

MERIT MEDICAL SYSTEMS INC

Form 10-K

February 29, 2016

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
for the fiscal year ended December 31, 2015,

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, registered on the NASDAQ  
Global Select Market

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 checked="" type="checkbox"/>	Accelerated filer <input 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  
o No x

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant, on June 30, 2015, 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, 2015), was approximately \$911,939,002. Shares of common stock held by each officer and director of the registrant and by each person who may be deemed to be an affiliate have been excluded.

As of February 24, 2016, the registrant had 44,266,986 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 26, 2016.

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PART I

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

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This report includes “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). All statements 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 likely differ, and could differ materially, from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including risks relating to product liability claims and product recalls; risks related to the unauthorized use of our intellectual property; possible infringement of our technology or assertions that our operations, activities or assets infringe the intellectual property rights of others; potential for significant adverse changes in, or our failure to comply with governing regulations; international and national economic conditions adversely affecting our business or results of operations generally; greater governmental scrutiny and increasing regulation of the medical device industry; disruption of critical information systems or material breaches in the security of our systems; restrictions and limitations imposed by our debt agreements and instruments, which could significantly affect our ability to operate our business, and could substantially limit our liquidity; 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; violation of laws targeting fraud and abuse in the healthcare industry; modification or limitation of governmental or private insurance reimbursement policies; inability to compete in our markets, particularly if there is a significant change in relevant practices or technology; fluctuations in foreign currency exchange rates; termination or interruption of our supply relationships or increases in the price of our component parts, finished products, third-party services or raw materials, particularly petroleum-based products; our potential inability to successfully manage growth through acquisitions, including the inability to commercialize technology acquired through completed, proposed, or future acquisitions; 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, procedures or customers; volatility in the market price of our common stock; healthcare reform legislation affecting our financial results and its effects on our business, operations or financial condition; changes in key personnel; manufacturing facilities may be negatively impacted by certain factors, including work stoppage or transportation risks, severe weather conditions and natural disasters; fluctuations in our effective tax rate; 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 16.

Item 1. Business.

The Company

Merit Medical Systems, Inc. is a worldwide designer, developer, manufacturer and marketer of medical devices used in a vast array of interventional and diagnostic medical procedures. Our mission is to be the most customer-focused company in healthcare. Each day we are determined to make a difference by understanding our customers’ needs, and innovating and delivering a diverse range of products that improve the lives of people and communities throughout the world. We fundamentally believe that long-term value is created for our patients, employees, shareholders, and communities when we focus outward and are determined to deliver an exceptional customer experience.

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Merit Medical Systems, Inc. was founded in 1987 by Fred P. Lampropoulos, Kent W. Stanger, Darla Gill and William Padilla. Initially we focused on injection and insert molding of plastics, and electronic and sensor-based technologies. Our first product was a specialized control syringe used to inject contrast solution into a patient's arteries for a diagnostic cardiac procedure called an angiogram. Since that time, our sales and product lines have increased substantially, both through strategic acquisitions and product expansion through internal research and development projects.

Our business strategy focuses on four target areas as follows:

• Enhancing growth and profitability through research and development, sales model optimization, cost discipline, and operational focus.

• Optimizing our operational capability through lean processes, cost effective environments, and asset utilization.

• Targeting high-growth, high-return opportunities by understanding, innovating and delivering in peripheral, cardiac, OEM and endoscopy business lines.

• Maintaining a highly-disciplined, customer-focused enterprise guided by strong core values to globally address unmet or underserved healthcare needs.

We 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 medical products that offer a high level of quality, value and safety to our customers, as well as the patients they serve. Our products are used in the following clinical areas: diagnostic and interventional cardiology; interventional radiology; vascular, general and thoracic surgery; electrophysiology; cardiac rhythm management; interventional pulmonology; interventional nephrology; oncology; pain management; outpatient access centers; computed tomography; ultrasound; and interventional gastroenterology.

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 provide custom procedural solutions such as 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.

Our business is currently focused in three core areas: peripheral intervention, cardiac intervention, and endoscopy.

## Peripheral Intervention

We manufacture and sell various products designed to alleviate patient suffering from peripheral vascular and non-vascular diseases. These technologies support minimally invasive treatment of disease in peripheral vessels and organs throughout the body excluding the heart. Our peripheral intervention business line is organized into product portfolios as follows: Access, Angiography, Intervention, Embolotherapy and Interventional Oncology.

## Peripheral Access Portfolio

We offer a broad line of devices used to gain and maintain vascular access. These devices include an extensive line of Prelude® sheath introducers and related products to provide clinicians with smooth, convenient, and less traumatic access to the patient's vasculature. Our newest Prelude product is the PreludeEASE™ Hydrophilic Sheath Introducer. The PreludeEASE is designed to provide access to the radial artery while minimizing the potential for spasm with a hydrophilic coating that extends to the tip of the sheath.

#### Peripheral Angiography Portfolio

We market an extensive line of guide wires, inflation devices and diagnostic catheters for use in angiography procedures. 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



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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.

In 2015, we launched a new line of Peripheral Performa® catheters designed to meet the growing trends of transradial access, a procedure which uses the wrist as the entry point for cardiac catheterization and peripheral procedures rather than the more traditional femoral artery approach.

We offer diagnostic catheters for use during peripheral angiographic procedures. Our diagnostic catheters include our Impress® and the Performa® lines of peripheral catheters. These catheters offer physicians superior performance in a variety of angiography procedures.

For more than two decades, we have offered innovative inflation devices that accurately measure pressures during balloon and stent deployment. We offer the basixTOUCH™ Inflation Device for one-handed preparation and priming for faster preparation time. Additionally, we offer the the BasixCompak™ Inflation Device and the Blue Diamond™ Digital Inflation Device featuring an angled gauge for better viewing.

### Peripheral Intervention Portfolio

We have a broad line of interventional products, including drainage catheters and drainage access products, therapeutic products, support catheters, vascular retrieval devices and dialysis access products. On February 4, 2016, we acquired our newest dialysis access product, the HeRO® Graft, from CryoLife, Inc. The HeRO Graft is a fully subcutaneous vascular access system that is intended for use in maintaining long-term vascular access for chronic hemodialysis patients who have exhausted peripheral venous access sites suitable for fistulas or grafts.

The CentrosFLO® Long-Term Hemodialysis Catheters anchor our chronic dialysis line. In 2015, we launched a new stiffening stylette with the CentrosFLO catheter to assist in over-the-wire catheter placements, allowing us to reach a broader physician population. We also offer the ProGuide™ Chronic Dialysis Catheter, a “workhorse” catheter for chronic dialysis.

We offer peritoneal dialysis catheters and accessories as part of our dialysis access product line, including the Flex-Neck® and ExxTended™ Peritoneal Dialysis Catheters, and Y-TEC® Implantation Kits. Additionally, we have expanded our peritoneal dialysis portfolio to include a new implantation system for an over-the-wire catheter placement technique familiar to interventionists.

The Prelude® Short Sheath provides vascular access to dialysis grafts, along with our extensive line of micro access devices such as the MAK™ and S-MAK™ line of mini access kits. We also offer a wide range of guide wires, diagnostic catheters, therapeutic infusion systems and safety products that can be used during dialysis-related procedures. In addition, we offer the Impress® 30 cm Fistula Catheters, which can be used by interventional nephrologists.

Our One-Step™ Drainage Catheter, Safety Paracentesis Procedure Tray (“SPPT”) and Thoracentesis and Paracentesis Set (“TAPS”) are designed to provide clinicians with safe, convenient and cost-effective methods for removing fluid accumulation. The Valved One-Step™ Centesis Catheter and TAPS may also be used to remove excess fluid in the pleural space during a thoracentesis.

The ReSolve® Locking Drainage Catheter's unique, convenient locking mechanism is appreciated by clinicians and patients who comment on the enhanced comfort the catheter provides. We also offer a range of catheter fixation devices, including the StayFIX® Fixation Device and 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 kits feature an echo-enhanced needle and radiopaque marker tip on the introducer.

We market 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, or blood clots, in the peripheral vessels of the body, including native dialysis fistula and synthetic grafts. We offer standard and low-profile ASAP® 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.

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For crossing tight, difficult lesions, we market our line of Merit SureCross® Support Catheters. Our SureCross catheters offer trackability, pushability and visibility utilized by physicians to cross partial and total chronic occlusions in the peripheral arteries.

Our 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. In 2015, our EN Snare® Endovascular Snare System was enhanced and launched with a new robust delivery catheter and peel-away insertion tool to simplify the snare deployment process and increase reliability during use. We also offer the One Snare® Endovascular Snare System. Both snare systems are offered in multiple sizes to accommodate a broad range of vessels throughout the body.

### Peripheral Embolotherapy and Interventional Oncology Portfolio

In 2015 we launched a number of new peripheral devices and obtained expanded indications for use within the U.S. and Europe. In our interventional oncology portfolio, we received a 510(k) clearance from the Food and Drug Administration ("FDA") for our QuadraSphere® Microspheres allowing us to expand the indication for use to include the embolization of hepatoma. This new indication provides another treatment option for patients and physicians in their battle against primary liver cancer. In Europe, we received an expanded indication for use to market our HepaSphere™ Microspheres with the chemotherapy drug, irinotecan. This new indication compliments our already approved doxorubicin indication in Europe and leads the way for additional regulatory filings in the future.

We offer embolic microspheres and embolic delivery systems to provide for the reduction of blood flow within target vessels and for the targeted occlusion of blood vessels with or without drug delivery in the treatment of primary and metastatic liver cancer. We offer Embosphere® Microspheres to treat symptomatic uterine fibroids, hypervascularized tumors, and arteriovenous malformations in the United States, Europe, and several other international markets. Additionally, in certain markets outside of the U.S. we now offer Embosphere Microspheres to embolize the prostatic arteries for the relief of symptoms related to benign prostatic hyperplasia ("BPH").

We offer Bearing nsPVA® Particles to treat symptomatic uterine fibroids, hypervascularized tumors, and arteriovenous malformations throughout the world. We offer HepaSphere™ Microspheres in Europe, Brazil, and Russia and other emerging markets for drug delivery in the treatment of primary and metastatic liver cancer and QuadraSphere® Microspheres for the treatment of hypervascularized tumor, embolization of hepatoma and arteriovenous malformations in the United States.

We offer microcatheters for the controlled and selective infusion of diagnostic, embolic microspheres or particles, or therapeutic agents into vessels. Our primary microcatheter, the Merit Maestro®, 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.

### Cardiac Intervention

We manufacture and sell various products designed to aid in the treatment of various cardiac conditions specific to interventional cardiology and electrophysiology including cardiac rhythm management ("CRM") and cardiac resynchronization therapy ("CRT").

Our two program drivers in cardiac intervention during 2015 were the Think Radial™ Program and Think Interventional CRT™. Think Radial is a global education program that provides clinicians with the tools needed to begin or further their transradial practice. The transradial practice uses the artery in the wrist as the entry point for either cardiac catheterization or peripheral procedures, rather than the more traditional femoral artery in the groin. In 2015, we hosted four Think Radial training courses at our headquarters for interventional cardiologists as well as interventional

radiologists from across the US, Europe, and Canada. We also hosted programs for physicians from South America and South Africa. In 2015 we provided clinical education to over 220 health care professionals from around the world.

The Think Interventional CRT training program showcases a new interventional approach to implanting left ventricle leads. This new approach utilizes new products and techniques to electrophysiologists who are relatively new to telescoping support catheters, subclavian vein venoplasty, and using snares to provide guidewire support. In 2015, our Think Interventional CRT training programs globally assisted with the training and education of over 200 electrophysiologists.

Our Cardiac Intervention business line is organized between a variety of product portfolios which include: Access, Angiography, Hemostasis, Intervention, Custom Procedural Solutions, and Electrophysiology.

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### Cardiac Access Portfolio

We offer a broad line of devices used to gain and maintain vascular access for cardiology procedures, including needles, scalpels, hemostasis devices, arm boards and sheath introducers. Our line of Prelude® Sheath Introducers are designed to provide clinicians with quick and convenient access to the patient's vasculature. The PreludeEASE™ Hydrophilic Sheath Introducer is our anchor product for cardiologists, designed to provide access to the radial artery while minimizing the potential for spasm with a hydrophilic coating that extends to the tip of the sheath.

In an effort to provide a more complete offering for radial access procedures, we offer the Rad Board® family of products. The Rad Board is designed to provide x-ray protection and radiation protection to physicians, provide a larger work space for physicians and an area for patients to rest their arms during radial procedures.

### Cardiac Angiography Portfolio

For angiography procedures we market guide wires, fluid management and tubing, manifolds, syringes, transducers and diagnostic catheters. We offer the Performa® line of diagnostic catheters for use in interventional cardiology procedures. These catheters offer physicians superior performance during a variety of angiography procedures. Our MIV™ Radial Ventriculogram Pigtail Catheter addresses the difficulty in accessing the left ventricle from the radial artery when using standard femoral approach catheters.

### Cardiac Hemostasis Portfolio

Catheterization for diagnostic and interventional cardiology procedures generally take one of two approaches, femoral or radial. We offer products to assist clinicians in obtaining and maintaining hemostasis following arterial catheterization by either approach. For hemostasis of the femoral artery, we offer the Safeguard® Pressure Assisted Device and for hemostasis of the radial artery, we offer the Safeguard Radial™.

We have developed a broad line of 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®, PhD™, AccessPLUS™, Access-9™, DoublePlay™, MBA™, PhD and the Passage™.

### Cardiac Intervention Portfolio

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 VacLok® Vacuum Pressure Syringe. 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 designed 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.

For more than two decades, we have offered an extensive, innovative line of inflation devices that accurately measure pressures during balloon and stent deployment. The basixTOUCH™ Inflation Syringe offers 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.

During coronary catheterization procedures, guiding catheters are used to access the heart. Our line of Concierge® Guiding Catheters have an advanced braiding technology and proprietary polymer-blend shaft, which allow for an increased lumen size while maintaining exceptional backup support.

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.

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For Angiography and Angioplasty procedures 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. Additional angiographic accessories include the Flow Control Switch™, an integrated, one-handed, single-channel switch designed with clinician and patient safety in mind.

### Cardiac Custom Procedural Solutions Portfolio

Custom procedural solutions or CPS products are critical products used in angiographic procedures. Our CPS products consist of kits, packs and trays. 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 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.

### Electrophysiology Portfolio

We offer innovative solutions to address lead implantation and therapeutic delivery in the rapidly-expanding cardiac rhythm management and electrophysiology markets.

CRM is the field of cardiac disease therapy that relates to the diagnosis and treatment of cardiac arrhythmias or the improper beating of the heart. Our CRM products include the Classic Sheath™ Splittable Hemostatic Introducer System for the insertion of cardiac pacer leads for pacemakers and implantable cardioverter defibrillators. In 2015, we launched the Prelude SNAP™, which is a second generation splittable, hemostatic sheath providing an improved sheath-to-dilator transition and reduced break force. 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.

Electrophysiology (“EP”) 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® Transseptal Sheath, which features an improved hemostasis valve for reduced blood loss and air embolism, smooth sheath to dilator transition for easier transseptal crossing, and reinforced stainless steel tubing for excellent torque response. The HeartSpan® Steerable Sheath Introducer is designed to reduce the risk of atrial wall perforation when navigating cardiac chambers.

### Endoscopy

Our Endotek division, Merit Endotek, integrates advanced non-vascular stent technology with balloon dilators, inflation devices, guide wires, procedure kits, and other devices used by gastroenterologists (“GI”), endoscopists, pulmonologists, and thoracic and general surgeons. Merit Endotek has a dedicated marketing and sales organization serving these growing markets.

Merit Endotek sells a variety of non-vascular stents, including AERO® and AERO DV® Fully Covered Tracheobronchial Stents. These fully covered self-expanding nitinol stents are used by interventional pulmonologists and thoracic surgeons to treat strictures and fistulae in the airways, and to offer palliation to patients suffering from

strictures caused by cancer. The new AEROMini™ fully covered bronchial stent was launched in the first quarter of 2015. The AEROMini's low-profile delivery system is designed to provide additional flexibility, and to aid in the accurate placement of stents in difficult airway anatomy.

Merit Endotek's esophageal stents, the Alimaxx-ES™ and the EndoMAXX® Fully Covered Esophageal Stents, are used by interventional gastroenterologists, otolaryngologists and thoracic surgeons to palliate symptoms associated with malignant tumors and strictures affecting the esophagus, as well as to treat concomitant tracheoesophageal fistulae. The new EndoMAXX EVT™ is an esophageal stent with a reflux control valve, and is currently only available for sale outside the United States.

Merit Endotek's biliary stent systems are marketed under the Alimaxx-B® brand name. The Alimaxx-B 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



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biliary system. These stents are often used to “stage” treatment of malignant tumors such as pancreatic cancer and other serious conditions.

Merit Endotek's new esophageal balloon dilator, the Elation™ Fixed Wire Balloon Dilator, was introduced late in the fourth quarter of 2015, and is intended for use in adult and adolescent populations to endoscopically dilate strictures of the esophagus. This new device can be paired with Merit Endotek's BIG60® Inflation Device.

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 Device to customers in pulmonology, gastroenterology, and thoracic surgery.

For non-vascular procedures we market the MAXXWIRE® guide wire, our line of specialty guide wires that have pulmonology and gastroenterology applications.

For endoscopy and bronchoscopy we offer a variety of kits and accessories for the endoscopy and bronchoscopy markets, for example the AEROSIZER® tracheobronchial stent sizing device, the Brighton® Bipolar Probe, the BiliQUICK™ Cholangiography Rapid Refill Continuous Injection Kit, the TIO™ Three-in-One combination oral airway, bite block and oxygen administration device, the Vaclok® Negative Pressure Syringe, and the convenient BAL (bronchoalveolar lavage) Convenience Kit™.

Specialty Procedure Products

In addition to the procedures and devices detailed above, interventional radiology and other special procedure labs perform a variety of invasive diagnostic and interventional procedures. Our digital inflation devices, the IntelliSystem®, Monarch and Blue Diamond™ are used in discography, a technique used to determine whether a disc is the source of pain in patients with back or neck pain.

We provide coating services for medical tubes and wires under OEM brands. 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. We have state-of-the-art hypotube manufacturing in Galway, Ireland, which features advanced laser cutting and ablation, passivation, cleaning and other hypotube manufacturing processes. Our Merit Hypotube™ is used as the catheter shaft in PTCA and PTA balloon catheters, as well as functional guide wires.

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 fully calibrated components for numerous applications.

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### Marketing and Sales

**Target Market/Industry.** Our principal target markets are peripheral intervention, cardiac intervention and endoscopy. Within these markets our products are used in the following clinical areas: diagnostic and interventional cardiology; interventional radiology; vascular, general and thoracic surgery; electrophysiology; cardiac rhythm management; interventional pulmonology; interventional nephrology; oncology; pain management; outpatient access centers; computed tomography; ultrasound; and interventional gastroenterology.

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 and in electrophysiology, we continue our efforts to develop and distribute other devices used in our target markets. For example, we have developed and are distributing products used for percutaneous drainage. Prior to the widespread use of computed tomography 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.

As part of our embolic sales and marketing efforts, we attend major medical conventions throughout the world pertaining to our target 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 offer products to service the growing dialysis access market. These products are used in renal replacement therapies, including the treatment of acute renal failure, chronic renal failure and end-stage renal disease. Our hemodialysis access products include catheters and kits for interventional radiologists and interventional nephrologists. Our family of peritoneal dialysis products is designed to support specific implantation techniques for interventional radiologists, interventional nephrologists and laparoscopic surgeons. We also offer a variety of products for dialysis access interventions for these customers.

We believe the development of Merit Endotek and the move into the areas of interventional gastroenterology, pulmonology and thoracic surgery will open up new opportunities to sell our existing products, such as inflation devices, syringes, centesis catheters and procedure kits to those markets, but will also provide additional products incorporating 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 profitable products that meet customer needs. In order to stay abreast of customer needs, we frequently seek suggestions from health care professionals working in multiple fields of medicine, including diagnostic and interventional cardiology, interventional radiology, vascular surgery, electrophysiology, cardiac rhythm management, interventional pulmonology, interventional nephrology, oncology, pain management, outpatient access centers, computed

tomography, ultrasound, interventional gastroenterology, thoracic surgery and interventional pulmonology. 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.

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U.S. and International Sales. Sales of our products in the U.S. accounted for 61%, 61% and 63% of our total sales for the years ended December 31, 2015, 2014 and 2013, respectively. In the U.S. we have a dedicated, direct corporate sales organization primarily focused on selling to end user physicians, hospitals and clinics, major buying groups, and integrated healthcare networks.

Internationally, we have direct sales representatives and have contracted 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 2015, our international sales grew approximately 7.9% over our 2014 international sales, and accounted for approximately \$214.0 million, or 39% of our total sales. Merit Endotek has a growing domestic presence and a presence in international markets. With the recent and planned additions to our product lines, we believe 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 clinical marketers, our staff professionals, consulting physicians, and senior field trainers in their respective territories.

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), general surgeons, thoracic surgeons, oncologists, electrophysiologists, technicians, and nurses. Hospitals and acute care facilities in the United States generally 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 generally purchase our products through our direct sales force, or, in the absence of a sales force, through independent distributors or OEM partners.

In 2015, our U.S. sales force made approximately 42% of our sales directly to U.S. hospitals (including three percent of our total sales for Merit Endotek) and approximately seven 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 2015 sales. Approximately 39% of our 2015 sales were made to international markets by our direct sales force, international distributors, and our OEM sales force. Sales to our largest customer accounted for approximately three percent of total sales during the year ended December 31, 2015.

## Research and Development

Our research and development operations have been central to our historical growth, and we believe they will be critical to our continued growth. In 2015, our commitment to innovation led to the introduction of several new products, enhancements to our existing products and expansion of our product lines, as well as improvements to our manufacturing processes and equipment.

Our research and development expenses were approximately \$40.8 million, \$36.6 million, and \$33.9 million in 2015, 2014 and 2013, respectively.

We continue to develop new products and make improvements to our existing products utilizing many different sources. Our Chief Executive Officer and Vice President of Research and Development work closely with our sales and marketing teams to incorporate feedback from physicians and clinicians in the field, which can lead to innovative new products and improvements to our existing products.

Currently we have research and development facilities in:

• Dallas, Texas

• Galway, Ireland

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♣ Jackson Township, New Jersey  
♣ Malvern, Pennsylvania  
♣ Paris, France  
♣ Pearland, Texas  
♣ South Jordan, Utah  
♣ 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, The Netherlands, Ireland, France and Mexico. 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 develops and markets silicon pressure sensors. Merit Sensors presently supplies all of the sensors we utilize in our digital inflation devices and blood pressure transducers.

We currently produce and package all of our embolics. Manufacturing of our embolic 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; Pearland, Texas; Tijuana, Mexico; and Chester, Virginia. See Item 2. “Properties.”

We have distribution centers located in South Jordan, Utah; Chester, Virginia; Malvern, Pennsylvania; Beijing and Hong Kong, China; Maastricht, The Netherlands; Melbourne, Australia; Ontario, Canada and Joinville, Brazil.

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, we are experiencing a growing trend from suppliers of polymer resins to refuse to supply resin to medical device manufacturers or require that we assume additional risks due to the potential for products liability claims. 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, general and thoracic surgery; electrophysiology; cardiac rhythm management; interventional pulmonology; interventional nephrology; oncology; pain management; outpatient access centers; computed tomography; ultrasound; and interventional gastroenterology.

The principal competitive factors in the markets in which our products are sold are quality, price, value, device features, customer service, breadth of line, and customer relationships. We believe our products have achieved market acceptance primarily 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. Some of our primary competitive strengths are 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.

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 (Cardinal Health), 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 Vascular Solutions, B. Braun, Olympus, Edwards Lifesciences, Argon Medical Devices, AngioDynamics, Medcomp, and ICU Medical.

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

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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.

We derive a substantial majority of our revenues from sales of products used in diagnostic angiography, interventional cardiology and radiology procedures. We believe medical professionals are starting to use new interventional methods, procedures and devices, as well as drugs, for the treatment and prevention of cardiovascular disease. These new methods, procedures, devices and drugs 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.

Within the field of uterine fibroid embolization ("UFE"), 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 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.

Our primary competitive embolotherapy product has been Embosphere Microspheres. Currently, the primary products with which our microspheres and embolic particles compete are Beadblock® and DC Bead®, sold by BTG, plc; Embozene™ and Contour® sold by Boston Scientific, Inc; PVA Foam Embolization Particles, sold by Cook Medical; HydroPearl®, sold by Terumo International Systems ("Terumo"); and Gelfoam®, sold by Pfizer Inc. Our principal competitors in UFE are BTG, plc, Boston Scientific and Terumo, as well as companies selling or developing non-embolotherapy solutions to treat uterine fibroids.

## Proprietary Rights and Litigation

Our intellectual property and licenses thereto are protected by patents, trade secrets, trademarks, copyright, and confidentiality agreements. 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, 2015, we owned or had a license to more than 700 U.S. and international patents and patent applications. In the aggregate, our patents are critical to our business, but no single patent is of material importance to our business.

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.

There is substantial litigation regarding patents and other intellectual property rights in the medical device industry. We have been required, and may in the future, be required to defend against claims and actions alleging infringement of the intellectual rights of others. If a court rules against us in any patent litigation we could be subject to significant liabilities, be forced to seek licenses from third parties, or be prevented from marketing certain products.

## Regulation



U.S. Regulation. The FDA and other federal, state and local authorities regulate our products and product-related activities. Under the Federal Food, Drug, and Cosmetic Act (“FDCA”) and accompanying regulations, the FDA regulates the design, development, clinical trials, testing, manufacture, packaging, labeling, storage, distribution and promotion of medical devices. We believe 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 business. In addition, if we experience regulatory problems with a product or manufacturer, we could become subject to fines, delays or suspensions of regulatory clearances, seizures or recalls of products, operating restrictions and/or criminal prosecution. Such actions could have a material adverse effect on our business, financial condition or results of operations.

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,

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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”).

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.

If the FDA approves the PMA application, it may place restrictions on the device. If the FDA's evaluation of the PMA application is not favorable, the FDA may deny approval of the PMA application or issue a “not approvable” letter. The FDA may also require additional testing or clinical trials prior to approval or as a condition of approval. The PMA application process can be expensive, generally takes several years to complete and typically includes, among other things, human clinical trials, manufacturing facility inspection, bench tests, and laboratory and animal studies, which can be costly to conduct. There is also a substantial “user fee” that must be paid to FDA in connection with the submission of each PMA application. After a PMA application 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 the FDA before the modification to the device, the labeling, or the manufacturing process may be implemented. The FDA may determine that additional information, including clinical data, be submitted before a determination is made, which could significantly delay the introduction of new or modified devices.

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 in the USA. We, the FDA, or an independent committee designated to monitor biomedical research, known as an institutional review board, 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 ensure 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 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.

We are currently conducting a clinical trial in an effort to obtain PMA approval from the FDA to claim the use of the QuadraSphere Microspheres with doxorubicin for the treatment of liver cancer in the United States. We are also conducting clinical trials to obtain FDA PMA approval to claim the use of our Embosphere Microspheres for the indication of prostate artery embolization, and 510(k) clearance for the use of our EndoMAXX EVT Valved Esophageal Stent to relieve dysphagia in patients with malignant stricture of the esophagus. In order for us to obtain FDA approval or clearance to promote the use of QuadraSphere Microspheres, Embosphere Microspheres, and the EndoMAXX EVT Valved Esophageal Stent 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 depending on other factors, we will likely not be able to complete those trials. Even if we complete any or all of the three clinical trials, the FDA may require us to undertake additional testing, or the trial results may not be sufficient to obtain FDA approval or clearance for other reasons. If we do not obtain FDA approval or clearance 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.

**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.

**Quality System Requirements.** The FDCA requires us to comply with the Quality System Regulation (“QSR”) and various foreign regulations require compliance with ISO 13485 or national law requirements pertaining to all aspects of our product design and manufacturing processes, including requirements for packaging, labeling and record keeping, complaint handling,

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corrective and preventive actions and internal auditing. The FDA and foreign regulators enforce these requirements through periodic inspections of medical device manufacturers. These requirements are complex, technical and require substantial resources to remain compliant. Our failure or the failure of our suppliers to maintain compliance with these 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.

**Labeling and Promotion.** Our labeling and promotional activities are also subject to scrutiny by the FDA and foreign regulators. 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 approved or cleared labeling violate the FDCA and other applicable regulations. Allegations of off-label promotion can result in enforcement action by both federal, state, or foreign enforcement authorities, 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 or the United States are subject to foreign countries' import requirements and the exporting requirements of the FDA or European regulating bodies, as applicable. In particular, international sales of medical devices manufactured in the United States that are not approved or cleared by the FDA for use in the United States, or are banned or deviate from lawful performance standards, are subject to FDA export requirements and we may not be able to export such products.

Foreign countries often require, among other things, an FDA certificate for products for export, also called a Certificate to Foreign Government. To obtain this certificate from the FDA, the device manufacturer must apply to the FDA. The FDA certifies that the product has been granted clearance or approval in the United States and that the manufacturing facilities were in compliance with 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, scope, complexity, and cost of these requirements are increasing.

Foreign regulatory approval processes for medical devices are expensive, uncertain and lengthy. There can be no assurance that we will be able to obtain necessary regulatory approvals for any product on a timely basis or at all. Delays in receipt of or failure to receive such approvals, the loss of previously received 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.

Additionally, the European Commission is currently revising the legal framework for medical devices in the European Economic Area ("EEA"). Approval of the new regulations is anticipated in 2016. 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

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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, or cash flows could suffer a material adverse impact.

**Patient Protection and Affordable Care Act.** The Patient Protection and Affordable Care Act (“PPACA”) has changed the way healthcare in the United States is financed by both governmental and private insurers and has significantly affected 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 affect existing government healthcare programs and result in the development of new programs. The PPACA 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. Under recently passed legislation, the excise tax has been suspended for the tax years 2016 and 2017.

The recently enacted U.S. Physician Payment Sunshine Act, and similar state laws, also include annual reporting and disclosure requirements for device manufacturers aimed at increasing the transparency of the interactions between device manufacturers and healthcare providers. Reports submitted under these new requirements are placed in a public database. In addition to the burden of establishing processes for compliance, if we fail to provide these reports, or if the reports we provide are not accurate, we could be subject to significant penalties.

**Anti-Corruption Laws.** Anti-bribery and/or anti-corruption laws are in place in the United States and in many jurisdictions throughout the world. In the United States, the Foreign Corrupt Practices Act (the “FCPA”) prohibits corrupt payments to foreign officials for the purpose of procuring or maintaining business and requires that we maintain our books and records for accounting transparency purposes under the Securities Exchange Act of 1934. We are required to train our U.S. and international employees to ensure compliance with these anti-corruption laws. Failing to comply with any anti-corruption law could result in fines, penalties or other adverse consequences.

**Anti-Kickback Statutes.** 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 regulatory “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. 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 the manufacturer’s products. In addition, kickback arrangements can provide the basis for an action under the False Claims Act, which is discussed in more detail below. A party’s failure to fully satisfy a regulatory “safe harbor” provision may result in increased scrutiny by government enforcement authorities.

Government officials have recently increased 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 government cases have involved significant fines and/or penalties and in some instances criminal pleas.

In addition to the 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. The False Claims Act prohibits 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 False Claims Act. The 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 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.

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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 accompanying rules, 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. We generally do not meet the definition of a Business Associate in most cases, but we are nevertheless committed to maintaining the security and privacy of patients’ health information and believe that we meet the expectations of the HIPAA rules. Although we believe we are and will continue to be in substantial compliance with HIPAA standards, there is no guarantee that the government will agree. Enforcement actions can be costly and interrupt regular operations of our business. We believe the ongoing costs and impacts of assuring compliance with the HIPAA privacy and security rules are not material to our business.

Additionally, 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, Health and Safety 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 employee 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. These environmental laws and regulations may 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 non-compliance with all applicable laws at the time the acts were performed. Failure to comply with applicable environmental 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 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, 2015, we employed 3,754 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.

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Item 1A. Risk Factors.

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

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. 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, divert our management's attention from other business matters or operations, increase our product liability insurance rates, or 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 the return of product due to defects in quality and workmanship. We attempt to estimate our potential liability for future product returns and establish reserves on our financial statements in amounts that we believe will be sufficient to address our warranty obligations; however, our actual liability for product returns may significantly exceed the amount of our reserves. If we underestimate our potential liability for future product returns, or if unanticipated events result in returns that exceed our historical experience, our financial condition and operating results could be materially and adversely affected.

We may not be able to effectively protect our intellectual property, which could have a material adverse effect on our business.

Our ability to remain competitive is dependent, in part, upon our ability to prevent other companies from using our intellectual property. We seek to protect our intellectual property rights through a combination of confidentiality and license agreements, and through copyright, patent, trademark, and trade secrets laws. However, all these measures afford only limited protection and may be challenged, invalidated, or circumvented by third parties. Third parties may copy all or portions of our products or otherwise use our intellectual property which could have an adverse effect on our business, operations, or financial condition.

Third parties may also develop similar or superior technology independently and/or by designing around our patents. In addition, the laws of some foreign countries do not offer the same level of protection of our intellectual property as the laws of the U.S. Further, 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.

Third Parties claiming that we infringe their intellectual property rights could cause us to incur significant legal expenses and prevent us from selling our products.

From time to time, third parties may claim that we have infringed their intellectual property rights, including claims regarding patents, copyrights, trademarks, and trade secrets. Because of constant technological change in the medical device industry in which we compete, the extensive patent coverage of existing technologies, and the rapid rate of issuance of new patents, it is possible that the number of these claims may grow. In addition, former employers of our former, current, or future employees may assert claims that such employees have improperly disclosed to us the confidential or proprietary information of these former employers. Any such claim, with or without merit, could result in costly litigation and distract management from day-to-day operations. If we are not successful in defending such claims, we could be required to stop selling, delay shipments of, redesign our products, pay monetary amounts as damages, enter into royalty or licensing arrangements, or satisfy indemnification obligations that we have with some of our customers. We cannot be assured that any royalty or licensing arrangements that we may seek in such circumstances will be available to us on commercially reasonable terms or at all. We have made and expect to continue

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making significant expenditures to investigate, defend and settle claims related to the use of technology and intellectual property rights as part of our strategy to manage this risk.

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.

International and national economic and industry conditions constantly change, and 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, inflation and trade protection measures, may negatively affect consumer preferences, perceptions, spending patterns or demographic trends, any of which could adversely affect our business or results of operations. 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. 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.

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 government authorities 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.

Disruption of critical information systems or material breaches in the security of our systems may adversely affect our business and customer relationships.

We rely on information technology systems to process, transmit, and store electronic information in our day-to-day operations. We also rely on our technology infrastructure, among other functions, to interact with customers and suppliers, fulfill orders and bill, collect and make payments, ship products, provide support to customers, fulfill contractual obligations and otherwise conduct business. Our internal information technology systems, as well as those systems maintained by third-party providers, may be subjected to computer viruses or other malicious codes, unauthorized access attempts, and cyber-attacks, any of which could result in data leaks or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyber-attacks are becoming more sophisticated and frequent, and there can be no assurance that our protective measures will prevent security breaches that could have a significant impact on our business, reputation and financial results. If we fail to monitor, maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to these systems, we could, among other things, lose customers, have difficulty preventing fraud, have disputes with

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customers, physicians, other health care professionals and other employees, be subject to regulatory sanctions or penalties, incur expenses or lose revenues or suffer other adverse consequences. Any of these events could have a material adverse effect on our business, operations or financial condition.

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, on September 18, 2014 by a Second Amendment to Amended and Restated Credit Agreement and on February 3, 2016 by a Third 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.

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 our products 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 three clinical trials in an effort to obtain approval from the FDA that would enable us to expand our efforts to commercialize the QuadraSphere Microspheres, Embosphere Microspheres and EndoMAXX EVT Valved Esophageal Stent. European Union regulations do not currently require such applications for these classes of medical device. In order for us to obtain FDA approval or clearance to promote the use of QuadraSphere Microspheres, Embosphere Microspheres and EndoMAXX EVT Valved Esophageal Stent 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 any of the currently pending clinical trials, the FDA may require us to undertake additional testing, or the trial results may not be sufficient to obtain FDA approval or clearance for other reasons. If we do not obtain FDA approval or clearance 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.

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.

We are also subject to the FCPA, the U.K. Bribery Act, and similar anti-bribery laws in non-U.S. jurisdictions. These laws generally prohibit companies and their intermediaries from illegally offering things of value to any individual 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

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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.

Limits on reimbursement imposed by governmental and other programs may adversely affect our business and results of operation.

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 and results of operations.

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.

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 2015, the exchange rate between all applicable foreign currencies and the U.S. Dollar resulted in a decrease in our gross revenues of approximately \$11.3 million.

For the year ended December 31, 2015, approximately \$111.1 million, or 20%, 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.

Termination or interruption of our supply relationships or increases in the price of our component parts, finished products, third-party services or raw materials, particularly petroleum-based products, could have an adverse effect on our business, operations or financial condition.

We rely on raw materials, component parts, finished products and third-party services in connection with our business. For example, substantially all of our products are sterilized by only a few different entities. Additionally, many of our products have components that are manufactured using resins, plastics and other petroleum-based materials which are available from a limited number of suppliers. We are experiencing a growing trend among suppliers of polymer resins



to refuse to supply resin to the medical device manufacturers or to require such manufacturers to assume additional risks due to the potential for product liability claims. Additionally, there is no assurance that crude oil supplies will be uninterrupted or that petroleum-based manufacturing materials will be available for purchase in the future. Any interruption to the supply of polymers or petroleum-based resins could have an adverse effect on our ability to produce, or on the cost to produce, our products.

The availability and price of these materials is affected by a variety of factors beyond our control, including the willingness of suppliers to sell into the medical device industry, 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 around the world. 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

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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 or we experience terminations or interruption of our relationships with our suppliers we could experience lower margins and profitability, and our results of operations, financial condition and cash flows could be materially and adversely affected.

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

Successful implementation of our business strategy will require that we effectively manage any associated growth. To manage growth effectively, our management will need to continue to implement changes in certain aspects of our business, to improve our information systems, infrastructure 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.

Over the past several years, we completed a series of significant acquisitions, including our acquisitions of BioSphere Medical, Inc. ("Biosphere") and Thomas Medical Products, Inc. ("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.

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, 2015, sales of our inflation devices (including inflation devices sold in custom kits and through OEM channels) accounted for approximately 14% 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.

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, 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.

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

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The PPACA was enacted into law in March 2010, and most of the core pieces of the PPACA are now in 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. Although this tax has been recently suspended for the tax years 2016 and 2017, during the year ended December 31, 2015 we incurred \$4.3 million related to this tax, which reduced our gross profit by 0.8%.

In addition, the costs of compliance with the PPACA's new reporting and disclosure requirements, frequently identified as the Sunshine Act, with regard to payments or other transfers of value made to healthcare providers may have a material, negative impact on our results of operations and our cash flows. We cannot predict what healthcare programs and regulations will be ultimately implemented at the federal or state level, or the effect of any future legislation or regulation in the U.S. or internationally. However, any changes that lower reimbursements for our products or reduce medical procedure volumes could adversely affect our business and results of operations. As we cannot ultimately predict the long-term effect of the PPACA provisions as they are implemented, any changes to healthcare reform that lower reimbursement amounts for our products could adversely affect our business, results of operation 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, severe weather, natural disasters and related risks.

We manufacture products at various locations in the United States and foreign countries and sell our products worldwide. We depend on third-party transportation companies to deliver supplies necessary to manufacture our products from vendors to our various facilities and to move our products to customers, operating divisions, and other subsidiaries located worldwide. Our manufacturing operations, and the operations of the transportation companies on which we depend, may be adversely affected by natural disasters or significant human events, such as a war, civil unrest, 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.

Furthermore, our manufacturing operations could be affected by many other factors beyond our control, including severe weather conditions and natural disasters, including hurricanes, earthquakes and tornadoes. These conditions could cause substantial damage to our facilities, interrupt our production and disrupt our ability to deliver products to our customers.

Fluctuations in our effective tax rate may adversely affect our business, financial condition or results of operation.

We are subject to taxation in numerous countries, states and other jurisdictions. Our effective tax rate is derived from a combination of applicable tax rates in the various countries, states and other jurisdictions in which we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of these jurisdictions. Our effective tax rate may, however, differ from the estimated amount due to numerous factors, including a change in the mix of our profitability from country to country and changes in tax laws. Any of these

factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations, which could have an adverse effect on our business, financial condition or results of operation.

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

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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, Ireland. We also support our European operations from a European distribution and customer service facility located in Maastricht, The Netherlands. In addition, we lease office space in Dallas, Texas; Jackson Township, New Jersey; Beijing, Hong Kong and Shanghai, China; Tokyo, Japan; Bangalore, India; Rockland, Massachusetts; Melbourne, Australia; Ontario, Canada; and Joinville and São Paulo, Brazil. Our principal manufacturing facilities are located in South Jordan and West Jordan, Utah; Pearland, Texas; Chester, Virginia; Malvern, Pennsylvania; Galway, Ireland; Tijuana, Mexico; Paris, France; and Venlo, The Netherlands. Our research and development activities are conducted principally at facilities located in Galway, Ireland; South Jordan, Utah; Pearland and Dallas, Texas; Malvern, Pennsylvania; Jackson Township, New Jersey; Paris, France; and Venlo, The Netherlands. The following is an approximate summary of our facilities as of December 31, 2015 (in square feet):

	Owned	Leased	Total
U.S.	544,525	412,780	957,305
International	216,103	359,063	575,166
Total	760,628	771,843	1,532,471

In 2015, we took occupancy of two leased manufacturing buildings in Tijuana, Mexico, totaling 195,987 square-feet, and commenced manufacturing operations in an effort to reduce manufacturing costs. These manufacturing operations include manufacturing activities that were previously contracted to third parties.

In 2014, we completed construction of a production, clean room, warehouse and administrative office building in Pearland, Texas, which totals approximately 94,000 square feet and we completed the relocation of our Angleton, Texas manufacturing facility to the new Pearland building. The Pearland facility is designed to provide better protection from natural disasters, modernized facilities and room for future expansion. In 2015, we sold our Angleton, Texas facility.

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

## Item 3. Legal Proceedings.

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

matters such as outside counsel fees and expenses are charged to expense in the period incurred.

Item 4. Mine Safety Disclosures.

The disclosure required by this item is not applicable.

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## PART II

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

## Market Price for the Common Stock

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

For the year ended December 31, 2015	High	Low
First Quarter	\$19.96	\$15.20
Second Quarter	\$22.15	\$18.28
Third Quarter	\$26.42	\$21.00
Fourth Quarter	\$25.50	\$17.60
For the year ended December 31, 2014	High	Low
First Quarter	\$16.49	\$13.25
Second Quarter	\$16.76	\$12.45
Third Quarter	\$15.77	\$11.41
Fourth Quarter	\$17.69	\$11.61

As of February 24, 2016, the number of shares of Common Stock outstanding was 44,266,986 held by approximately 127 shareholders of record, not including shareholders whose shares are held in securities position listings.

## Dividends

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



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## Performance

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, 2010 to December 31, 2015.

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

	12/2010	12/2011	12/2012	12/2013	12/2014	12/2015
Merit Medical Systems, Inc.	\$100	\$106	\$110	\$124	\$137	\$147
NASDAQ Stock Market (U.S. Companies)	100	101	119	166	191	206
NASDAQ Stocks (SIC 3840-3849 U.S. Companies)	100	114	127	151	173	187

The stock performance graph assumes for comparison that the value of the Common Stock and of each index was \$100 on December 31, 2010 and that all dividends were reinvested. Past performance is not necessarily an indicator of future results.

Performance graph data is complete through last fiscal year. Performance graph with peer group uses peer group only performance (excludes only Merit). Peer group indices use beginning of period market capitalization weighting. 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 2016. Used with permission. All rights reserved.

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## Securities Authorized for Issuance Under Equity Compensation Plans

The following table contains information regarding our equity compensation plans as of December 31, 2015 (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	2,408 (1),(3)	\$ 14.25	2,707 (2),(3)

(1) Consists of 2,407,913 shares of Common Stock subject to the options granted under the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan.

(2) Consists of 233,341 shares available to be issued under the Merit Medical Systems, Inc. Non-Qualified Employee Stock Purchase Plan and 2,473,867 shares available to be issued under the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan.

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

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

	2015	2014	2013	2012	2011
<b>OPERATING DATA:</b>					
Net Sales	\$542,149	\$509,689	\$449,049	\$394,288	\$359,449
Cost of Sales	306,368	284,467	254,682	212,296	193,981
Gross Profit	235,781	225,222	194,367	181,992	165,468
Operating Expenses:					
Selling, general, and administrative	156,348	147,894	128,642	122,106	104,502
Research and development	40,810	36,632	33,886	27,795	21,938
Intangible asset impairment charge	—	1,102	8,089	—	—
Contingent consideration expense (benefit)	80	(572 )	(4,094 )	—	—
Acquired in-process research and development	1,000	—	—	2,450	5,838
Total operating expenses	198,238	185,056	166,523	152,351	132,278
Income From Operations	37,543	40,166	27,844	29,641	33,190
Other Income (Expense):					
Interest income	272	217	255	226	129
Interest expense	(6,229 )	(8,829 )	(8,044 )	(604 )	(789 )
Other income (expense)	(386 )	18	(216 )	(1,645 )	345
Other income (expense)—net	(6,343 )	(8,594 )	(8,005 )	(2,023 )	(315 )
Income Before Income Taxes	31,200	31,572	19,839	27,618	32,875
Income Tax Expense	7,398	8,598	3,269	7,908	9,831
Net Income	\$23,802	\$22,974	\$16,570	\$19,710	\$23,044
Earnings Per Common Share:					
Diluted	\$0.53	\$0.53	\$0.39	\$0.46	\$0.58
Average Common Shares:					
Diluted	44,511	43,409	42,884	42,610	39,733
<b>BALANCE SHEET DATA:</b>					
Working capital	\$116,093	\$116,910	\$100,321	\$88,992	\$89,857
Total assets	778,728	747,165	728,283	705,309	447,017
Long-term debt, less current portion	197,593	214,490	238,854	227,566	30,737
Stockholders' equity	466,103	435,259	405,706	381,577	357,089

We recorded no impairment charges during the year ended December 31, 2015. During the quarters ended September 30, 2014 and 2013, we recorded impairment charges of approximately \$1.1 million and \$8.1 million, respectively, related to certain intangible assets we acquired from Ostial Solutions, LLC ("Ostial"), which were offset by approximately \$874,000 and \$3.8 million, respectively, 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

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our estimated cash flows were 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.

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

The following discussion and analysis of our financial condition and results of operation should be read in conjunction with the Consolidated Financial Statements and related Notes thereto, which are included in Item 8 of this report. Although our financial statements are prepared in accordance with accounting principles which are generally accepted in the United States of America ("GAAP"), our management believes that certain non-GAAP financial measures provide investors with useful information regarding the underlying business trends and performance of our ongoing operations, and can be useful for period-over-period comparisons of such operations. Included in our management's discussion and analysis of our financial condition and results of operation are references to some non-GAAP financial measures. Readers should consider these non-GAAP measures in addition to, not as a substitute for, financial reporting measures prepared in accordance with GAAP. These non-GAAP financial measures exclude some, but not all, items that may affect our net income. Additionally, these financial measures 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, as well as our embolotherapeutic products. 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, 2015, we reported sales of approximately \$542.1 million, up approximately \$32.5 million or 6.4%, over 2014 sales of approximately \$509.7 million.

Gross profit as a percentage of sales decreased to 43.5% for the year ended December 31, 2015 as compared to 44.2% for the year ended December 31, 2014.

Net income for the year ended December 31, 2015 was approximately \$23.8 million, or \$0.53 per share, as compared to \$23.0 million, or \$0.53 per share, for the year ended December 31, 2014.

We continue to focus our efforts on expanding our presence in foreign markets, particularly Europe, Middle East and Africa ("EMEA"), China, Southeast Asia, Japan and Brazil, in an effort to expand our market opportunities. These efforts have increased our selling, general and administrative expenses in the short term, but we believe over time they will help us improve our profitability. Our international sales growth was strong for the year ended December 31, 2015. In 2015, international sales were approximately \$214.0 million, or 39% of our total sales, up 7.9% from 2014.

We recently announced the receipt of regulatory approvals for four new products:

• Our Centros® Dialysis Catheter has received CE Marking. The device has been available in the United States since 2014 and can now be marketed in European territories.

• We also received CE Marking for HepaSphere™ Microspheres with irinotecan indication, which is expected to complement the doxorubicin indication.

• In the United States, we received FDA approval for the Elation® Wireguided Balloon Dilation Catheter with biliary indication, which is expected to complement the company's esophageal indication.

Our Prelude SNAP™ Splittable Hydrophilic Sheath gained approval from the FDA and is expected to complement our existing uncoated sheath.

We believe these four new approvals will considerably strengthen our product portfolio and that upon successful launch of these products, we will be able to achieve greater market penetration, which, in turn, is expected to drive top-line growth. We also have an encouraging product pipeline, which includes a safety centesis catheter, the PAL™ Planner and the 40 atm. BasixTouch™ Inflation Device.

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## Results of Operations

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

	2015	2014	2013
Net sales	100%	100%	100%
Gross profit	43.5	44.2	43.3
Selling, general and administrative expenses	28.8	29.0	28.6
Research and development expenses	7.5	7.2	7.5
Acquired in-process research and development	0.2	—	—
Intangible asset impairment charge	—	0.2	1.8
Contingent consideration expense (benefit)	0.0	(0.1)	(0.9)
Income from operations	6.9	7.9	6.2
Income before income taxes	5.8	6.2	4.4
Net income	4.4	4.5	3.7

Listed below are the sales by product category within each business segment for the years ended December 31, 2015, 2014 and 2013 (in thousands):

	% Change	2015	% Change	2014	% Change	2013
Cardiovascular						
Stand-alone devices	8%	\$155,414	15%	\$143,712	10%	\$125,445
Custom kits and procedure trays	5%	116,368	7%	111,076	10%	103,700
Inflation devices	1%	73,373	10%	72,538	(4)%	66,182
Catheters	11%	96,833	17%	87,550	16%	75,131
Embolization devices	3%	45,025	31%	43,855	(1)%	33,395
CRM/EP	3%	33,902	17%	32,975	1,359%	28,271
Total	6%	520,915	14%	491,706	14%	432,124
Endoscopy						
Endoscopy devices	18%	21,234	6%	17,983	7%	16,925
Total	6%	\$542,149	14%	\$509,689	14%	\$449,049

Cardiovascular Sales. Our cardiovascular sales for the year ended December 31, 2015 were approximately \$520.9 million, up 5.9%, when compared to the corresponding period for 2014 of approximately \$491.7 million. Sales for the year ended December 31, 2015 were favorably affected by increased sales of our stand-alone devices (particularly our pressure monitoring tubing product lines and our Laureate® hydrophilic guide wires) of approximately \$11.7 million, up 8.1%, catheters (particularly our Prelude® introducer sheath product line, ReSolve® drainage catheters, and our Maestro® microcatheters) of approximately \$9.3 million, up 10.6%, and custom kits and procedure trays of approximately \$5.3 million, up 4.8%. Our cardiovascular sales for the year ended December 31, 2014 were approximately \$491.7 million, up 13.8%, when compared to the corresponding period for 2013 of approximately \$432.1 million. Sales for the year ended December 31, 2014 were favorably affected by increased sales of our stand-alone devices (particularly our Safeguard® Pressure Assisted Device, hemostasis product line and Laureate® hydrophilic guide wires) of approximately \$18.3 million, up 14.6%, catheters (particularly our Prelude® introducer sheath product line, ReSolve® drainage catheters, guiding catheters and aspiration catheters) of approximately \$12.4 million, up 16.5%, embolization devices of approximately \$10.5 million, up 31.3%, and custom kits and procedure trays of approximately \$7.4 million, up 7.1%. Our cardiovascular sales for the year ended December 31, 2013 were approximately \$432.1 million, up 14.2%, when compared to sales in 2012 of approximately \$378.5 million. Sales for



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

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Our cardiovascular sales increased during 2015, 2014 and 2013, 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 2015, 2014 and 2013 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 decreased sales 2.0% in 2015 compared to 2014, increased sales 0.1% in 2014 compared to 2013, and increased sales by 0.2% in 2013 compared to 2012. 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, 2015 were approximately \$21.2 million, up 18.1%, when compared to sales in the corresponding period of 2014 of approximately \$18.0 million. This increase was primarily due to the increase in our sales of the EndoMAXX™ Fully Covered Esophageal Stent, AEROMini™, fully covered tracheobronchial stent system and BIG60™ inflation device. Our endoscopy sales for the year ended December 31, 2014 were approximately \$18.0 million, up 6.3%, when compared to sales in the corresponding period of 2013 of approximately \$16.9 million. This increase was also primarily due to the increase in our sales of the EndoMAXX™ Fully Covered Esophageal Stent and BIG60™ inflation device. 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 due to sales of our EndoMAXX™ Fully Covered Esophageal Stent.

**International Sales.** International sales for the year ended December 31, 2015 were approximately \$214.0 million, or 39% of total sales, up 7.9% from the same period in 2014. International sales for the year ended December 31, 2014 were approximately \$198.3 million, or 39% of total sales, up 19.6% from the same period in 2013. 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. The increase in our international sales during 2015 was primarily related to year-over-year sales increases in China of approximately \$9.9 million, up 24.4%, and in EMEA of approximately \$2.4 million, up 7.4%. The increase in our international sales during 2014 was primarily related to year-over-year sales increases in EMEA of approximately \$18.1 million, up 25.1%; China of approximately \$8.8 million, up 27.4%; and Japan of approximately \$3.8 million, up 23.4%. 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 20.3%; Europe Direct of approximately \$5.3 million, up 13.1% (would have been up 11% in constant currency); and Russia of approximately \$2.4 million, up 54.0%.

**Gross Profit.** Our gross profit as a percentage of sales was 43.5%, 44.2%, and 43.3% in 2015, 2014, and 2013, respectively. The decrease in gross profit as a percentage of sales in 2015, as compared to 2014, was primarily the result of higher average fixed overhead unit costs related to the start-up of our Tijuana, Mexico facility, as well as lower production volumes related to our embolic products and sales discounts provided to various international distributors in an effort to counter devaluation against the U.S. Dollar, all of which were partially offset by a decrease in our Euro-based manufacturing expenses due to the weakening of the Euro against the U.S. Dollar. The increase in gross profit as a percentage of sales in 2014 was primarily related to a favorable product mix (primarily from sales of BioSphere products) and lower average fixed overhead unit costs as the result of higher production volumes for 2014 when compared to the corresponding period of 2013. The decrease in gross profit as a percentage of sales 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.

**Selling, General and Administrative Expenses.** Our selling, general and administrative expenses increased approximately \$8.5 million, or 5.7%, in 2015 compared to 2014; \$19.3 million, or 15.0%, in 2014 compared to 2013; and approximately \$6.5 million, or 5.4%, in 2013 compared to 2012. The increase was primarily related to SG&A

headcount additions, higher severance costs, termination of our agreement with a third-party contract manufacturer in Tijuana, Mexico and increased litigation costs, which were partially offset by a decrease in our Euro-based SG&A expenses of approximately \$6.0 million due to the strengthening of the U.S. Dollar against the Euro. As a percentage of sales, selling, general and administrative expenses decreased from 29.0% in 2014 to 28.8% in 2015. The increase in selling, general and administrative expenses as a percentage of sales, from 28.6% in 2013 to 29.0% in 2014, was primarily related to headcount additions to support our domestic sales force reorganization, international sales expansions, and costs of approximately \$2.5 million associated with our new facility in Pearland, Texas, which were recorded as selling, general and administrative expenses during a transition period of approximately nine months as we completed the movement and qualification of production equipment from the old facility to the new facility. The decrease in selling, general and administrative expenses as a percentage of sales, from 31.0% in 2012 to 28.6% for 2013, was primarily related to the implementation of cost-cutting initiatives in expenses such as trade shows and conventions, 401(k) employer match and bonuses. Selling, general and administrative expenses as a percentage of sales were 28.8%, 29.0%, and 28.6% in 2015, 2014, and 2013, respectively.

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Research and Development Expenses. Research and development expenses increased by 11.4% to approximately \$40.8 million in 2015, compared to approximately \$36.6 million in 2014. The increase in research and development expenses for the year ended December 31, 2015 was primarily due to the expense of external R&D work related to a new catheter design, increased clinical costs as a result of higher patient enrollment in our three clinical trials, and additional R&D headcount to support the completion of numerous R&D projects. Research and development expenses increased by 8.1% to approximately \$36.6 million in 2014, compared to approximately \$33.9 million in 2013. The increase in research and development expenses for the year ended December 31, 2014 was primarily due to headcount additions to support new product development. 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. Our research and development expenses as a percentage of sales were 7.5% for 2015, 7.2% for 2014, and 7.5% for 2013. 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.

In addition, during the year ended December 31, 2015, we incurred in-process research and development charges of \$1.0 million related to the purchase of technology for a steerable snare.

Our operating profits by business segment for the years ended December 31, 2015, 2014 and 2013 were as follows (in thousands):

	2015	2014	2013
Operating Income			
Cardiovascular	\$34,052	\$38,601	\$26,597
Endoscopy	3,491	1,565	1,247
Total operating income	\$37,543	\$40,166	\$27,844

Cardiovascular Operating Income. Our cardiovascular operating income for the year ended December 31, 2015 was approximately \$34.1 million, compared to operating income of approximately \$38.6 million for the year ended December 31, 2014. The decrease was due primarily to lower gross profit percentage and higher operating expenses, including the \$1.0 million acquired in-process R&D charge and higher R&D expenses in general. Our cardiovascular operating income for the year ended December 31, 2014 was approximately \$38.6 million, compared to operating income of approximately \$26.6 million for the year ended December 31, 2013. The increase was due primarily to higher sales and gross profits which were partially offset by higher operating expenses. 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.

Endoscopy Net Operating Income. Our endoscopy operating income for the year ended December 31, 2015 was approximately \$3.5 million, compared to approximately \$1.6 million for the year ended December 31, 2014. The increase in operating income for 2015 compared to 2014 was largely driven by higher sales and gross profits and lower operating expenses as a percentage of sales. Our endoscopy operating income for the year ended December 31, 2014 was approximately \$1.6 million, compared to approximately \$1.2 million for the year ended December 31, 2013. The increase in operating income for 2014 compared to 2013 was largely driven by higher sales and gross profits, which were partially offset by higher operating expenses, as discussed above. Our endoscopy operating income 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.

**Effective Tax Rate.** Our effective income tax rate for 2015, 2014 and 2013 was 23.7%, 27.2%, and 16.5%, respectively. The decrease in the effective income tax rate for 2015 compared to 2014 was due primarily to a higher mix of earnings from our foreign operations, which are generally taxed at lower rates than our U.S. operations. The increase in the effective income tax rate for 2014 compared to 2013 is primarily related to the increased profit of our U.S. operations, which are generally taxed at a higher rate than our foreign operations. During 2013, our effective tax rate was lower as a result of a higher mix of earnings from our foreign operations, which are generally 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. We recognized the federal research and development credit as a discrete benefit in 2013, the period in which the reinstatement was enacted.

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**Other Expense.** Our other expense for the years ended December 2015, 2014, and 2013 was approximately \$6.3 million, \$8.6 million, and \$8.0 million, respectively. The decrease in other expenses for 2015 over 2014 was principally the result of decreased interest expense related to lower interest rates and lower balances associated with our outstanding debt. The increase in other expenses for 2014 over 2013 was principally the result of increased interest expense related to higher interest rates associated with our outstanding debt. The increase in other expenses for 2013 over 2012 was also principally the result of higher average outstanding debt balances and the corresponding increase in interest expense.

**Net Income.** Our net income for 2015, 2014, and 2013 was approximately \$23.8 million, \$23.0 million, and \$16.6 million, respectively. The increase in net income for 2015, when compared to 2014, was due primarily to increased sales, lower SG&A expenses as a percentage of sales, lower interest expense, and a lower effective income tax rate, all of which were partially offset by higher R&D expenses as a percentage of sales. The increase in net income for 2014, when compared to 2013, was primarily related to higher sales and gross profits and lower research and development expenses as a percent of sales, as well as a smaller intangible asset impairment charge, net of the change in the contingent consideration, in 2014 (approximately \$228,000 or approximately \$141,000 net of tax), compared to 2013 (approximately \$4.3 million or approximately \$2.7 million net of tax), which was partially offset by a higher selling, general and administrative expenses and a higher effective income tax rate as a result of a higher mix of earnings from our U.S. operations, which are taxed at a higher rate than our foreign operations. 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 non-recurring items discussed below.

**Total Assets.** Total assets utilized in our cardiovascular segment were approximately \$768.0 million as of December 31, 2015, compared to approximately \$734.9 million as of December 31, 2014. Total assets utilized in our endoscopy segment were approximately \$10.8 million as of December 31, 2015, compared to approximately \$12.2 million as of December 31, 2014.

## Liquidity and Capital Resources

## Capital Commitments and Contractual Obligations

The following table summarizes our capital commitments and contractual obligations as of December 31, 2015, 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	\$207,593	\$10,000	\$197,593	\$—	\$—
Interest on long-term debt (1)	11,864	5,946	5,918	—	—
Operating leases	73,791	9,168	15,166	12,137	37,320
Royalty obligations	383	50	100	100	133
Total contractual cash	\$293,631	\$25,164	\$218,777	\$12,237	\$37,453

(1) Interest payments on our variable long-term debt were forecasted using the LIBOR forward curves plus a base of 1.75%. Interest payments on a portion of our long-term debt were forecasted using a fixed rate of 2.73% 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, 2015, we had approximately \$1.0 million of contingent consideration liability, \$768,000 of unrecognized tax positions, and \$8.5 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.

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Cash Flows

At December 31, 2015 and 2014, we had cash and cash equivalents of approximately \$4.2 million and \$7.4 million respectively, of which \$3.7 million and \$6.6 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, 2015 and 2014, we had cash and cash equivalents of approximately \$1.7 million and \$5.2 million, respectively, held by our subsidiary in China.

Cash flows provided by operating activities. Our cash flow from operations was approximately \$69.5 million in 2015, an increase of approximately \$16.1 million over 2014. This increase in cash flow from operations in 2015, compared to 2014, was primarily affected by cash provided by changes related to trade payables of \$9.4 million, accounts receivable of \$7.7 million, other receivables of \$3.4 million, and other assets of \$1.0 million, which was offset by changes in cash used in inventories of \$3.7 million and prepaid income taxes of \$1.7 million. Our cash flow from operations was approximately \$53.3 million in 2014, an increase of approximately \$1.9 million over 2013. This increase in cash flow from operations in 2014, compared to 2013, was primarily affected by changes in cash provided by increases in net income of \$6.4 million, accrued expenses of \$6.4 million, trade payables of \$5.3 million, deferred income taxes of \$2.5 million, which was offset by changes in cash used in inventories of \$11.7 million and trade receivables of \$7.2 million.

Our working capital for the years ended December 31, 2015, 2014 and 2013 was approximately \$116.1 million, \$116.9 million, and \$100.3 million, respectively. The decrease in working capital for 2015 from 2014 was primarily related to decreases in cash and trade receivables of approximately \$3.2 million and \$2.4 million, respectively; increases in trade payables and accrued expenses of approximately \$8.2 million and \$4.0 million, respectively; offset by increases in inventory of approximately \$14.2 million, prepaid income taxes of approximately \$1.7 million and income tax refund receivables of approximately \$800,000. The increase in working capital for 2014 from 2013 was primarily related to an increase in accounts receivable and inventory of approximately \$12.5 million and \$9.4 million, respectively, and was partially offset by increases in accrued expenses and trade payables of approximately \$6.1 million and \$3.3 million, respectively.

During the year ended December 31, 2015, our inventory balance increased approximately \$14.2 million, from approximately \$91.8 million at December 31, 2014 to approximately \$106.0 million at December 31, 2015. The increase in the inventory balance was due to several factors, including the manufacturing of product in our Tijuana, Mexico facility in 2015 which was previously done by a third-party manufacturer, increased inventory levels to support increased sales in China, and our entrance in to the Australian market. The trailing twelve months inventory turns for the period ended December 31, 2015 decreased to 3.10, compared to 3.27 for the twelve-month period ended December 31, 2014. During the year ended December 31, 2014, our inventory balance increased approximately \$9.4 million, from approximately \$82.4 million at December 31, 2013 to approximately \$91.8 million at December 31, 2014.

Cash flows (used in) financing activities. Our cash flow used in financing activities was approximately \$10.2 million for the year ended December 31, 2015. This compares to cash flow used in financing activities of approximately \$17.0 million for the year ended December 31, 2014. 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

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

The Credit Agreement contains customary covenants, representations and warranties and other terms customary for revolving credit loans of this nature. In this regard, the Credit Agreement requires us to not, among other things, (a) permit the Consolidated Total Leverage Ratio (as defined in the Credit Agreement) to be greater than 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, 2015, we were in compliance with all covenants set forth in the Credit Agreement.

As of December 31, 2015, we had outstanding borrowings of approximately \$207.6 million under the Credit Agreement, with available borrowings of approximately \$32.4 million, based on the leverage ratio in the terms of the Credit Agreement. Our interest rate as of December 31, 2015 was a fixed rate of 2.48% on \$135.0 million as a result of an interest rate swap (see Note 8), a variable floating rate of 1.74% on \$65.8 million and a variable floating rate of 2.12% on approximately \$6.8 million. Our interest rate as of December 31, 2014 was a fixed rate of 2.98% on \$140.0 million as a result of an interest rate swap, variable floating rate of 2.17% on \$84.3 million and a variable floating rate of 2.26% on approximately \$0.2 million.

Cash flows (used in) investing activities. Our cash flow used in investing activities for the year ended December 31, 2015 was approximately \$62.0 million, compared to approximately \$36.2 million for the year ended December 31, 2014. Capital expenditures for property and equipment were approximately \$51.0 million, \$34.2 million, and \$59.5 million for the years ended December 31, 2015, 2014 and 2013, respectively. We anticipate that we will spend approximately \$34.0 million in 2016 for buildings, property and equipment.

Historically, we have incurred significant expenses in connection with facility construction, production automation, product development and the introduction of new products. We spent approximately \$12.4 million on acquisitions of certain assets and businesses in 2015 (see Note 2). In 2014 and 2013, we spent a substantial amount of cash in connection with our acquisitions of certain assets and businesses (including approximately \$5.9 million for various license agreements, distribution agreements, and ownership interests in various technologies in 2014; and approximately \$30.0 million to acquire assets of Datascope and Radial Assist, among other transactions during 2013). In 2013, we completed construction of new production facilities in South Jordan, Utah and Pearland, Texas. As of December 31, 2013, we had incurred total costs of approximately \$98.7 million with respect to those construction projects. During 2015 and 2014, we financed equipment of approximately \$2.0 million and \$5.5 million, respectively. 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, equipment financing 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.

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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, 2015, 2014 and 2013, we recorded obsolescence expense of approximately \$2.8 million, \$2.3 million, and \$2.7 million, respectively, and wrote off approximately \$2.5 million, \$2.4 million, and \$2.8 million, respectively. Based on this historical trend, we believe that our inventory balances as of December 31, 2015 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 using a combination of a market-based approach with a guideline public company method and a discounted cash flow method. 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

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of the reporting unit goodwill over implied fair value of that goodwill. This analysis requires 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 2015, which was completed during the third quarter of 2015, 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 changes to 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 each of the years ended December 31, 2014 and 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 \$874,000 and \$3.8 million, respectively. We had no adjustments for the year ended December 31, 2015. 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 our Ostial intangible assets, which resulted in an intangible asset write-down of approximately \$1.1 million and \$8.1 million related to those assets during each of the years ended December 31, 2014 and 2013, respectively. These adjustments reduced operating income for each of the years ended December 31, 2014 and 2013 by approximately \$228,000 and \$4.3 million, respectively, or approximately \$141,000 and \$2.7 million, respectively, net of tax. The reduction of the Ostial contingent consideration liability and the impairment of the Ostial intangible assets were 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.

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

Our principal market risk relates to changes in the value of the Euro, Chinese Yuan Renminbi, and British Pound relative to the value of the U.S. Dollar. We also have a limited market risk relating to the Hong Kong Dollar, Mexican Peso, Australian Dollar, Brazilian Real, 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, 2015, a portion of our revenues (approximately \$111.1 million, representing approximately 20% of our aggregate revenues), was attributable to sales that were denominated in foreign currencies. All other international sales were denominated in U.S. Dollars. Our Euro-denominated revenue represents our largest single currency risk. However, our Euro-denominated expenses associated with our European operations (manufacturing sites, a distribution facility and sales representatives) provide a natural hedge. Accordingly, changes in the Euro, and in particular a strengthening of the U.S. Dollar against the Euro, will positively affect our net income. A strengthening U.S. dollar against the Euro of 10% would increase net income by approximately \$3.0 million dollars. Conversely, a weakening U.S. dollar against the Euro of 10% would have decrease net income by approximately \$3.0 million dollars. A strengthening U.S. dollar against the Chinese Yuan Renminbi of 10% would decrease net income by approximately \$4.0 million dollars. Conversely, a weakening U.S. dollar against the Chinese Yuan Renminbi of 10% would increase net income by approximately \$4.0 million dollars. During the year ended December 31, 2015, the exchange rate between our foreign currencies against the U.S. Dollar resulted in a decrease in our gross revenues of approximately \$11.3 million, or 2.0%, and an increase of 0.7% in gross profit, primarily as a result of an increase in Irish manufacturing operating costs denominated in Euros.

As of December 31, 2015, we entered into foreign currency forward contracts for the Euro (EUR), British Pound (GBP), Chinese Yuan Renminbi (CNY), Mexican Peso (MXN), Brazilian Real (BRL), and Australian Dollar (AUD). On November 25, 2015, we forecasted a net exposure for December 31, 2015 (representing the difference between EUR, GBP, CNY, MXN, BRL, and AUD-denominated receivables and EUR, GBP, CNY, MXN, BRL, and AUD-denominated payables) of approximately 1.7 million EUR, 610,000 GBP, 38.4 million CNY, 32.0 million MXN, 1.5 million BRL, and 830,000 AUD. In order to partially offset such risks, on November 25, 2015 we entered into short-term forward contracts for the EUR, GBP, CNY, MXN, BRL, and AUD with notional amounts of approximately 1.7 million EUR, 610,000 GBP, 38.4 million CNY, 32.0 million MXN, 1.5 million BRL, and 830,000 AUD. On November 28, 2014, we forecasted a net exposure for December 31, 2014 (representing the difference between EUR and GBP-denominated receivables and EUR and GBP-denominated payables) of approximately 899,000 EUR and 572,000 GBP. In order to partially offset such risks at November 28, 2014, we entered into short-term forward contracts for the EUR and GBP with notional amounts of approximately 899,000 EUR and 572,000 GBP. 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. The fair value of our open positions at December 31, 2015 and 2014 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, 2015, we had outstanding borrowings of approximately \$207.6 million under the Credit Agreement. Accordingly, our earnings and after-tax cash flow are affected by changes in interest rates. As part of our efforts to mitigate interest rate risk, on December 19, 2012, we entered into a LIBOR-based interest rate swap agreement having an initial notional amount of \$150.0 million with Wells Fargo to fix the one-month LIBOR rate at 0.98%. As of December 31, 2015, a notional amount of \$135.0 million remained on the interest rate swap agreement. 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 \$726,000 annually for each one percentage point change in the average interest rate under these borrowings.

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



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Item 8. Financial Statements and Supplementary Data.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of Merit Medical Systems, Inc. and subsidiaries (the “Company”) as of December 31, 2015 and 2014, 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, 2015. 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, 2015 and 2014, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, 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, 2015, based on the criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 29, 2016, expressed an unqualified opinion on the Company’s internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Salt Lake City, Utah  
February 29, 2016

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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES  
 CONSOLIDATED BALANCE SHEETS  
 DECEMBER 31, 2015 AND 2014  
 (In thousands)

	2015	2014
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$4,177	\$7,355
Trade receivables — net of allowance for uncollectible accounts — 2015 — \$1,297 and 2014 — \$893	70,292	72,717
Employee receivables	217	173
Other receivables	6,799	7,507
Inventories	105,999	91,773
Prepaid expenses	5,634	5,012
Prepaid income taxes	2,955	1,273
Deferred income tax assets	7,025	6,375
Income tax refund receivables	905	155
<b>Total current assets</b>	<b>204,003</b>	<b>192,340</b>
<b>PROPERTY AND EQUIPMENT:</b>		
Land and land improvements	19,307	16,830
Buildings	136,595	130,447
Manufacturing equipment	158,775	145,022
Furniture and fixtures	39,301	35,201
Leasehold improvements	27,561	16,096
Construction-in-progress	26,292	21,858
<b>Total property and equipment</b>	<b>407,831</b>	<b>365,454</b>
Less accumulated depreciation	(140,053)	(121,283)
<b>Property and equipment — net</b>	<b>267,778</b>	<b>244,171</b>
<b>OTHER ASSETS:</b>		
<b>Intangible assets:</b>		
Developed technology — net of accumulated amortization — 2015 — \$38,497 and 2014 — \$27,982	69,861	79,172
Other — net of accumulated amortization — 2015 — \$26,603 and 2014 — \$22,480	39,493	31,136
Goodwill	184,472	184,464
Deferred income tax assets	—	9
Other assets	13,121	15,873
<b>Total other assets</b>	<b>306,947</b>	<b>310,654</b>
<b>TOTAL</b>	<b>\$778,728</b>	<b>\$747,165</b>

See notes to consolidated financial statements.

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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES  
 CONSOLIDATED BALANCE SHEETS  
 DECEMBER 31, 2015 AND 2014  
 (In thousands)

	2015	2014
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Trade payables	\$37,977	\$29,810
Accrued expenses	37,846	33,826
Current portion of long-term debt	10,000	10,000
Advances from employees	589	381
Income taxes payable	1,498	1,413
Total current liabilities	87,910	75,430
<b>LONG-TERM DEBT</b>	197,593	214,490
<b>DEFERRED INCOME TAX LIABILITIES</b>	10,985	6,385
<b>LIABILITIES RELATED TO UNRECOGNIZED TAX BENEFITS</b>	768	1,353
<b>DEFERRED COMPENSATION PAYABLE</b>	8,500	8,635
<b>DEFERRED CREDITS</b>	2,721	2,891
<b>OTHER LONG-TERM OBLIGATIONS</b>	4,148	2,722
Total liabilities	312,625	311,906
<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, 2015 and 2014; no shares issued		
Common stock, no par value; shares authorized — 2015 and 2014 - 100,000; issued and outstanding as of December 31, 2015 - 44,267 and December 31, 2014 - 43,614	197,826	187,709
Retained earnings	273,764	249,962
Accumulated other comprehensive loss	(5,487	) (2,412
Total stockholders' equity	466,103	435,259
<b>TOTAL</b>	<b>\$778,728</b>	<b>\$747,165</b>
See notes to consolidated financial statements.		(concluded)



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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF INCOME  
YEARS ENDED DECEMBER 31, 2015, 2014 AND 2013  
(In thousands, except per share amounts)

	2015	2014	2013
NET SALES	\$542,149	\$509,689	\$449,049
COST OF SALES	306,368	284,467	254,682
GROSS PROFIT	235,781	225,222	194,367
OPERATING EXPENSES:			
Selling, general and administrative	156,348	147,894	128,642
Research and development	40,810	36,632	33,886
Intangible asset impairment charges	—	1,102	8,089
Contingent consideration expense (benefit)	80	(572)	(4,094)
Acquired in-process research and development	1,000	—	—
Total operating expenses	198,238	185,056	166,523
INCOME FROM OPERATIONS	37,543	40,166	27,844
OTHER INCOME (EXPENSE):			
Interest income	272	217	255
Interest expense	(6,229)	(8,829)	(8,044)
Other income (expense) — net	(386)	18	(216)
Other expense — net	(6,343)	(8,594)	(8,005)
INCOME BEFORE INCOME TAXES	31,200	31,572	19,839
INCOME TAX EXPENSE	7,398	8,598	3,269
NET INCOME	\$23,802	\$22,974	\$16,570
EARNINGS PER COMMON SHARE:			
Basic	\$0.54	\$0.53	\$0.39
Diluted	\$0.53	\$0.53	\$0.39
AVERAGE COMMON SHARES:			
Basic	44,036	43,143	42,607
Diluted	44,511	43,409	42,884

See notes to consolidated financial statements.



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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES  
 CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME  
 YEARS ENDED DECEMBER 31, 2015, 2014 AND 2013

(In thousands)

	2015	2014	2013
Net income	\$23,802	\$22,974	\$16,570
Other comprehensive income (loss):			
Interest rate swap	(571 )	(630 )	2,992
Less income tax benefit (expense)	222	245	(1,164 )
Foreign currency translation adjustment	(3,037 )	(3,160 )	292
Less income tax benefit	311	190	5
Total other comprehensive income (loss)	(3,075 )	(3,355 )	2,125
Total comprehensive income	\$20,727	\$19,619	\$18,695

See notes to consolidated financial statements.



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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY  
YEARS ENDED DECEMBER 31, 2015, 2014 AND 2013  
(In thousands)

	Total	Common Stock		Retained	Accumulated Other
		Shares	Amount	Earnings	Comprehensive
					Income (Loss)
BALANCE — January 1, 2013	\$381,577	42,489	\$172,341	\$210,418	\$ (1,182 )
Net income	16,570			16,570	
Other comprehensive income	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
Net income	22,974			22,974	
Other comprehensive loss	(3,355 )				(3,355 )
Excess tax benefits from stock-based compensation	576		576		
Stock-based compensation expense	1,460		1,460		
Options exercised	9,638	878	9,638		
Issuance of common stock under Employee Stock Purchase Plans	450	33	450		
Shares surrendered in exchange for payment of payroll tax liabilities	(249 )	(16 )	(249 )		
Shares surrendered in exchange for exercise of stock options	(1,941 )	(127 )	(1,941 )		
BALANCE — December 31, 2014	435,259	43,614	187,709	249,962	(2,412 )
Net income	23,802			23,802	
Other comprehensive loss	(3,075 )				(3,075 )
Excess tax benefits from stock-based compensation	2,124		2,124		
Stock-based compensation expense	2,243		2,243		
Options exercised	10,029	858	10,029		
Issuance of common stock under Employee Stock Purchase Plans	441	23	441		
Shares surrendered in exchange for payment of payroll tax liabilities	(918 )	(43 )	(918 )		
Shares surrendered in exchange for exercise of stock options	(3,802 )	(185 )	(3,802 )		
BALANCE — December 31, 2015	\$466,103	44,267	\$197,826	\$273,764	\$ (5,487 )

See notes to consolidated financial statements.



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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
YEARS ENDED DECEMBER 31, 2015, 2014 AND 2013  
(In thousands)

	2015	2014	2013
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net income	\$23,802	\$22,974	\$16,570
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	37,425	35,929	32,542
Losses (gains) on sales and/or abandonment of property and equipment	(23	) 916	177
Write-off of patents and intangible assets	141	1,427	8,208
Acquired in-process research and development	1,000	—	—
Amortization of deferred credits	(171	) (175	) (139
Amortization of long-term debt issuance costs	987	987	845
Deferred income taxes	3,450	3,870	1,359
Excess tax benefits from stock-based compensation	(2,124	) (576	) (259
Stock-based compensation expense	2,243	1,460	1,467
Changes in operating assets and liabilities, net of effects from acquisitions:			
Trade receivables	(5,872	) (13,599	) (6,445
Employee receivables	(52	) 46	(53
Other receivables	387	(3,042	) (609
Inventories	(13,113	) (9,396	) 2,334
Prepaid expenses	(696	) (58	) (758
Prepaid income taxes	(1,788	) (41	) 18
Income tax refund receivables	(784	) 11	1,267
Other assets	(362	) (1,388	) (1,806
Trade payables	14,766	5,326	(5
Accrued expenses	5,656	6,137	(276
Advances from employees	217	142	(277
Income taxes payable	2,199	1,083	255
Liabilities related to unrecognized tax benefits	536	(76	) (520
Deferred compensation payable	(135	) 802	1,877
Other long-term obligations	1,769	566	(4,399
Total adjustments	45,656	30,351	34,803
Net cash provided by operating activities	69,458	53,325	51,373
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Capital expenditures for:			
Property and equipment	(50,959	) (34,181	) (59,505
Intangible assets	(1,956	) (1,714	) (1,617
Proceeds from sale-leaseback transactions	2,017	5,521	24,000
Proceeds from the sale of property and equipment	1,247	98	113
Cash paid in acquisitions, net of cash acquired	(12,368	) (5,927	) (31,600

Net cash used in investing activities (62,019 ) (36,203 ) (68,609 )

See notes to consolidated financial statements. (continued)

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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
YEARS ENDED DECEMBER 31, 2015, 2014 AND 2013  
(In thousands)

	2015	2014	2013
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from issuance of common stock	\$6,668	\$8,146	\$3,729
Proceeds from issuance of long-term debt	152,375	144,018	176,764
Payments on long-term debt	(169,272)	) (169,392)	) (165,477)
Proceeds from industrial assistant grants	—	—	389
Excess tax benefits from stock-based compensation	2,124	576	259
Long-term debt issuance costs	—	—	(798)
Contingent payments related to acquisitions	(1,212)	) (67)	) (77)
Payment of taxes related to an exchange of common stock	(918)	) (249)	) (21)
Net cash provided by (used in) financing activities	(10,235)	) (16,968)	) 14,768
EFFECT OF EXCHANGE RATES ON CASH	(382)	) (258)	) 208
NET DECREASE IN CASH AND CASH EQUIVALENTS	(3,178)	) (104)	) (2,260)
<b>CASH AND CASH EQUIVALENTS:</b>			
Beginning of year	7,355	7,459	9,719
End of year	\$4,177	\$7,355	\$7,459
<b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION</b>			
Cash paid during the year for:			
Interest (net of capitalized interest of \$325, \$389 and \$1,038 respectively)	\$6,273	\$9,014	\$7,877
Income taxes	\$3,409	\$3,289	\$735
<b>SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES</b>			
Property and equipment purchases in accounts payable	\$3,199	\$2,896	\$4,055
Receivable due for sale of equipment	\$—	\$1,256	\$—
Cost method investment converted to intangible asset in acquisition in lieu of additional cash payment	\$1,010	\$—	\$—
Acquisition purchases in accrued expenses and other long-term obligations	\$1,300	\$1,000	\$350
Merit common stock surrendered (185, 127 and 45 shares, respectively) in exchange for exercise of stock options	\$3,802	\$1,941	\$452

See notes to consolidated financial statements.

(concluded)

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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
YEARS ENDED DECEMBER 31, 2015, 2014 and 2013

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization. Merit Medical Systems, Inc. ("Merit," "we," or "us") designs, develops, manufactures and markets single-use medical products for interventional and diagnostic procedures. For financial reporting purposes, we report our operations in two operating segments: cardiovascular and endoscopy. Our cardiovascular segment consists of cardiology and radiology devices which assist in diagnosing and treating coronary arterial disease, peripheral vascular disease and other non-vascular diseases; embolotherapeutic products; and cardiac rhythm management and electrophysiology ("CRM/EP") devices. Our endoscopy segment consists of gastroenterology and pulmonology medical devices which assist in the palliative treatment of expanding esophageal, tracheobronchial and biliary strictures caused by malignant tumors.

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

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

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

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

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

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

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

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

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Customer lists	5 - 15 years
Developed technology	8 - 15 years
Distribution agreements	3 - 12 years
License agreements and trademarks	4 - 15 years
Covenants not to compete	3 - 10 years
Patents	17 years
Royalty agreements	5 years

**Long-Lived Assets.** We periodically review the carrying amount of our long-lived assets for impairment. An asset is considered impaired when estimated future cash flows are less than the carrying amount of the asset. In the event the carrying amount of such asset is not considered recoverable, the asset is adjusted to its fair value. Fair value is generally determined based on discounted future cash flow. There were no impairments of long-lived assets during the years ended December 31, 2015, 2014 and 2013, except as noted in Note 4.

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

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

Depreciation expense related to property and equipment for the years ended December 31, 2015, 2014 and 2013 was approximately \$22.6 million, \$21.0 million, and \$18.4 million, respectively.

**Deferred Compensation.** We have a deferred compensation plan that permits certain management employees to defer a portion of their salary until the future. We established a Rabbi trust to finance obligations under the plan with corporate-owned variable life insurance contracts. The cash surrender value totaled approximately \$8.8 million and \$9.0 million at December 31, 2015 and 2014, respectively, which is included in other assets in our consolidated balance sheets. We have recorded a deferred compensation payable of approximately \$8.5 million and \$8.6 million at December 31, 2015 and 2014, respectively, to reflect the liability to our employees under this plan.

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

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

**Revenue Recognition.** We sell our single-use disposable medical products through a direct sales force in the U.S., and through OEM relationships, custom procedure tray manufacturers and a combination of direct sales force and

independent distributors in international markets. Revenues from these customers are recognized when all of the following have occurred: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or services have been rendered, (iii) the price is fixed or determinable and (iv) the ability to collect is reasonably assured. These criteria are generally satisfied at the time of shipment when risk of loss and title passes to the customer. We have certain written agreements with group purchasing organizations to sell our products to participating hospitals. These agreements have destination shipping terms which require us to defer the recognition of a sale until the product has arrived at the participating hospitals. We reserve for sales returns, including returns related to defective products, as a reduction in net sales, based on our historical experience. We also offer sales rebates and discounts to purchasing

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groups. These reserves are recorded as a reduction in net sales and are not considered material to our consolidated statements of income for the years ended December 31, 2015, 2014 and 2013. In addition, we invoice our customers for taxes assessed by governmental authorities such as sales tax and value added taxes. We present these taxes on a net basis.

**Shipping and Handling.** We bill our customers for shipping and handling charges, which are included in net sales for the applicable period, and the corresponding shipping and handling expense is reported in cost of sales.

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

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

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

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

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

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

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

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

**Stock-Based Compensation.** We recognize the fair value compensation cost relating to share-based payment transactions in accordance with Accounting Standards Codification (“ASC”) 718, Compensation — Stock Compensation. Under the provisions of ASC 718, share-based compensation cost is measured at the grant date, based on the fair value of the award and is recognized over the employee’s requisite service period, which is generally the vesting period. The fair value of our stock options is estimated using a Black-Scholes option valuation model. Stock-based compensation expense for the years ended December 31, 2015, 2014 and 2013 was approximately \$2.2 million, \$1.5 million and \$1.5 million, respectively.

**Concentration of Credit Risk.** Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. We provide credit, in the normal course of business, primarily to hospitals and independent third-party custom procedure tray manufacturers and distributors. We perform

ongoing credit evaluations of our customers and maintain allowances for potential credit losses. Sales to our single largest customer approximated 3%, 3% and 3% of total sales for the years ended December 31, 2015, 2014 and 2013, respectively.

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

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

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whether the maturity of the instrument is less than or greater than 12 months. We do not purchase or hold derivative financial instruments for speculative or trading purposes (see Note 8).

Accumulated Other Comprehensive Income (Loss). As of December 31, 2015, accumulated other comprehensive income (loss) included approximately \$1,000 (net of tax of \$(1,000)) related to an interest rate swap and (\$5.5) million (net of tax of \$513,000) related to foreign currency translation. As of December 31, 2014, accumulated other comprehensive income (loss) included approximately \$350,000 (net of tax of \$(223,000)) related to an interest rate swap and (\$2.8) million (net of tax of \$202,000) related to foreign currency translation.

Recently Issued Financial Accounting Standards. In November 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes, which will require deferred tax assets and deferred tax liabilities to be presented as noncurrent within a classified balance sheet. The ASU simplifies the current guidance which requires an entity to separate deferred income tax liabilities and assets into current and noncurrent amounts in a classified balance sheet. The current requirement that deferred tax assets and liabilities of a tax-paying component of an entity be offset and presented as a single amount is not affected. The ASU is effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Earlier application is permitted for all entities as of the beginning of an interim or annual reporting period. We do not presently anticipate that the adoption of this standard will have a material impact on our financial statements.

In September 2015, the FASB issued ASU 2015-16, Simplifying the Accounting for Measurement-Period Adjustments, which eliminates the requirement to retrospectively account for measurement-period adjustments. This standard is effective for our financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted for financial statements that have not been previously issued. We intend to apply the new guidance on a prospective basis. We do not presently anticipate that the adoption of this standard will have a material impact on our financial statements.

In August 2015, the FASB issued ASU 2015-15, Presentation and Subsequent Measurement of Debt Issuance Costs Associated With Line-of-Credit Arrangements - Amendments to SEC Paragraphs Pursuant to Staff Announcement at June 18, 2015 EITF Meeting, to clarify that given the absence of authoritative guidance within ASU No. 2015-03 for debt issuance costs related to the line-of-credit arrangements, such costs may be presented as an asset and subsequently amortized ratably over the term of the line-of-credit arrangement. We do not presently expect the adoption of this update to have a material effect on our consolidated financial statements.

In July 2015, the FASB issued ASU 2015-11, Simplifying the Measurement of Inventory. This standard requires that inventory be measured at the lower of cost or net realizable value. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. Inventory measured using last-in, first-out or the retail inventory method are excluded from the scope of this update which is effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. We do not anticipate that the implementation of ASU 2015-11 will have a material impact on our consolidated financial statements.

In April 2015, the FASB issued ASU 2015-03, Simplifying the Presentation of Debt Issuance Costs, which requires debt issuance costs to be presented in the balance sheet as a direct deduction from the associated debt liability. This standard is effective for our financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted for financial statements that have not been previously issued. The new guidance will be applied on a retrospective basis. We do not presently anticipate that the adoption of this standard will have a material impact on our financial statements.

In May 2014, the FASB issued authoritative guidance amending the FASB Accounting Standards Codification and creating a new Topic 606, Revenue from Contracts with Customers. The new guidance clarifies the principles for recognizing revenue and develops a common revenue standard for U.S. GAAP applicable to revenue transactions. This guidance provides that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The existing industry guidance will be eliminated when the new guidance becomes effective and annual disclosures will be substantially revised. Additional disclosures will also be required under the new standard. In July 2015, the FASB approved a proposal that extended the required implementation date one year to the first quarter of 2018 but also would permit companies to adopt the standard at the original effective date of 2017. Implementation may be either through retrospective application to each period from the first quarter of 2016 or with a cumulative effect adjustment upon adoption in 2018. We are assessing the impact this new standard is anticipated to have on our consolidated financial statements.

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2. ACQUISITIONS

On December 4, 2015, we entered into a license agreement with a medical device company for the right to manufacture and sell certain percutaneous transluminal angioplasty balloon catheter products. As of December 31, 2015, we had paid \$500,000 in connection with the agreement. We are obligated to pay an additional \$1.5 million if certain milestones set forth in the license agreement are reached. We accounted for the transaction as an asset purchase and intend to amortize the asset over a period of 12 years.

On September 29, 2015, we entered into a license agreement with Blockade Medical, LLC, a Delaware limited liability company ("Blockade"), for rights to manufacture, market and sell a set of endovascular embolization products. As part of the agreement, we paid \$1.7 million during the year ended December 31, 2015 and, in lieu of any additional payment, we converted the cost method investment in Blockade of \$1.0 million we had previously recorded, toward the purchase price of the license. As of December 31, 2015, we recorded \$2.7 million to a license agreement intangible asset, which we intend to amortize over ten years.

On August 19, 2015, we purchased 116,279 shares of Series A Preferred Stock of Xablecath, Inc., a Delaware corporation ("Xablecath"), for an aggregate price of approximately \$300,000. Our ownership interest Xablecath is approximately 14% and is accounted for at cost. Xablecath is developing an over-the-wire crossing catheter.

On July 17, 2015, we entered into an asset purchase agreement with LeMaitre Vascular, Inc., a Delaware corporation ("LeMaitre"), for rights to the Unballoon® non-occlusive modeling catheter. We accounted for the transaction as an asset purchase. The full purchase price of \$400,000 was paid as of December 31, 2015, and the purchase price was recorded as a developed technology intangible asset, which we intend to amortize over a period of 10 years.

On July 14, 2015, we entered into an asset purchase agreement with Quellent, LLC, a California limited liability company ("Quellent"), for superabsorbent pad technology. The purchase price for the asset was \$1.0 million, payable in two installments. We accounted for this acquisition as a business combination. The first payment of \$500,000 was paid as of December 31, 2015, and the second payment of \$500,000 was recorded as an accrued liability as of December 31, 2015. We also recorded \$270,000 of contingent consideration related to royalties payable to Quellent pursuant to this agreement. The sales and results of operations related to this acquisition have been included in our cardiovascular segment since the acquisition date and were not material. The purchase price was allocated as follows: \$1.21 million to a developed technology intangible asset and \$60,000 to goodwill as of December 31, 2015. We intend to amortize the developed technology intangible asset over 13 years. The pro forma consolidated results of operations are not presented, as we do not deem the pro forma effect of the transaction to be material.

On July 1, 2015, we entered into an agreement with Catch Medical, LLC, a Utah limited liability company ("Catch Medical"), to purchase rights to a steerable snare. We expensed the full purchase price of \$1.0 million to in-process research and development during the year ended December 31, 2015, because the initial costs of in-process research and development acquired in this asset purchase do not have an alternative future use. These costs include payments incurred prior to regulatory approval in connection with acquired research and development projects that provide rights to develop, manufacture, market and sell products. During the year ended December 31, 2015, we paid cash of \$200,000 and recorded \$200,000 as a current liability for the portion that will be due in less than a year. We also recorded \$600,000 as a long-term obligation for the portion that will be due in over a year.

On July 1, 2015, we entered into a license agreement with Distal Access, LLC, a Utah limited liability company ("Distal"), for guidewire controller technology. We made a payment of \$3.5 million upon the closing of the agreement during the year ended December 31, 2015. We accounted for this acquisition as an asset purchase. We recorded the purchase price to a license agreement intangible asset of \$3.5 million, which we intend to amortize over a period of six years.

On March 26, 2015, we entered into an asset purchase agreement with Teleflex Incorporated, a Delaware corporation ("Teleflex"). We accounted for the transaction as an asset purchase. During the year ended December 31, 2015, we paid \$400,000 to acquire the asset, which we recorded as a customer list intangible asset. We will be obligated to pay an additional \$400,000 if Teleflex meets certain obligations under the agreement, which will be recorded to the customer list intangible asset at that time. We intend to amortize the asset over a period of five years.

On January 6, 2015, we amended a distribution and patent sublicense agreement with Catheter Connections, Inc., a Utah corporation ("CathConn"), which we had originally entered into on August 21, 2012 for CathConn's MaleCap Solo technology. The amendment provides exclusive rights for certain aspects of CathConn's DualCap disinfecting cap technology. We paid CathConn an additional \$250,000 in January 2015. The purchase price was allocated to a distribution agreement for \$250,000, which we intend to amortize over ten years.



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On November 25, 2014, we entered into a marketing, distribution, and license agreement with a medical device company for the right to market and distribute certain introducer shaft products. During the year ended December 31, 2014, we paid \$624,800 in connection with this agreement. During the year ended December 31, 2015, we paid an additional \$1.1 million as a milestone related to 510(k) clearance was achieved. We are obligated to pay an additional €500,000 if certain milestones set forth in the agreement are reached. We accounted for the transaction as an asset purchase. We recorded the amount paid as a license agreement asset, which we intend to amortize over a period of ten years.

On August 8, 2014, we entered into a license agreement and a distribution agreement with a medical device company for the right to manufacture and sell certain percutaneous transluminal angioplasty balloon catheter products. As of December 31, 2014, we had paid \$3.0 million and recorded an additional \$1.0 million obligation to accrued liabilities in connection with these two agreements. During 2015, we paid \$3.5 million, which included the amount that was accrued as of December 31, 2014 and the amount related to the achievement of certain milestones under the agreements. As of December 31, 2015, we had paid all obligations under these two agreements. We accounted for the transaction as an asset purchase. Of the purchase price paid as of December 31, 2015, \$200,000 was allocated to a distribution agreement asset, which we are amortizing over a period of three years, and \$6.3 million was allocated to a license agreement asset, which we intend to amortize over a period of 12 years.

On July 15, 2014, we entered into a purchase agreement to acquire certain assets from a limited liability company. In connection with this agreement, we paid approximately \$752,000. The primary assets acquired from this entity were manufacturing and export licenses. We accounted for the transaction as an asset purchase. We recorded the amount paid on the closing date as a license agreement asset, which we intend to amortize over a period of ten years.

On May 8, 2014, we purchased 737,628 shares of the common stock of G Medix, Inc., a Minnesota corporation ("G Medix"), for an aggregate price of approximately \$1.8 million. Our purchase of the G Medix shares, which represents an ownership interest in G Medix of approximately 19%, has been accounted for at cost. We made a refundable advance to G Medix of \$350,000 in 2013 that was credited against the final purchase amount, resulting in \$1.45 million of cash purchase price paid to G Medix during 2014. G Medix develops catheter-based therapeutic devices.

On December 20, 2013, we acquired a license to sell our Hepasphere products in China. We paid \$700,000 to purchase the license, \$350,000 of which was included in accrued liabilities at December 31, 2013. The purchase price was allocated to a license agreement for \$700,000, which we are amortizing over four years.

On October 4, 2013, we acquired certain assets contemplated by an Asset Purchase Agreement we executed with Datascope Corp. ("Datascope"), a Delaware corporation. The primary assets we acquired consist of 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. We accounted for this acquisition as a business combination. We made a payment of approximately \$27.5 million to acquire these assets. Acquisition-related costs during the year ended December 31, 2013, which were included in selling, general, and administrative expenses in the accompanying consolidated statements of income, were not material. The results of operations related to this acquisition have been included in our cardiovascular segment since the acquisition date. During the year ended December 31, 2013, our net sales of Datascope products were approximately \$1.6 million. It is not practical to separately report the earnings related to the Datascope acquisition, as we cannot split out sales costs related to Datascope products, principally because our sales representatives are selling multiple products (including Datascope products) in the cardiovascular business segment. The total purchase price was allocated as follows (in thousands):

Assets Acquired

Inventories	\$478
Intangibles	
Developed technology	18,200
Customer lists	390
Trademarks	320
Goodwill	8,112
Total assets acquired	\$27,500

With respect to the Datascope assets, we are amortizing developed technology over ten years and customer lists on an accelerated basis over six years. While U.S. trademarks can be renewed indefinitely, we currently estimate that we will generate

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cash flow from the acquired trademarks for a period of 15 years from the acquisition date. The total weighted-average amortization period for these acquired intangible assets is ten years.

On October 4, 2013, we acquired certain assets contemplated by an Asset Purchase Agreement with Radial Assist, LLC ("Radial Assist"), a Georgia limited liability company. The primary assets we acquired consist of the Rad Board, Rad BoardXtra, 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. 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 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. We accounted for this acquisition as a business combination. We made a payment of approximately \$2.5 million to acquire these assets. Acquisition-related costs during the year ended December 31, 2013, which were included in selling, general, and administrative expenses in the accompanying consolidated statements of income, were not material. The results of operations related to this acquisition have been included in our cardiovascular segment since the acquisition date. During the year ended December 31, 2013, our net sales of Radial Assist products were approximately \$191,000. It is not practical to separately report the earnings related to the Radial Assist acquisition, as we cannot split out sales costs related to Radial Assist products, principally because our sales representatives are selling multiple products (including Radial Assist products) in the cardiovascular business segment. The total purchase price was allocated as follows (in thousands):

Assets Acquired	
Inventories	\$ 16
Intangibles	
Developed technology	1,520
Customer lists	20
Trademarks	40
Goodwill	904
Total assets acquired	\$2,500

With respect to the Radial Assist assets, we are amortizing developed technology over ten years and customer lists on an accelerated basis over six years. While U.S. trademarks can be renewed indefinitely, we currently estimate that we will generate cash flow from the acquired trademarks for a period of 15 years from the acquisition date. The total weighted-average amortization period for these acquired intangible assets is 10.07 years.

In connection with our Datascope and Radial Assist acquisitions, we paid approximately \$798,000 in long-term debt issuance costs to Wells Fargo Bank related to the amendment of our Credit Agreement (see Note 7). These costs consist primarily of loan origination fees that we are amortizing over the remaining contract term of our Credit Agreement, which matures December 19, 2017.

On September 10, 2013, we entered into a license agreement with a medical device company for the exclusive rights to sell certain biocompatible gloves, instrument cleaners, and surgical wipes. Upon signing, we paid \$250,000 for the use of the license. We paid an additional \$250,000 during the year ended December 31, 2015 after 30 days of our first commercial sale of the product. The purchase price was allocated to a license agreement for \$500,000, which we intend to amortize over ten years.

The following table summarizes our consolidated results of operations for the year ended December 31, 2013, as well as unaudited pro forma consolidated results of operations as though the Datascope acquisition had occurred on

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January 1, 2012 (in thousands, except per common share amounts):

	2013	
	As Reported	Pro Forma
Net sales	\$449,049	\$454,333
Net income	16,570	17,112
Earnings per common share:		
Basic	\$0.39	\$0.40
Diluted	\$0.39	\$0.40

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The unaudited pro forma information set forth above is for informational purposes only and includes adjustments related to the step-up of acquired inventories, amortization expense related to acquired intangible assets, and interest expense on long-term debt. The pro forma information should not be considered indicative of actual results that would have been achieved if the Datascope acquisition had occurred on January 1, 2012, or results that may be obtained in any future period. The pro forma consolidated results of operations do not include the Radial Assist acquisition, as we do not deem the pro forma effect of the transaction to be material.

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

## 3. INVENTORIES

Inventories at December 31, 2015 and 2014, consisted of the following (in thousands):

	2015	2014
Finished goods	\$59,170	\$50,000
Work-in-process	8,540	7,680
Raw materials	38,289	34,093
Total	\$105,999	\$91,773

## 4. GOODWILL AND INTANGIBLE ASSETS

The changes in the carrying amount of goodwill for the years ended December 31, 2015 and 2014, are as follows (in thousands):

	2015	2014
Goodwill balance at January 1	\$184,464	\$184,505
Effect of foreign exchange	(52	) (41
Additions as the result of acquisitions	60	—
Goodwill balance at December 31	\$184,472	\$184,464

As of December 31, 2015, we had recorded \$8.3 million of accumulated goodwill impairment charges. All of the goodwill balance as of December 31, 2015 and 2014 is related to our cardiovascular segment.

Other intangible assets at December 31, 2015 and 2014, consisted of the following (in thousands):

	2015		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patents	\$12,014	\$(2,595)	) \$9,419
Distribution agreements	5,626	(2,853)	) 2,773
License agreements	19,109	(2,438)	) 16,671
Trademarks	7,259	(2,554)	) 4,705
Covenants not to compete	1,028	(873)	) 155
Customer lists	20,793	(15,023)	) 5,770
Royalty agreements	267	(267)	) —

Total	\$66,096	\$(26,603	) \$39,493
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	2014		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patents	\$10,199	\$(2,196)	) \$8,003
Distribution agreements	5,376	(2,285)	) 3,091
License agreements	8,995	(1,823)	) 7,172
Trademarks	7,298	(2,079)	) 5,219
Covenants not to compete	1,029	(636)	) 393
Customer lists	20,452	(13,194)	) 7,258
Royalty agreements	267	(267)	) —
Total	\$53,616	\$(22,480)	) \$31,136

Aggregate amortization expense for the years ended December 31, 2015, 2014 and 2013 was approximately \$14.8 million, \$14.9 million and \$14.2 million, respectively.

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 acquired in our January 2012 acquisition of Ostial 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 slower than anticipated sales growth in the products acquired from our Ostial acquisition 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. We did not record any impairment charges during the year ended December 31, 2015. During the third quarter of 2014 and 2013, we recorded an impairment charge for Ostial of approximately \$1.1 million and \$8.1 million, respectively, which was offset by approximately \$874,000 and \$3.8 million of fair value reductions to the related contingent consideration liability.

Estimated amortization expense for the developed technology and other intangible assets for the next five years consists of the following as of December 31, 2015 (in thousands):

Year Ending December 31	
2016	\$15,659
2017	15,515
2018	14,982
2019	14,640
2020	13,807

## 5. INCOME TAXES

For the years ended December 31, 2015, 2014 and 2013, income before income taxes is broken out between U.S. and foreign-sourced operations and consisted of the following (in thousands):

	2015	2014	2013
Domestic	\$9,470	\$16,961	\$5,435
Foreign	21,730	14,611	14,404

Total	\$31,200	\$31,572	\$19,839
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The components of the provision for income taxes for the years ended December 31, 2015, 2014 and 2013, consisted of the following (in thousands):

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	2015	2014	2013
Current expense (benefit):			
Federal	\$(17	) \$1,316	\$(747
State	747	768	333
Foreign	3,218	2,644	2,324
Total current expense	3,948	4,728	1,910
Deferred expense (benefit):			
Federal	3,250	4,078	1,089
State	294	(119	) 278
Foreign	(94	) (89	) (8
Total deferred expense	3,450	3,870	1,359
Total income tax expense	\$7,398	\$8,598	\$3,269

The difference between the income tax expense reported and amounts computed by applying the statutory federal rate of 35.0% to pretax income for the years ended December 31, 2015, 2014 and 2013, consisted of the following (in thousands):

	2015	2014	2013
Computed federal income tax expense at statutory rate of 35%	\$10,920	\$11,050	\$6,943
State income taxes	698	438	397
Tax credits	(1,019	) (888	) (1,385
Foreign tax rate differential	(3,564	) (1,958	) (2,374
Uncertain tax positions	536	(76	) (520
Deferred compensation insurance assets	182	(81	) (358
Other — including the effect of graduated rates	(355	) 113	566
Total income tax expense	\$7,398	\$8,598	\$3,269

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Deferred income tax assets and liabilities at December 31, 2015 and 2014, consisted of the following temporary differences and carry-forward items (in thousands):

	2015	2014
Deferred income tax assets:		
Allowance for uncollectible accounts receivable	\$ 531	\$ 366
Accrued compensation expense	5,534	5,492
Inventory differences	2,043	2,401
Net operating loss carryforwards	11,434	13,542
Deferred revenue	118	87
Stock-based compensation expense	2,532	2,479
Uncertain tax positions	—	284
Federal research and development credit carryforward	2,355	1,413
Foreign Tax Credits	600	1,374
Other	5,754	4,173
Total deferred income tax assets	30,901	31,611
Deferred income tax liabilities:		
Prepaid expenses	(841	) (708
Property and equipment	) (24,467	) (23,298
Intangible assets	) (6,495	) (4,853
Other	) (1,077	) (1,150
Total deferred income tax liabilities	) (32,880	) (30,009
Valuation allowance	) (1,981	) (1,603
Net deferred income tax assets (liabilities)	) \$(3,960	) \$(1
Reported as:		
Deferred income tax assets - Current	\$ 7,025	\$ 6,375
Deferred income tax assets - Long-term	—	9
Deferred income tax liabilities - Current	—	—
Deferred income tax liabilities - Long-term	(10,985	) (6,385
Net deferred income tax liabilities	) \$(3,960	) \$(1

The long-term deferred income tax balances are not netted as they represent deferred amounts applicable to different taxing jurisdictions. Deferred income tax balances reflect the temporary differences between the carrying amounts of assets and liabilities and their tax bases and are stated at enacted tax rates expected to be in effect when taxes are actually paid or recovered. The valuation allowance is primarily related to state credit carryforwards and capital losses for which we believe it is more likely than not that the deferred tax assets will not be realized. The valuation allowance increased by approximately \$378,000, \$240,000, and \$138,000 during the years ended December 31, 2015, 2014 and 2013, respectively.

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

As of December 31, 2015 and 2014, we had U.S federal net operating loss carryforwards of approximately \$32.7 million and \$38.7 million, respectively. These net operating loss carryforwards, which expire at various dates through 2030, are subject to an annual limitation under Internal Revenue Code Section 382. We anticipate that we will utilize the net operating loss carryforwards over the next 11 years. We utilized a total of approximately \$6.0 million and \$13.5 million in U.S. federal net operating loss carryforwards during the year ended December 31, 2015 and 2014, respectively.

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As of December 31, 2015, we had \$0 of non-U.S. net operating loss carryforwards. As of December 31, 2014, we had non-U.S. net operating loss carryforwards of approximately \$53,000, which have no expiration date. Non-U.S. net operating loss carryforwards utilized during 2015 and 2014 were not material.

We are subject to income taxes in the United States and numerous foreign jurisdictions. Significant judgment is required in determining our worldwide provision for income taxes and recording the related assets and liabilities. In the ordinary course of our business, there are many transactions and calculations where the ultimate tax determination is uncertain. In our opinion, we have made adequate provisions for income taxes for all years subject to audit. We are no longer subject to U.S. federal, state, and local income tax examinations by tax authorities for years before 2012. In foreign jurisdictions, we are no longer subject to income tax examinations for years before 2009.

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

The total liability for unrecognized tax benefits at December 31, 2015, including interest and penalties, was approximately \$2.2 million, of which approximately \$2.2 million would favorably impact our effective tax rate if recognized. Approximately \$1.4 million of the total liability at December 31, 2015 was presented as a reduction to non-current deferred income tax assets on our consolidated balance sheet. The total liability for unrecognized tax benefits at December 31, 2014, including interest and penalties, was approximately \$1.9 million, of which approximately \$1.6 million would favorably impact our effective tax rate if recognized. Approximately \$563,000 of the total liability at December 31, 2014 was presented as a reduction to non-current deferred income tax assets on our consolidated balance sheet. As of December 31, 2015 and 2014, we had accrued approximately \$187,000 and \$181,000 respectively, in total interest and penalties related to unrecognized tax benefits. We account for interest and penalties for unrecognized tax benefits as part of our income tax provision. During the years ended December 31, 2015 and 2014, we added interest and penalties of approximately \$6,000 and \$42,000, respectively, to our liability for unrecognized tax benefits. During the year ended December 31, 2013, we removed interest and penalties of approximately \$22,000 from our liability for unrecognized tax benefits. It is reasonably possible that within the next 12 months the total liability for unrecognized tax benefits may increase, net of potential decreases due to the expiration of statutes of limitation, up to \$400,000 .

A reconciliation of the beginning and ending amount of liabilities associated with uncertain tax benefits for the years ended December 31, 2015, 2014 and 2013, consisted of the following (in thousands):

Tabular Roll-forward	2015	2014	2013
Unrecognized tax benefits, opening balance	\$1,736	\$2,129	\$2,776
Gross increases in tax positions taken in a prior year	187	142	107
Gross increases in tax positions taken in the current year	763	309	236
Lapse of applicable statute of limitations	(704	) (844	) (990
Unrecognized tax benefits, ending balance	\$1,982	\$1,736	\$2,129

The tabular roll-forward ending balance does not include interest and penalties related to unrecognized tax benefits.

## 6. ACCRUED EXPENSES

Accrued expenses at December 31, 2015 and 2014, consisted of the following (in thousands):

	2015	2014
Payroll taxes	\$2,369	\$1,931

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Payroll	4,971	4,086
Bonuses	5,283	7,301
Commissions	790	980
Vacation	7,748	6,753
Royalties	1,499	1,497
Value-added tax	1,797	1,555
Other accrued expenses	13,389	9,723
Total	\$37,846	\$33,826

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

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 the Amended and Restated Credit Agreement by and among Merit, certain subsidiaries of Merit, the Lenders and Wells Fargo as administrative agent for the Lenders (as amended, the "Credit Agreement"). Pursuant to the terms of the Credit Agreement, the Lenders have agreed to make revolving credit loans up to an aggregate amount of \$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 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 or debt, the issuance of equity, the payment of dividends and certain distributions, the entry into related party transactions and other provisions customary in similar types of agreements. As of December 31, 2015, we were in compliance with all covenants set forth in the Credit Agreement.

We had originally entered into an unsecured credit agreement, dated September 30, 2010, with certain lenders who were or became party thereto and Wells Fargo, as administrative agent for the lenders. Pursuant to the terms of that credit agreement, the lenders agreed to make revolving credit loans up to an aggregate amount of \$175 million. Wells Fargo also agreed to make swingline loans from time to time through the maturity date of September 10, 2015 in amounts equal to the difference between the amount actually loaned by the lenders and the aggregate credit agreement. The unsecured credit agreement was amended and restated as of December 19, 2012, as the Credit Agreement.

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In summary, principal balances under our long-term debt as of December 31, 2015 and 2014, consisted of the following (in thousands):

	2015	2014
Term loan	\$64,962	\$82,500
Revolving credit loans	142,631	141,990
Total long-term debt	207,593	224,490
Less current portion	10,000	10,000
Long-term portion	\$ 197,593	\$ 214,490

Future minimum principal payments on our long-term debt as of December 31, 2015, are as follows (in thousands):

Years Ending	Future Minimum Principal Payments
December 31	
2016	10,000
2017	197,593
Total future minimum principal payments	\$ 207,593

As of December 31, 2015, we had outstanding borrowings of approximately \$207.6 million under the Credit Agreement, with available borrowings of approximately \$32.4 million, based on the leverage ratio in the terms of the Credit Agreement. Our interest rate as of December 31, 2015 was a fixed rate of 2.48% on \$135.0 million as a result of an interest rate swap (see Note 8), a variable floating rate of 1.74% on \$65.8 million and a variable floating rate of 2.12% on approximately \$6.8 million. Our interest rate as of December 31, 2014 was a fixed rate of 2.98% on \$140.0 million as a result of an interest rate swap, variable floating rate of 2.17% on \$84.3 million and a variable floating rate of 2.26% on approximately \$174,000.

## 8. DERIVATIVES

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

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

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



On December 19, 2012, we entered into a pay-fixed, receive-variable interest rate swap having an initial notional amount of \$150 million with Wells Fargo to fix the one-month LIBOR rate at 0.98%. The variable portion of the interest rate swap is tied to the one-month LIBOR rate (the benchmark interest rate). The interest rates under both the interest rate swap and the underlying debt reset, the swap is settled with the counterparty, and interest is paid, on a monthly basis. The notional amount of the interest rate swap is reduced quarterly by 50% of the minimum principal payment due under the terms of our Credit Agreement. The interest rate swap is scheduled to expire on December 19, 2017.

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At December 31, 2015 and 2014, our interest rate swap qualified as a cash flow hedge. The fair value of our interest rate swap at December 31, 2015 was an asset of approximately \$2,000, which was partially offset by approximately \$1,000 in deferred taxes. The fair value of our interest rate swap at December 31, 2014 was an asset of approximately \$573,000, which was offset by approximately \$223,000 in deferred taxes.

During the years ended December 31, 2015, 2014 and 2013, the amount reclassified from accumulated other comprehensive income to earnings due to hedge effectiveness were included in interest expense in the accompanying consolidated statements of income and were not material.

**Foreign Currency Forward Contracts.** We forecast our net exposure to various currencies and enter into foreign currency forward contracts to mitigate that exposure. As of December 31, 2015, we entered into foreign currency forward contracts for the Euro (EUR), British Pound (GBP), Chinese Yuan Renminbi (CNY), Mexican Peso (MXN), Brazilian Real (BRL), and Australian Dollar (AUD). On November 25, 2015, we forecasted a net exposure for December 31, 2015 (representing the difference between EUR, GBP, CNY, MXN, BRL, and AUD-denominated receivables and EUR, GBP, CNY, MXN, BRL, and AUD-denominated payables) of approximately 1.7 million EUR, 610,000 GBP, 38.4 million CNY, 32.0 million MXN, 1.5 million BRL, and 830,000 AUD. In order to partially offset such risks, on November 25, 2015 we entered into short-term forward contracts for the EUR, GBP, CNY, MXN, BRL, and AUD with notional amounts of approximately 1.7 million EUR, 610,000 GBP, 38.4 million CNY, 32.0 million MXN, 1.5 million BRL, and 830,000 AUD. On November 28, 2014, we forecasted a net exposure for December 31, 2014 (representing the difference between EUR and GBP-denominated receivables and EUR and GBP-denominated payables) of approximately 899,000 EUR and 572,000 GBP. In order to partially offset such risks at November 28, 2014, we entered into short-term forward contracts for the EUR and GBP with notional amounts of approximately 899,000 EUR and 572,000 GBP. 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. The fair value of our open positions at December 31, 2015 and 2014 was not material.

On October 23, 2015, we entered into a foreign currency forward contract to partially offset the currency risk related to an intercompany loan denominated in CNY. The loan matures and the forward contract is deliverable on September 16, 2016. The notional amount of the forward contract is approximately 46.3 million CNY. This contract is marked to market at each month-end. The fair value of our open position at December 31, 2015 was a liability of approximately \$278,000.

During the years ended December 31, 2015, 2014 and 2013, we recorded a net gain (loss) on all foreign currency transactions of approximately \$(400,000), \$36,000 and \$(202,000), respectively, which is included in other income in the accompanying consolidated statements of income.

## 9. COMMITMENTS AND CONTINGENCIES

We are obligated under non-terminable operating leases for manufacturing facilities, finished good distribution, office space and equipment. Total rental expense on these operating leases and on our manufacturing and office building for the years ended December 31, 2015, 2014 and 2013, approximated \$10.7 million, \$8.1 million and \$5.5 million, respectively.

The future minimum lease payments for operating leases as of December 31, 2015, consisted of the following (in thousands):

Years Ending December 31	Operating Leases
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2016	\$9,168
2017	7,961
2018	7,205
2019	7,110
2020	5,027
Thereafter	37,320
Total minimum lease payments	\$73,791

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**Sale-Leaseback.** During the year ended December 31, 2015, we entered into sale and leaseback transactions to finance certain production equipment for \$2.0 million. During the year ended December 31, 2014, we entered into sale and leaseback transactions to finance certain production equipment for \$5.5 million. The lease agreements from the sale and leaseback transactions are accounted for as operating leases. Under the terms of the lease agreement, we have agreed to operate and maintain the equipment. The lease term is seven years. During the year ended December 31, 2013, we entered into a sale and leaseback transaction with a third-party lessor for the sale and leaseback of our Pearland, Texas facility for \$24.0 million. The lease agreement from this sale and leaseback transaction is accounted for as an operating lease. Under the terms of the lease agreement, we have agreed to operate and maintain the building. The lease term is 19.8 years. Payments under the lease agreement are fixed. The lease agreement contains standard termination events, including termination upon a breach of our obligation to make rental payments and upon any other material breach of obligations under the lease, and standard maintenance and return condition provisions.

**Irish Government Development Agency Grants.** As of December 31, 2015, we had entered into several grant agreements with the Irish Government Development Agency. We have recorded the grants related to research and development projects and costs of hiring and training employees as a reduction of operating expenses for the years ended December 31, 2015, 2014 and 2013 in the amounts of approximately \$0, \$0 and \$1.2 million, respectively. Grants related to the acquisition of property and equipment purchased in Ireland are amortized as a reduction to depreciation expense over lives corresponding to the depreciable lives of such property and equipment. The balance of deferred credits related to such grants as of December 31, 2015 and 2014, was approximately \$2.7 million and \$2.9 million, respectively. During the years ended December 31, 2015, 2014 and 2013, approximately \$171,000, \$175,000 and \$139,000, respectively, of the deferred credit was amortized as a reduction of operating expenses.

We have committed to repay the Irish government for grants received if we cease production in Ireland prior to the expiration of the grant liability period. The grant liability period is usually between five and eight years from the last claim made on a grant. As of December 31, 2015, the total amount of grants that could be subject to refund was approximately \$3.9 million, and the remaining grant liability period was three years. Our management does not currently believe we will have to repay any of these grant monies, as we have no current intention of ceasing operations in Ireland.

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

10. EARNINGS PER COMMON SHARE (EPS)

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

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	Net Income	Shares	Per Share Amount
Year ended December 31, 2015:			
Basic EPS	\$23,802	44,036	\$0.54
Effect of dilutive stock options and warrants		475	
Diluted EPS	\$23,802	44,511	\$0.53
Year ended December 31, 2014:			
Basic EPS	\$22,974	43,143	\$0.53
Effect of dilutive stock options and warrants		266	
Diluted EPS	\$22,974	43,409	\$0.53
Year ended December 31, 2013:			
Basic EPS	\$16,570	42,607	\$0.39
Effect of dilutive stock options and warrants		277	
Diluted EPS	\$16,570	42,884	\$0.39

For the years ended December 31, 2015, 2014 and 2013, approximately 423,000, 1,292,000 and 1,823,000, respectively, of stock options were not included in the computation of diluted earnings per share because their effect would have been anti-dilutive.

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

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

**2006 Long-Term Incentive Plan.** In May 2006, our Board of Directors adopted and our shareholders approved, the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan (the “2006 Incentive Plan”). The 2006 Incentive Plan provides for the granting of stock options, stock appreciation rights, restricted stock, stock units (including restricted stock units) and performance awards. Options may be granted to directors, officers, outside consultants and key employees and may be granted upon such terms and such conditions as the Compensation Committee of our Board of Directors determines. Options will typically vest on an annual basis over a three to five year life (or one year if performance based) with a contractual life of seven years. As of December 31, 2015, a total of approximately 2.5 million shares remained available to be issued under the 2006 Incentive Plan.

**Employee Stock Purchase Plan.** We have a non-qualified Employee Stock Purchase Plan (“ESPP”), which has an expiration date of June 30, 2026. As of December 31, 2015, the total number of shares of Common Stock that remained available to be issued under our non-qualified plan was approximately 233,000 shares. ESPP participants purchase shares on a quarterly basis at a price equal to 95% of the market price of the Common Stock at the end of the applicable offering period.

**Stock-Based Compensation Expense.** The stock-based compensation expense before income tax expense for the years ended December 31, 2015, 2014 and 2013, consisted of the following (in thousands):

	2015	2014	2013
Cost of goods sold	\$398	\$198	\$145
Research and development	122	69	87

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Selling, general, and administrative	1,723	1,193	1,235
Stock-based compensation expense before taxes	\$2,243	\$1,460	\$1,467

We recognize stock-based compensation expense (net of a forfeiture rate) for those awards which are expected to vest on a straight-line basis over the requisite service period. We estimate the forfeiture rate based on our historical experience and expectations about future forfeitures. As of December 31, 2015, the total remaining unrecognized compensation cost related to non-vested stock options, net of expected forfeitures, was approximately \$5.9 million and is expected to be recognized over a weighted average period of 3.4 years.

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

	2015	2014	2013
Risk-free interest rate	1.53% - 1.66%	1.53% - 1.97%	0.65% - 1.16%
Expected option life	5.0	5.0 - 5.5 years	4.2 - 6.0 years
Expected dividend yield	—%	—%	—%
Expected price volatility	33.72% - 35.11%	34.52% - 36.90%	34.08% - 41.67%

The average risk-free interest rate is determined using the U.S. Treasury rate in effect as of the date of grant, based on the expected term of the stock option. We determine the expected term of the stock options using the historical exercise behavior of employees. The expected price volatility was determined using a weighted average of daily historical volatility of our stock price over the corresponding expected option life and implied volatility based on recent trends of the daily historical volatility. For options with a vesting period, compensation expense is recognized on a straight-line basis over the service period, which corresponds to the vesting period. Compensation expense is recognized immediately for options that are fully vested on the date of grant. During the years ended December 31, 2015, 2014 and 2013, approximately 618,000, 666,000 and 348,000 stock-based compensation grants were made, respectively, for a total fair value of approximately \$3.7 million, \$2.8 million and \$1.4 million, net of estimated forfeitures, respectively.

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The table below presents information related to stock option activity for the years ended December 31, 2015, 2014 and 2013 (in thousands):

	2015	2014	2013
Total intrinsic value of stock options exercised	\$7,548	\$3,505	\$1,649
Cash received from stock option exercises	6,227	7,697	3,281
Excess tax benefit from the exercise of stock options	2,124	576	259

Changes in stock options for the year ended December 31, 2015, consisted of the following (shares and intrinsic value in thousands):

	Number of Shares	Weighted Average Exercise Price	Remaining Contractual Term (in years)	Intrinsic Value
2015:				
Beginning balance	2,791	\$12.59		
Granted	618	18.16		
Exercised	(858)	) 11.63		
Forfeited/expired	(143)	) 14.38		
Outstanding at December 31	2,408	14.25	4.3	\$10,752
Exercisable	2,329	14.23	4.3	10,461
Ending vested and expected to vest	992	13.34	2.9	5,206

The weighted average grant-date fair value of options granted during the years ended December 31, 2015, 2014 and 2013 was \$5.98, \$4.27 and \$5.31, respectively.

The following table summarizes information about stock options outstanding at December 31, 2015 (shares in thousands):

Range of Exercise	Options Outstanding		Weighted Average Exercise Price	Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life (in years)		Number Exercisable	Weighted Average Exercise Price
\$9.95 - \$12.91	671	5.20	\$11.82	187	\$11.85
\$13.14 - \$13.16	216	3.36	13.15	129	13.15
\$13.75 - \$13.75	638	2.61	13.75	511	13.75
\$13.77 - \$21.98	883	5.19	16.76	165	13.92
\$9.95 - \$21.98	2,408			992	



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## 12. SEGMENT REPORTING AND FOREIGN OPERATIONS

We report our operations in two operating segments: cardiovascular and endoscopy. Our cardiovascular segment consists of cardiology and radiology medical device products which assist in diagnosing and treating coronary artery disease, peripheral vascular disease and other non-vascular diseases and includes embolization devices and CRM/EP devices. Our endoscopy segment consists of gastroenterology and pulmonology medical device products which assist in the palliative treatment of expanding esophageal, tracheobronchial and biliary strictures caused by malignant tumors. We evaluate the performance of our operating segments based on operating income (loss). Listed below are the sales by business segment for the years ended December 31, 2015, 2014 and 2013 (in thousands):

	% Change	2015	% Change	2014	% Change	2013
Cardiovascular						
Stand-alone devices	8	% \$155,414	15	% \$143,712	10	% \$125,445
Custom kits and procedure trays	5	% 116,368	7	% 111,076	10	% 103,700
Inflation devices	1	% 73,373	10	% 72,538	(4)	)% 66,182
Catheters	11	% 96,833	17	% 87,550	16	% 75,131
Embolization devices	3	% 45,025	31	% 43,855	(1)	)% 33,395
CRM/EP	3	% 33,902	17	% 32,975	1,359	% 28,271
Total	6	% 520,915	14	% 491,706	14	% 432,124
Endoscopy						
Endoscopy devices	18	% 21,234	6	% 17,983	7	% 16,925
Total	6	% \$542,149	14	% \$509,689	14	% \$449,049

During the years ended December 31, 2015, 2014 and 2013, we had foreign sales of approximately \$214.0 million, \$198.3 million and \$165.8 million, respectively, or approximately 39%, 39% and 37%, respectively, of total sales, primarily in China, Japan, Germany, France, the United Kingdom and Russia. Foreign sales are attributed based on location of the customer receiving the product.

Our long-lived assets by geographic area at December 31, 2015, 2014 and 2013, consisted of the following (in thousands):

	2015	2014	2013
United States	\$186,389	\$177,627	\$178,130
Ireland	48,896	49,708	50,274
Other foreign countries	32,493	16,836	14,866
Total	\$267,778	\$244,171	\$243,270

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Financial information relating to our reportable operating segments and reconciliations to the consolidated totals for the years ended December 31, 2015, 2014 and 2013, are as follows (in thousands):

	2015	2014	2013
Revenues			
Cardiovascular	\$520,915	\$491,706	\$432,124
Endoscopy	21,234	17,983	16,925
Total revenues	542,149	509,689	449,049
Operating expenses			
Cardiovascular	187,492	175,152	157,479
Endoscopy	10,746	9,904	9,044
Total operating expenses	198,238	185,056	166,523
Operating income (loss)			
Cardiovascular	34,052	38,601	26,597
Endoscopy	3,491	1,565	1,247
Total operating income	37,543	40,166	27,844
Total other expense - net	(6,343	) (8,594	) (8,005
Income tax expense	7,398	8,598	3,269
Net income	\$23,802	\$22,974	\$16,570

Total assets by business segment at December 31, 2015, 2014 and 2013, consisted of the following (in thousands):

	2015	2014	2013
Cardiovascular	\$767,952	\$734,940	\$716,659
Endoscopy	10,776	12,225	11,624
Total	\$778,728	\$747,165	\$728,283

Total depreciation and amortization by business segment for the years ended December 31, 2015, 2014 and 2013, consisted of the following (in thousands):

	2015	2014	2013
Cardiovascular	\$36,474	\$34,975	\$31,594
Endoscopy	951	954	948
Total	\$37,425	\$35,929	\$32,542

Total capital expenditures for property and equipment by business segment for the years ended December 31, 2015, 2014 and 2013, consisted of the following (in thousands):

	2015	2014	2013
Cardiovascular	\$50,927	\$33,660	\$59,421
Endoscopy	32	521	84
Total	\$50,959	\$34,181	\$59,505

13. ROYALTY AGREEMENTS

During 2010, in connection with our acquisition of BioSphere, we entered into a running royalty agreement as part of a partnership between BioSphere and L'Assistance Publique-Hôpitaux de Paris, referred to as "AP-HP," pursuant to which AP-HP has granted us the exclusive license to use two United States patents and their foreign counterparts that we jointly own with AP-HP relating to microspheres. We are required to pay to AP-HP a royalty on the commercial sale of any products that incorporate technology covered by the subject patents. We may sublicense these exclusive rights under the agreement only with the prior

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written consent of AP-HP, which consent cannot be unreasonably withheld. Under the terms of the royalty agreement, our exclusive license extends for both (i) the term of jointly owned U.S. and foreign counterpart patents and (ii) as long as the products and specialties implementing the patents are marketed. BioSphere filed patent applications which, if issued, will expire in approximately January 2031. The royalty rate in the agreement is 5.0% of net sales until the patents expire, and 2.5% of net sales thereafter as long as the product is sold. We paid or accrued approximately \$1.5 million, \$1.5 million and \$1.3 million in royalty payments to AP-HP for the years ended December 31, 2015, 2014 and 2013, respectively.

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

## 14. EMPLOYEE BENEFIT PLANS

We have a contributory 401(k) savings and profit sharing plan (the “Plan”) covering all U.S. full-time employees who are at least 18 years of age. The Plan has a 90-day minimum service requirement. We may contribute, at our discretion, matching contributions based on the employees’ compensation. Contributions we made to the Plan for the years ended December 31, 2015, 2014 and 2013, totaled approximately \$2.0 million, \$1.8 million and \$429,000, respectively. We have defined contribution plans covering some of our foreign employees. We contribute between 2% and 32% of the employee’s compensation for certain foreign non-management employees, and between 2% and 32% of the employee’s compensation for certain foreign management employees. Contributions made to these plans for the years ended December 31, 2015, 2014 and 2013, totaled approximately \$893,000, \$912,000 and \$748,000, respectively.

## 15. QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)

Quarterly data for the years ended December 31, 2015 and 2014 consisted of the following (in thousands, except per share amounts):

	Quarter Ended			
	March 31	June 30	September 30	December 31
2015				
Net sales	\$ 129,577	\$ 138,082	\$ 136,086	\$ 138,404
Gross profit	55,383	60,886	59,205	60,307
Income from operations	8,704	12,242	8,547	8,050
Income tax expense	2,289	3,122	1,842	145
Net income	5,174	7,401	4,818	6,409
Basic earnings per common share	0.12	0.17	0.11	0.14
Diluted earnings per common share	0.12	0.17	0.11	0.14
2014				
Net sales	\$ 119,236	\$ 128,865	\$ 128,808	\$ 132,780
Gross profit	52,043	55,624	57,421	60,134
Income from operations	6,489	7,384	12,076	14,217
Income tax expense	1,063	1,366	2,489	3,680
Net income	2,823	3,716	7,764	8,671
Basic earnings per common share	0.07	0.09	0.18	0.20
Diluted earnings per common share	0.07	0.09	0.18	0.20

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



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## 16. FAIR VALUE MEASUREMENTS

Our financial assets and (liabilities) carried at fair value measured on a recurring basis as of December 31, 2015 and 2014, consisted of the following (in thousands):

Description	Total Fair Value at December 31, 2015	Fair Value Measurements Using		
		Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant Unobservable inputs (Level 3)
Interest rate contracts (1)	\$2	\$—	\$2	\$—
Foreign currency contracts (2)	\$(278	) \$—	\$(278	) \$—

Description	Total Fair Value at December 31, 2014	Fair Value Measurements Using		
		Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant Unobservable inputs (Level 3)
Interest rate contracts (1)	\$573	\$—	\$573	\$—

(1) The fair value of the interest rate contracts is determined using Level 2 fair value inputs and is recorded as other assets in the Consolidated Balance Sheets.

(2) The fair value of the foreign currency contracts is determined using Level 2 fair value inputs and is recorded as accrued expenses in the Consolidated Balance Sheets.

Certain of our business combinations involve the potential for the payment of future contingent consideration, generally based on a percentage of future product sales or upon attaining specified future revenue milestones. See Note 2 for further information regarding these acquisitions. The contingent consideration liability is re-measured at the estimated fair value at each reporting period with the change in fair value recognized within operating expenses in the accompanying consolidated statements of income. We measure the initial liability and re-measure the liability on a recurring basis using Level 3 inputs as defined under authoritative guidance for fair value measurements. Changes in the fair value of our contingent consideration liability during the years ended December 31, 2015 and 2014, consisted of the following (in thousands):

	2015	2014
Beginning balance	\$1,886	\$2,526
Contingent consideration liability recorded as the result of acquisitions (see Note 2)	270	—
Fair value adjustments recorded to income during the period	80	(572
Contingent payments made	(1,212	) (68
Ending balance	\$1,024	\$1,886



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The recurring Level 3 measurement of our contingent consideration liability includes the following significant unobservable inputs at December 31, 2015 and 2014 (amount in thousands):

Contingent consideration liability	Fair value at December 31, 2015	Valuation technique	Unobservable inputs	Range
Revenue-based payments	\$874	Discounted cash flow	Discount rate	5% - 15%
			Probability of milestone payment	100%
			Projected year of payments	2016-2028
Other payments	\$150	Discounted cash flow	Discount rate	—%
			Probability of milestone payment	100%
			Projected year of payments	2016
Contingent consideration liability	Fair value at December 31, 2014	Valuation technique	Unobservable inputs	Range
Revenue-based payments	\$1,610	Discounted cash flow	Discount rate	1% - 14%
			Probability of milestone payment	90%
			Projected year of payments	2015-2028
Other payments	\$276	Discounted cash flow	Discount rate	5%
			Probability of milestone payment	100%
			Projected year of payments	2015-2016

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

Our determination of the fair value of the contingent consideration liability could change in future periods based upon our ongoing evaluation of these significant unobservable inputs. We intend to record any such change in fair value to operating expenses in our consolidated statements of income. As of December 31, 2015, approximately \$775,000 was included in other long-term obligations and \$249,000 was included in accrued expenses in our consolidated balance sheet. As of December 31, 2014, approximately \$803,000 was included in other long-term obligations and \$1.1 million was included in accrued expenses in our consolidated balance sheet. The cash paid to settle the contingent consideration liability recognized at fair value as of the acquisition date (including measurement-period adjustments) has been reflected as a cash outflow from financing activities in the accompanying consolidated statements of cash flows.

During the years ended December 31, 2015, 2014 and 2013, we had losses of approximately \$141,000, \$1.4 million, and \$8.2 million, respectively, related to the measurement of non-financial assets at fair value on a nonrecurring basis



subsequent to their initial recognition.

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

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17. SUBSEQUENT EVENTS

We have evaluated whether any subsequent events have occurred from December 31, 2015 to the time of filing of this report that would require disclosure in the consolidated financial statements. We note the following two events below.

Third Amendment to Amended and Restated Credit Agreement

On February 3, 2016, we entered into a Third Amendment to Amended and Restated Credit Agreement (the “Amendment”), by and among Merit, certain subsidiaries of Merit, the lenders who are party to the Amendment and Wells Fargo, as administrative agent for those lenders. The Amendment sets forth the terms and conditions upon which Merit, Wells Fargo and the other parties to the Amendment have agreed to amend our Credit Agreement. Among other provisions, the Amendment provides for an increase in our borrowing capacity under our Credit Agreement by \$50 million. The Credit Agreement, after giving effect to the Amendment (the “Amended Credit Agreement”), sets forth the agreement of the lenders who are party to the Amendment to make revolving credit loans to us in an aggregate amount of \$225 million on the terms and subject to the conditions set forth in the Amended Credit Agreement. Those lenders have previously made a term loan to us in the amount of \$100 million, repayable in quarterly installments in the amounts provided in the Amended Credit Agreement until the maturity date of December 19, 2017, at which time the term loan, together with accrued interest thereon, is required to be paid in full. In addition, certain mandatory prepayments are required to be made upon the occurrence of certain events described in the Amended Credit Agreement. Wells Fargo has agreed to make “Swingline” loans from time to time through the maturity date of December 19, 2017 in amounts equal to the difference between the amounts actually loaned by the Lenders and the aggregate revolving credit commitment, on the terms and subject to the conditions set forth in the Amended Credit Agreement.

HeRO® Acquisition

On February 4, 2016, we purchased the HeRO®Graft device and other related assets from CryoLife, Inc., a developer of medical devices based in Kennesaw, GA. The purchase price was \$18.5 million. We are currently evaluating the accounting treatment of this purchase, as well as performing the valuation of the assets acquired and the related purchase price allocation.

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Supplementary Financial Data

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

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

None.

Item 9A. Controls and Procedures.

EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934 ("Exchange Act"), as of December 31, 2015. Based on this evaluation, our principal executive officer and principal financial officer concluded that as of December 31, 2015, our disclosure controls and procedures were effective, at a reasonable assurance level, to ensure that information we are required to disclose in the reports we file or submit under the Exchange Act is (a) recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and is (b) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

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MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2015. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control-Integrated Framework (2013). Based on those criteria and our management's assessment, our management concluded that, as of December 31, 2015, our internal control over financial reporting was effective.

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

During the quarter ended December 31, 2015, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934).

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

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the internal control over financial reporting of Merit Medical Systems, Inc. and subsidiaries (the “Company”) as of December 31, 2015, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements and financial statement schedule as of and for the year ended December 31, 2015 of the Company and our report dated February 29, 2016 expressed an unqualified opinion on those financial statements and financial statement schedule.

/s/ DELOITTE & TOUCHE LLP

Salt Lake City, Utah  
February 29, 2016

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Item 9B. Other Information.

None.

PART III

Items 10, 11, 12, 13 and 14.

These items are incorporated by reference to our definitive proxy statement relating to our Annual Meeting of Shareholders scheduled for May 26, 2016. We anticipate that our definitive proxy statement will be filed with the SEC not later than 120 days after December 31, 2015, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) Documents filed as part of this Report:

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

Report of Independent Registered Public Accounting Firm — Internal Control

Report of Independent Registered Public Accounting Firm — Financial Statements

Consolidated Balance Sheets as of December 31, 2015 and 2014

Consolidated Statements of Income for the Years Ended December 31, 2015, 2014, and 2013

Consolidated Statements of Comprehensive Income for the Years Ended December 31, 2015, 2014 and 2013

Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2015, 2014 and 2013

Consolidated Statements of Cash Flows for the Years Ended December 31, 2015, 2014 and 2013

Notes to Consolidated Financial Statements

(2) Financial Statement Schedule.

— Schedule II - Valuation and qualifying accounts

Years Ended December 31, 2015, 2014 and 2013  
(In thousands)

Description	Balance at Beginning of Year	Additions Charged to Costs and Expenses (a)	Deduction (b)	Balance at End of Year
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ALLOWANCE FOR UNCOLLECTIBLE  
ACCOUNTS:

2013	(892	) (376	) 428	(840	)
2014	(840	) (83	) 30	(893	)
2015	(893	) (607	) 203	(1,297	)

- (a) We record a bad debt provision based upon historical experience and a review of individual customer balances.  
 (b) When an individual customer balance becomes impaired and is deemed uncollectible, a deduction is made against the allowance for uncollectible accounts.



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Years Ended December 31, 2015, 2014 and 2013  
(In thousands)

Description	Balance at Beginning of Year	Additions Charged to Costs and Expenses (c)	Deduction	Balance at End of Year
TAX VALUATION ALLOWANCE:				
2013	(1,225	) (138	) —	(1,363 )
2014	(1,363	) (240	) —	(1,603 )
2015	(1,603	) (378	) —	(1,981 )

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

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## (b) Exhibits:

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

Description	Exhibit No.
2.1 Agreement and Plan of Merger dated May 13, 2010 by and among Merit Medical Systems, Inc., Merit BioAcquisition Co., and BioSphere Medical, Inc.*	[Form 8-K filed May 13, 2010, Exhibit 2.1]
2.2 Stock Purchase Agreement dated November 26, 2012 by and between Merit Medical Systems, Inc. and Vital Signs, Inc.*	[Form 8-K/A filed January 24 2013, Exhibit 2.1]
3.1 Articles of Incorporation as amended and restated*	[Form 10-Q filed August 14, 1996, Exhibit No. 1]
3.2 Second Amended and Restated Bylaws*	[Form 8-K filed December 16, 2015 Exhibit No. 3.1]
4.1 Specimen Certificate of the Common Stock*	[Form S-18 filed October 19, 1989, Exhibit No. 10]
4.2 Articles of Amendment of the Articles of Incorporation dated May 14, 1993*	[Form S-3 filed February 14, 2005, Exhibit 4.3]
4.3 Articles of Amendment to Articles of Incorporation dated June 6, 1996*	[Form S-3 filed February 14, 2005, Exhibit 4.4]
4.4 Articles of Amendment to Articles of Incorporation dated June 12, 1997*	[Form S-3 filed February 14, 2005, Exhibit 4.5]
4.5 Articles of Amendment to the Articles of Incorporation dated May 22, 2003*	[Form S-3 filed February 14, 2005, Exhibit 4.7]
4.6 Articles of Amendment to the Articles of Incorporation dated May 23, 2008*	[Form 8-K filed May 28, 2008, Exhibit 3.1]
10.1 Merit Medical Systems, Inc. Long Term Incentive Plan (as amended and restated) dated March 25, 1996*†	[Form 10-Q filed August 14, 1996, Exhibit No. 2]
10.2 Merit Medical Systems, Inc. 401(k) Profit Sharing Plan (as amended effective January 1, 1991)*†	[Form S-1 filed February 14, 1992, Exhibit No. 8]
10.3 Lease Agreement dated as of June 8, 1993 for office and manufacturing facility*	[Form 10-K for year ended December 31, 1994, Exhibit No. 10.4]
10.4 Amended and Restated Deferred Compensation Plan*†	

		[Form 10-K for year ended December 31, 2003, Exhibit No. 10.12]
10.5	Seventh Amendment to the First Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan*†	[Form 10-K for year ended December 31, 2006, Exhibit No. 10.18]
10.6	Stock Purchase Agreement by and between Merit Medical Systems, Inc. and Sheen Man Co. LTD, dated April 1, 2007*	[Form 10-Q filed May 9, 2007, Exhibit No. 10.19]
10.7	Eighth Amendment to the First Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan*†	[Form 10-K for year ended December 31, 2007, Exhibit No. 10.20]
10.8	Ninth Amendment to the First Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan*†	[Form 10-K for year ended December 31, 2007, Exhibit No. 10.21]
10.9	Tenth Amendment to the First Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan*†	[Form 10-K for year ended December 31, 2007, Exhibit No. 10.22]

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10.10	Merit Medical Systems, Inc. Amended and Restated Deferred Compensation Plan, effective January 1, 2008*†	[Form 8-K filed December 18, 2008, Exhibit 10.1]
10.11	Eleventh Amendment to the First Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan*†	[Form 10-K for year ended December 31, 2008, Exhibit No. 10.29]
10.12	Twelfth Amendment to the First Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan*†	[Form 10-K for year ended December 31, 2008, Exhibit No. 10.30]
10.13	Second Amendment to the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan*†	[Form 8-K filed May 27, 2009, Exhibit 10.1]
10.14	Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan*†	[Form 8-K filed January 7, 2010, Exhibit 10.1]
10.15	Credit Agreement dated as of September 10, 2010 by and among Merit Medical Systems, Inc. and Wells Fargo Bank, National Association*	[Form 8-K/A filed September 16, 2010, Exhibit 10.1]
10.16	Amended and Restated Employment Agreement of Fred P. Lampropoulos dated December 30, 2010*†	[Form 10-K for year ended December 31, 2010, Exhibit No. 10.36]
10.17	Stock Purchase Agreement by and between Vital Signs, Inc. and Merit Medical Systems, Inc., dated as of November 26, 2012*	[Form 8-K/A filed November 30, 2012, Exhibit 2.1]
10.18	Amended and Restated Credit Agreement dated December 19, 2012 by and among Merit Medical Systems, Inc. and Wells Fargo Bank, National Association*	[Form 8-K filed December 21, 2012, Exhibit 10.1]
10.19	Amended and Restated Stock Purchase Agreement by and between Vital Signs, Inc. and Merit Medical Systems, Inc., dated as of November 26, 2012*	[Form 8-K/A filed January 24, 2013, Exhibit 2.1]
10.20	First Amendment to Amended and Restated Credit Agreement, dated as of October 4, 2013, by and among Merit Medical Systems, Inc., certain subsidiaries of Merit Medical Systems, Inc., the lenders identified therein and Wells Fargo Bank, as administrative agent for the lenders*	[Form 10-Q for quarter ended September 30, 2013, Exhibit No. 10.1]
10.21	Employment Agreement of Ron Frost dated December 12, 2014*†	[Form 10-K for year ended December 31, 2014, Exhibit No. 10.45]
10.22	Second Amendment to Amended and Restated Credit Agreement, dated as of September 18, 2014, by and among Merit Medical Systems, Inc., certain subsidiaries of Merit Medical Systems, Inc., the lenders identified therein and Wells Fargo Bank, as administrative agent for the lenders	Filed herewith

10.23	Separation Agreement and Release of All Claims of Greg Barnett dated November 3, 2015†	Filed herewith
10.24	Separation Agreement and Release of All Claims of Rashelle Perry dated December 1, 2015†	Filed herewith
10.25	Separation Agreement and Release of All Claims of Kent W. Stanger dated January 4, 2016†	Filed herewith
10.26	Third Amendment to Amended and Restated Credit Agreement, dated as of February 3, 2016, by and among Merit Medical Systems, Inc., certain subsidiaries of Merit Medical Systems, Inc., the lenders identified therein and Wells Fargo Bank, as administrative agent for the lenders	Filed herewith
21	Subsidiaries of Merit Medical Systems, Inc.	Filed herewith
23.1	Consent of Independent Registered Public Accounting Firm	Filed herewith
31.1	Certification of Chief Executive Officer	Filed herewith
31.2	Certification of Chief Financial Officer	Filed herewith
32.1	Certification of Chief Executive Officer	Filed herewith

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32.2 Certification of Chief Financial Officer Filed herewith

The following materials from the Merit Medical Systems, Inc. Annual Report on Form 10-K for the fiscal year ended December 31, 2015, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Statements of Operations, (ii) Consolidated Balance Sheets, (iii) Consolidated Statements of Comprehensive Income (iv) Consolidated Statements of Stockholders' Equity, (v) Consolidated Statements of Cash Flows, and (vi) related notes. Filed herewith

\* These exhibits are incorporated herein by reference.  
† Indicates management contract or compensatory plan or arrangement.

(c) Schedules:

None

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, on February 29, 2016.

MERIT MEDICAL SYSTEMS, INC.

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

ADDITIONAL SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on form 10-K has been signed below by the following persons in the capacities indicated on February 29, 2016.

Signature	Capacity in Which Signed
/s/: FRED P. LAMPROPOULOS Fred P. Lampropoulos	President, Chief Executive Officer and Director (Principal executive officer)
/s/: BERNARD J. BIRKETT Bernard J. Birkett	Chief Financial Officer, Secretary and Treasurer (Principal financial and accounting officer)
/s/: A. SCOTT ANDERSON A. Scott Anderson	Director
/s/: RICHARD W. EDELMAN Richard W. Edelman	Director
/s/: NOLAN E. KARRAS Nolan E. Karras	Director
/s/: FRANKLIN J. MILLER Franklin J. Miller	Director
/s/: F. ANN MILLNER F. Ann Millner	Director
/s/: KENT W. STANGER Kent W. Stanger	Director
/s/: MICHAEL E. STILLABOWER Michael E. Stillabower	Director