changes, the increased funding of comparative effectiveness research for use in healthcare decision-making, and enhancements to fraud and abuse requirements and enforcement, that we believe will affect existing government healthcare programs and 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 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 certain healthcare providers. The first report under these provisions will be due March 31, 2014 and will relate to payments or other transfers of value made between August 1 and December 31, 2013. Thereafter, annual reports due in March will relate to payments or other transfers of value during the previous calendar year. 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. Several states have adopted similar reporting requirements.

**Anti-Kickback Statutes.** The Medicare and Medicaid Patient Protection Act of 1987, as amended, which is more commonly known as the federal healthcare 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 healthcare program such as Medicare or Medicaid, unless the arrangement fits within one of several “safe harbors.” 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 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 healthcare programs, the statute has been violated. Violations can result in significant penalties, imprisonment and exclusion from Medicare, Medicaid and other federal healthcare programs. Exclusion of a manufacturer would preclude any federal healthcare 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 healthcare 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 healthcare 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 healthcare 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. Under the PPACA, a violation of the Anti-Kickback Statute is deemed to be a violation of the Federal False Claims Act. The Federal False Claims Act also includes whistleblower 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 healthcare 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 programs. 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 healthcare 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 protected health information to us. Also, many state laws regulate the use and disclosure of health information and require notification in the event of breach of such 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 a broader range of requirements under HIPAA, HITECH, the rules issued thereunder and their 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, 2012, we employed 2,760 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](http://www.sec.gov).

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

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

For financial information relating to our foreign and domestic sales see Note 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, QSR 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 are not in compliance with applicable laws or regulations, or have improperly promoted our products for uncleared or unapproved indications, the FDA or such other agency could require a recall of products or 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”) alleging that a modification to the hydrophilic coating process for our Merit Laureate® Hydrophilic Guidewire (the “Guidewire”) constituted a significant change that could significantly affect the Guidewire safety or effectiveness. In the Warning Letter, the FDA claimed that we did not have an approved application for premarket approval of the Guidewire 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 FDA also claimed in the Warning Letter that the Guidewire was misbranded under Section 502(o) of the Act 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 FDCA. We submitted a formal response to the FDA in which we committed to completing corrective actions that would address the alleged violation in a comprehensive and sustainable manner, and we temporarily ceased all commercial distribution of the Guidewire within the United States. On September 24, 2012, we announced that we received Section 510(k) clearance from the FDA to market the Guidewire, and we recommenced commercial distribution of the Guidewire in the United States. On October 23, 2012, we received a letter from the FDA stating that it appears we have addressed the violation alleged in the Warning Letter.

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 product liability claims.**

Our products are used in connection with invasive procedures and in other medical contexts that entail an inherent risk of product liability claims. If medical personnel or their patients suffer injury in connection with the use of our products, whether as a result of a failure of our products to function as designed, an inappropriate design, inadequate disclosure of product-related risks or information, improper use, 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 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.

In addition, the occurrence of such an event or claim could result in a recall of products from the market or a safety alert relating to such products. Such a recall could result in significant costs and could divert management's attention from our business.

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 are, from time to time, involved in litigation, regulatory proceedings or other disputes. The outcomes of litigation are difficult to predict or quantify; however, an adverse outcome could limit our ability to sell certain products or reduce our operating margin on the sale of our products. The expense of defending litigation may be costly and the demands of litigation would 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 litigation could negatively impact our business, results of operations or cash flows. Intellectual property infringement or other 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 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.

**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 Amended and Restated Credit Agreement, dated December 19, 2012 (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.

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

The PPACA was enacted into law in the U.S. in March 2010. Certain provisions of the legislation are not scheduled to become 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 PPACA’s new reporting and disclosure requirements with regard to payments or other transfers of value made to healthcare 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.

**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 or 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; be successfully marketed; or be 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.

**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 healthcare 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 the federal Anti-Kickback Statute and other 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. Jurisdictions outside the United States may also have laws, including anti-bribery statutes, prohibiting similar conduct and providing for significant penalties.

**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. government 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 challenges 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 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 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.

We have recently completed a series of significant acquisitions, including our acquisition of BioSphere and Thomas Medical. As we grow through acquisitions, we 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 will likely continue to incur, significant expenses in connection with negotiating and consummating various acquisition 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 2012, the exchange rate between all applicable foreign currencies and the U.S. Dollar resulted in a decrease in our gross revenues of approximately \$2.7 million.

For the year ended December 31, 2012, approximately \$67.6 million, or 17.1%, 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 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, 2012, sales of our inflation devices (including inflation devices sold in custom kits and through

OEM channels) accounted for approximately 17% of our total revenues. Sales of our inflation devices to a single OEM customer, representing our largest customer, were approximately 13% of our total inflation device sales for the year ended December 31, 2012. 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 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 manufacture, dispose of or release. 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 European distribution and customer service facility located in Maastricht, The Netherlands. In addition, we lease office space in Washington D.C.; Jackson Township, 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; Malvern, Pennsylvania; 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, 2012 (in square feet):

	<u>Owned</u>	<u>Leased</u>	<u>Total</u>
U.S.	358,525	378,703	737,228
International	170,680	38,147	208,827
	<u>529,205</u>	<u>416,850</u>	<u>946,055</u>

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 completed construction of the new building in the second 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 the first quarter of 2013. 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 94,000 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.

With the acquisition of Thomas Medical in December 2012, we assumed the lease of a 32,691 square foot production and administration office building located in Malvern, Pennsylvania.

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.

## 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.

<b>For the year ended December 31, 2012</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 14.52	\$ 11.51
Second Quarter	\$ 13.85	\$ 11.58
Third Quarter	\$ 15.37	\$ 12.20
Fourth Quarter	\$ 15.24	\$ 12.67
<b>For the year ended December 31, 2011</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 16.08	\$ 11.38
Second Quarter	\$ 19.36	\$ 13.62
Third Quarter	\$ 19.23	\$ 12.52
Fourth Quarter	\$ 14.24	\$ 12.32

As of February 26, 2013, the number of shares of Common Stock outstanding was 42,530,822 held by approximately 136 shareholders of record, not including shareholders whose shares are held in securities position listings.

#### DIVIDENDS

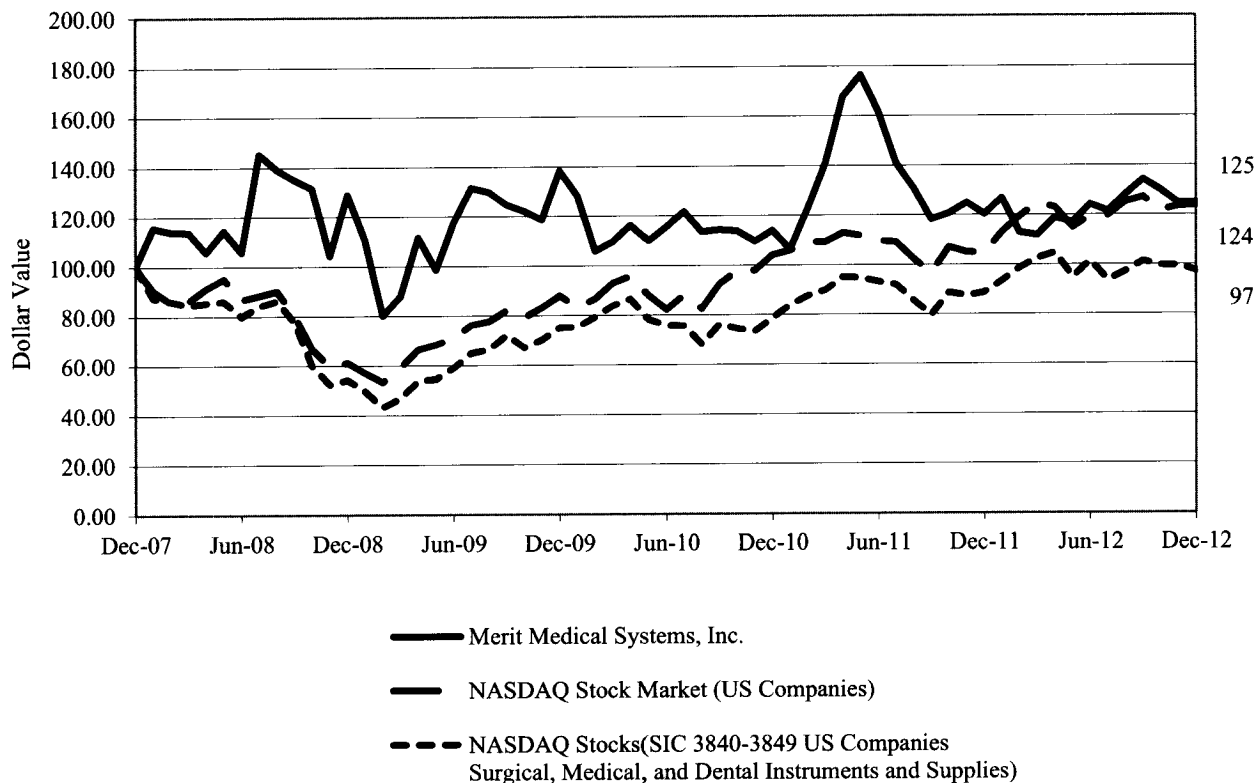
We have never declared or paid cash dividends on the Common Stock. We presently intend to retain any future earnings for use in our business and, therefore, do not anticipate paying any dividends on the Common Stock in the foreseeable future. In addition, our Credit Agreement contains covenants prohibiting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



**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, 2007 to December 31, 2012.

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



	12/2007	12/2008	12/2009	12/2010	12/2011	12/2012
Merit Medical Systems, Inc.	\$ 100	\$ 129	\$ 138	\$ 114	\$ 120	\$ 125
NASDAQ Stock Market (U.S. Companies)	100	61	88	104	105	124
NASDAQ Stocks (SIC 3840-3849 U.S. Companies)	100	54	75	79	89	97

The stock performance graph assumes for comparison that the value of the Common Stock and of each index was \$100 on December 31, 2007 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 2013. Used with permission. All rights reserved.

## SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

The following table contains information regarding our equity compensation plans as of December 31, 2012 (in thousands):

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a) ) (c)
Equity compensation Plans approved by security holders	3,535 (1),(3)	\$ 12.55	1,662 (2),(3)

(1) Consists of 3,535,425 shares of Common Stock subject to the options granted under the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan.

(2) Consists of 326,227 shares available to be issued under the Merit Medical Systems, Inc. Qualified and Non-Qualified Employee Stock Purchase Plan and 1,335,500 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.

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

	Years Ended December 31,				
	2012	2011	2010	2009	2008
<b>OPERATING DATA:</b>					
Net Sales	\$ 394,288	\$ 359,449	\$ 296,755	\$ 257,462	\$ 227,143
Cost of Sales	212,296	193,981	168,257	148,660	133,872
Gross Profit	181,992	165,468	128,498	108,802	93,271
<b>Operating Expenses:</b>					
Selling, general, and administrative	122,106	104,502	87,615	64,787	53,127
Research and development	27,795	21,938	15,335	11,168	9,160
Acquired in-process research and development	2,450	5,838	—	—	—
Goodwill impairment charge	—	—	8,344	—	—
Total operating expenses	152,351	132,278	111,294	75,955	62,287
Income From Operations	29,641	33,190	17,204	32,847	30,984
<b>Other Income (Expense):</b>					
Interest income	226	129	34	178	781
Interest expense	(604)	(789)	(596)	(28)	(17)
Other income (expense)	(1,645)	345	146	97	97
Other income (expense)—net	(2,023)	(315)	(416)	247	861
Income Before Income Taxes	27,618	32,875	16,788	33,094	31,845
Income Tax Expense	7,908	9,831	4,328	10,564	11,118
Net Income	\$ 19,710	\$ 23,044	\$ 12,460	\$ 22,530	\$ 20,727
<b>Earnings Per Common Share:</b>					
Diluted	\$ 0.46	\$ 0.58	\$ 0.35	\$ 0.63	\$ 0.58
<b>Average Common Shares:</b>					
Diluted	42,610	39,733	35,976	35,758	35,688
<b>BALANCE SHEET DATA:</b>					
Working capital	\$ 88,992	\$ 89,857	\$ 72,125	\$ 57,706	\$ 84,283
Total assets	705,309	447,017	369,480	271,513	231,776
Line of credit	—	—	—	7,000	—
Long-term debt, less current portion	227,566	30,737	81,538	—	—
Stockholders' equity	381,577	357,089	235,615	218,809	194,305

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 carrying value amount of this reporting unit was more 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. See Note 2 to our consolidated financial statements set forth in Item 8 of this report for information related to acquisitions, as these acquisitions impact the comparability of our annual results.

**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 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, 2012, we reported record sales of approximately \$394.3 million, up approximately \$34.8 million or 9.7%, over 2011 sales of approximately \$359.4 million. Gross profits as a percentage of sales was 46.2% for the year ended December 31, 2012, compared to 46.0% for the year ended December 31, 2011.

During the year ended December 31, 2012, we recorded a charge of approximately \$2.5 million for acquired in-process research and development, primarily related to the purchase of several new product technologies. These technologies included the purchase of four patents for the development of future products, primarily a new cross-support catheter and an exclusive license for certain nanotechnology.

Net income for the year ended December 31, 2012 was approximately \$19.7 million, or \$0.46 per share, as compared to \$23.0 million, or \$.58 per share, for the year ended December 31, 2011.

During the year ended December 31, 2012, we made significant investments to expand our international sales distribution. We expanded our sales presence primarily in Russia, India, Brazil, certain Middle Eastern Countries, and the Balkan countries, as well as countries located in the Pacific Rim. Our international sales for the year ended December 31, 2012 increased by \$20.4 million and now represents 37% of our total sales, compared to 35% of our total sales for the corresponding period in 2011. This international growth has been important to our financial results, as we have experienced slower sales growth in U.S. markets.

Our endoscopy operating segment made significant progress during 2012 in reducing its operating loss to approximately \$770,000 for the year ended December 31, 2012, when compared to the operating loss of approximately \$4.8 million for the corresponding period of 2011. This reduction in operating loss was largely driven by a sales increase of 31% in our endoscopy segment for the year ended December 31, 2012, when compared to the year ended December 31, 2011, and an improvement in gross margins. During the first quarter of 2012, we launched our new EndoMAXX® Fully-Covered Esophageal Stent, which aided our sales growth for the year ended December 31, 2012. We have completed the qualification of a new contract stent manufacturer which will lower our product costs and improve gross profits for this operating segment. It is anticipated that these lower costs should begin to help increase our gross margins starting in the second quarter of 2013, which would help us move toward profitability in the near future for this operating segment.

In December 2012, we completed the largest acquisition in our history when we acquired stock of Thomas Medical from Vital Signs, Inc., a subsidiary of GE Healthcare, in an all-cash transaction valued at approximately \$165.6 million (net of cash acquired). The purchase price includes an agreement with GE Healthcare to treat this acquisitions for tax purposes as an asset deal (section 338(h) (10) election) , which could give us approximately \$59.0 million in tax savings over a period of fifteen years. Thomas Medical's sales for the year ended December 31, 2012 were approximately \$37.8 million, of which approximately \$1.9 million occurred subsequent to the acquisition date and is included in our consolidated statement of income for the year ended December 31, 2012. A significant portion of these sales were made to OEM customers as part of their product offerings in catheter-based vascular access delivery devices for diagnostic and therapeutic procedures in electrophysiology ("EP"), cardiac rhythm management ("CRM"), interventional cardiology and interventional radiology applications. Thomas Medical's primary product was a splittable hemostatic introducer sheath system for the delivery of pacemaker and defibrillator leads. Using the splittable hemostatic introducer sheath as an entry product, we intend to develop a portfolio of premium accessories for EP physicians.

Our product pipeline is promising with new cardiology, radiology and endoscopy products in the queue. We expect to launch a number of new products in 2013, including the TIO™ Three-in-One Oral Airway Bite Block, the One Snare™ Single-Loop Device, the basixTOUCH™ Inflation Device, the PHD™ Hemostasis Valve, the PreludeEASE™ Hydrophilic Radial Sheath, the ASAP LP™ Aspiration Catheter, the Worley™ Snare System, the Bearing™ NS PVA Embolization Particles, Steerable EP Sheath, the DialEase™ Splittable Sheath, the EndoMAXX EDT™ Esophageal Stent, the Merit SureCross™ Support Catheter and the ConcierGE® Guiding Catheter.

We are facing several head winds during 2013 that will effect our earnings. The Medical Device Excise Tax ("MDET"), which was included as part of the Patient Protection and Affordable Care Act, will take effect on January 1, 2013. We have raised our prices to most of our OEM customers to offset the associated MDET to this customer group, but have chosen not to raise the prices to our direct U.S. hospital customers which make up a majority of our U.S. customers. The MDET will decrease our gross profits and earnings by \$3.5 to \$4.0 million dollars in 2013 for sales made to our direct U.S. hospital customers. Expectations from many of our U.S. hospitals was for the medical manufacturing companies to absorb the costs of the MDET. We have decided that we would rather have our sales force promoting our products and increasing our market share, instead of defending a price increase for the MDET which could influence the hospital to seek competitive products.

In addition to the MDET, we will complete the construction of two new buildings in the U.S. Both buildings will provide production, warehouse and administration offices. The new South Jordan building of 253,000 square feet will be completed during the first quarter of 2013 and the new Pearland, Texas facility of 94,000 square is expected to be completed in October of 2013. The additional costs associated with the new facilities over the current production facilities will have an effect on our gross margins, operating expenses and earnings for 2013 of approximately \$2.5 to \$3.5 million. Some of the building costs will be expensed into selling, general and administrative costs as opposed to cost of sales, during a transition period of three to six months as it will take this long to complete the movement and qualification of production equipment from the old facilities into the new facilities. These new facilities in the U.S. are needed to allow us to expand our manufacturing operations for new and existing products and increase our research and development pilot lab capacity for new product development, given the growth we are experiencing in our international markets.

## RESULTS OF OPERATIONS

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

	2012	2011	2010
Net sales	100%	100%	100%
Gross profit	46.2	46.0	43.3
Selling, general, and administrative expenses	31.0	29.1	29.5
Research and development expenses	7.0	6.1	5.2
Acquired in-process research and development	0.6	1.6	—
Goodwill impairment charge	—	—	2.8
Income from operations	7.5	9.2	5.8
Income before income taxes	7.0	9.1	5.7
Net income	5.0	6.4	4.2

Listed below are the sales by product category within each business segment for the years ended December 31, 2012, 2011 and 2010 (in thousands):

	% Change	2012	% Change	2011	% Change	2010
<b>Cardiovascular</b>						
Stand-alone devices	12%	\$ 114,242	15%	\$ 101,959	16%	\$ 88,586
Custom kits and procedure trays	3%	94,586	11%	91,532	11%	82,799
Inflation devices	2%	68,979	8%	67,353	2%	62,495
Catheters	17%	64,878	23%	55,357	18%	44,824
Embolization devices	8%	33,870	247%	31,229	—%	9,003
CRM/EP	—%	1,938	—%	—	—%	—
Total	9%	378,493	21%	347,430	15%	287,707
<b>Endoscopy</b>						
Endoscopy devices	31%	15,795	33%	12,019	18%	9,048
Total	10%	\$ 394,288	21%	\$ 359,449	15%	\$ 296,755

**Cardiovascular Sales.** Our cardiovascular sales for the year ended December 31, 2012 were approximately \$378.5 million, up 8.9%, when compared to the corresponding period for 2011 of approximately \$347.4 million. Sales were favorably affected by an increase in sales of our stand-alone devices (particularly our hemostasis valves, guidewires and newly-acquired Scion Clo-SurPLUS P.A.D.<sup>TM</sup>) of approximately \$12.3 million, or 12.0%; an increase in sales of catheter devices (particularly our Prelude® sheath product line, micro catheter product line, aspiration catheter product line and diagnostic catheters) of approximately \$9.5 million, or 17.2%; and an increase in custom kits and procedure trays of approximately \$3.1 million, or 3.3%. Our cardiovascular sales for the year ended December 31, 2011 were approximately \$347.4 million, up 20.8%, when compared to the corresponding 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 246.9%, compared to \$9.0 million for the three and half months in 2010; 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 15.1%; 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 23.5%. 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 2012, 2011 and 2010 notwithstanding the fact that the markets for many of our products experienced slight pricing declines as our customers tried to reduce their costs. Substantially all of the increase in our revenues was attributable to increased unit sales. Sales by our European direct sales force are subject to foreign currency exchange rate fluctuations between the natural currency of a foreign country and the U.S. Dollar. Foreign currency exchange rate fluctuations decreased sales by 0.7% in 2012 compared to 2011, and decreased sales by 0.5% in 2011 compared to 2010, decreased sales by 0.3% in 2010 compared to 2009. New products and market share gains in our existing product lines were additional sources of revenue growth.

Endoscopy Sales. Our endoscopy sales for the year ended December 31, 2012 were approximately \$15.8 million, up 31.4%, when compared to sales in the corresponding period of 2011 of approximately \$12.0 million. This increase was primarily related to the increase sales related to our new *EndoMAXX*® Fully-Covered Esophageal Stent. Our endoscopy sales for the year ended December 31, 2011 were approximately \$12.0 million, up 32.8%, 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, 2012 were approximately \$146.3 million, or 37% of total sales; 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. This increase in our international sales during 2012 was primarily related to year-over-year sales increases in China of approximately \$5.9 million, up 29%, Europe Direct of approximately \$2.7 million, up 7% (would have been up 16% in constant currency), United Arab Emirates (“UAE”) of approximately \$2.0 million, up 55%, Russia of approximately \$1.8 million, up 67%, Japan of approximately \$1.8 million, up 14%, and Brazil of approximately \$1.7 million, up 50%. The increase in our international sales during 2011 was primarily related to year-over-year sales increases in Europe Direct of approximately \$9.7 million, up 31%, China of approximately \$8.1 million, up 66%, Europe, the Middle East, and Africa (“EMEA”) distributor of approximately \$5.6 million, up 46%, and Pacific Rim (excluding China) of approximately \$4.8 million, up 21%. The increase in our international sales during 2010 was primarily related to year-over-year sales increases in China, Japan, Germany and the U.K. Our total European direct sales were approximately \$42.6 million, \$39.9 million, and \$29.7 million in 2012, 2011, and 2010, respectively.

Our gross profit as a percentage of sales was 46.2%, 46.0%, and 43.3% in 2012, 2011 and 2010, respectively. Gross profit for 2012, compared to the corresponding period 2011, remained relatively unchanged. 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 0.6% 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.

Our selling, general and administrative expenses increased approximately \$17.6 million, or 17%, in 2012 compared to 2011; approximately \$16.9 million, or 19%, in 2011 compared to 2010; approximately \$22.8 million, or 35%, in 2010 compared to 2009. The increase in selling, general and administrative expenses in 2012 was primarily due to the hiring of additional sales and marketing representatives, both domestically and internationally, to expand our sales distribution and increase market share for new and existing products. In connection with the Thomas Medical acquisition, we had approximately \$2.7 million or 0.7% of total sales, in non-recurring severance

costs and acquisition costs included in selling, general and administrative costs. 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. Selling, general and administrative expenses as a percentage of sales was 31.0% (30.3 % without non-recurring Thomas Medical acquisition costs), 29.1%, and 29.5% (27.8% in 2009 without non-recurring BioSphere acquisition costs) in 2012, 2011 and 2010, respectively.

Research and development expenses increased by 26.7% to approximately \$27.8 million in 2012, compared to approximately \$21.9 million in 2011. The increase was primarily due to headcount additions for our research and development group to support new products and personnel increases in our regulatory department to support product registrations in foreign countries as we expand our international sales distribution. 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. Our research and development expenses as a percentage of sales were 7.0% for 2012, 6.1% for 2011, and 5.2% for 2010. We have a pipeline of new products and we believe that we have an effective level of capabilities and expertise to continue the flow of new internally-developed products into the future with average gross margins that are higher than our historical gross margins.

During 2012, we incurred in-process research and development charges of approximately \$2.5 million related to the purchase of several new product technologies. These technologies included the purchase of four patents for the development of future products, primarily a new cross-support catheter and an exclusive license for certain nanotechnology. 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 the development of certain biomaterial technology and our covered biliary in-process research and development, resulting in charges of \$500,000 and \$400,000, respectively.

Our operating profits by business segment for the years ended December 31, 2012, 2011 and 2010 were as follows (in thousands):

	2012	2011	2010
<b>Operating Income (Loss)</b>			
Cardiovascular	\$ 30,411	\$ 38,010	\$ 30,176
Endoscopy	(770)	(4,820)	(12,972)
Total operating income	<u>\$ 29,641</u>	<u>\$ 33,190</u>	<u>\$ 17,204</u>

Cardiovascular Operating Income. Our cardiovascular operating income for the year ended December 31, 2012 was approximately \$30.4 million, compared to operating income of approximately \$38.0 million for the year ended December 31, 2011. This decrease was due primarily to higher selling, general and administrative expenses and higher research and development expenses. 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 Net Operating Loss.* Our endoscopy net operating loss from operations for the year ended December 31, 2012 was approximately \$770,000, compared to an operating loss of approximately \$4.8 million for the year ended December 31, 2011. The decrease in net operating loss from operations was favorably affected by higher sales and gross margins, lower research and development expenses and was negatively affected by higher selling, general and administrative expenses as we added some additional sales representatives to this segment. 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 certain biomaterial technology and our covered biliary in-process research and development, which resulted in charges of \$500,000 and \$400,000, respectively, 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 nonrecurring 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. The increase in research and development expense in the endoscopy segment during 2011 was principally the result of our investment in new product development to help this business segment to profitability. 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. In addition, we have completed the qualification of a new contract stent manufacturer which will lower our product costs and improve gross profits for this operating segment. It is anticipated that these lower costs should begin to help increase our gross margins starting in the second quarter of 2013, which would help us move toward profitability in the near future for this operating segment.

Our effective income tax rates for 2012, 2011 and 2010 were 29%, 30% and 26%, respectively. During 2012, our effective tax rate was negatively impacted by a valuation allowance related to a capital loss carryforward. Excluding the effect of this discrete item, our 2012 effective tax rate would have been approximately 25%. The decrease in the effective income tax rate for the year ended December 31, 2012, when compared to the same period of 2011, was the result of a higher mix of foreign income, which is primarily due to Ireland being taxed at a lower rate than our U.S. income. 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 (primarily Ireland) operations income. 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.

On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which includes a reinstatement of the federal research and development credit for the tax year ended December 31, 2012. We estimate that our credit for 2012 will be approximately \$500,000. As a result, we will recognize the retroactive benefit of the federal research and development credit as a discrete item in the first quarter of 2013, the period in which the reinstatement was enacted.

Our other expense for the years ended December 2012, 2011, and 2010 was approximately \$2.0 million, \$315,000, and \$416,000, respectively. The increase in other expenses for 2012 over 2011 related to the write-off of approximately \$2.4 million of a cost-method investment, which was partially offset by a gain on marketable securities of approximately \$745,000. 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 acquisition of BioSphere.

Our net income for 2012, 2011, and 2010 was approximately \$19.7 million, \$23.0 million, and \$12.5 million, respectively. Our 2012 net income included charges related to Thomas Medical acquisition costs including legal, accounting, investment banking, and severance of approximately \$2.7 million, or approximately \$1.6 million net of tax, an increase in cost of sales related to Thomas Medical's mark-up on finished goods of approximately \$831,000, or approximately \$508,000 net of tax, charges related to acquired in-process research and development of approximately \$2.5 million, or approximately \$1.5 million net of tax, and an approximately \$631,000 related to a deferred income tax valuation allowance related to a certain capital loss carry forwards. Excluding these charges, our 2012 net income would have been approximately \$24.0 million, compared to \$27.0 million excluding the 2011 items discussed below. The decrease in net income for 2012, when compared to the comparable period for 2011, was unfavorably affected by higher selling, general and administrative expenses and higher research and development expenses. 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, of approximately \$4.3 million, net of tax. 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.

## LIQUIDITY AND CAPITAL RESOURCES

### Capital Commitments and Contractual Obligations

The following table summarizes our capital commitments and contractual obligations as of December 31, 2012, as well as the future periods in which such payments are currently anticipated to become due:

Contractual Obligations	Payment due by period (in thousands)				
	Total	Less than 1 Year	1-3 Years	4-5 Years	After 5 Years
Long-term debt	\$ 237,566	\$ 10,000	\$ 20,000	\$ 207,566	\$ —
Interest on long-term debt (1)	29,249	5,774	11,596	11,879	—
Operating leases	19,462	3,892	6,765	4,474	4,331
Royalty obligations	598	100	108	100	290
Total contractual cash	<u>\$ 286,875</u>	<u>\$ 19,766</u>	<u>\$ 38,469</u>	<u>\$ 224,019</u>	<u>\$ 4,621</u>

(1) Interest payments on our variable long-term debt were forecasted using the LIBOR forward curves plus a base of 2.00%. Interest payments on \$150.0 million of our long-term debt were forecasted using a fixed rate of 2.98% as a result of an interest rate swap (see Note 8 to our consolidated financial statements set forth in Item 8 of this report).

As of December 31, 2012, we had approximately \$6.7 million of contingent consideration liability, \$2.9 million of unrecognized tax positions, and \$6.0 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 to our consolidated financial statements set forth in Item 8 below.

### **Cash Flows**

At December 31, 2012 and 2011, we had cash and cash equivalents of approximately \$9.7 million and \$10.1 million respectively, of which \$8.1 million and \$9.0 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, 2012 and 2011, we had cash and cash equivalents of approximately \$6.4 million and \$5.9 million, respectively, held by our subsidiary in China.

Our cash flow from operations was approximately \$46.9 million in 2012, an increase of approximately \$12.9 million over 2011. This increase in cash flow from operations in 2012, compared to 2011 was primarily affected by changes in cash provided by increases in accounts payable of \$9.9 million and accrued expenses of \$3.1 million. Our working capital for the years ended December 31, 2012, 2011 and 2010 was approximately \$89.0 million, \$89.9 million, and \$72.1 million, respectively. Working capital remained relatively unchanged when comparing 2012 to 2011. The increase in working capital for 2011 from 2010 was favorably affected by an increase in our cash and inventory balances.

During the year ended December 31, 2012, our inventory balances increased approximately \$14.7 million, from approximately \$69.9 million at December 31, 2011 to approximately \$84.6 million at December 31, 2012. The increase in inventory primarily related to higher inventory levels of approximately \$6.4 million attributable to a 9.2% increase in our base business, and our acquisition of Thomas Medical's inventory of approximately \$5.5 million.

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.

We entered into the Credit Agreement in December 2012. Pursuant to the terms of the Credit Agreement, the Lenders have agreed to make revolving credit loans up to an aggregate amount of \$175 million. The Lenders also made a term loan in the amount of \$100 million, repayable in quarterly installments in the amounts provided in the Credit Agreement until the maturity date of December 19, 2017, at which time the term and revolving credit loans, together with accrued interest thereon, will be due and payable. In addition, certain mandatory prepayments are required to be made upon the occurrence of certain events described in the Credit Agreement. Wells Fargo has agreed, upon satisfaction of certain conditions, to make swingline loans from time to time through the maturity date

of December 19, 2017 in amounts equal to the difference between the amounts actually loaned by the Lenders and the aggregate revolving credit commitment. The Credit Agreement is collateralized by substantially all of our assets.

The Credit Agreement contains customary covenants, representations and warranties and other terms customary for revolving credit loans of this nature. In this regard, the Credit Agreement requires us to not, among other things, (a) permit the Consolidated Total Leverage Ratio (as defined in the Credit Agreement) to be greater than 3.5 to 1 as of any fiscal quarter ending during 2013, no more than 3.35 to 1 as of any fiscal quarter ending during 2014, no more than 3 to 1 as of any fiscal quarter ending during 2015, no more than 2.75 to 1 as of any fiscal quarter ending during 2016, and no more than 2.5 to 1 as of any fiscal quarter ending thereafter; (b) for any period of four consecutive fiscal quarters, permit the ratio of Consolidated EBITDA (as defined in the Credit Agreement and subject to certain adjustments) to Consolidated Fixed Charges (as defined in the Credit Agreement) to be less than 1.75 to 1; (c) subject to certain adjustments, permit Consolidated Net Income (as defined in the Credit Agreement) for certain periods to be less than \$0; or (d) subject to certain conditions and adjustments, permit the aggregate amount of all Facility Capital Expenditures (as defined in the Credit Agreement) in any fiscal year beginning in 2013 to exceed \$30 million. Additionally, the Credit Agreement contains various negative covenants with which we must comply, including, but not limited to, limitations respecting: the incurrence of indebtedness, the creation of liens or pledges on our assets, mergers or similar combinations or liquidations, asset dispositions, the repurchase or redemption of equity interests and debt, the issuance of equity, the payment of dividends and certain distributions, the entrance into related party transactions and other provisions customary in similar types of agreements. As of December 31, 2012, we were in material compliance with all covenants set forth in the Credit Agreement.

As of December 31, 2012, we had outstanding borrowings of approximately \$237.6 million under the Credit Agreement, with available borrowings of approximately \$33.8 million, based on the leverage ratio in the terms of the Credit Agreement. Our interest rate as of December 31, 2012 was a fixed rate of 2.98% on \$150.0 million as a result of an interest rate swap (see Note 8 to our consolidated financial statements set forth in Item 8 of this report), a variable floating rate of 2.22% on \$87.0 million and a variable floating rate of 2.31% on approximately \$0.6 million. Our interest rate 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.

Capital expenditures for property and equipment were approximately \$64.6 million, \$59.2 million, and \$23.6 million, for the years ended December 31, 2012, 2011 and 2010, respectively. During 2012, 2011 and 2010, we spent approximately \$31.9 million, \$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 \$46.0 million in 2013 for property and equipment, of which \$18.0 million will be spent on building construction.

On June 22, 2011, we completed a registered public 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 (the "Equity Offering"). We primarily used the proceeds of the Equity Offering to pay down amounts owing under our Credit Agreement and reduce interest costs. 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 facility construction, production automation, product development and the introduction of new products. Over the last four years, we spent a substantial amount of cash in connection with our acquisition of certain assets and businesses (including approximately \$165.6 million (net of cash acquired) to acquire Thomas Medical and \$16.5 million to acquire the assets of Ostial, among other transactions, during 2012; \$5 million to acquire the assets of Ash Access Technology, Inc., and AAT Catheter Technologies, LLC, among other transactions, during 2011; approximately \$86.0 million (net of acquired cash) to acquire BioSphere Medical, Inc. 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 new production facilities in South Jordan, Utah and Pearland, Texas. During 2011, we also finished construction of a parking terrace in South Jordan, Utah. In May of 2012, we completed our 74,680 square-foot manufacturing facility in Galway, Ireland. The total anticipated cost of these construction projects is approximately \$89.0 million. As of December 31, 2012, we had incurred total costs of approximately \$70.8 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**

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, 2012, 2011 and 2010, we recorded obsolescence expense of approximately \$2.3 million, \$1.5 million, and \$1.9 million, respectively, and wrote off approximately \$1.5 million, \$1.1 million, and \$1.1 million, respectively. Based on this historical trend, we believe that our inventory balances as of December 31, 2012 have 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.

**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 2012, which was completed during the third quarter of 2012, we determined that the fair value of each reporting unit with goodwill exceeded the carrying amount by a significant amount.

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 performance targets. Certain of our business combinations involve the potential for the payment of future contingent consideration, generally based on a percentage of future product sales or upon attaining specified future revenue milestones. 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 discounted cash flow method, which includes a probability factor for milestone payments, in valuing the contingent consideration liability. We re-measure the estimated liability each quarter and record changes in the estimated fair value through operating expense in our consolidated statements of income. Significant increases or decreases in our estimates 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.

**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, 2012, a portion of our revenues (approximately \$67.6 million, representing approximately 17% 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, 2012 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, 2012, the exchange rate between our foreign currencies against the U.S. Dollar resulted in a decrease in our gross revenues of approximately \$2.7 million, or .69%, and an increase of .47% in gross profit, primarily as a result of a decrease in Irish manufacturing operating costs denominated in Euros.

On November 30, 2012, we forecasted a net exposure for December 31, 2012 (representing the difference between Euro and GBP-denominated receivables and Euro-denominated payables) of approximately 527,000 Euros and 565,000 GBPs. In order to partially offset such risks at November 30, 2012, we entered into a 30-day forward contract for the Euro and GBP with a notional amount of approximately 527,000 Euros and notional amount of 565,000 GBPs. 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. 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, 2012, 2011 and 2010, we recorded a net gain (loss) on all foreign currency transactions of approximately \$(11,000), \$221,000 and \$126,000, respectively, which is included in other income in the accompanying consolidated statements of income. The fair value of our open positions at December 31, 2012 and 2011 was not material.

As discussed in Note 7 to our consolidated financial statements set forth in Item 8 of this report, as of December 31, 2012, we had outstanding borrowings of approximately \$237.6 million under the Credit Agreement. Accordingly, our earnings and after-tax cash flow are affected by changes in interest rates. As part of our efforts to mitigate interest rate risk, on December 19, 2012, we entered into a LIBOR-based interest rate swap agreement that effectively fixed the interest rate on \$150.0 million at 2.98%. This instrument is intended to reduce our exposure to interest rate fluctuations and was not entered into for speculative purposes. Excluding the \$150.0 million that is subject to a fixed rate under the interest rate swap and 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 \$876,000 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.

**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, 2012 and 2011, and the related consolidated statements of income, comprehensive income, stockholders’ equity, and cash flows for each of the three years in the period ended December 31, 2012. 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, 2012 and 2011, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, 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, 2012, based on the criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 1, 2013, expressed an unqualified opinion on the Company’s internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Salt Lake City, Utah  
March 1, 2013



**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**  
**DECEMBER 31, 2012 AND 2011**  
(In thousands)

	<u>2012</u>	<u>2011</u>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 9,719	\$ 10,128
Trade receivables — net of allowance for uncollectible accounts — 2012 — \$892 and 2011 — \$464	53,402	40,550
Employee receivables	169	154
Other receivables	2,672	1,750
Inventories	84,599	69,911
Prepaid expenses	4,133	3,775
Prepaid income taxes	1,250	883
Deferred income tax assets	4,976	3,704
Income tax refund receivable	1,076	2,797
Total current assets	<u>161,996</u>	<u>133,652</u>
<b>PROPERTY AND EQUIPMENT:</b>		
Land and land improvements	17,346	16,288
Buildings	81,223	59,905
Manufacturing equipment	117,601	103,629
Furniture and fixtures	26,307	22,559
Leasehold improvements	13,236	12,659
Construction-in-progress	74,643	47,534
Total property and equipment	<u>330,356</u>	<u>262,574</u>
Less accumulated depreciation	<u>(95,553)</u>	<u>(83,434)</u>
Property and equipment — net	<u>234,803</u>	<u>179,140</u>
<b>OTHER ASSETS:</b>		
Intangible assets:		
Developed technology — net of accumulated amortization — 2012 — \$8,146 and 2011 — \$4,759	87,332	35,415
Other — net of accumulated amortization — 2012 — \$14,034 and 2011 — \$10,215	30,799	21,254
Goodwill	175,108	61,144
Deferred income tax assets	4,237	5,366
Marketable securities	—	2,798
Other assets	11,034	8,248
Total other assets	<u>308,510</u>	<u>134,225</u>
<b>TOTAL</b>	<u><u>\$ 705,309</u></u>	<u><u>\$ 447,017</u></u>

See notes to consolidated financial statements.

(Continued)

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**  
**DECEMBER 31, 2012 AND 2011**  
(In thousands)

	<u>2012</u>	<u>2011</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Trade payables	\$ 34,637	\$ 22,727
Accrued expenses	27,269	20,197
Current portion of long-term debt	10,000	—
Advances from employees	551	225
Income taxes payable	547	646
Total current liabilities	<u>73,004</u>	<u>43,795</u>
LONG-TERM DEBT	227,566	30,737
DEFERRED INCOME TAX LIABILITIES	2,373	2,112
LIABILITIES RELATED TO UNRECOGNIZED TAX BENEFITS	2,938	3,489
DEFERRED COMPENSATION PAYABLE	5,956	4,585
DEFERRED CREDITS	2,980	1,984
OTHER LONG-TERM OBLIGATIONS	8,915	3,226
Total liabilities	<u>323,732</u>	<u>89,928</u>
<b>COMMITMENTS AND CONTINGENCIES (Notes 2, 7, 8, 9 and 13)</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Preferred stock — 5,000 shares authorized as of December 31, 2012 and 2011; no shares issued		
Common stock, no par value; shares authorized — 2012 and 2011 - 100,000; issued and outstanding as of December 31, 2012 - 42,489 and December 31, 2011 - 42,008	172,341	166,231
Retained earnings	210,418	190,708
Accumulated other comprehensive income (loss)	(1,182)	150
Total stockholders' equity	<u>381,577</u>	<u>357,089</u>
<b>TOTAL</b>	<u>\$ 705,309</u>	<u>\$ 447,017</u>

See notes to consolidated financial statements.

(Concluded)

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF INCOME**  
**YEARS ENDED DECEMBER 31, 2012, 2011 AND 2010**  
(In thousands, except per share amounts)

	<u>2012</u>	<u>2011</u>	<u>2010</u>
NET SALES	\$ 394,288	\$ 359,449	\$ 296,755
COST OF SALES	212,296	193,981	168,257
GROSS PROFIT	<u>181,992</u>	<u>165,468</u>	<u>128,498</u>
OPERATING EXPENSES:			
Selling, general, and administrative	122,106	104,502	87,615
Research and development	27,795	21,938	15,335
Acquired in-process research and development	2,450	5,838	—
Goodwill impairment charge	—	—	8,344
Total operating expenses	<u>152,351</u>	<u>132,278</u>	<u>111,294</u>
INCOME FROM OPERATIONS	<u>29,641</u>	<u>33,190</u>	<u>17,204</u>
OTHER INCOME (EXPENSE):			
Interest income	226	129	34
Interest expense	(604)	(789)	(596)
Other income (expense)	(1,645)	345	146
Other income (expense) — net	<u>(2,023)</u>	<u>(315)</u>	<u>(416)</u>
INCOME BEFORE INCOME TAXES	27,618	32,875	16,788
INCOME TAX EXPENSE	7,908	9,831	4,328
NET INCOME	<u>\$ 19,710</u>	<u>\$ 23,044</u>	<u>\$ 12,460</u>
EARNINGS PER COMMON SHARE:			
Basic	<u>\$ 0.47</u>	<u>\$ 0.59</u>	<u>\$ 0.35</u>
Diluted	<u>\$ 0.46</u>	<u>\$ 0.58</u>	<u>\$ 0.35</u>
AVERAGE COMMON SHARES:			
Basic	<u>42,176</u>	<u>39,086</u>	<u>35,290</u>
Diluted	<u>42,610</u>	<u>39,733</u>	<u>35,976</u>

See notes to consolidated financial statements.

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**  
**YEARS ENDED DECEMBER 31, 2012, 2011 AND 2010**  
**(In thousands)**

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Net income	\$ 19,710	\$ 23,044	\$ 12,460
Other comprehensive income (loss):			
Unrealized gain (loss) on marketable securities:			
Unrealized holding gain arising during the period, net of tax effect of \$215, \$115, \$0	336	180	—
Less: reclassification adjustment for gains included in net income, net of tax effect of \$330, \$0, \$0	(516)	—	—
Interest rate swap, net of tax effect of \$696, \$451, \$451	(1,093)	(708)	708
Foreign currency translation adjustment, net of tax effect of \$15, \$44, \$0	(59)	(182)	237
Total other comprehensive income (loss)	<u>(1,332)</u>	<u>(710)</u>	<u>945</u>
Total comprehensive income	<u>\$ 18,378</u>	<u>\$ 22,334</u>	<u>\$ 13,405</u>

See notes to consolidated financial statements.

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
**YEARS ENDED DECEMBER 31, 2012, 2011 AND 2010**  
(In thousands)

	Total	Common Stock		Retained Earnings	Accumulated Other Comprehensive Income (Loss)
		Shares	Amount		
BALANCE — January 1, 2010	\$218,809	35,226	\$ 63,690	\$155,204	\$ (85)
Net income	12,460			12,460	
Other comprehensive income, net of tax	945				945
Excess tax benefits from stock-based compensation	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
Net income	23,044			23,044	
Other comprehensive loss, net of tax	(710)				(710)
Excess tax benefits from stock-based compensation	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		
Issuance of common stock under Employee Stock Purchase Plans	430	31	430		
Options exercised	8,449	1,099	8,449		
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
Net income	19,710			19,710	
Other comprehensive loss, net of tax	(1,332)				(1,332)
Excess tax benefits from stock-based compensation	877		877		
Stock-based compensation expense	1,917		1,917		
Options exercised	5,156	610	5,156		
Issuance of common stock under Employee Stock Purchase Plans	430	33	430		
Shares surrendered in exchange for payment of payroll tax liabilities	(439)	(31)	(439)		
Shares surrendered in exchange for exercise of stock options	(1,831)	(131)	(1,831)		
BALANCE — December 31, 2012	\$381,577	42,489	\$172,341	\$210,418	\$ (1,182)

See notes to consolidated financial statements.

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**YEARS ENDED DECEMBER 31, 2012, 2011 AND 2010**  
(In thousands)

	2012	2011	2010
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net income	\$ 19,710	\$ 23,044	\$ 12,460
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	22,534	19,194	14,856
Losses on sales and/or abandonment of property and equipment	204	31	533
Write-off of patents and license agreement	55	103	134
Goodwill impairment charge	—	—	8,344
Impairment of cost-method investment	2,368	—	—
Acquired in-process research and development	2,450	5,838	—
Amortization of deferred credits	(174)	(106)	(111)
Purchase of trading investments	—	—	(644)
Unrealized gains on trading investments	—	—	(382)
Realized gain on sale of marketable securities	(745)	—	—
Deferred income taxes	549	1,677	(554)
Excess tax benefits from stock-based compensation	(877)	(3,122)	(399)
Stock-based compensation expense	1,917	1,644	1,294
Changes in operating assets and liabilities, net of effects from acquisitions:			
Trade receivables	(6,576)	(3,323)	(2,088)
Employee receivables	(11)	(62)	29
Other receivables	(760)	(245)	223
Inventories	(8,965)	(9,314)	(7,614)
Prepaid expenses	736	(1,726)	(192)
Prepaid income taxes	(367)	(431)	(60)
Income tax refund receivable	452	(733)	(1,573)
Other assets	(1,178)	(283)	(43)
Trade payables	7,721	(2,129)	5,643
Accrued expenses	4,448	1,334	3,090
Advances from employees	317	(65)	99
Income taxes payable	2,057	2,658	1,037
Liabilities related to unrecognized tax benefits	(209)	(226)	(372)
Deferred compensation payable	1,371	327	876
Other long-term obligations	(89)	(70)	174
Total adjustments	27,228	10,971	22,300
Net cash provided by operating activities	46,938	34,015	34,760

See notes to consolidated financial statements.

(Continued)

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**YEARS ENDED DECEMBER 31, 2012, 2011 AND 2010**  
(In thousands)

	<u>2012</u>	<u>2011</u>	<u>2010</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Capital expenditures for:			
Property and equipment	\$ 64,643	\$ (59,195)	\$ (23,648)
Intangible assets	(1,460)	(2,077)	(1,083)
Purchase of marketable securities	—	(2,503)	—
Proceeds from the sale of marketable securities	3,248	—	9,673
Proceeds from the sale of property and equipment	43	5	17
Cash paid in acquisitions, net of cash acquired	(192,762)	(10,250)	(97,785)
Net cash used in investing activities	<u>(255,574)</u>	<u>(74,020)</u>	<u>(112,826)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from issuance of common stock	3,755	95,454	1,708
Payment of offering costs related to issuance of common stock	—	(127)	—
Proceeds from issuance of long-term debt	330,630	104,585	108,491
Payments on long-term debt	(123,801)	(155,386)	(26,953)
Borrowings on line of credit	—	—	1,500
Payments on line of credit	—	—	(8,500)
Proceeds from industrial assistant grants	1,029	—	—
Excess tax benefits from stock-based compensation	877	3,122	399
Long-term debt issuance costs	(3,706)	—	(522)
Contingent payments related to acquisitions	(57)	—	—
Payment of taxes related to an exchange of common stock	(439)	(953)	—
Net cash provided by financing activities	<u>208,288</u>	<u>46,695</u>	<u>76,123</u>
EFFECT OF EXCHANGE RATES ON CASH	<u>(61)</u>	<u>(297)</u>	<u>(455)</u>
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(409)	6,393	(2,398)
<b>CASH AND CASH EQUIVALENTS:</b>			
Beginning of year	10,128	3,735	6,133
End of year	<u>\$ 9,719</u>	<u>\$ 10,128</u>	<u>\$ 3,735</u>

See notes to consolidated financial statements.

(Continued)

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**YEARS ENDED DECEMBER 31, 2012, 2011 AND 2010**  
**(In thousands)**

	<u>2012</u>	<u>2011</u>	<u>2010</u>
<b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION</b>			
Cash paid during the year for:			
Interest (net of capitalized interest of \$456, \$299 and \$13, respectively)	\$ 434	\$ 509	\$ 512
Income taxes	\$ 5,277	\$ 7,023	\$ 6,050
<b>SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES</b>			
Property and equipment purchases in accounts payable	\$ 12,372	\$ 8,849	\$ 3,778
Acquisition of customer list in exchange for a settlement of trade receivables	\$ 377	\$ —	\$ —
Acquisition purchases in accrued expenses and other long-term obligations	\$ 5,149	\$ 1,270	\$ 250
Merit common stock surrendered (131, 78 and 0 shares, respectively) in exchange for exercise of stock options	\$ 1,831	\$ 1,252	\$ —

See notes to consolidated financial statements.

(Concluded)



**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**YEARS ENDED DECEMBER 31, 2012, 2011 and 2010**

**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”) and the cardiac rhythm management and electrophysiology (“CRM/EP”) devices we acquired through our acquisition of Thomas Medical 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:

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, 2012, 2011 and 2010.

**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, 2012, 2011 and 2010 was approximately \$15.0 million, \$13.2 million, and \$11.4 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 \$6.1 million and \$4.8 million at December 31, 2012 and 2011, respectively, which is included in other assets in our consolidated balance sheets. We have recorded a deferred compensation payable of approximately \$6.0 million and \$4.6 million at December 31, 2012 and 2011, 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 were included in accumulated other comprehensive income of approximately \$295,000. There were no marketable securities held as of December 31, 2012.

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

**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 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, including returns related to defective products (i.e. warranty liability), as a reduction in net sales, based on our historical experience. We also offer sales rebates and discounts to purchasing groups. These reserves are recorded as a reduction in net sales and are not considered material to our consolidated statements of income for the years ended December 31, 2012, 2011 and 2010. 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 net sales for the applicable period, and the corresponding shipping and handling expense is reported in cost of sales.

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

**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, 2012, 2011 and 2010 was approximately \$1.9 million, \$1.6 million and \$1.3 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 4% of total sales for the years ended December 31, 2012, 2011 and 2010, respectively.

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

**Derivatives.** We use forward contracts to mitigate our exposure to volatility in foreign exchange rates, and we 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, 2012, accumulated other comprehensive loss included approximately (\$1.1) million (net of tax of \$696,000) related to an interest rate swap and \$(89,000) (net of tax of \$7,000) related to foreign currency translation. 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.

**Recently Issued Financial Accounting Standards.** In July 2012, the Financial Accounting Standards Board ("FASB") issued authoritative guidance related to testing indefinite-lived intangible assets for impairment. This guidance simplifies how entities test indefinite-lived intangible assets for impairment and permits an entity to first assess qualitative factors to determine whether it is more likely than not that the indefinite-lived intangible asset is impaired. This guidance is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012, with early adoption permitted. We do not anticipate that the adoption of this guidance will have a material effect on our consolidated financial statements.

In September 2011, the 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. The adoption of this guidance did not have a material effect 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. The adoption of this guidance did not have a material effect on our consolidated financial statements as it amended only the presentation of comprehensive income.

In May 2011, the FASB issued amendments to authoritative guidance related to fair value measurement and disclosure requirements. The new guidance changes some fair value measurement principles and enhances disclosure requirements related to activities in Level 3 of the fair value hierarchy. The amendments are effective for interim and annual periods beginning after December 15, 2011. The adoption of this guidance did not have a material effect on our consolidated financial statements.

## 2. ACQUISITIONS

On December 19, 2012, we consummated the transactions contemplated by a Stock Purchase Agreement with Vital Signs, Inc., an affiliate of GE Healthcare (“Vital Signs”), as seller, and purchased all of the issued and outstanding shares of Thomas Medical Products, Inc. (“Thomas Medical”), a Pennsylvania corporation. The primary assets of Thomas Medical are the various patents, trademarks, and business related to introducers, hemostatic valves, and sheaths. Using the splittable hemostatic introducer sheath as an entry product, we intend to develop a portfolio of premium accessories for EP physicians. We accounted for this acquisition as a business combination. We made an initial payment of \$167.0 million to Vital Signs in December 2012. We also accrued an additional \$445,000 at December 31, 2012, related to a final payment made to Vital Signs in February 2013 for net working capital received in excess of the target net working capital specified. The results of operations related to this acquisition have been included in our cardiovascular segment since the acquisition date. Our consolidated financial statements for the year ended December 31, 2012 include approximately \$1.9 million and \$51,000 of net sales and income before tax, respectively, related to the Thomas Medical acquisition. The total purchase price was preliminarily allocated as follows (in thousands):

<b>Assets Acquired</b>	
Trade receivables	\$ 6,507
Inventories	5,459
Prepaid expenses	340
Property and equipment	2,685
Intangibles	
Developed technology	43,000
Non-compete agreements	500
Customer lists	5,000
Trademarks	1,400
Goodwill	102,407
Total assets acquired	<u>167,298</u>
<b>Liabilities Assumed</b>	
Trade payables	588
Accrued expenses	1,094
Total liabilities assumed	<u>1,682</u>
Net assets acquired, net of cash acquired of \$1,829	<u>\$ 165,616</u>

The gross amount of trade receivables we acquired in the Thomas Medical transaction was approximately \$6.5 million, of which \$34,000 was expected to be uncollectible. With respect to the Thomas Medical assets, we intend to amortize developed technology over eight years, customer lists on an accelerated basis over 12 years, and

non-compete agreements over three 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 8.55 years.

In connection with our Thomas Medical acquisition, we paid approximately \$3.7 million in long-term debt issuance costs to Wells Fargo Bank related to our Credit Agreement (see Note 7). These costs consist primarily of loan origination fees and related legal costs that we intend to amortize over five years, which is the contract term of our Credit Agreement, dated December 19, 2012. We also incurred approximately \$2.7 million of acquisition-related costs during the year ended December 31, 2012, which are included in selling, general and administrative expense in the accompanying consolidated statements of operations.

On November 19, 2012, we entered into an Asset Purchase Agreement with Janin Group, Inc. (dba MediGroup) ("MediGroup"), an Illinois corporation, to purchase substantially all of the assets of MediGroup. The primary assets of MediGroup are the patented Flex-Neck® Peritoneal Dialysis Catheters and Y-TEC™ Peritoneal Dialysis Implantation Kits. We accounted for this acquisition as a business combination. We made an initial payment of approximately \$4.0 million in November 2012. In addition, we are obligated to make contingent payments of up to \$150,000 per year during 2013, 2014 and 2015. Furthermore, we are obligated to make contingent purchase price payments of \$150,000 per year in 2016 through 2022 if net sales of MediGroup products increase at least 8% in each subsequent year. If net sales of MediGroup products have not increased by the percentage set forth in any year, our obligation to make these contingent payments shall cease. The acquisition-date fair value of the contingent consideration liability of approximately \$403,000 has been included as part of the purchase consideration. Acquisition-related costs during the year ended December 31, 2012, which are included in selling, general, and administrative expense in the accompanying consolidated statements of income, were not material. The results of operations related to this acquisition have been included in our cardiovascular segment since the acquisition date. During the year ended December 31, 2012, our net sales of MediGroup products were approximately \$169,000. It is not practical to separately report the earnings related to the MediGroup acquisition, as we cannot split out sales costs related to MediGroup products, principally because our sales representatives are selling multiple products (including MediGroup products) in the cardiovascular business segment. The total purchase price, which includes the contingent consideration liability described above, was preliminarily allocated as follows (in thousands):

**Assets Acquired**

Inventories	\$	263
Property and equipment		79
Intangibles		
Developed technology		2,000
Non-compete agreements		210
Customer lists		110
Trademarks		80
Goodwill		1,697
Total assets acquired	<u>\$</u>	<u>4,439</u>

With respect to the MediGroup assets, we intend to amortize developed technology over eight years, customer lists on an accelerated basis over eight years, and non-compete agreements over seven 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 8.15 years.

On August 27, 2012, we entered into a license agreement with a medical device company for the use of certain patents. We paid \$750,000 for the use of the license. The purchase price was allocated to a license agreement for \$750,000, which we intend to amortize over three years.

On August 21, 2012, we entered into a distribution and patent sublicense agreement with Catheter Connections, Inc. ("CathConn"), a Utah corporation, for the exclusive rights to sell certain disinfecting cap technologies. We paid CathConn \$250,000 in August 2012 for the exclusive rights to distribute CathConn's MaleCap Solo technology in the field of interventional radiology and interventional cardiology. We can elect to pay an additional \$250,000 for each of the exclusive rights to other aspects of CathConn's DualCap disinfecting cap technology. The purchase price was allocated to a distribution agreement for \$250,000, which we intend to amortize over 10 years.

On August 7, 2012, we purchased 422,594 special membership units, which represents an ownership interest of approximately 11.9%, of Blockade Medical LLC ("Blockade"), a Delaware limited liability company, for an aggregate price of approximately \$1.0 million, which is accounted for at cost. Blockade develops, markets and sells catheter-based therapeutic devices.

On January 31, 2012, we consummated the transactions contemplated by an Asset Purchase Agreement with Ostial Solutions, LLC ("Ostial"), a Michigan limited liability company, to purchase substantially all of the assets of Ostial. The primary asset of Ostial is the patented Ostial PRO Stent Positioning System, which is designed to facilitate precise stent implantation in coronary and renal aorto-ostial lesions. We accounted for this acquisition as a business combination. We made an initial payment of \$10.0 million to Ostial in January 2012 and an additional payment of \$6.5 million to Ostial in August 2012. In addition, we are obligated to make contingent purchase price payments of up to \$13.5 million based on a percentage of future sales of products utilizing the Ostial PRO Stent Positioning System. The acquisition-date fair value of this contingent consideration liability of \$4.3 million has been included as part of the purchase consideration and was determined using a discounted cash flow model based upon the expected timing and amount of these future contingent payments. Acquisition-related costs during the year ended December 31, 2012, which are included in selling, general, and administrative expense in the accompanying consolidated statements of income, were not material. The results of operations related to this acquisition have been included in our cardiovascular segment since the acquisition date. During the year ended December 31, 2012, our net sales of products utilizing the Ostial PRO Stent Positioning System were approximately \$457,000. It is not practical to separately report the earnings related to the Ostial acquisition, as we cannot split out sales costs related to Ostial products, principally because our sales representatives are selling multiple products (including Ostial products) in the cardiovascular business segment. The total purchase price, which includes the contingent consideration liability described above, was allocated as follows (in thousands):

**Assets Acquired**

Intangibles

Developed technology	\$	10,500
Customer lists		600
Trademark		110
Non-compete agreements		10
Goodwill		9,580
Total assets acquired	\$	<u>20,800</u>

With respect to the Ostial assets, we intend to amortize developed technology over 15 years, customer lists on an accelerated basis over eight years, and non-compete agreements over five 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 14.6 years.

The following table summarizes our unaudited consolidated results of operations for the years ended December 31, 2012 and 2011, as well as unaudited pro forma consolidated results of operations as though the Thomas Medical, MediGroup and Ostial acquisitions had occurred on January 1, 2011 (in thousands, except per common share amounts):

	2012		2011	
	As Reported	Pro Forma	As Reported	Pro Forma
Net sales	\$ 394,288	\$431,861	\$ 359,449	\$396,767
Net income	19,710	24,296	23,044	22,033
Earnings per common share:				
Basic	\$ 0.47	\$ 0.58	\$ 0.59	\$ 0.56
Diluted	\$ 0.46	\$ 0.57	\$ 0.58	\$ 0.55

The unaudited pro forma information set forth above is for informational purposes only and includes adjustments related to the step-up of acquired inventories, amortization expense related to acquired intangible assets, and interest expense on long-term debt. The pro forma information should not be considered indicative of actual results that would have been achieved if Thomas Medical, MediGroup and Ostial had been acquired at the beginning of 2011 or results that may be obtained in any future period.

On January 5, 2012, we entered into a Marketing and Distribution Agreement with Scion Cardio-Vascular, Inc. ("Scion"), a Florida corporation, wherein we purchased the exclusive, worldwide right to distribute the Clo-Sur<sup>PLUS</sup> P.A.D.<sup>TM</sup> for \$2.5 million. We made an initial payment of \$1.5 million to Scion in January 2012. We made an additional payment of \$1.0 million in May 2012 upon reaching a milestone set forth in the purchase agreement. The purchase price was allocated to a distribution agreement for \$2.5 million, which we intend to amortize over 12 years. As a result of entering into this agreement, we terminated several exclusive Scion sales distributor agreements where we 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 \$95,000 and was allocated to other intangible assets in the accompanying consolidated balance sheet as of December 31, 2012. We intend to amortize the customer lists on an accelerated basis over five years.

During the year ended December 31, 2012, we purchased several patents for the development of future products. A total charge of approximately \$2.5 million related to these asset acquisitions has been recorded to acquired in-process research and development in the accompanying consolidated statements of income for the year ended December 31, 2012, since both technological feasibility of the underlying research and development projects had not yet been reached and such technology had no future alternative use as of the respective date of each asset acquisition.

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 accounted for this acquisition as a business combination. 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 milestone set forth in the purchase agreement and future royalties based on a percentage of related product sales. The acquisition-date fair value of the contingent consideration liability of approximately \$1.3 million 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 ended December 31, 2011, net sales subsequent to the acquisition date related to



our dialysis catheter acquired were not material. The total purchase price, which includes the contingent consideration liability described above, was allocated as follows (in thousands):

<b>Assets Acquired</b>	
Property and equipment	\$ 73
Intangibles	
Developed technology	3,200
Customer lists	300
Goodwill	2,697
Total assets acquired	<u>\$ 6,270</u>

During the year ended December 31, 2012, the goodwill related to the Ash acquisition was increased by approximately \$280,000 due to adjustments to the contingent consideration liability.

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 \$968,000 and \$948,000 has been reflected in our consolidated balance sheets as a long-term liability as of December 31, 2012 and 2011, respectively.

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 a payment of \$1.0 million in May 2012 based on a certain obligation set forth in the agreement having been met. We are obligated to pay up to an additional \$1.0 million if certain 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.

The vena cava filter technology, introducer sheath technology, and support guide technology discussed above represented asset acquisitions related to a research and development project and 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 both technological feasibility of the underlying research and development projects had not yet been reached and such technology had no future alternative use as of the respective date of each asset acquisition. During the year ended December 31, 2011, we also abandoned the development of certain biomaterial technology and our covered biliary in-process research and development, resulting in charges of \$500,000 and \$400,000, respectively.

On April 6, 2011, we acquired the manufacturing rights for certain valve technology. We made an initial payment of \$500,000 in April 2011 and a final payment of \$500,000 in August 2011. We 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 ten years.

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):

**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	<u>102,290</u>
<b>Liabilities Assumed</b>	
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	<u>6,565</u>
Net assets acquired, net of cash acquired of \$274	<u>\$ 95,725</u>

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 ten years and customer lists on an accelerated basis over ten 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 consisted primarily of loan origination fees and related legal costs that we intend to amortize over the contract term of our Credit Agreement. 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 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 ten 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 ten years.

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

	Year Ended December 31, 2010	
	As Reported	Pro Forma
Sales	\$ 296,755	\$ 317,382
Net income	12,460	7,258
Earnings per common share:		
Basic	\$ 0.35	\$ 0.21
Diluted	\$ 0.35	\$ 0.20

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 2010, or results that may be obtained in any future period.

The goodwill arising from the acquisitions discussed above consists largely of the synergies and economies of scale we hope to achieve from combining the acquired assets and operations with our historical operations (see Note 4). The goodwill recognized from these acquisitions is expected to be deductible for income tax purposes, except for the goodwill recognized in connection with our stock acquisition of BioSphere in 2010.

### 3. INVENTORIES

Inventories at December 31, 2012 and 2011, consisted of the following (in thousands):

	2012	2011
Finished goods	\$ 48,233	\$ 38,095
Work-in-process	6,051	6,047
Raw materials	30,315	25,769
Total	\$ 84,599	\$ 69,911

#### 4. GOODWILL AND INTANGIBLE ASSETS

The changes in the carrying amount of goodwill for the years ended December 31, 2012 and 2011, are as follows (in thousands):

	2012	2011
Goodwill balance at January 1	\$ 61,144	\$ 58,675
Adjustment related to previous acquisitions	280	(228)
Additions as the result of acquisitions	113,684	2,697
Goodwill balance at December 31	<u>\$ 175,108</u>	<u>\$ 61,144</u>

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 carrying value amount of this reporting unit was more than its estimated fair value. Some of the factors that influenced our estimated cash flows were slower sales growth in the products acquired from our Alveolus acquisition in March of 2009, uncertainty regarding acceptance of new products and continued operating losses in our endoscopy business segment. During the year ended December 31, 2010, we recorded an impairment charge of approximately \$8.3 million, which was offset by approximately \$3.2 million of deferred tax asset. As of December 31, 2012 and 2011, total accumulated goodwill impairment loss was approximately \$8.3 million, all of which is related to the endoscopy segment. The remaining goodwill balance at December 31, 2012 and 2011 relates entirely to our cardiovascular segment.

Other intangible assets at December 31, 2012 and 2011, consisted of the following (in thousands):

	2012		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patents	\$ 7,843	\$ (2,045)	\$ 5,798
Distribution agreement	5,176	(1,301)	3,875
License agreements	2,733	(861)	1,872
Trademarks	7,311	(1,362)	5,949
Covenant not to compete	1,035	(160)	875
Customer lists	20,468	(8,038)	12,430
Royalty agreements	267	(267)	—
Total	<u>\$ 44,833</u>	<u>\$ (14,034)</u>	<u>\$ 30,799</u>
	2011		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patents	\$ 6,455	\$ (1,704)	\$ 4,751
Distribution agreement	2,426	(900)	1,526
License agreements	1,983	(436)	1,547
Trademarks	5,746	(1,014)	4,732
Covenant not to compete	315	(108)	207
Customer lists	14,277	(5,786)	8,491
Royalty agreements	267	(267)	—
Total	<u>\$ 31,469</u>	<u>\$ (10,215)</u>	<u>\$ 21,254</u>

Aggregate amortization expense for the years ended December 31, 2012, 2011 and 2010 was approximately \$7.5 million, \$6.0 million and \$3.5 million, respectively.

Estimated amortization expense for the intangible assets for the next five years consists of the following as of December 31, 2012 (in thousands):

<u>Year Ending December 31</u>	2013	\$ 13,934
	2014	13,264
	2015	12,738
	2016	12,274
	2017	11,917

## 5. INCOME TAXES

For the years ended December 31, 2012, 2011 and 2010, income before income taxes is broken out between U.S. and foreign-sourced operations and consisted of the following (in thousands):

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Domestic	\$ 15,958	\$ 21,123	\$ 10,551
Foreign	11,660	11,752	6,237
Total	<u>\$ 27,618</u>	<u>\$ 32,875</u>	<u>\$ 16,788</u>

The components of the provision for income taxes for the years ended December 31, 2012, 2011 and 2010, consisted of the following (in thousands):

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Current expense:			
Federal	\$ 5,350	\$ 5,662	\$ 3,547
State	1,014	1,001	595
Foreign	995	1,491	740
Total current expense	<u>7,359</u>	<u>8,154</u>	<u>4,882</u>
Deferred expense (benefit):			
Federal	871	1,121	30
State	(343)	74	(545)
Foreign	21	482	(39)
Total deferred expense (benefit)	<u>549</u>	<u>1,677</u>	<u>(554)</u>
Total	<u>\$ 7,908</u>	<u>\$ 9,831</u>	<u>\$ 4,328</u>

The difference between the income tax expense reported and amounts computed by applying the statutory federal rate of 35.0% to pretax income for the years ended December 31, 2012, 2011 and 2010, consisted of the following (in thousands):

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Computed federal income tax expense at statutory rate of 35%	\$ 9,667	\$ 11,506	\$ 5,876
State income taxes	436	699	33
Tax credits	(779)	(778)	(530)
Production activity deduction	(388)	(425)	(355)
Foreign tax rate differential	(1,419)	(1,297)	(1,212)
Uncertain tax positions	(42)	281	(372)
Deferred compensation insurance assets	(155)	88	(133)
Transaction-related expenses	—	—	323
Other — including the effect of graduated rates	588	(243)	698
Total income tax expense	<u>\$ 7,908</u>	<u>\$ 9,831</u>	<u>\$ 4,328</u>

Deferred income tax assets and liabilities at December 31, 2012 and 2011, consisted of the following temporary differences and carry-forward items (in thousands):

	<u>2012</u>	<u>2011</u>
Deferred income tax assets:		
Allowance for uncollectible accounts receivable	\$ 348	\$ 188
Accrued compensation expense	3,954	3,064
Inventory differences	1,949	364
Net operating loss carry-forwards	19,622	22,689
Deferred revenue	237	273
Stock-based compensation expense	2,465	2,166
Uncertain tax positions	709	1,052
Other	3,762	1,848
Total deferred income tax assets	<u>33,046</u>	<u>31,644</u>
Deferred income tax liabilities:		
Prepaid expenses	(757)	(823)
Property and equipment	(19,001)	(17,236)
Intangible assets	(4,107)	(6,169)
Other	(1,116)	(97)
Total deferred income tax liabilities	<u>(24,981)</u>	<u>(24,325)</u>
Valuation allowance	(1,225)	(361)
Net deferred income tax assets	<u>\$ 6,840</u>	<u>\$ 6,958</u>
Reported as:		
Deferred income tax assets - Current	\$ 4,976	\$ 3,704
Deferred income tax assets - Long-term	4,237	5,366
Deferred income tax liabilities - Current	—	—
Deferred income tax liabilities - Long-term	(2,373)	(2,112)
Net deferred income tax assets	<u>\$ 6,840</u>	<u>\$ 6,958</u>

The long-term deferred income tax balances are not netted as they represent deferred amounts applicable to different taxing jurisdictions. Deferred income tax balances reflect the temporary differences between the carrying amounts of assets and liabilities and their tax bases and are stated at enacted tax rates expected to be in effect when taxes are actually paid or recovered. The valuation allowance is primarily related to state credit carryforwards and capital loss carryforwards for which we believe it is more likely than not that the deferred tax assets will not be realized. The valuation allowance increased by approximately \$864,000 and \$361,000 during the years ended December 31, 2012 and 2011, respectively.

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

As of December 31, 2012 and 2011, we had U.S. federal net operating loss carryforwards of approximately \$56 million and \$64.6 million, respectively, which were generated by BioSphere prior to our acquisition of BioSphere in September 2010. These net operating loss carryforwards, which expire at various dates through 2030, are subject to an annual limitation under Internal Revenue Code Section 382. We anticipate that we will utilize the net operating loss carryforwards over the next 14 years. We utilized a total of approximately \$8.6 million in U.S. federal net operating loss carryforwards during both 2012 and 2011.

As of December 31, 2012 and 2011, we had non-U.S. net operating loss carryforwards of approximately \$150,000 and \$250,000, respectively, which have no expiration date. Non-U.S. net operating loss carryforwards utilized during 2012 were not material. During 2011, we utilized approximately \$2.6 million in non-U.S. net operating loss carryforwards.

On January 2, 2013, the American Taxpayer Relief Act of 2012, which includes a reinstatement of the federal research and development credit for the tax year ended December 31, 2012, was signed into law. We estimate that our credit for 2012 will be approximately \$500,000. As a result, we will recognize the retroactive benefit of the federal research and development credit as a discrete item in the first quarter of 2013, the period in which the reinstatement was enacted.

We are subject to income taxes in the United States and numerous foreign jurisdictions. Significant judgment is required in determining our worldwide provision for income taxes and recording the related assets and liabilities. In the ordinary course of our business, there are many transactions and calculations where the ultimate tax determination is uncertain. In our opinion, we have made adequate provisions for income taxes for all years subject to audit. We are no longer subject to U.S. federal, state, and local income tax examinations by tax authorities for years before 2009. In foreign jurisdictions, we are no longer subject to income tax examinations for years before 2006.

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

The total liability for unrecognized tax benefits at December 31, 2012 and 2011, including interest and penalties, was approximately \$2.9 million and \$3.5 million, respectively, of which approximately \$2.2 million and \$2.4 million, respectively, would favorably impact our effective tax rate if recognized. As of December 31, 2012 and 2011, we have accrued approximately \$161,000 and \$376,000 respectively, in total interest and penalties related to unrecognized tax benefits. We account for interest and penalties for unrecognized tax benefits as part of our income tax provision. During the year ended December 31, 2012, we removed interest and penalties of approximately \$215,000 from our liability for unrecognized tax benefits. The decrease in interest and penalties was primarily related to an interest payment to the IRS in order to settle a withholding tax issue related to our acquisition of BioSphere. During the years ended December 31, 2011 and 2010, we added interest and penalties of approximately \$12,000 and \$400,000, respectively, to our liability for unrecognized tax benefits. We anticipate the total liability for unrecognized tax benefits may be reduced, net of potential increases and decreases due to the expiration of statutes of limitation, by a range of approximately \$250,000 to \$750,000 within the next 12 months.

A reconciliation of the beginning and ending amount of liabilities associated with uncertain tax benefits for the years ended December 31, 2012, 2011 and 2010, consisted of the following (in thousands):

<b>Tabular Roll-forward</b>	<b>2012</b>	<b>2011</b>	<b>2010</b>
Unrecognized tax benefits, opening balance	\$ 3,113	\$ 2,952	\$ 2,790
Gross increases in tax positions taken in a prior year	83	347	518
Gross decreases in tax positions taken in a prior year	—	—	(51)
Gross increases in tax positions taken in the current year	260	865	520
Settlements with taxing authorities	—	(507)	—
Lapse of applicable statute of limitations	(680)	(544)	(825)
Unrecognized tax benefits, ending balance	<u>\$ 2,776</u>	<u>\$ 3,113</u>	<u>\$ 2,952</u>

The tabular roll-forward ending balance does not include interest and penalties related to unrecognized tax benefits. During the year ended December 31, 2011, we paid approximately \$507,000 to the IRS in order to settle a withholding tax issue related to our acquisition of BioSphere. The payment of the withholding tax did not have a material impact on our consolidated financial statements for the year ended December 31, 2011, as the tax liability had been identified as part of our acquisition accounting of BioSphere and recorded in our consolidated financial statements.

## 6. ACCRUED EXPENSES

Accrued expenses at December 31, 2012 and 2011, consisted of the following (in thousands):

	<b>2012</b>	<b>2011</b>
Payroll taxes	\$ 1,893	\$ 1,786
Payroll	3,141	2,075
Bonuses	5,778	2,736
Commissions	894	912
Vacation	5,066	4,362
Royalties	1,368	1,310
Value-added tax	1,158	1,018
Other accrued expenses	7,971	5,998
Total	<u>\$ 27,269</u>	<u>\$ 20,197</u>

## 7. REVOLVING CREDIT FACILITY AND LONG-TERM DEBT

We entered into an Amended and Restated Credit Agreement, dated as of December 19, 2012 (the "Credit Agreement"), with the lenders who are or may become party thereto (the "Lenders") and Wells Fargo, as administrative agent for the Lenders. Pursuant to the terms of the Credit Agreement, the Lenders have agreed to make revolving credit loans up to an aggregate amount of \$175 million. The Lenders also made a term loan in the amount of \$100 million, repayable in quarterly installments of \$2.5 million until the maturity date of December 19, 2017, at which time the term loan and revolving credit loans, together with accrued interest thereon, will be due and payable. In addition, certain mandatory prepayments are required to be made upon the occurrence of certain events described in the Credit Agreement. Wells Fargo has agreed to make swingline loans from time to time through the maturity date of December 19, 2017 in amounts equal to the difference between the amounts actually loaned by the Lenders and the aggregate revolving credit commitment. The Credit Agreement is collateralized by substantially all of our assets.

On December 19, 2017, all principal, interest and other amounts outstanding under the Credit Agreement are payable in full. At any time prior to the maturity date, we may repay any amounts owing under all revolving



credit loans, term loans, and all swingline loans in whole or in part, subject to certain minimum thresholds, without premium or penalty, other than breakage costs.

The term loan and any revolving credit loans made under the Credit Agreement bear interest, at our election, at either (i) the base rate (described below) plus 0.25% (subject to adjustment if the Consolidated Total Leverage Ratio, as defined in the Credit Agreement, is at or greater than 2.25 to 1), (ii) the London Inter-Bank Offered Rate ("LIBOR") Market Index Rate (as defined in the Credit Agreement) plus 1.25% (subject to adjustment if the Consolidated Total Leverage Ratio, as defined in the Credit Agreement, is at or greater than 2.25 to 1), or (iii) the LIBOR Rate (as defined in the Credit Agreement) plus 1.25% (subject to adjustment if the Consolidated Total Leverage Ratio, as defined in the Credit Agreement, is at or greater than 2.25 to 1). Initially, the term loan and revolving credit loans under the Credit Agreement bear interest, at our election, at either (x) the base rate plus 1.00%, (y) the LIBOR Market Index Rate, plus 2.00%, or (z) the LIBOR Rate plus 2.00%. Swingline loans bear interest at the LIBOR Market Index Rate plus 1.25% (subject to adjustment if the Consolidated Total Leverage Ratio, as defined in the Credit Agreement, is at or greater than 2.25 to 1). Initially, swingline loans bear interest at the LIBOR Market Index Rate plus 2.00%. Interest on each loan featuring the base rate or the LIBOR Market Index Rate is due and payable on the last business day of each calendar month; interest on each loan featuring the LIBOR Rate is due and payable on the last day of each interest period selected by us when selecting the LIBOR Rate as the benchmark for interest calculation. For purposes of the Credit Agreement, the base rate means the highest of (i) the prime rate (as announced by Wells Fargo), (ii) the federal funds rate plus 0.50%, and (iii) LIBOR for an interest period of one month plus 1.00%. Our obligations under the Credit Agreement and all loans made thereunder are fully secured by a security interest in our assets pursuant to a separate collateral agreement entered into in conjunction with the Credit Agreement.

The Credit Agreement contains customary covenants, representations and warranties and other terms customary for revolving credit loans of this nature. In this regard, the Credit Agreement requires us to not, among other things, (a) permit the Consolidated Total Leverage Ratio (as defined in the Credit Agreement) to be greater than 3.5 to 1 as of any fiscal quarter ending during 2013, no more than 3.35 to 1 as of any fiscal quarter ending during 2014, no more than 3 to 1 as of any fiscal quarter ending during 2015, no more than 2.75 to 1 as of any fiscal quarter ending during 2016, and no more than 2.5 to 1 as of any fiscal quarter ending thereafter; (b) for any period of four consecutive fiscal quarters, permit the ratio of Consolidated EBITDA (as defined in the Credit Agreement and subject to certain adjustments) to Consolidated Fixed Charges (as defined in the Credit Agreement) to be less than 1.75 to 1; (c) subject to certain adjustments, permit Consolidated Net Income (as defined in the Credit Agreement) for certain periods to be less than \$0; or (d) subject to certain conditions and adjustments, permit the aggregate amount of all Facility Capital Expenditures (as defined in the Credit Agreement) in any fiscal year beginning in 2013 to exceed \$30 million. Additionally, the Credit Agreement contains various negative covenants with which we must comply, including, but not limited to, limitations respecting: the incurrence of indebtedness, the creation of liens or pledges on our assets, mergers or similar combinations or liquidations, asset dispositions, the repurchase or redemption of equity interests and debt, the issuance of equity, the payment of dividends and certain distributions, the entrance into related party transactions and other provisions customary in similar types of agreements. As of December 31, 2012, we were in material compliance with all covenants set forth in the Credit Agreement.

We had originally entered into an unsecured credit agreement, dated September 30, 2010, with certain lenders who were or became party thereto and Wells Fargo, as administrative agent for the lenders. Pursuant to the terms of that credit agreement, the lenders agreed to make revolving credit loans up to an aggregate amount of \$125 million. Wells Fargo also agreed to make swingline loans from time to time through the maturity date of September 10, 2015 in amounts equal to the difference between the amount actually loaned by the lenders and the aggregate credit agreement. The unsecured credit agreement was amended and restated as of December 19, 2012, as the Credit Agreement.

In summary, principal balances under our long-term debt as of December 31, 2012 and 2011, consisted of the following (in thousands):

	<u>2012</u>	<u>2011</u>
Term loan	\$ 100,000	\$ —
Revolving credit loans	137,566	30,737
Total long-term debt	237,566	30,737
Less current portion	10,000	—
Long-term portion	<u>\$ 227,566</u>	<u>\$ 30,737</u>

Future minimum principal payments on our long-term debt as of December 31, 2012, are as follows (in thousands):

<u>Years Ending December 31</u>	<u>Future Minimum Principal Payments</u>
2013	\$ 10,000
2014	10,000
2015	10,000
2016	10,000
2017	197,566
Total future minimum principal payments	<u>\$ 237,566</u>

As of December 31, 2012, we had available borrowings of approximately \$33.8 million, based on the leverage ratio in the terms of the Credit Agreement. Our interest rate as of December 31, 2012 was a fixed rate of 2.98% on \$150.0 million as a result of an interest rate swap (see Note 8), a variable floating rate of 2.22% on \$87.0 million and a variable floating rate of 2.31% on approximately \$566,000. Our interest rate 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.

On December 7, 2006, we entered into an unsecured loan agreement with Bank of America, whereby Bank of America agreed to provide us with a line of credit in the amount of \$30.0 million, which expired on December 7, 2010. The loan agreement required us to pay interest at a rate equal to the lesser of (i) the maximum lawful rate of interest permitted under applicable usury laws, or (ii) Bank of America's prime rate, plus a negative margin, as defined in the loan agreement. Alternatively, we could elect optional interest rates based on LIBOR during interest periods we agreed to with Bank of America. During the year ended December 31, 2010, all outstanding amounts were repaid and the loan agreement was terminated.

## 8. DERIVATIVES

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

We formally document, designate and assess the effectiveness of transactions that receive hedge accounting initially and on an ongoing basis. Changes in the fair value of derivatives that qualify for hedge accounting treatment are recorded, net of applicable taxes, in accumulated other comprehensive income (loss), a component of stockholders' equity in the accompanying consolidated balance sheets. For the ineffective portions of qualifying hedges, the change in fair value is recorded through earnings in the period of change. Changes in the fair value of

derivatives not designated as cash flow hedges are recorded in earnings throughout the term of the derivative instrument.

**Interest Rate Swap.** A portion of our debt bears interest at variable interest rates and therefore, we are subject to variability in the cash paid for interest expense. In order to mitigate a portion of this risk, we used a hedging strategy to reduce the variability of cash flows in the interest payments associated with the first \$150 million of the total variable-rate debt outstanding under our Credit Agreement that is solely due to changes in the benchmark interest rate.

On December 19, 2012, we entered into a \$150 million pay-fixed, receive-variable interest rate swap with Wells Fargo at a fixed interest rate of 2.98%. The variable portion of the interest rate swap is tied to the one-month LIBOR rate (the benchmark interest rate). The interest rates under both the interest rate swap and the underlying debt reset, the swap is settled with the counterparty, and interest is paid, on a monthly basis. The interest rate swap is scheduled to expire on December 19, 2017.

At December 31, 2012, the interest rate swap qualified as a cash flow hedge. The fair value of our interest rate swap at December 31, 2012 was a liability of approximately \$1.8 million, which was offset by approximately \$696,000 in deferred taxes .

During the year ended December 31, 2011, we terminated a \$55.0 million pay-fixed receive-variable interest rate swap agreement, which resulted in a cash receipt and gain of approximately \$28,000 upon final settlement.

During the years ended December 31, 2012, 2011 and 2010, the amount reclassified from accumulated other comprehensive income to earnings due to hedge effectiveness were included in interest expense in the accompanying consolidated statements of income and were not material.

**Foreign Currency Forward Contracts.** On November 30, 2012, we forecasted a net exposure for December 31, 2012 (representing the difference between Euro and GBP-denominated receivables and Euro-denominated payables) of approximately 527,000 Euros and 565,000 GBPs. In order to partially offset such risks at November 30, 2012, we entered into a 30-day forward contract for the Euro and GBP with a notional amount of approximately 527,000 Euros and notional amount of 565,000 GBPs. 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. 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, 2012, 2011 and 2010, we recorded a net gain (loss) on all foreign currency transactions of approximately \$(11,000), \$221,000 and \$126,000, respectively, which is included in other income in the accompanying consolidated statements of income. The fair value of our open positions at December 31, 2012 and 2011 was not material.

## 9. COMMITMENTS AND CONTINGENCIES

We are obligated under non-terminable operating leases for manufacturing facilities, finished good distribution, office space and equipment. Total rental expense on these operating leases and on our manufacturing and office building for the years ended December 31, 2012, 2011 and 2010, approximated \$4.8 million, \$4.1 million and \$3.7 million, respectively.

The future minimum lease payments for operating leases as of December 31, 2012, consisted of the following (in thousands):

Years Ending December 31	Operating Leases
2013	\$ 3,892
2014	3,619
2015	3,146
2016	2,399
2017	2,075
Thereafter	4,331
Total minimum lease payments	<u>\$ 19,462</u>

**Irish Government Development Agency Grants.** As of December 31, 2012, we had entered into several grant agreements with the Irish Government Development Agency. We have recorded the grants related to research and development projects and costs of hiring and training employees as a reduction of operating expenses for the years ended December 31, 2012, 2011 and 2010 in the amounts of approximately \$424,000, \$261,000 and \$40,000, respectively. Grants related to the acquisition of property and equipment purchased in Ireland are amortized as a reduction to depreciation expense over lives corresponding to the depreciable lives of such property and equipment. The balance of deferred credits related to such grants as of December 31, 2012 and 2011, was approximately \$3.0 million and \$2.0 million, respectively. During the years ended December 31, 2012, 2011 and 2010, approximately \$174,000, \$106,000 and \$111,000, respectively, of the deferred credit was amortized as a reduction of operating expenses.

We have committed to repay the Irish government for grants received if we were to cease production in Ireland prior to the expiration of the grant liability period. The grant liability period is usually between five and eight years from the last claim made on a grant. As of December 31, 2012, the total amount of grants that could be subject to refund was approximately \$3 million. Our management does not believe we will ever have to repay any of these grant monies, as we have no intention of ceasing operations in Ireland.

**Litigation.** In the ordinary course of business, we are involved in various claims and litigation matters. These claims and litigation matters may include actions involving product liability, intellectual property, contractual, and employment matters. We do not believe that any such actions are likely to be, individually or in the aggregate, material to our business, financial condition, results of operations or liquidity. However, in the event of unexpected further developments, it is possible that the ultimate resolution of these matters, or other similar matters, if unfavorable, may be materially adverse to our business, financial condition, results of operations or liquidity. Legal costs for these matters such as outside counsel fees and expenses are charged to expense in the period incurred.

Intellectual property rights, particularly patents, play a significant role in product development and help differentiate competitors in the medical device market. Competing companies may file infringement lawsuits in attempts to bolster their intellectual property portfolios or enhance their financial standing. Intellectual property litigation is time consuming, costly and unpredictable. Monetary judgments, remedies or restitution are often not determined until the conclusion of trial court proceedings, which can be modified on appeal. Accordingly, the outcomes of pending litigation are difficult to predict or quantify. In late 2011, a third party asserted that certain of our product offerings infringed its patents. During the year ended December 31, 2012, we settled the litigation for an immaterial amount and we received a fully-paid up license going forward. There are no future payments due under the settlement.

**FDA Warning Letter.** 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”) alleging that a modification to the hydrophilic coating process for our Merit Laureate® Hydrophilic Guidewire (the “Guidewire”) constituted a significant change that could significantly affect the Guidewire safety or effectiveness. In the Warning Letter, the FDA claimed that we did not have an approved application for premarket approval of the Guidewire in effect pursuant to Section 515(a) of the U.S. Food, Drug and Cosmetic Act (the “Act”) or an approved application for an investigational device exemption under Section 520(g) of the Act. The FDA also claimed in the Warning Letter that the Guidewire was misbranded under Section 502(o) of the Act 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. We submitted a formal response to the FDA in which we committed to completing corrective actions that would address the alleged violation in a comprehensive and sustainable manner, and we temporarily ceased all commercial distribution of the Guidewire within the United States. On September 24, 2012, we announced that we received Section 510(k) clearance from the FDA to market the Guidewire, and we re-commenced commercial distribution of the Guidewire in the United States. On October 23, 2012, we received a letter from the FDA stating that it appears we have addressed the violation contained in the Warning Letter.

## 10. EARNINGS PER COMMON SHARE (EPS)

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

	Net Income	Shares	Per Share Amount
Year ended December 31, 2012:			
Basic EPS	\$ 19,710	42,176	\$ 0.47
Effect of dilutive stock options and warrants		434	
Diluted EPS	\$ 19,710	42,610	\$ 0.46
Year ended December 31, 2011:			
Basic EPS	\$ 23,044	39,086	\$ 0.59
Effect of dilutive stock options and warrants		647	
Diluted EPS	\$ 23,044	39,733	\$ 0.58
Year ended December 31, 2010:			
Basic EPS	\$ 12,460	35,290	\$ 0.35
Effect of dilutive stock options and warrants		686	
Diluted EPS	\$ 12,460	35,976	\$ 0.35

For the years ended December 31, 2012, 2011 and 2010, approximately 1,588,000, 909,000 and 878,000, respectively, of stock options were not included in the computation of diluted earnings per share because their effect would have been anti-dilutive.

## 11. EMPLOYEE STOCK PURCHASE PLAN STOCK OPTIONS AND WARRANTS.

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

**2006 Long-Term Incentive Plan.** In May 2006, our Board of Directors adopted and our shareholders approved, the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan (the “2006 Incentive Plan”). The 2006 Incentive Plan provides for the granting of stock options, stock appreciation rights, restricted stock, stock units (including restricted stock units) and performance awards. Options may be granted to directors, officers, outside consultants and key employees and may be granted upon such terms and such conditions as the Compensation Committee of our Board of Directors determines. Options will typically vest on an annual basis over a three to five

year life (or one year if performance based) with contractual lives of seven to ten years. As of December 31, 2012, a total of approximately 1.3 million shares remained available to be issued under the 2006 Incentive Plan.

**Employee Stock Purchase Plan.** We have a qualified and a non-qualified Employee Stock Purchase Plan (“ESPP”), which has an expiration date of June 30, 2016. As of December 31, 2012, the total number of shares of Common Stock that remained available to be issued under our qualified plan was approximately 257,000 shares and 69,000 shares for our non-qualified plan. ESPP participants purchase shares on a quarterly basis at a price equal to 95% of the market price of the Common Stock at the end of the applicable offering period.

**Stock-Based Compensation Expense.** The stock-based compensation expense before income tax expense for the years ended December 31, 2012, 2011 and 2010, consisted of the following (in thousands):

	2012	2011	2010
Cost of goods sold	\$ 245	\$ 241	\$ 201
Research and development	119	86	56
Selling, general, and administrative	1,553	1,317	1,037
Stock-based compensation expense before taxes	<u>\$ 1,917</u>	<u>\$ 1,644</u>	<u>\$ 1,294</u>

We recognize stock-based compensation expense (net of a forfeiture rate) for those awards which are expected to vest on a straight-line basis over the requisite service period. We estimate the forfeiture rate based on our historical experience and expectations about future forfeitures. As of December 31, 2012, the total remaining unrecognized compensation cost related to non-vested stock options, net of expected forfeitures, was approximately \$4.5 million and is expected to be recognized over a weighted average period of 3.2 years.

In applying the Black-Scholes methodology to the option grants, the fair value of our stock-based awards granted were estimated using the following assumptions for the periods indicated below:

	2012	2011	2010
Risk-free interest rate	0.54% - 0.95%	0.68% - 1.34%	2.24%
Expected option life	4.2 - 6.0 years	4.2 - 6.0 years	6.0 years
Expected dividend yield	—%	—%	—%
Expected price volatility	42.01% - 44.56%	42.11% - 45.29%	41.4%

The average risk-free interest rate is determined using the U.S. Treasury rate in effect as of the date of grant, based on the expected term of the stock option. We determine the expected term of the stock options using the historical exercise behavior of employees. The expected price volatility was determined using a weighted average of daily historical volatility of our stock price over the corresponding expected option life and implied volatility based on recent trends of the daily historical volatility. For options with a vesting period, compensation expense is recognized on a straight-line basis over the service period, which corresponds to the vesting period. Compensation expense is recognized immediately for options that are fully vested on the date of grant. During the years ended December 31, 2012, 2011 and 2010, approximately 128,000, 844,000 and 125,000 stock-based compensation grants were made, respectively, for a total fair value of approximately \$677,000, \$4.3 million and \$705,000, net of estimated forfeitures, respectively.

The table below presents information related to stock option activity for the years ended December 31, 2012, 2011 and 2010 (in thousands):

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Total intrinsic value of stock options exercised	\$ 3,472	\$ 9,433	\$ 1,928
Cash received from stock option exercises	3,325	7,197	1,330
Net income tax benefit from the exercises of stock options	877	3,122	399

Changes in stock options for the year ended December 31, 2012, consisted of the following (shares and intrinsic value in thousands):

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Remaining Contractual Term (in years)</u>	<u>Intrinsic Value</u>
2012:				
Beginning balance	4,077	\$ 11.96		
Granted	128	13.04		
Exercised	(610)	8.51		
Forfeited/expired	(60)	14.82		
Outstanding at December 31	<u>3,535</u>	12.55	3.0	\$ 6,161
Exercisable	2,521	12.55	3.0	6,156
Ending vested and expected to vest	3,521	12.21	2.2	5,635

The weighted average grant-date fair value of options granted during the years ended December 31, 2012, 2011 and 2010 was \$5.31, \$5.28 and \$5.64, respectively.

The following table summarizes information about stock options outstanding at December 31, 2012 (shares in thousands):

<u>Range of Exercise</u>	<u>Options Outstanding</u>			<u>Options Exercisable</u>	
	<u>Number Outstanding</u>	<u>Weighted Average Remaining Contractual Life (in years)</u>	<u>Weighted Average Exercise Price</u>	<u>Number Exercisable</u>	<u>Weighted Average Exercise Price</u>
\$ 7.79 - \$11.05	932	1.74	\$ 9.83	932	\$ 9.83
\$11.41 - \$12.02	922	2.24	11.69	812	11.71
\$12.10 - \$13.75	1,042	5.59	13.59	206	13.63
\$13.82 - \$17.34	639	1.90	16.05	571	16.30
\$ 7.79 - \$17.34	<u>3,535</u>			<u>2,521</u>	

## 12. SEGMENT REPORTING AND FOREIGN OPERATIONS

We report our operations in two operating segments: cardiovascular and endoscopy. Our cardiovascular segment consists of cardiology and radiology medical device products which assist in diagnosing and treating coronary artery disease, peripheral vascular disease and other non-vascular diseases and includes the embolization devices we acquired through our acquisition of BioSphere and the CRM/EP devices we acquired through our acquisition of Thomas Medical. Our endoscopy segment consists of gastroenterology and pulmonology medical device products which assist in the palliative treatment of expanding esophageal, tracheobronchial and biliary strictures caused by malignant tumors. We evaluate the performance of our operating segments based on operating income (loss). Listed below are the sales by business segment for the years ended December 31, 2012, 2011 and 2010 (in thousands):

	<u>% Change</u>	<u>2012</u>	<u>% Change</u>	<u>2011</u>	<u>% Change</u>	<u>2010</u>
<b>Cardiovascular</b>						
Stand-alone devices	12%	\$ 114,242	15%	\$ 101,959	16%	\$ 88,586
Custom kits and procedure trays	3%	94,586	11%	91,532	11%	82,799
Inflation devices	2%	68,979	8%	67,353	2%	62,495
Catheters	17%	64,878	23%	55,357	18%	44,824
Embolization devices	8%	33,870	247%	31,229	—%	9,003
CRM/EP	—%	1,938	—%	—	—%	—
<b>Total</b>	<b>9%</b>	<b>378,493</b>	<b>21%</b>	<b>347,430</b>	<b>15%</b>	<b>287,707</b>
<b>Endoscopy</b>						
Endoscopy devices	31%	15,795	33%	12,019	18%	9,048
<b>Total</b>	<b>10%</b>	<b>\$ 394,288</b>	<b>21%</b>	<b>\$ 359,449</b>	<b>15%</b>	<b>\$ 296,755</b>

During the years ended December 31, 2012, 2011 and 2010, we had foreign sales of approximately \$146.3 million, \$125.9 million and \$95.2 million, respectively, or approximately 37%, 35% and 32%, respectively, of total sales, primarily in China, Japan, Germany, France, the United Kingdom and Russia. Foreign sales are attributed based on location of the customer receiving the product.

Our long-lived assets by geographic area at December 31, 2012, 2011 and 2010, consisted of the following (in thousands):

	<u>2012</u>	<u>2011</u>	<u>2010</u>
United States	\$ 176,644	\$ 134,393	\$ 97,881
Ireland	48,182	36,008	22,203
Other foreign countries	9,977	8,739	7,971
<b>Total</b>	<b>\$ 234,803</b>	<b>\$ 179,140</b>	<b>\$ 128,055</b>



Financial information relating to our reportable operating segments and reconciliations to the consolidated totals for the years ended December 31, 2012, 2011 and 2010, are as follows (in thousands):

	<u>2012</u>	<u>2011</u>	<u>2010</u>
<b>Revenues</b>			
Cardiovascular	\$ 378,493	\$ 347,430	\$ 287,707
Endoscopy	15,795	12,019	9,048
Total revenues	<u>394,288</u>	<u>359,449</u>	<u>296,755</u>
<b>Operating expenses</b>			
Cardiovascular	142,089	122,600	93,884
Endoscopy	10,262	9,678	9,066
Total operating expenses	<u>152,351</u>	<u>132,278</u>	<u>102,950</u>
<b>Goodwill impairment charge</b>			
Cardiovascular	—	—	—
Endoscopy	—	—	8,344
Total goodwill impairment charge	<u>—</u>	<u>—</u>	<u>8,344</u>
<b>Operating income (loss)</b>			
Cardiovascular	30,411	38,010	30,176
Endoscopy	(770)	(4,820)	(12,972)
Total operating income	<u>29,641</u>	<u>33,190</u>	<u>17,204</u>
Total other expense – net	(2,023)	(315)	(416)
Income tax expense	7,908	9,831	4,328
Net income	<u>\$ 19,710</u>	<u>\$ 23,044</u>	<u>\$ 12,460</u>

Total assets by business segment at December 31, 2012, 2011 and 2010, consisted of the following (in thousands):

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Cardiovascular	\$ 692,689	\$ 434,747	\$ 355,718
Endoscopy	12,620	12,270	13,762
Total	<u>\$ 705,309</u>	<u>\$ 447,017</u>	<u>\$ 369,480</u>

Total depreciation and amortization by business segment for the years ended December 31, 2012, 2011 and 2010, consisted of the following (in thousands):

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Cardiovascular	\$ 21,441	\$ 18,219	\$ 13,851
Endoscopy	1,093	975	1,005
Total	<u>\$ 22,534</u>	<u>\$ 19,194</u>	<u>\$ 14,856</u>

Total capital expenditures by business segment for the years ended December 31, 2012, 2011 and 2010, consisted of the following (in thousands):

	2012	2011	2010
Cardiovascular	\$ 64,059	\$ 58,775	\$ 23,494
Endoscopy	584	420	154
Total	<u>\$ 64,643</u>	<u>\$ 59,195</u>	<u>\$ 23,648</u>

### 13. ROYALTY AGREEMENTS

During 2007, in connection with the purchase of the ProGuide™ chronic dialysis catheter from Datascope Corporation ("Datascope"), a New Jersey corporation, we entered into a running royalty agreement as partial consideration of the assignment of acquired intellectual property to us. Under this agreement, we agreed to pay Datascope a royalty of 5% of net sales, with annual minimum royalty payments of \$50,000 for calendar years 2009 through 2013. During each of the years ended December 31, 2012, 2011 and 2010, we paid or accrued a royalty of \$50,000 under this agreement.

During 2010, in connection with our acquisition of BioSphere, we entered into a running royalty agreement as part of a partnership between BioSphere and L'Assistance Publique-Hôpitaux de Paris, referred to as "AP-HP," pursuant to which AP-HP has granted us the exclusive license to use two United States patents and their foreign counterparts that we jointly own with AP-HP relating to microspheres. We are required to pay to AP-HP a royalty on the commercial sale of any products that incorporate technology covered by the subject patents. We may sublicense these exclusive rights under the agreement only with the prior written consent of AP-HP, which consent cannot be unreasonably withheld. Under the terms of the royalty agreement, our exclusive license extends for both (i) the term of jointly owned U.S. and foreign counterpart patents and (ii) as long as the products and specialties implementing the patents are marketed. BioSphere filed patent applications which, if issued, will expire in approximately January 2031. The royalty rate in the agreement is 5.0% of net sales until the patents expire, and 2.5% of net sales thereafter as long as the product is sold. We paid or accrued approximately \$1.4 million, \$1.3 million and \$401,000 in royalty payments to AP-HP for the years ended December 31, 2012, 2011 and 2010, respectively, after the BioSphere acquisition.

See Note 2 for a discussion of additional future royalty commitments related to acquisitions.

### 14. EMPLOYEE BENEFIT PLANS

We have a contributory 401(k) savings and profit sharing plan (the "Plan") covering all U.S. full-time employees who are at least 18 years of age. The Plan has a 90-day minimum service requirement. We may contribute, at our discretion, matching contributions based on the employees' compensation. Contributions we made to the Plan for the years ended December 31, 2012, 2011 and 2010, totaled approximately \$1.5 million, \$1.2 million and \$1.2 million, respectively. We have defined contribution plans covering some of our foreign employees. We contribute between three percent and 31% of the employee's compensation for certain foreign non-management employees, and between ten percent and 31% of the employee's compensation for certain foreign management employees. Contributions made to these plans for the years ended December 31, 2012, 2011 and 2010, totaled approximately \$724,000, \$469,000 and \$565,000, respectively.

## 15. QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)

Quarterly data for the years ended December 31, 2012 and 2011 consisted of the following (in thousands, except per share amounts):

	Quarter Ended			
	March 31	June 30	September 30	December 31
<b>2012</b>				
Net sales	\$ 95,618	\$ 100,532	\$ 95,907	\$ 102,231
Gross profit	44,170	47,024	45,335	45,463
Income from operations	8,007	8,222	9,082	4,330
Income tax expense	2,169	2,719	1,811	1,209
Net income	5,748	6,095	7,226	641
Basic earnings per common share	0.14	0.14	0.17	0.02
Diluted earnings per common share	0.14	0.14	0.17	0.01
<b>2011</b>				
Net sales	\$ 86,631	\$ 91,249	\$ 90,477	\$ 91,092
Gross profit	39,785	42,484	41,054	42,145
Income from operations	10,210	10,847	6,507	5,626
Income tax expense	3,159	3,746	2,120	806
Net income	6,639	6,872	4,563	4,970
Basic earnings per common share	0.19	0.19	0.11	0.12
Diluted earnings per common share	0.18	0.18	0.11	0.12

Basic and diluted earnings per share are computed independently for each of the quarters presented. Therefore, the sum of the quarterly amounts may not equal the total computed for the year. Net income for the quarter ended December 31, 2012 was negatively impacted primarily by acquisition-related costs arising from our acquisition of Thomas Medical and the impairment of a cost-method investment. See Notes 2 and 16 for additional information related to these items.

## 16. FAIR VALUE MEASUREMENTS

Our financial assets and (liabilities) carried at fair value measured on a recurring basis as of December 31, 2012 and 2011, consisted of the following (in thousands):

Description	Total Fair Value at December 31, 2012	Fair Value Measurements Using		
		Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant Unobservable inputs (Level 3)
Interest rate swap (1)	\$ (1,788)	\$ —	\$ (1,788)	\$ —
Description	Total Fair Value at December 31, 2011	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant Unobservable inputs (Level 3)
Marketable securities (2)	\$ 2,798	\$ 2,798	\$ —	\$ —

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

(2) Our marketable securities, which consist entirely of available-for-sale equity securities, are valued using market prices in active markets. Level 1 instrument valuations are obtained from real-time quotes for transactions in active exchange markets involving identical assets.

Certain of our business combinations involve the potential for the payment of future contingent consideration, generally based on a percentage of future product sales or upon attaining specified future revenue milestones. See Note 2 for further information regarding these acquisitions. The contingent consideration liability is re-measured at the estimated fair value at each reporting period with the change in fair value recognized within selling, general, and administrative expenses in the accompanying consolidated statements of income. We measure the initial liability and re-measure the liability on a recurring basis using Level 3 inputs as defined under authoritative guidance for fair value measurements. Changes in the fair value of our contingent liability during the years ended December 31, 2012 and 2011 consisted of the following (in thousands):

	2012	2011
Beginning balance	\$ 1,290	\$ —
Contingent consideration liability recorded as the result of acquisitions (see Note 2)	4,704	1,270
Initial purchase price adjustments finalized over the period (see Note 2)	280	—
Fair value adjustments recorded to expense during the period	480	20
Contingent payments made	(57)	—
Ending balance	<u>\$ 6,697</u>	<u>\$ 1,290</u>

The recurring Level 3 measurement of our contingent consideration liability includes the following significant unobservable inputs at December 31, 2012 and 2011 (amount in thousands):

Contingent consideration liability	Fair value at December 31, 2012	Valuation technique	Unobservable inputs	Range
Revenue-based payments	\$ 6,370	Discounted cash flow	Discount rate	10% - 14.5%
			Probability of milestone payment	90%
			Projected year of payments	2013-2028
Other payments	327	Discounted cash flow	Discount rate	4.5%
			Probability of milestone payment	100%
			Projected year of payments	2013-2015
Contingent consideration liability	Fair value at December 31, 2011	Valuation technique	Unobservable inputs	Range
Revenue-based payments	\$ 1,290	Discounted cash flow	Discount rate	10% - 14.5%
			Probability of milestone payment	90%
			Projected year of payments	2012-2028

The contingent consideration liability is re-measured to fair value each reporting period using projected revenues, discount rates, probabilities of payment, and projected payment dates. Projected contingent payment amounts are discounted back to the current period using a discounted cash flow model. Projected revenues are based on our most recent internal operational budgets and long-range strategic plans. Increases (decreases) in discount rates and the time to payment may result in lower (higher) fair value measurements. A decrease in the probability of any milestone payment may result in lower fair value measurements. An increase (decrease) in either the discount rate or the time to payment, in isolation, may result in a significantly lower (higher) fair value measurement.

Our determination of the fair value of the contingent consideration liability could change in future periods based upon our ongoing evaluation of these significant unobservable inputs. We intend to record any such change in fair value to selling, general, and administrative expenses in our consolidated statements of income. As of December 31, 2012, approximately \$5.9 million was included in other long-term obligations and \$723,000 was included in accrued expenses in our consolidated balance sheet. As of December 31, 2011, the entire balance was included in other long-term obligations in our consolidated balance sheet. The cash paid to settle the contingent consideration liability recognized at fair value as of the acquisition date (including measurement-period adjustments) has been reflected as a cash outflow from financing activities in the accompanying consolidated statements of cash flows.

During the years ended December 31, 2012, 2011 and 2010, we had losses of approximately \$55,000, \$103,000, and \$8.5 million, respectively, related to the measurement of non-financial assets at fair value on a nonrecurring basis subsequent to their initial recognition. Of the total loss in 2010, approximately \$8.3 million was related to the impairment of our goodwill related to our endoscopy reporting unit (see Note 4). The fair value of these non-financial assets was measured using Level 3 inputs. As of December 31, 2010, there was no goodwill remaining in our consolidated financial statements related to the endoscopy reporting unit.

During the quarter ended December 31, 2012, we recognized an impairment charge of approximately \$2.4 million, which is included in other expense in the accompanying consolidated statement of income, related to an investment in a privately-held company accounted for at cost. As of December 31, 2012, there was no remaining cost included in our consolidated balance sheet related to this investment.

The carrying amount of cash and cash equivalents, receivables, and trade payables approximates fair value because of the immediate, short-term maturity of these financial instruments. The carrying amount of long-term debt approximates fair value, as determined by borrowing rates estimated to be available to us for debt with similar terms and conditions. The fair value of assets and liabilities whose carrying value approximates fair value is determined using Level 2 inputs, with the exception of cash and cash equivalents (Level 1).

## **17. STOCKHOLDERS' EQUITY**

**Issuance of Common Stock.** On June 22, 2011, we completed an equity public 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 and approximately \$127,000 in other direct costs incurred and paid by us in connection with this equity offering.

**Stock Split.** On April 21, 2011, our Board of Directors authorized a 5-for-4 forward stock split of our Common Stock, which was effected in the form of a stock dividend of one share of Common Stock for every four shares of Common Stock outstanding on the record date. On May 5, 2011, we completed the forward stock split through a stock dividend to shareholders of record as of May 2, 2011. Our Board of Directors also made corresponding adjustments to the number of shares subject to, and the exercise price of, outstanding options and other rights to acquire shares of our Common Stock. All earnings per common share and common share data set forth in the foregoing consolidated financial statements (and notes thereto) have been adjusted to reflect the split.

## **SUPPLEMENTARY FINANCIAL DATA**

The supplementary financial information required by Item 302 of Regulation S-K is contained in Note 15 to our consolidated financial statements set forth above.

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

None.

**Item 9A. Controls and Procedures.**

**EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES**

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934 ("Exchange Act"), as of December 31, 2012. Based on this evaluation, our principal executive officer and principal financial officer concluded that as of December 31, 2012, our disclosure controls and procedures were effective, at a reasonable assurance level, to ensure that information we are required to disclose in the reports we file or submit under the Exchange Act is (a) recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and is (b) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

**MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING**

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2012. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in *Internal Control-Integrated Framework*. As permitted by SEC guidance, we excluded Thomas Medical from management's assessment of internal control over financial reporting as of December 31, 2012. Thomas Medical's financial statements constituted approximately 2.2% of total assets (excluding approximately \$152.1 million of goodwill and intangible assets, which were integrated into our systems and control environment), 0.5% of net sales, and 1.0% of pre-tax income (excluding approximately \$251,000 of amortization of intangible assets, which was integrated into our systems and control environment) of the consolidated financial statements amounts as of and for the year ended December 31, 2012. Based on those criteria and our management's assessment, our management concluded that, as of December 31, 2012, our internal control over financial reporting was effective.

**CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING**

Except as set forth below, during the quarter ended December 31, 2012, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934).

On December 19, 2012, we completed our acquisition of Thomas Medical. We are currently integrating policies, processes, employees, technology and operations for the combined company. Management will continue to evaluate our internal control over financial reporting as we execute acquisition integration activities.

Our independent registered public accountants have also issued an audit report on our internal control over financial reporting. Their report appears on the following page.

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the internal control over financial reporting of Merit Medical Systems, Inc. and subsidiaries (the "Company") as of December 31, 2012, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. As described in the accompanying Management's Report on Internal Control over Financial Reporting, management excluded from its assessment a portion of the internal control over financial reporting at Thomas Medical Products, Inc. ("Thomas Medical"), which was acquired on December 19, 2012 and whose financial statements constitute approximately 2.2% of total assets (excluding approximately \$152.1 million of goodwill and intangible assets, which were integrated into the Company's systems and control environment), 0.5% of net sales, and 1.0% of pre-tax income (excluding approximately \$251,000 of amortization of intangible assets, which was integrated into the Company's systems and control environment) of the consolidated financial statements amounts as of and for the year ended December 31, 2012. Accordingly, our audit did not include the portion of internal control over financial reporting at Thomas Medical that is excluded from management's assessment. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements and financial statement schedule as of and for the year ended December 31, 2012 of the Company and our report dated March 1, 2013 expressed an unqualified opinion on those financial statements and financial statement schedule.

/s/ DELOITTE & TOUCHE LLP  
Salt Lake City, Utah  
March 1, 2013

**Item 9B. Other Information.**

None.

**PART III**

**Items 10, 11, 12, 13 and 14.**

These items are incorporated by reference to our definitive proxy statement relating to our Annual Meeting of Shareholders scheduled for May 22, 2013. We anticipate that our definitive proxy statement will be filed with the SEC not later than 120 days after December 31, 2012, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended.

**PART IV**

**Item 15. Exhibits and Financial Statement Schedules.**

(a) Documents filed as part of this Report:

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

Report of Independent Registered Public Accounting Firm — Internal Control

Report of Independent Registered Public Accounting Firm — Financial Statements

Consolidated Balance Sheets as of December 31, 2012 and 2011

Consolidated Statements of Income for the Years Ended December 31, 2012, 2011 and 2010

Consolidated Statements of Comprehensive Income for the Years Ended December 31, 2012, 2011 and 2010

Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2012, 2011 and 2010

Consolidated Statements of Cash Flows for the Years Ended December 31, 2012, 2011 and 2010

Notes to Consolidated Financial Statements



(2) Financial Statement Schedule.

Schedule II - Valuation and qualifying accounts

**Years Ended December 31, 2012, 2011 and 2010**  
**(In thousands)**

<u>Description</u>	<u>Balance at</u> <u>Beginning of Year</u>	<u>Additions Charged to</u> <u>Costs and Expenses (a)</u>	<u>Deduction (b)</u>	<u>Balance at</u> <u>End of Year</u>
<b>ALLOWANCE FOR UNCOLLECTIBLE</b>				
<b>ACCOUNTS:</b>				
<b>2010</b>	\$ (541)	\$ (193)	\$ 141	\$ (593)
<b>2011</b>	(593)	(12)	141	(464)
<b>2012</b>	(464)	(545)	117	(892)

(a) We record a bad debt provision based upon historical experience and a review of individual customer balances.

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

**Years Ended December 31, 2012, 2011 and 2010**  
**(In thousands)**

<u>Description</u>	<u>Balance at</u> <u>Beginning of Year</u>	<u>Additions Charged to</u> <u>Costs and Expenses (c)</u>	<u>Deduction</u>	<u>Balance at</u> <u>End of Year</u>
<b>TAX VALUATION ALLOWANCE:</b>				
<b>2010</b>	\$ —	\$ —	\$ —	\$ —
<b>2011</b>	—	(361)	—	(361)
<b>2012</b>	(361)	(864)	—	(1,225)

(c) We record a valuation allowance against a deferred tax asset when it is determined that it is more likely than not that the deferred tax asset will not be realized.

(b) Exhibits:

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

	<u>Description</u>	<u>Exhibit No.</u>
2.1	Agreement and Plan of Merger dated May 13, 2010 by and among Merit Medical Systems, Inc., Merit BioAcquisition Co., and BioSphere Medical, Inc.*	[Form 8-K filed May 13, 2010, Exhibit 2.1]
2.2	Stock Purchase Agreement dated November 26, 2012 by and between Merit Medical Systems, Inc. and Vital Signs, Inc.*	[Form 8-K/A filed January 24 2013, Exhibit 2.1]
3.1	Articles of Incorporation as amended and restated*	[Form 10-Q filed August 14, 1996, Exhibit No. 1]
3.2	Amended and Restated Bylaws*	[Form 10-K filed February 29, 2012, Exhibit No. 3.2]
4	Specimen Certificate of the Common Stock*	[Form S-18 filed October 19, 1989, Exhibit No. 10]
4.3	Articles of Amendment of the Articles of Incorporation dated May 14, 1993*	[Form S-3 filed February 14, 2005, Exhibit 4.3]
4.4	Articles of Amendment to Articles of Incorporation dated June 6, 1996*	[Form S-3 filed February 14, 2005, Exhibit 4.4]
4.5	Articles of Amendment to Articles of Incorporation dated June 12, 1997*	[Form S-3 filed February 14, 2005, Exhibit 4.5]
4.7	Articles of Amendment to the Articles of Incorporation dated May 22, 2003*	[Form S-3 filed February 14, 2005, Exhibit 4.7]
4.8	Articles of Amendment to the Articles of Incorporation dated May 23, 2008*	[Form 8-K filed May 28, 2008, Exhibit 3.1]
10.1	Merit Medical Systems, Inc. Long Term Incentive Plan (as amended and restated) dated March 25, 1996*†	[Form 10-Q filed August 14, 1996, Exhibit No. 2]
10.2	Merit Medical Systems, Inc. 401(k) Profit Sharing Plan (as amended effective January 1, 1991)*†	[Form S-1 filed February 14, 1992, Exhibit No. 8]
10.3	License Agreement, dated April 8, 1992 with Utah Medical Products, Inc.*	[Form S-1 filed February 14, 1992, Exhibit No. 5]
10.4	Lease Agreement dated as of June 8, 1993 for office and manufacturing facility*	[Form 10-K for year ended December 31, 1994, Exhibit No. 10.4]
10.12	Amended and Restated Deferred Compensation Plan*†	[Form 10-K for year ended December 31, 2003, Exhibit No. 10.12]
10.13	Purchase Agreement dated November 17, 2004 between Merit Medical Systems, Inc. and MedSource Packaging Concepts LLC*	[Form 10-K for year ended December 31, 2004, Exhibit No. 10.13]
10.17	Unsecured Loan Agreement with Bank of America, N.A.*	[Form 8-K filed December 7, 2006, Exhibit 10.1]

	Description	Exhibit No.
10.18	Seventh Amendment to the First Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan*†	[Form 10-K for year ended December 31, 2006, Exhibit No. 10.18]
10.19	Stock Purchase Agreement by and between Merit Medical Systems, Inc. and Sheen Man Co. LTD, dated April 1, 2007*	[Form 10-Q filed May 9, 2007, Exhibit No. 10.19]
10.20	Eighth Amendment to the First Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan*†	[Form 10-K for year ended December 31, 2007, Exhibit No. 10.20]
10.21	Ninth Amendment to the First Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan*†	[Form 10-K for year ended December 31, 2007, Exhibit No. 10.21]
10.22	Tenth Amendment to the First Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan*†	[Form 10-K for year ended December 31, 2007, Exhibit No. 10.22]
10.23	Merit Medical Systems, Inc. Amended and Restated Deferred Compensation Plan, effective January 1, 2008*†	[Form 8-K filed December 18, 2008, Exhibit 10.1]
10.29	Eleventh Amendment to the First Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan*†	[Form 10-K for year ended December 31, 2008, Exhibit No. 10.29]
10.30	Twelfth Amendment to the First Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan*†	[Form 10-K for year ended December 31, 2008, Exhibit No. 10.30]
10.31	Second Amendment to the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan*†	[Form 8-K filed May 27, 2009, Exhibit 10.1]
10.32	Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan*†	[Form 8-K filed January 7, 2010, Exhibit 10.1]
10.33	Stockholder and Voting Agreement, dated as of May 13, 2010, among Merit Medical Systems, Inc., Cerberus Partners, L.P. and Cerberus International, Ltd.*	[Form 8-K/A filed May 14, 2010, Exhibit 10.1]
10.34	Amendment No. 1 to Stockholder and Voting Agreement, dated as of June 1, 2010, among Merit Medical Systems, Inc., Cerberus Partners, L.P. and Cerberus International, Ltd. *	[Form 8-K filed June 2, 2010, Exhibit 10.2]
10.35	Credit Agreement dated as of September 10, 2010 by and among Merit Medical Systems, Inc. and Wells Fargo Bank, National Association*	[Form 8-K/A filed September 16, 2010, Exhibit 10.1]
10.36	Amended and Restated Employment Agreement of Fred P. Lampropoulos dated December 30, 2010*†	[Form 10-K for year ended December 31, 2010, Exhibit No. 10.36]
10.37	Amended and Restated Employment Agreement of Kent Stanger dated December 30, 2010*†	[Form 10-K for year ended December 31, 2010, Exhibit No. 10.37]
10.38	Amended and Restated Employment Agreement of Marty Stephens dated December 30, 2010*†	[Form 10-K for year ended December 31, 2010, Exhibit No. 10.38]

	Description	Exhibit No.
10.39	Amended and Restated Employment Agreement of Rashelle Perry dated December 30, 2010*†	[Form 10-K for year ended December 31, 2010, Exhibit No. 10.39]
10.40	Amended and Restated Employment Agreement of Arlin D. Nelson dated December 30, 2010*†	[Form 10-K for year ended December 31, 2010, Exhibit No. 10.40]
10.41	Stock Purchase Agreement by and between Vital Signs, Inc. and Merit Medical Systems, Inc., dated as of November 26, 2012*	[Form 8-K/A filed November 30, 2012, Exhibit 2.1]
10.42	Amended and Restated Credit Agreement dated December 19, 2012 by and among Merit Medical Systems, Inc. and Wells Fargo Bank, National Association*	[Form 8-K filed December 21, 2012, Exhibit 10.1]
21	Subsidiaries of Merit Medical Systems, Inc	Filed herewith
23.1	Consent of Independent Registered Public Accounting Firm	Filed herewith
31.1	Certification of Chief Executive Officer	Filed herewith
31.2	Certification of Chief Financial Officer	Filed herewith
32.1	Certification of Chief Executive Officer	Filed herewith
32.2	Certification of Chief Financial Officer	Filed herewith
101	The following materials from the Merit Medical Systems, Inc. Annual Report on Form 10-K for the fiscal year ended December 31, 2012, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Statements of Operations, (ii) Consolidated Balance Sheets, (iii) Consolidated Statements of Comprehensive Income (iv) Consolidated Statements of Stockholders' Equity, (v) Consolidated Statements of Cash Flows, and (vi) related notes.	Filed herewith

\* These exhibits are incorporated herein by reference.

† Indicates management contract or compensatory plan or arrangement.

(c) Schedules:

None

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, on March 1, 2013.

MERIT MEDICAL SYSTEMS, INC.

By: /s/ FRED P. LAMPROPOULOS

Fred P. Lampropoulos, President and  
Chief Executive Officer

## ADDITIONAL SIGNATURE AND POWER OF ATTORNEY

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on March 1, 2013. In addition, each person whose signature to this report appears below hereby constitutes and appoints Fred P. Lampropoulos and Kent W. Stanger, and each of them, as his true and lawful attorney-in-fact and agent, with full power of substitution, to sign on his behalf individually and in the capacity stated below and to perform any acts necessary to be done in order to file all amendments and post-effective amendments to this report, and any and all instruments or documents filed as part of or in connection with this report or the amendments thereto and each of the undersigned does hereby ratify and confirm all that said attorney-in-fact and agent, or his substitutes, shall do or cause to be done by virtue hereof.

<u>Signature</u>	<u>Capacity in Which Signed</u>
<u>/s/: FRED P. LAMPROPOULOS</u> Fred P. Lampropoulos	President, Chief Executive Officer and Director (Principal executive officer)
<u>/s/: KENT W. STANGER</u> Kent W. Stanger	Chief Financial Officer, Secretary, Treasurer and Director (Principal financial and accounting officer)
<u>/s/: RICHARD W. EDELMAN</u> Richard W. Edelman	Director
<u>/s/: REX C. BEAN</u> Rex C. Bean	Director
<u>/s/: MICHAEL E. STILLABOWER</u> Michael E. Stillabower	Director
<u>/s/: FRANKLIN J. MILLER</u> Franklin J. Miller	Director
<u>/s/: NOLAN E. KARRAS</u> Nolan E. Karras	Director
<u>/s/: A. SCOTT ANDERSON</u> A. Scott Anderson	Director

(This page has been left blank intentionally)

# Corporate Information

## EXECUTIVE OFFICERS

Fred P. Lampropoulos  
Chairman, Chief Executive Officer

Kent W. Stanger  
Chief Financial Officer, Secretary, Treasurer

Martin R. Stephens  
Executive Vice President, Sales & Marketing

Arlin D. Nelson  
Chief Operating Officer

Rashelle Perry  
Chief Legal Officer

Gregory L. Barnett  
Chief Accounting Officer

## BOARD OF DIRECTORS

Fred P. Lampropoulos  
Chairman, Chief Executive Officer

A. Scott Anderson  
President and Chief Executive Officer  
of Zions First National Bank

Rex C. Bean  
Private Investor

Richard W. Edelman  
Private Investor

Nolan E. Karras  
Chairman and CEO of the Karras Company, Inc.

Franklin J. Miller, M.D.  
Emeritus Professor, Interventional Radiology  
University of Utah

Kent W. Stanger  
Chief Financial Officer, Secretary, Treasurer

Michael E. Stillabower, M.D.  
Director, Cardiovascular Clinical Trials,  
Christiana Care Heath Systems, Wilmington, Delaware  
Clinical Associate Professor of Medicine,  
Jefferson Medical College, Philadelphia, Pennsylvania

CORPORATE OFFICES  
Merit Medical Systems, Inc.  
1600 West Merit Parkway  
South Jordan, Utah 84095  
(801) 253-1600

INDEPENDENT ACCOUNTANTS  
Deloitte & Touche LLP

LEGAL COUNSEL  
Parr Brown Gee & Loveless  
Corporate and Securities Counsel  
Stoel Rives LLP  
Intellectual Property Counsel

## FORM 10-K

Merit Medical Systems, Inc. filed an annual report on Form 10-K with the Securities and Exchange Commission for the fiscal year ended December 31, 2012. A copy may be obtained by written request from Kent W. Stanger, CFO, at the Company's corporate office in South Jordan, Utah.

## ANNUAL MEETING

All shareholders are invited to attend our Annual Meeting on Wednesday, May 22, 2013 at 3:00 p.m. at the Company's corporate office in South Jordan, Utah.

## STOCK TRANSFER AGENT/REGISTRAR

Zions First National Bank  
Stock Transfer Department  
P. O. Box 30880  
Salt Lake City, Utah 84130

## MARKET INFORMATION

The Company's common stock is traded on the NASDAQ Global Select Market System under the symbol "MMSI." As of February 26, 2013, the number of shares of Common Stock outstanding was 42,530,822 held by approximately 136 shareholders of record, not including shareholders whose shares are held in securities position listings. The following chart sets forth the high and low closing sale prices for the Company's common stock for the last two years:

	High	Low
2011		
First Quarter	\$ 16.08	\$ 11.38
Second Quarter	19.36	13.62
Third Quarter	19.23	12.52
Fourth Quarter	14.24	12.32
2012		
First Quarter	\$ 14.52	\$ 11.51
Second Quarter	13.85	11.58
Third Quarter	15.37	12.20
Fourth Quarter	15.24	12.67

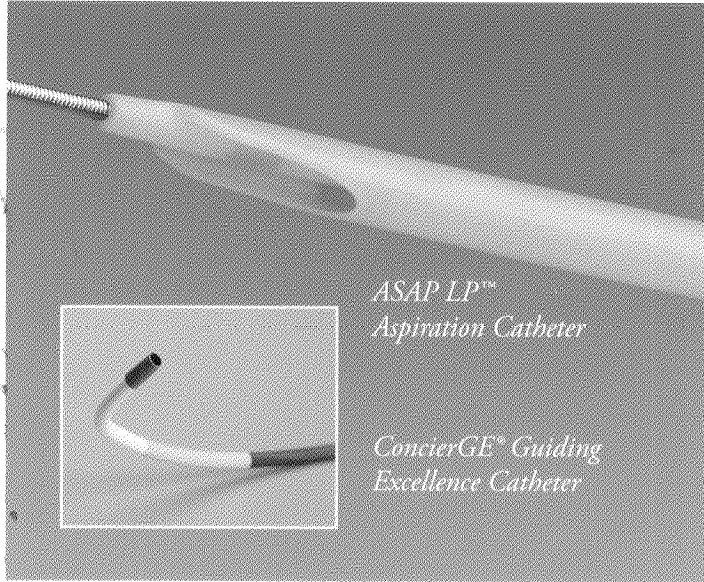
The Company has never declared or paid any cash dividends on its common stock. The Company intends to retain any earnings for use in its business and does not anticipate paying any cash dividends in the foreseeable future.

## INVESTOR RELATIONS CONTACT

Anne-Marie Wright  
Vice President, Corporate Communications  
(801) 253-1600

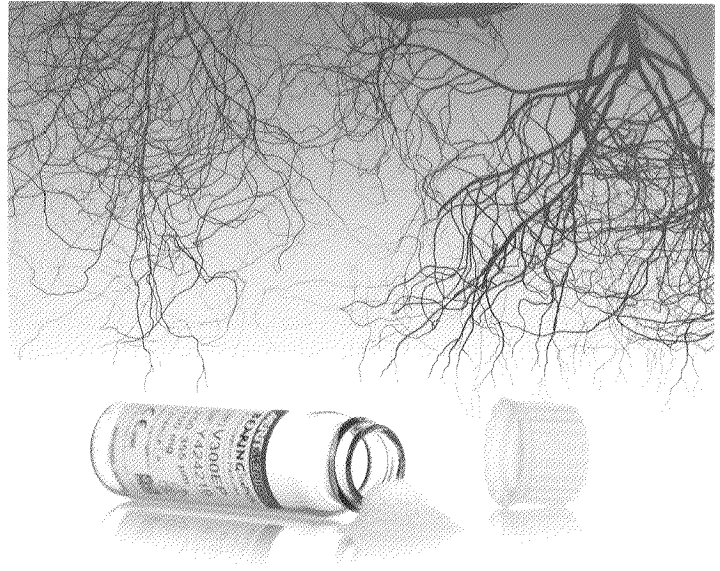
## FOR MORE INFORMATION, CONTACT

Kent W. Stanger, Chief Financial Officer  
Merit Medical Systems, Inc.  
(801) 253-1600



*ASAP LP™  
Aspiration Catheter*

*ConcierGE® Guiding  
Excellence Catheter*



In an effort to facilitate future growth, we are constructing a new facility at our campus in South Jordan, Utah, as well as a new catheter and extrusion facility in Pearland, Texas. We believe the completion of these manufacturing facilities will provide us with adequate capacity for our anticipated growth over the next five years or so.

The medical device business is entering a most challenging time. With the introduction of the Affordable Care Act and the imposition of a 2.3% gross receipts tax, as well as the increasing expense of compliance with continued regulatory requirements, a substantial amount of cost and burden will be placed on our company. We will adjust to this new environment, but we need some time to fine-tune our business model.

We are up to the task and believe at the same time that new opportunities, efficiency and growth will arise from present difficulties. We believe our investments in technology, product development and capacity will make us more competitive than ever. Internally, we are streamlining operations in every department in an effort to reduce costs. We appreciate and acknowledge the hard work that lies ahead in this increasingly competitive environment, but we believe that we are poised for a bright future. We thank you, our shareholders, for your support.

Sincerely,

A handwritten signature in black ink, appearing to read 'Fred P. Lampropoulos'.

Fred P. Lampropoulos

Chairman and CEO

This report includes "Forward-Looking Statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. All statements other than statements of historical fact are Forward-Looking Statements for purposes of these provisions. Merit assumes no obligation to update any Forward-Looking Statement. Although Merit believes 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 may differ materially, from those projected or assumed in the Forward-Looking Statements. Merit's future financial condition and results of operations, as well as any Forward-Looking Statements, are subject to inherent risks and uncertainties, including factors referenced in Merit's press releases and filings with the Securities and Exchange Commission. A number of the factors that may have a direct bearing on Merit's financial condition and operating results are described under "Risk Factors" beginning on page 15 of Merit's Annual Report on Form 10-K, filed with the U.S. Securities and Exchange Commission on March 1, 2013.



Merit Medical announces the opening of a new 257,000-square-foot facility on its South Jordan campus in a move toward greater capabilities, productivity and innovation.



Merit Medical Systems, Inc.

1600 West Merit Parkway

South Jordan, Utah 84095

Phone 801-253-1600

[www.merit.com](http://www.merit.com)