

MERIT MEDICAL SYSTEMS INC

Form 10-K

March 12, 2014

Table of Contents

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
for the fiscal year ended December 31, 2013,

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

1600 West Merit Parkway  
South Jordan, Utah 84095  
(Address of principal executive offices, including zip code)  
Registrant's telephone number, including area code: (801) 253-1600

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

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.  
Yes  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 <input type="checkbox"/>	Accelerated filer <input checked="" type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input type="checkbox"/>

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, 2013, 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, 2013), was approximately \$452,137,252. Shares of common stock held by each officer and director of the registrant and by each person who may be deemed to be an affiliate have been excluded.

As of March 10, 2014, the registrant had 42,862,172 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, 2014.

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Table of Contents

TABLE OF CONTENTS

PART I

<u>Item 1.</u>	<u>Business</u>	<u>1</u>
<u>Item 1A.</u>	<u>Risk Factors</u>	<u>15</u>
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	<u>22</u>
<u>Item 2.</u>	<u>Properties</u>	<u>22</u>
<u>Item 3.</u>	<u>Legal Proceedings</u>	<u>23</u>
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	<u>23</u>

PART II

<u>Item 5.</u>	<u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	<u>24</u>
<u>Item 6.</u>	<u>Selected Financial Data</u>	<u>27</u>
<u>Item 7.</u>	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>29</u>
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>39</u>
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	<u>40</u>
<u>Item 9.</u>	<u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	<u>74</u>
<u>Item 9A.</u>	<u>Controls and Procedures</u>	<u>74</u>
<u>Item 9B.</u>	<u>Other Information</u>	<u>77</u>

PART III

<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	<u>77</u>
<u>Item 11.</u>	<u>Executive Compensation</u>	<u>77</u>
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>77</u>
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	<u>77</u>
<u>Item 14.</u>	<u>Principal Accountant Fees and Services</u>	<u>77</u>

PART IV

Item 15. Exhibits and Financial Statement Schedules

77

SIGNATURES

82

---

Table of Contents

PART I

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

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This report includes “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). All statements 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 use of 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 possible infringement of our technology or the assertion that our technology infringes the rights of other parties; 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; potential for significant adverse changes in, or our failure to comply with governing regulations; healthcare reform legislation affecting our financial results and its effects on our business, operations or financial condition; greater governmental scrutiny and increasing regulation of the medical device industry; 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; reforms to the 510(k) process administered by the U.S. Food and Drug Administration (the “FDA”); modification or limitation of governmental or private insurance reimbursement policies; laws targeting fraud and abuse in the healthcare industry; 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; increases in the prices of commodity components or loss of supply; 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 completed, proposed, or future acquisitions; fluctuations in foreign currency 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; volatility in the market price of our common stock (the “Common Stock”); manufacturing facilities may be negatively impacted by certain factors, including severe weather conditions and natural disasters; changes in key personnel; work stoppage or transportation risks; international economic conditions affecting business and results of operations; failures to comply with applicable environmental laws; 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 15.

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 principal markets: diagnostic and interventional cardiology, interventional radiology, interventional gastroenterology, interventional pulmonology, vascular surgery, interventional nephrology, and thoracic

## Table of Contents

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 October 2013, we acquired from Radial Assist, LLC ("Radial Assist"), the Rad Board®, Rad Board Xtra™, Rad Trac™ and Rad Rest® devices which are used for patient positioning during radial access procedures.

Also in October 2013, we acquired from Datascope Corp. ("Datascope"), the Safeguard® Pressure Assisted Device, which assists in obtaining and maintaining hemostasis after a femoral procedure, and the Air-Band™ Radial Compression Device, which is indicated to assist hemostasis of the radial artery puncture site while maintaining visibility.

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: diagnostic and interventional cardiology, interventional radiology, interventional gastroenterology and interventional pulmonology. Our products are also used in other clinical areas such as thoracic surgery, interventional nephrology, vascular surgery, oncology and pain management.

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 these 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.

Vascular Access Products and Accessories. 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 provide clinicians with smooth, less traumatic, and convenient access to the patient's vasculature. Merit's sheath introducers are designed for radial and femoral approach when performing diagnostic and interventional procedures. We expanded our line of radial (mini-access) sheath introducers with the addition of a 7 French size Prelude Sheath Introducer during the year ended December 31, 2013.

In October 2013, we acquired the assets of Radial Assist, which include the Rad Board, Rad Board Xtra, Rad Trac, and Rad Rest devices. The Rad Board is designed to provide a larger work space for physicians and an area for patients to rest their arms during radial procedures and has a section of lead-free Xenolite embedded in the Rad Board to help reduce scatter radiation exposure. The Rad Board Xtra is designed to work in conjunction with the Rad Board by extending the usable work space and allowing for a 90-degree perpendicular extension of the arm for physicians who prefer to perform procedures at a 90-degree angle. The Rad Trac is also designed to be used with the Rad Board and facilitates placement and removal of the Rad Board with the patient still on the table. The Rad Rest is a disposable, single-use product designed to stabilize the arm by ergonomically supporting the elbow, forearm and wrist during radial procedures.



## Table of Contents

**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.

**Hemostasis Management 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. There are many ways to achieve hemostasis after a diagnostic or interventional procedure. In 2013, we acquired several pressure assisted devices from Datascope, including the Air-Band,™ which we have re-branded as the Safeguard Radial™ Compression Device (the “Safeguard Radial”). The Safeguard Radial is a self-adhesive wristband designed to assist hemostasis of the radial artery after a transradial procedure. The Safeguard Radial delivers adjustable compression of the radial puncture site with an inflatable bulb and standard luer valve for easy inflation and deflation with any standard luer syringe. Through the Datascope acquisition, we also acquired the Safeguard® Pressure Assisted Device, which is designed to obtain and maintain hemostasis after femoral access. The Safeguard Pressure Assisted Device offers hands-free adjustable pressure of the puncture site with an inflatable bulb.

We offer the Clo-Sur PLUS P.A.D™, which is intended for the local management of bleeding wounds and the creation of a barrier to bacterial penetration. Non-invasive 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, the Finale® Compression Device and the RADStat® Radial Artery Compression Device.

**Guide Wires and Accessories.** 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 intended to promote rapid catheter exchanges and minimize friction. The Merit Laureate was designed with one-to-one torque to reduce wire whipping. We also offer the BowTie™ Guide Wire Insertion Device, which 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.

**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. During 2013, we introduced the MIV™ Radial Ventriculogram Pigtail Catheter to address the difficulty in accessing the left ventricle from the radial artery when using standard femoral approach catheters. MIV Radial Catheters are designed to angle toward the left cusp from the radial approach, facilitating easier insertion into the ventricle.

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 the Passage®.

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. In 2013, we introduced the BASIXTouch™ Inflation Syringe, offering clinicians one-handed preparation and priming for faster preparation time. The Blue Diamond™ Digital Inflation Device features an angled gauge for better viewing. Additionally, our IntelliSystem® and Monarch® Inflation Devices (state-of-the-art digital inflation systems), as well as the BasixCOMPAK™ Inflation Syringe, offer clinicians a wide range of features and prices.

## Table of Contents

**Drainage Catheters and Accessories.** We have a broad line of catheters for nephrostomy, abscess and other drainage procedures. The ReSolve® Locking Drainage Catheter's 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 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.

**Thrombosis Products.** We offer an extensive line of products designed to treat clots that block the flow of blood in veins and arteries. Our therapeutic thrombolytic infusion systems include the Fountain® Infusion System and the Mistique® Infusion Catheter. These catheters are used to treat thrombus (blood clot) formation in the peripheral vessels of the body, including native dialysis fistula and synthetic grafts. A new low-profile aspiration catheter, the ASAP LP™ has been added to the ASAP® line of Aspiration Catheters, giving clinicians two options for the safe and efficient removal of fresh, soft emboli and thrombi from the vessels of the arterial system.

**Multipurpose Microcatheters.** We offer specialty catheters designed for intravascular use, including peripheral and coronary vasculature. Once the subselective region has been accessed, a microcatheter can be used for the controlled and selective infusion of diagnostic, embolic microspheres or particles, or therapeutic agents into 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. The EmboCath® Plus infusion microcatheter was part of the BioSphere acquisition.

**Embolic Particles and Products.** We offer embolic microspheres and particles and embolic delivery systems. 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 the European Union in 2013 to sell HepaSphere Microspheres in a smaller size (30-60 μm), giving physicians the ability to achieve more distal occlusions when embolizing hypervascularized tumors and arteriovenous malformations; and

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

Bearing nsPVA™ Particles, introduced in 2013 and also 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.

**Vascular Retrieval Devices.** Our snares or vascular retrieval devices are single-use products designed for foreign body manipulation and retrieval and can be used to retrieve inferior vena cava filters, reposition indwelling venous catheters, strip fibrin sheath formation, and assist in central venal access venipuncture. We offer the ONE Snare®, a single loop device, and the EN Snare® Endovascular Snare System, which has three interlaced loops. Both are offered in multiple sizes to accommodate a broad range of vessels throughout the body.

**Angiography and Angioplasty Accessories.** We offer 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

4

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## Table of Contents

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.

**Hemodialysis and Peritoneal Dialysis.** We offer peritoneal dialysis catheters and accessories as part of our dialysis and interventional nephrology product line, including 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.

**Electrophysiology (“EP”) Products.** With our acquisition of Thomas Medical Products, Inc. (“Thomas Medical”) in 2012, we now offer innovative solutions to address lead implantation and therapeutic delivery in the rapidly-expanding cardiac rhythm management and electrophysiology fields.

Cardiac rhythm management is the field of cardiovascular disease therapy that relates to the detection and treatment of abnormally fast (tachycardia) and abnormally slow (bradycardia) heart rhythms, or electrical patterns in the heart, and heart failure. We offer products that improve lead delivery and vessel access. The ClassicSheath™ Splittable Hemostatic Introducer System allows for insertion of cardiac pacer leads for pacemakers and implantable cardioverter defibrillators. Its robust valve design reduces the risk of air embolism and backbleed. We also offer the Worley™ Advanced LV Delivery System to aid in the insertion and implantation of left ventricular leads, which are wire electrodes inserted into the coronary sinus to the left lateral wall of the heart to pace the left side of the heart for heart failure patients. The Worley™ Advanced LV Delivery System has been shown to reduce lead failure, improve target lead location and reduce procedure times.

Cardiac electrophysiology is the study of diagnosing and treating the electrical activities of the heart. Common procedures include diagnostic EP studies and therapeutic ablation procedures designed to deter arrhythmia. We offer the HeartSpan® Transseptal Needle, which is designed with a larger ergonomic handle, unique unibody needle design and optimal needle sharpness; the Heartspan® Transeptal Sheath, which features an improved hemostasis valve for reduced blood loss and air embolism, smooth sheath to dilator transition for easier transeptal crossing, and reinforced

stainless steel tubing for excellent torque response; and the Heartspan® Resilience Dilator, which is designed to minimize the risk of the needle cutting out small pieces of plastic inside the dilator.

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 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.

## Table of Contents

**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.

**Oropharyngeal Airway, Bite Block and Oxygen Administration Device.** The TIO™ Three-in-One is a combination product that incorporates the benefits of an oropharyngeal airway, bite block and oxygen administration device into one convenient, easy to use device, enhancing procedure efficiency.

## 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.

**Coated Wires and Tubes.** We provide coating services for medical tubes and wires under the Merit Medical OEM brand. We offer coated tubes and wires to customers on a spool or as further manufactured components like hypotubes, guide wire components, coated mandrels/stylets and coated needles. Our coating operation facility is located in Venlo, The Netherlands, where PFOA-free PTFE and Hydrophilic coatings are applied to bulk lengths of bare wire and tubing, prior to cutting, using a proprietary spool-to-spool coating method. Our coating technology, developed more than 20 years ago, results in consistently coated medical tubes and wires with tight tolerances. In the summer of 2013, we opened a state-of-the-art hypotube manufacturing Center of Excellence in Galway, Ireland,

including advanced laser cutting and ablation, passivation, cleaning and other hypotube manufacturing processes. The Merit Hypotube™ is used as the catheter shaft in PTCA and PTA balloon catheters, as well as functional guide wires.

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.



Table of Contents

MARKETING AND SALES

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

According to U.S. 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 interventional radiology, vascular surgery and cardiology catheter lab procedures 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 the development of our Endotek division and the move into the areas of interventional gastroenterology, pulmonology and thoracic surgery will open up new opportunities to sell existing Merit products, such as inflation devices, syringes, centesis catheters and procedure kits to those markets, but will also 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 health care professionals working in multiple fields of medicine, including cardiology, radiology, gastroenterology, pulmonology and thoracic surgery. Suggestions for new products and product improvements may

also come from engineers, sales people, physicians and technicians who perform 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%, 63% and 65% of our total sales for the years ended December 31, 2013, 2012 and 2011, respectively. In the U.S. we have a dedicated corporate sales organization primarily focused on selling to end user hospitals and clinics, major buying groups and integrated healthcare networks.

## Table of Contents

We have direct sales representatives and contract with independent dealer organizations and custom procedure tray manufacturers to distribute our products worldwide, including territories in Europe, Africa, the Middle East, Asia, South and Central America, Oceania and Canada. In 2013, our international sales grew approximately 13% over our 2012 international sales, and accounted for approximately \$165.8 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 components and finished devices, including molded components, sub-assembled goods, custom kits and bulk non-sterile goods, to medical device manufacturers. These products may be combined with other components and/or products from other companies and sold under a Merit or third-party label. Products sold by the OEM division can be customized and enhanced to customer specifications, including packaging, labeling and a variety of physical modifications. The OEM division serves customers with a staff of regional sales representatives based in the U.S., Europe and Asia and a dedicated OEM Engineering and Customer Service Group.

## CUSTOMERS

We provide products to hospitals and clinic-based cardiologists, radiologists, neurologists, nephrologists, vascular surgeons, interventional gastroenterologists and pulmonologists, thoracic surgeons, physiatrists (pain management physicians), 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 2013, our U.S. sales force made approximately 43% of our sales directly to U.S. hospitals (including three percent of our total sales for our Merit Endotek division) and approximately eight percent 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 15% of our 2013 sales. Approximately 37% of our 2013 sales were made to international markets by our direct European sales force, international distributors, and our OEM sales force (includes three percent of our total sales for OEM international). Sales to our largest customer accounted for approximately three percent of total sales during the year ended December 31, 2013.

## RESEARCH AND DEVELOPMENT

Our commitment to innovation is demonstrated through the delivery of several new products by our research and development team. In 2013, we launched the BASIXTouch™ Inflation Syringe. This device is designed to improve the ability of physicians to inflate and deflate angioplasty products, which includes higher-volume and higher-pressure

balloons, improved inflation times, one-handed prep, and an ergonomic handle.

The ASAP LP™ Aspiration Catheter is a new smaller size aspiration catheter which facilitates the extraction of clots from within coronary arteries. The addition of the ASAP LP Aspiration Catheter broadens our aspiration catheter line by giving physicians the choice for treating small or large vessels. These products offer time saving convenience during interventional cardiology procedures.

The ConcierGE® Guiding Catheter is another interventional cardiology product we released, which facilitates access to coronary arteries. We now offer a catheter with improved torque control and kink resistance. This product gives the physician the confidence to advance balloons and stents to meet the clinical need.

## Table of Contents

Our Bearing nsPVA™ Embolization Particles rounds out our top releases. These are irregularly shaped, hydrophilic, nonresorbable particles produced from polyvinyl alcohol. These embolization particles are intended to provide vascular occlusion or reduction of blood flow within target vessels upon selective placement through a variety of catheters.

Our research and development expenses were approximately \$33.9 million, \$27.8 million, and \$21.9 million in 2013, 2012 and 2011, respectively. We frequently develop new product ideas or implement product improvements through the collaborative efforts of skilled physicians with whom we have long-term relationships, our Chief Executive Officer, our Vice President of Research and Development and our research and development, sales and marketing teams. Currently, we have research and development facilities in Galway, Ireland; South Jordan, Utah; Angleton and Dallas, Texas; Malvern, Pennsylvania; Jackson Township, New Jersey; Paris, France; and Venlo, The Netherlands.

## MANUFACTURING

We manufacture many of our products utilizing our proprietary technology and our expertise in plastic injection and insert molding. We generally contract with third parties for the tooling of our molds, but we design and own most of our molds. We utilize our experience in injection and insert molding technologies in the manufacture of most of the custom components used in our products. We have received International Standards Organization (“ISO”) 13485:2003 certification for our facilities in Utah, Texas, Virginia, 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 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 and West Jordan, 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; Chester, Virginia; Malvern, Pennsylvania; 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; however, there can be no assurance that we will not experience supply disruptions in the future. 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, thoracic surgery, interventional gastroenterology and pulmonology.

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, St. Jude Medical, 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 Embosphere Microspheres. 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 CeloNova BioSciences, and Terumo, as well as companies selling or developing non-embolotherapy solutions for UFE.

## Table of Contents

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 a market leader 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, 2013, we owned more than 500 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; 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 300 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 September 20, 2013, a third party filed suit for patent infringement against us in the United States District Court, District of Delaware, alleging that we infringe certain patents. The patents generally relate to aspiration catheters. The suit is in its early stages and we are still evaluating the complaint and our defenses.

## 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 are subject to change. We cannot predict the effect, if any, that these changes might have on our



## Table of Contents

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/or 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 negatively affected.

**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 premarket 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 or results of operations.

In November 2010, we received FDA approval of our IDE application to conduct a phase 3 clinical trial protocol to treat primary liver cancer with QuadraSphere Microspheres, combined with the chemotherapeutic agent doxorubicin, compared to

Table of Contents

conventional transarterial chemoembolization, or cTACE, with doxorubicin. Enrollment in the clinical trial has begun both in Europe and in the United States. Additionally, in October 2012 we received FDA approval of our IDE application to conduct a phase 3 clinical trial to compare the effectiveness and safety of prostate artery embolization compared to transurethral resection of the prostate for the treatment of benign prostatic hyperplasia. Our Embosphere Microspheres to be used in these trials have already received the CE mark for the indication of prostate artery embolization in the EU. Our inability to complete either of these trials, or our receipt of unfavorable or inconsistent data from either trial may adversely affect our ability to obtain approval for these new indications

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 devices.

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 require 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 the FTC may deem 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, the 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.

## Table of Contents

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 the Quality Systems Regulation 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 or other foreign medical device laws and regulations would likely have a material adverse effect on our business. In addition, the European Commission is currently revising the legal framework for medical devices in the EEA. Approval of the new regulations is anticipated in 2014. 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 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. The law imposes on medical device manufacturers a 2.3% excise tax on U.S. sales of certain medical devices, which has adversely affected our gross profit and earnings for our marketed products, and is expected to adversely affect our gross profit and earnings in the future.

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

## Table of Contents

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



## Table of Contents

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 on our business, operations or financial condition. 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. Changes in those regulations could have a material adverse effect on our business, operations or financial condition.

## EMPLOYEES

As of December 31, 2013, we employed 2,888 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 Reports 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:

## Table of Contents

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

We have obtained U.S. and foreign patents and filed applications for additional U.S. and foreign patents; 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 technology.
- 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.

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; however, 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

## Table of Contents

liability insurance rates, or could prevent us from securing insurance 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.

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 entered into an Amended and Restated Credit Agreement, dated December 19, 2012, 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, which was amended on October 4, 2013 by a First Amendment to Amended and Restated Credit Agreement (as amended, the "Credit Agreement"). The Credit Agreement contains a number of significant covenants that could adversely affect our ability to operate our business, our liquidity or our results of operations. These covenants restrict, among other things, our incurrence of indebtedness, creation of liens or pledges on our assets, mergers or similar combinations or liquidations, asset dispositions, repurchases or redemptions of equity interests or debt, issuances of equity, payment of dividends and certain distributions, and entry into related party transactions.

Our breach of any covenant 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.

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.

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.

Recent healthcare reform legislation has negatively affected our financial results and may have a material adverse effect on our business, operations or financial condition.

The PPACA was enacted into law in March 2010. Effective January 1, 2014, most of the core pieces of the PPACA went into effect. Certain other 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 law imposes on medical device manufacturers a 2.3% excise tax on U.S. sales of certain medical devices. During the year ended December 31, 2013 we incurred \$4.3 million related to this tax, which reduced our gross profit by 1%. 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

## Table of Contents

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. As we cannot ultimately predict what will happen as the PPACA provisions begin to take effect, any changes to healthcare reform that lower reimbursement amounts for our products could adversely affect our revenues and results of operation and financial condition.

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.

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. We are also currently conducting a clinical trial to obtain FDA approval to claim the use of our Embosphere Microspheres for the indication of prostate artery embolization. European Union regulations do not currently require such an application for these classes of medical device. In order for us to obtain FDA approval or clearance to promote the use of QuadraSphere Microspheres and the Embosphere Microspheres for the purposes indicated in our clinical trials, we will need to complete those trials 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 trials or if any other factors preclude us from completing the trials in a timely manner we will likely not be able to complete those trials. Even if we complete either or both clinical trials, 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 of the product use claimed in a clinical trial, we will not be able to promote the subject product for the indicated treatment of the specific disease or condition in the United States.

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. The 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.



Table of Contents

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 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, industry 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, disruptions in the credit markets have previously resulted, and could again result, in volatility, decreased liquidity, widening of credit spreads, and reduced availability of financing. There can be no assurance that future 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 implement our business plan.

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

Table of Contents

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 are currently engaged in litigation regarding the termination of our rights under a Purchasing Agreement we executed with Specialized Health Products, Inc., a medical device manufacturer which was subsequently acquired by Bard Access Systems, Inc. If we are unsuccessful in that litigation, our ability to market products which are the subject of that Purchasing Agreement would be terminated. If we are unable to sell those products, and incorporate them into other products and kits that we sell, our operating and financial results may be negatively affected. We may also incur significant expenses in the course of conducting the litigation.

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, operations or financial condition.

Fluctuations in foreign currency exchange rates may negatively impact our financial results.

As our operations have grown outside the United States, we have also become subject to market risk relating to foreign currency. Those fluctuations could have a negative impact on our margins and financial results. For example, during 2013, the exchange rate between all applicable foreign currencies and the U.S. Dollar resulted in an increase in our gross revenues of approximately \$859,000.

For the year ended December 31, 2013, approximately \$79.4 million, or 18%, of our sales, were denominated in foreign currencies. If the rate of exchange between foreign currencies decline 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 those respective foreign currencies. 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 foreign currencies 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 is derived from a few products, procedures and/or customers.

A significant portion of our revenues is attributable to sales of our inflation devices. During the year ended December 31, 2013, sales of our inflation devices (including inflation devices sold in custom kits and through OEM channels) accounted for

Table of Contents

approximately 15% of our total revenues. 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. 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

21

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Table of Contents

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.

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

Over the last several years we have expanded our business globally, and have become increasingly subject to the risks arising from adverse changes in global economic conditions. Recent currency devaluations in South America and India have affected our sales growth in these regions. 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. The strength and timing of any economic recovery remains uncertain, and we cannot predict to what extent the global economic slowdown may negatively impact our results of operation or financial condition.

Our failure to comply with applicable environmental laws and regulations could affect our business, operations or financial condition.

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, operations or financial condition. 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 business, operations or financial condition, 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; Tokyo, Japan; Bangalore, India; and São Paulo, Brazil. Our principal manufacturing facilities are located in South Jordan and West Jordan, Utah; Pearland, 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; Malvern, Pennsylvania; Angleton, Texas; Paris, France; and Galway, Republic of Ireland. The following is an approximate summary of our facilities as of December 31, 2013 (in square feet):

	Owned	Leased	Total
U.S.	619,525	429,190	1,048,715

International	201,033	56,205	257,238
	820,558	485,395	1,305,953

In early 2013, we completed construction of a production, warehouse and administration office building, which totals approximately 253,000 square feet, at our world headquarters in South Jordan, Utah.

In late 2013, we substantially completed construction of a production, clean room, warehouse and administrative office building in Pearland, Texas, which totals approximately 94,000 square feet. In 2014, we plan to relocate our Angleton, Texas manufacturing facility to the new Pearland building, which is designed to provide better protection from natural disasters, modernized facilities and room for future expansion.



Table of Contents

We believe 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.

23

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Table of Contents

## PART II

- Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

## MARKET PRICE FOR THE COMMON STOCK

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

For the year ended December 31, 2013	High	Low
First Quarter	\$14.35	\$10.10
Second Quarter	\$12.36	\$9.15
Third Quarter	\$14.30	\$11.15
Fourth Quarter	\$17.08	\$12.12
For the year ended December 31, 2012	High	Low
First Quarter	\$14.52	\$11.51
Second Quarter	\$13.85	\$11.58
Third Quarter	\$15.37	\$12.20
Fourth Quarter	\$15.24	\$12.67

As of March 10, 2014, the number of shares of Common Stock outstanding was 42,862,172 held by approximately 140 shareholders of record, not including shareholders whose shares are held in securities position listings.

## DIVIDENDS

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

Table of Contents

## PERFORMANCE GRAPH

The following graph compares the performance of the Common Stock with the performance of the NASDAQ Stock Market (U.S. Companies) and NASDAQ Stocks (SIC 3840-3849 U.S. Companies - Surgical, Medical and Dental Instruments and Supplies) for a five-year period by measuring the changes in Common Stock prices from December 31, 2008 to December 31, 2013.

## Comparison of 5 Year Cumulative Total Return

Among Merit Medical Systems, Inc., NASDAQ Stock Market (U.S.)  
and NASDAQ Stocks (SIC 3840-3849)

	12/2008	12/2009	12/2010	12/2011	12/2012	12/2013
Merit Medical Systems, Inc.	\$100	\$107	\$88	\$93	\$97	\$110
NASDAQ Stock Market (U.S. Companies)	100	144	170	171	202	282
NASDAQ Stocks (SIC 3840-3849 U.S. Companies)	100	139	147	166	184	214

The stock performance graph assumes for comparison that the value of the Common Stock and of each index was \$100 on December 31, 2008 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 2014. Used with permission. All rights reserved.

Table of Contents

## SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

The following table contains information regarding our equity compensation plans as of December 31, 2013 (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	3,008 (1),(3)	\$ 12.14	1,392 (2),(3)

(1) Consists of 3,008,420 shares of Common Stock subject to the options granted under the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan.

(2) Consists of 288,776 shares available to be issued under the Merit Medical Systems, Inc. Qualified and Non-Qualified Employee Stock Purchase Plan and 1,102,750 shares available to be issued under the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan.

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

Table of Contents

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

	Years Ended December 31,				
	2013	2012	2011	2010	2009
<b>OPERATING DATA:</b>					
Net Sales	\$449,049	\$394,288	\$359,449	\$296,755	\$257,462
Cost of Sales	254,682	212,296	193,981	168,257	148,660
Gross Profit	194,367	181,992	165,468	128,498	108,802
Operating Expenses:					
Selling, general, and administrative	128,642	122,106	104,502	87,615	64,787
Research and development	33,886	27,795	21,938	15,335	11,168
Intangible asset impairment charge	8,089	—	—	—	—
Contingent consideration benefit	(4,094)	) —	—	—	—
Acquired in-process research and development	—	2,450	5,838	—	—
Goodwill impairment charge	—	—	—	8,344	—
Total operating expenses	166,523	152,351	132,278	111,294	75,955
Income From Operations	27,844	29,641	33,190	17,204	32,847
Other Income (Expense):					
Interest income	255	226	129	34	178
Interest expense	(8,044)	) (604)	) (789)	) (596)	) (28)
Other income (expense)	(216)	) (1,645)	) 345	146	97
Other income (expense)—net	(8,005)	) (2,023)	) (315)	) (416)	) 247
Income Before Income Taxes	19,839	27,618	32,875	16,788	33,094
Income Tax Expense	3,269	7,908	9,831	4,328	10,564
Net Income	\$16,570	\$19,710	\$23,044	\$12,460	\$22,530
Earnings Per Common Share:					
Diluted	\$0.39	\$0.46	\$0.58	\$0.35	\$0.63
Average Common Shares:					
Diluted	42,884	42,610	39,733	35,976	35,758
<b>BALANCE SHEET DATA:</b>					
Working capital	\$100,321	\$88,992	\$89,857	\$72,125	\$57,706
Total assets	728,283	705,309	447,017	369,480	271,513
Line of credit	—	—	—	—	7,000
Long-term debt, less current portion	238,854	227,566	30,737	81,538	—
Stockholders' equity	405,706	381,577	357,089	235,615	218,809

During the quarter ended September 30, 2013, we recorded an impairment charge of approximately \$8.1 million related to certain intangible assets we acquired from Ostial, which was offset by approximately \$3.8 million of fair value reductions to the related contingent consideration liability. We evaluate long-lived assets, including amortizing

intangible assets, for impairment whenever events or changes in circumstances indicate that their carrying amounts may not be recoverable. We perform the impairment analysis at the asset group for which the lowest level of identifiable cash flows are largely independent of the cash flows of other assets and liabilities. We compared the carrying value of the amortizing intangible assets we acquired from Ostial in January 2012 to the undiscounted cash flows expected to result from the asset group and determined that the carrying amount was not recoverable. We then determined the fair value of the amortizing assets related to the Ostial acquisition based on estimated future cash flows discounted back to their present value using a discount rate that reflects the risk profiles of the underlying activities. Some of the factors that influenced our estimated cash flows were

27

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Table of Contents

slower than anticipated sales growth in the products acquired from Ostial and uncertainty about future sales growth. The excess of the carrying value compared to the fair value was recognized as an intangible asset impairment charge.

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 a 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 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 Alveolus, Inc. ("Alveolus") 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.

Table of Contents

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

The following discussion and analysis of our financial condition and results of operation should be read in conjunction with the Consolidated Financial Statements and related Notes thereto, which are included in 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 devices which assist in the palliative treatment of expanding esophageal, tracheobronchial and biliary strictures caused by malignant tumors.

For the year ended December 31, 2013, we reported record sales of approximately \$449.0 million, up approximately \$54.8 million or 13.9%, over 2012 sales of approximately \$394.3 million. Gross profits as a percentage of sales was 43.3% for the year ended December 31, 2013, compared to 46.2% for the year ended December 31, 2012.

During the year ended December 31, 2013, we reduced the amount of the contingent consideration liability related to the Ostial PRO Stent Positioning System, which we acquired in January 2012, by approximately \$3.8 million. Under the terms of the Asset Purchase Agreement we executed with Ostial, we are obligated to make contingent purchase price payments based on a percentage of future sales of products utilizing the Ostial PRO Stent Positioning System. The adjustment to the contingent consideration liability triggered a review of the intangible assets we acquired from Ostial, which resulted in an intangible asset write-down of approximately \$8.1 million related to those assets. These adjustments reduced operating income for year ended December 31, 2013 by approximately \$4.3 million, or approximately \$2.7 million net of tax. The reduction of the Ostial contingent consideration liability and the impairment of the Ostial intangible assets was the result of our assessment that we are not likely to generate the level of revenues from sales of the Ostial PRO Stent Positioning System that we anticipated at the acquisition date.

Net income for the year ended December 31, 2013 was approximately \$16.6 million, or \$0.39 per share, as compared to \$19.7 million, or \$0.46 per share, for the year ended December 31, 2012.

Our endoscopy segment made significant progress and generated operating income of approximately \$1.2 million for the year ended December 31, 2013, when compared to an operating loss of approximately \$770,000 for the year ended December 31, 2012. This increase in operating income for the year ended December 31, 2013 over the prior year was largely driven by higher sales and lower operating expenses associated with the endoscopy segment.

During the year ended December 31, 2013, we completed the construction of two new buildings in the U.S. to expand our production, warehouse and administration offices. The new South Jordan, Utah building of 253,000 square feet



was completed in February of 2013 and the new Pearland, Texas facility of 94,000 square was completed in December of 2013. We anticipate that the additional costs associated with the operation of our new Texas facility could increase our selling, general and administrative expenses and could decrease gross profits and earnings for 2014. We believe the total impact of such costs will be approximately \$3.0 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 approximately six months, as we believe it will take this long to complete the movement and qualification of production equipment from the old facility into the new facility. We anticipate that our new U.S. facilities will 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.

During the fourth quarter of 2013, we acquired from Datascope the Safeguard Pressure Assisted Device, which assists in obtaining and maintaining hemostasis after a femoral procedure, and the Air-Band Radial Compression Device, which is indicated to assist hemostasis of the radial artery puncture site while maintaining visibility. During the fourth quarter of 2013, we also purchased from Radial Assist, the Rad Board, Rad Board Xtra, Rad Trac, and Rad Rest devices. The Rad Board is designed to

Table of Contents

provide a larger work space for physicians and an area for patients to rest their arms during radial procedures. The Rad Board Xtra is designed to work in conjunction with the Rad Board by extending the usable work space and allowing for a 90-degree perpendicular extension of the arm for physicians who prefer doing procedures at a 90-degree angle. The Rad Trac is also designed to be used with the Rad Board and facilitates easy placement and removal of the Rad Board with the patient still on the table. The Rad Rest is a disposable, single-use product designed to stabilize the arm by ergonomically supporting the elbow, forearm and wrist during radial procedures. With the purchase of these products for radial procedures, along with our existing radial products and those under development, we plan to launch a complete line of radial approach products to a U.S. market which is growing rapidly and to an international market where, in some countries, this procedure accounts for more than 50% of percutaneous coronary interventions.

We intend to continue to invest in emerging international markets such as Brazil, Russia, India and China, in an effort to expand our market opportunities.

## RESULTS OF OPERATIONS

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

	2013	2012	2011
Net sales	100%	100%	100%
Gross profit	43.3	46.2	46.0
Selling, general, and administrative expenses	28.6	31.0	29.1
Research and development expenses	7.5	7.0	6.1
Acquired in-process research and development	—	0.6	1.6
Intangible asset impairment charge	1.8	—	—
Contingent consideration benefit	(0.9)	—	—
Income from operations	6.2	7.5	9.2
Income before income taxes	4.4	7.0	9.1
Net income	3.7	5.0	6.4

Listed below are the sales by product category within each business segment for the years ended December 31, 2013, 2012 and 2011 (in thousands):

	% Change	2013	% Change	2012	% Change	2011
Cardiovascular						
Stand-alone devices	10%	\$125,445	12%	\$114,242	15%	\$101,959
Custom kits and procedure trays	10%	103,700	3%	94,586	11%	91,532
Inflation devices	(4)%	66,182	2%	68,979	8%	67,353
Catheters	16%	75,131	17%	64,878	23%	55,357
Embolization devices	(1)%	33,395	8%	33,870	247%	31,229
CRM/EP	1,359%	28,271	—%	1,938	—%	—
Total	14%	432,124	9%	378,493	21%	347,430
Endoscopy						
Endoscopy devices	7%	16,925	31%	15,795	33%	12,019
Total	14%	\$449,049	10%	\$394,288	21%	\$359,449

Cardiovascular Sales. Our cardiovascular sales for the year ended December 31, 2013 were approximately \$432.1 million, up 14.2%, when compared to the corresponding period for 2012 of approximately \$378.5 million. Sales for

the year ended December 31, 2013 were favorably affected by sales of our cardiac rhythm management ("CRM") and electrophysiology ("EP") products acquired from Thomas Medical of \$26.3 million, an increase in sales of our stand-alone devices (particularly our Merit Laureate®)

30

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Table of Contents

hydrophilic guide wires, newly-acquired Safeguard product and EN Snare endovascular snare) of approximately \$11.2 million, or 9.8%; an increase in sales of catheter devices (particularly our peritoneal dialysis catheter acquired from MediGroup, micro catheter product line, Prelude sheath product line and Maestro microcatheter) of approximately \$10.2 million, or 15.8%; and an increase in sales of custom kits and procedure trays of approximately \$9.1 million, or 9.6%. 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. Cardiovascular sales for the year ended December 31, 2012 were favorably affected by an increase in sales of our stand-alone devices (particularly our hemostasis valves, guidewires and Scion Clo-SurPLUS P.A.D.) 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. Cardiovascular sales for the year ended December 31, 2011 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 one-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 increased during 2013, 2012 and 2011, 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 increases in our revenues during the three years were 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 increased sales by 0.2% in 2013 compared to 2012, decreased sales by 0.7% in 2012 compared to 2011, and decreased sales by 0.5% in 2011 compared to 2010. 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, 2013 were approximately \$16.9 million, up 7.2%, when compared to sales in the corresponding period of 2012 of approximately \$15.8 million. This increase was primarily the result of sales of our EndoMAXX Fully-Covered Esophageal stent. 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 2011 were approximately \$12.0 million, compared to 2010 sales 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.

**International Sales.** International sales for the year ended December 31, 2013 were approximately \$165.8 million, or 37% of total sales, up 13.3% from the same period in 2012; international sales for the year ended December 31, 2012 were approximately \$146.3 million, or 37% of total sales, up 16.2% from the same period in 2011; and international sales for the year ended December 31, 2011 were approximately \$125.9 million, or 35% of total sales, up 32.2% from the same period in 2010. The increase in our international sales during 2013 was primarily related to year-over-year sales increases in China of approximately \$5.4 million, up 20%; Europe Direct of approximately \$5.3 million, up 13% (would have been up 11% in constant currency); and Russia of approximately \$2.4 million, up 54%. The 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%. Our total European direct sales were approximately \$46.2 million, \$42.6 million, and \$39.9 million in 2013, 2012, and 2011, respectively.

Gross Profit. Our gross profit as a percentage of sales was 43.3%, 46.2%, and 46.0% in 2013, 2012 and 2011, respectively. The decrease in gross profit in 2013 was primarily related to amortization of developed technology costs of 1.3% associated with the Thomas Medical and Datascope acquisitions, implementation of the Medical Device Excise Tax of 1.0% which was part of the Affordable Care Act, and higher standard costs of 0.9% resulting from lower production volumes at the beginning of 2013. Gross profit for 2012, compared to the corresponding period of 2011, remained relatively unchanged. The increase in gross profit in 2011 was attributable primarily 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.

Table of Contents

**Selling, General and Administrative Expenses.** Our selling, general and administrative expenses increased approximately \$6.5 million, or 5.4%, in 2013 compared to 2012; approximately \$17.6 million, or 17%, in 2012 compared to 2011; and approximately \$16.9 million, or 19%, in 2011 compared to 2010. The decrease in selling, general and administrative as a percentage of sales of 28.6% for 2013, when compared to 2012 of 31.0%, was primarily related to the implementation of cost-cutting initiatives in expenses such as trade shows and conventions, 401(k) employer match and bonuses. The increase in selling, general and administrative expenses in 2012, compared to 2011, was primarily due to the hiring of additional domestic and international sales and marketing representatives, in an effort to expand our sales distribution and increase market share for new and existing products. In connection with the Thomas Medical acquisition, we incurred 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 for 2012. The increase in selling, general and administrative expenses in 2011 was primarily related to the addition of sales and marketing employees, trade show expenses, commission payments and amortization of intangibles relating to the BioSphere acquisition and commencement of our Chinese distribution system. Selling, general and administrative expenses as a percentage of sales were 28.6% (28.0% if not for approximately \$489,000 and approximately \$2.4 million, respectively, of non-recurring transaction costs attributable to acquisitions and severance expenses), 31.0% (30.3 % without non-recurring Thomas Medical acquisition costs), and 29.1% in 2013, 2012 and 2011, respectively.

**Research and Development Expenses.** Research and development expenses increased by 21.9% to approximately \$33.9 million in 2013, compared to approximately \$27.8 million in 2012. The increase in research and development expenses for the year ended December 31, 2013 was primarily due to research and development costs associated with the acquisition of the products we acquired from Thomas Medical, headcount additions for research and development to support new product development, and personnel increases in Merit's regulatory department to support registrations in foreign countries to expand international product offerings. 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 expanded our international sales distribution. Research and development expenses increased 43.1% to approximately \$21.9 million in 2011, compared to approximately \$15.3 million in 2010. The increase was primarily related to headcount additions to support various new product launches, regulatory costs for seeking product approvals from 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. Our research and development expenses as a percentage of sales were 7.5% for 2013, 7.0% for 2012, and 6.1% for 2011. 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, during the year ended December 31, 2011.

Our operating profits by business segment for the years ended December 31, 2013, 2012 and 2011 were as follows (in thousands):

	2013	2012	2011
Operating Income (Loss)			
Cardiovascular	\$26,597	\$30,411	\$38,010
Endoscopy	1,247	(770	) (4,820
Total operating income	\$27,844	\$29,641	\$33,190

Cardiovascular Operating Income. Our cardiovascular operating income for the year ended December 31, 2013 was approximately \$26.6 million, compared to operating income of approximately \$30.4 million for the year ended December 31, 2012. The decrease was due primarily to lower gross profits during the year ended December 31, 2013. 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. The decrease was due primarily to higher selling, general and administrative expenses and higher research and development expenses during the year ended December 31, 2012. Our cardiovascular operating

Table of Contents

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. The 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.

Endoscopy Net Operating Income (Loss). Our endoscopy net operating income from operations for the year ended December 31, 2013 was approximately \$1.2 million, compared to a net operating loss of approximately \$770,000 for the year ended December 31, 2012. The generation of net operating income for 2013, compared to a net operating loss for 2012, was largely driven by higher sales and lower operating expenses. 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 for 2012, compared to 2011, 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 non-recurring 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 effective income tax rates for 2013, 2012 and 2011 were 16%, 29% and 30%, respectively. During 2013, our effective tax rate was lower as a result of a higher mix of earnings from our foreign operations, which are taxed at lower rates than our U.S. operations. In addition, the 2013 effective tax rate was lower than the 2012 rate, due primarily to the reinstatement in 2013 of the federal research and development credit for the 2012 tax year. The credit was reinstated by the American Taxpayer Relief Act of 2012, which was signed on January 2, 2013. We recognized the federal research and development credit as a discrete benefit in 2013, the period in which the reinstatement was enacted. 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 2011, was the result of a higher mix of foreign income, which is primarily due to our income in 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 was primarily related to the increased profit of our U.S. operations, which are taxed at a higher rate than our foreign (primarily Ireland) income.

Our other expense for the years ended December 2013, 2012, and 2011 was approximately \$8.0 million, \$2.0 million, and \$315,000, respectively. The increase in other expenses for 2013 over 2012 was principally the result of higher average outstanding debt balances and the corresponding increase in interest expense. The increase in other expenses for 2012 over 2011 related primarily 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.

Our net income for 2013, 2012, and 2011 was approximately \$16.6 million, \$19.7 million, and \$23.0 million, respectively. The decrease in net income for 2013, when compared to 2012, was primarily related to lower gross profits, partially offset by lower selling, general and administrative expenses as a percent of sales. Our 2013 net income included intangible asset impairment charges, net of fair value reductions to the related contingent consideration liability, of approximately \$4.3 million or approximately \$2.7 million net of tax, severance expense of



approximately \$1.8 million or approximately \$1.1 million net of tax, and Thomas Medical's mark-up on finished goods of approximately \$744,000 or approximately \$461,000 net of tax. Excluding these charges, our 2013 net income would have been \$20.9 million, compared to \$24.0 million of net income in 2012, excluding the extraordinary items discussed below. The decrease in net income for 2012, when compared to 2011, was unfavorably affected by higher selling, general and administrative expenses and higher research and development expenses. 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 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 of net income in 2011, excluding the extraordinary items discussed below. The increase in net income in 2011 as compared to 2010 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. Our 2011 net income included charges

Table of Contents

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.

## LIQUIDITY AND CAPITAL RESOURCES

## Capital Commitments and Contractual Obligations

The following table summarizes our capital commitments and contractual obligations as of December 31, 2013, 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	\$248,854	\$10,000	\$20,000	\$218,854	\$—
Interest on long-term debt (1)	39,952	9,585	19,818	10,549	—
Operating leases	61,761	6,569	10,930	8,195	36,067
Royalty obligations	483	50	100	100	233
Total contractual cash	\$351,050	\$26,204	\$50,848	\$237,698	\$36,300

(1) Interest payments on our variable long-term debt were forecasted using the LIBOR forward curves plus a base of 3.25%. Interest payments on a portion of our long-term debt were forecasted using a fixed rate of 4.23% 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, 2013, we had approximately \$2.5 million of contingent consideration liability, \$2.0 million of unrecognized tax positions, and \$7.8 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.

Table of Contents

Cash Flows

At December 31, 2013 and 2012, we had cash and cash equivalents of approximately \$7.5 million and \$9.7 million respectively, of which \$6.9 million and \$8.1 million, respectively, were held by foreign subsidiaries. For each of our foreign subsidiaries, we make an evaluation 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, 2013 and 2012, we had cash and cash equivalents of approximately \$6.0 million and \$6.4 million, respectively, held by our subsidiary in China.

Our cash flow from operations was approximately \$51.4 million in 2013, an increase of approximately \$4.4 million over 2012. This increase in cash flow from operations in 2013, compared to 2012, was primarily affected by changes in cash provided by a decrease in inventory of \$11.3 million which was partially offset by a decrease in trade payables of \$7.7 million. 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, 2013, 2012 and 2011 was approximately \$100.3 million, \$89.0 million, and \$89.9 million, respectively. The increase in working capital for 2013 from 2012 was primarily related to an increase in accounts receivable of approximately \$6.8 million and a decrease in trade payables of approximately \$8.1 million. Working capital remained relatively unchanged when comparing 2012 to 2011.

During the year ended December 31, 2013, our inventory balance decreased approximately \$2.2 million, from approximately \$84.6 million at December 31, 2012 to approximately \$82.4 million at December 31, 2013. The decrease in inventory was primarily the result of an effort to improve inventory turns throughout our company. During the year ended December 31, 2012, our inventory balance 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 balance 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.

Pursuant to the terms of the Credit Agreement, the Lenders have agreed to make revolving credit loans up to an aggregate amount of \$215 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 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. 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

Table of Contents

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 4.75 to 1 through the end of 2013, no more than 4.00 to 1 as of the fiscal quarter ending March 31, 2014, no more than 3.75 to 1 as of the fiscal quarter ending June 30, 2014, no more than 3.50 to 1 as of the fiscal quarter ending September 30, 2014, no more than 3.25 to 1 as of the fiscal quarter ending December 31, 2014, no more than 3.00 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 2.50 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, 2013, we were in compliance with all covenants set forth in the Credit Agreement.

As of December 31, 2013, we had outstanding borrowings of approximately \$248.9 million under the Credit Agreement, with available borrowings of approximately \$34.6 million, based on the leverage ratio in the terms of the Credit Agreement. Our interest rate as of December 31, 2013 was a fixed rate of 4.23% on \$145.0 million as a result of an interest rate swap (see Note 8), a variable floating rate of 3.42% on \$101.5 million and a variable floating rate of 3.50% on approximately \$2.4 million. 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, variable floating rate of 2.22% on \$87.0 million and a variable floating rate of 2.31% on approximately \$566,000.

Capital expenditures for property and equipment were approximately \$59.5 million, \$64.6 million, and \$59.2 million, for the years ended December 31, 2013, 2012 and 2011, respectively. During 2013, 2012 and 2011, we spent approximately \$29.9 million, \$31.9 million and \$36.9 million, respectively, for the construction of buildings and a parking lot as discussed below. We anticipate that we will spend approximately \$35 million in 2014 for property and equipment, of which we anticipate that approximately \$7.0 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 five years, we spent a substantial amount of

cash in connection with our acquisition of certain assets and businesses (including approximately \$30.0 million to acquire assets of Datascope and Radial Assist, among other transactions during 2013; \$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; and \$5 million to acquire the assets of Ash Access Technology, Inc. and AAT Catheter Technologies, LLC, among other transactions, during 2011). In 2013 we completed construction of new production facilities in South Jordan, Utah and Pearland, Texas. In 2012 we completed our 74,680 square-foot manufacturing facility in Galway, Ireland. As of December 31, 2013, we had incurred total costs of approximately \$98.7 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 and borrowings under the Credit Agreement, as amended, will be adequate to fund our current and currently planned future operations for the next twelve months and the foreseeable future.

Table of Contents

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, 2013, 2012 and 2011, we recorded obsolescence expense of approximately \$2.7 million, \$2.3 million, and \$1.5 million, respectively, and wrote off approximately \$2.8 million, \$1.5 million, and \$1.1 million, respectively. Based on this historical trend, we believe that our inventory balances as of December 31, 2013 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. These allowances are 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



Table of Contents

significant judgment, 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 2013, which was completed during the third quarter of 2013, 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 an asset's 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.

During the year ended December 31, 2013, we reduced the amount of the contingent consideration liability related to the Ostial PRO Stent Positioning System, which we acquired in January 2012, by approximately \$3.8 million. Under the terms of the Asset Purchase Agreement we executed with Ostial, we are obligated to make contingent purchase price payments based on a percentage of future sales of products utilizing the Ostial PRO Stent Positioning System. The adjustment to the contingent consideration liability triggered a review of the intangible assets we acquired from Ostial, which resulted in an intangible asset write-down of approximately \$8.1 million related to those assets. These adjustments reduced operating income for the year ended December 31, 2013 by approximately \$4.3 million, or approximately \$2.7 million net of tax. The reduction of the Ostial contingent consideration liability and the impairment of the Ostial intangible assets was the result of our assessment that we are not likely to generate the level of revenues from sales of the Ostial PRO Stent Positioning System that we anticipated at the acquisition date.

Table of Contents

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

Our principal market risk relates to changes in the value of the Euro and GBP relative to the value of the U.S. Dollar. 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, 2013, a portion of our revenues (approximately \$79.4 million, representing approximately 18% 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, 2013 were also denominated in foreign currencies, which partially offset risks associated with fluctuations of exchange rates between foreign currencies and the U.S. Dollar. During the year ended December 31, 2013, the exchange rate between our foreign currencies against the U.S. Dollar resulted in a increase in our gross revenues of approximately \$859,000 million, or 0.19%, and a decrease of 0.12% in gross profit, primarily as a result of an increase in Irish manufacturing operating costs denominated in Euros.

On November 29, 2013, we forecasted a net exposure for December 31, 2013 (representing the difference between Euro and GBP-denominated receivables and Euro-denominated payables) of approximately 494,000 Euros and 847,000 GBPs. In order to partially offset such risks at November 29, 2013, we entered into a 30-day forward contract for the Euro and GBP with a notional amount of approximately 494,000 Euros and notional amount of 847,000 GBPs. 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. 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, 2013, 2012 and 2011, we recorded a net gain (loss) on all foreign currency transactions of approximately \$(202,000), \$(11,000) and \$221,000, respectively, which is included in other income in the accompanying consolidated statements of income. The fair value of our open positions at December 31, 2013 and 2012 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, 2013, we had outstanding borrowings of approximately \$248.9 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 having an initial notional amount of \$150 million with Wells Fargo to fix the one-month LIBOR rate at 0.98%. This instrument is intended to reduce our exposure to interest rate fluctuations and was not entered into for speculative purposes. Excluding the amount 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 \$1.0 million 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.

Table of Contents

Item 8. Financial Statements and Supplementary Data.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of Merit Medical Systems, Inc. and subsidiaries (the "Company") as of December 31, 2013 and 2012, 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, 2013. 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, 2013 and 2012, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2013, 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, 2013, based on the criteria established in Internal Control — Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 12, 2014, expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Salt Lake City, Utah  
March 12, 2014

Table of Contents

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS  
DECEMBER 31, 2013 AND 2012  
(In thousands)

	2013	2012
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$7,459	\$9,719
Trade receivables — net of allowance for uncollectible accounts — 2013 — \$840 and 2012 — \$892	60,186	53,402
Employee receivables	224	169
Other receivables	3,279	2,672
Inventories	82,378	84,599
Prepaid expenses	5,121	4,133
Prepaid income taxes	1,232	1,250
Deferred income tax assets	5,638	4,976
Income tax refund receivables	398	1,076
<b>Total current assets</b>	<b>165,915</b>	<b>161,996</b>
<b>PROPERTY AND EQUIPMENT:</b>		
Land and land improvements	16,240	17,346
Buildings	127,747	81,223
Manufacturing equipment	136,768	117,601
Furniture and fixtures	32,327	26,307
Leasehold improvements	13,692	13,236
Construction-in-progress	25,172	74,643
<b>Total property and equipment</b>	<b>351,946</b>	<b>330,356</b>
Less accumulated depreciation	(108,676)	(95,553)
<b>Property and equipment — net</b>	<b>243,270</b>	<b>234,803</b>
<b>OTHER ASSETS:</b>		
<b>Intangible assets:</b>		
Developed technology — net of accumulated amortization — 2013 — \$17,602 and 2012 — \$8,146	91,052	87,332
Other — net of accumulated amortization — 2013 — \$18,870 and 2012 — \$14,034	28,935	30,799
Goodwill	184,505	175,108
Deferred income tax assets	800	4,237
Other assets	13,806	11,034
<b>Total other assets</b>	<b>319,098</b>	<b>308,510</b>
<b>TOTAL</b>	<b>\$728,283</b>	<b>\$705,309</b>

See notes to consolidated financial statements.

(Continued)

41

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Table of Contents

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS  
DECEMBER 31, 2013 AND 2012  
(In thousands)

	2013	2012
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Trade payables	\$26,511	\$34,637
Accrued expenses	27,702	27,269
Current portion of long-term debt	10,000	10,000
Advances from employees	292	551
Income taxes payable	1,089	547
Total current liabilities	65,594	73,004
<b>LONG-TERM DEBT</b>	238,854	227,566
<b>DEFERRED INCOME TAX LIABILITIES</b>	2,548	2,373
<b>LIABILITIES RELATED TO UNRECOGNIZED TAX BENEFITS</b>	2,031	2,938
<b>DEFERRED COMPENSATION PAYABLE</b>	7,833	5,956
<b>DEFERRED CREDITS</b>	3,065	2,980
<b>OTHER LONG-TERM OBLIGATIONS</b>	2,652	8,915
Total liabilities	322,577	323,732
<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, 2013 and 2012; no shares issued		
Common stock, no par value; shares authorized — 2013 and 2012 - 100,000; issued and outstanding as of December 31, 2013 - 42,846 and December 31, 2012 - 42,489	177,775	172,341
Retained earnings	226,988	210,418
Accumulated other comprehensive income (loss)	943	(1,182 )
Total stockholders' equity	405,706	381,577
<b>TOTAL</b>	<b>\$728,283</b>	<b>\$705,309</b>

See notes to consolidated financial statements.

(Concluded)



Table of Contents

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF INCOME  
YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011  
(In thousands, except per share amounts)

	2013	2012	2011
NET SALES	\$449,049	\$394,288	\$359,449
COST OF SALES	254,682	212,296	193,981
GROSS PROFIT	194,367	181,992	165,468
OPERATING EXPENSES:			
Selling, general, and administrative	128,642	122,106	104,502
Research and development	33,886	27,795	21,938
Intangible asset impairment charges	8,089	—	—
Contingent consideration benefit	(4,094	) —	—
Acquired in-process research and development	—	2,450	5,838
Total operating expenses	166,523	152,351	132,278
INCOME FROM OPERATIONS	27,844	29,641	33,190
OTHER INCOME (EXPENSE):			
Interest income	255	226	129
Interest expense	(8,044	) (604	) (789
Other income (expense) — net	(216	) (1,645	) 345
Other expense — net	(8,005	) (2,023	) (315
INCOME BEFORE INCOME TAXES	19,839	27,618	32,875
INCOME TAX EXPENSE	3,269	7,908	9,831
NET INCOME	\$16,570	\$19,710	\$23,044
EARNINGS PER COMMON SHARE:			
Basic	\$0.39	\$0.47	\$0.59
Diluted	\$0.39	\$0.46	\$0.58
AVERAGE COMMON SHARES:			
Basic	42,607	42,176	39,086
Diluted	42,884	42,610	39,733

See notes to consolidated financial statements.





Table of Contents

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES  
 CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME  
 YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

(In thousands)

	2013	2012	2011
Net income	\$16,570	\$19,710	\$23,044
Other comprehensive income (loss):			
Unrealized gain (loss) on marketable securities:			
Unrealized holding gain arising during the period, net of tax effect of \$0, \$215, \$115	—	336	180
Less: reclassification adjustment for gains included in net income, net of tax effect of \$0, \$330, \$0	—	(516)	—
Interest rate swap, net of tax effect of (\$1,164), \$696, \$451	1,828	(1,093)	(708)
Foreign currency translation adjustment, net of tax effect of \$5, \$15, \$44	297	(59)	(182)
Total other comprehensive income (loss)	2,125	(1,332)	(710)
Total comprehensive income	\$18,695	\$18,378	\$22,334

See notes to consolidated financial statements.

Table of Contents

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY  
YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011  
(In thousands)

	Total	Common Stock Shares	Common Stock Amount	Retained Earnings	Accumulated Other Comprehensive Income (Loss)
BALANCE — January 1, 2011	\$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 the 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)
Net income	16,570			16,570	
Other comprehensive income, net of tax	2,125				2,125
Excess tax benefits from stock-based compensation	259		259		
Stock-based compensation expense	1,467		1,467		
Options exercised	3,733	413	3,733		
Issuance of common stock under Employee Stock Purchase Plans	448	37	448		
Shares surrendered in exchange for payment of payroll tax liabilities	(21)	(48)	(21)		
Shares surrendered in exchange for exercise of stock options	(452)	(45)	(452)		
BALANCE — December 31, 2013	\$405,706	42,846	\$177,775	\$226,988	\$943

See notes to consolidated financial statements.



Table of Contents

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011  
(In thousands)

	2013	2012	2011
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net income	\$16,570	\$19,710	\$23,044
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	32,542	22,534	19,194
Losses on sales and/or abandonment of property and equipment	177	204	31
Write-off of patents and intangible assets	8,208	55	103
Impairment of cost-method investment	—	2,368	—
Acquired in-process research and development	—	2,450	5,838
Amortization of deferred credits	(139	) (174	) (106
Amortization of long-term debt issuance costs	845	—	—
Realized gain on sale of marketable securities	—	(745	) —
Deferred income taxes	1,359	549	