

# 2016 ANNUAL REPORT

**EN** ENDOSCOPY

**CI** CARDIAC  
INTERVENTION

**PI** PERIPHERAL  
INTERVENTION

**IOS** INTERVENTIONAL  
ONCOLOGY & SPINE





## A MESSAGE FROM THE CHAIRMAN & CEO



### DEAR SHAREHOLDERS,

2016 was another exciting year of growth and profitability. We accomplished all the goals we set out for the second year of our three-year plan. There were many growth drivers, including international expansion, internal product development, and acquisitions.

We expanded our presence in Australia and Canada, as we implemented our wholesale-to-retail strategy. We believe this strategy will help us get closer to and better understand the needs of our customers.

Internal product development proceeded at a rapid pace with new products including the Elation® Pulmonary Balloon, the CorVocet™ Biopsy System, the PreludeSYNC™ Hemostasis Device, and the Super HERO® Adapter. We are working on a number of follow-on products, which we believe will contribute to a full pipeline in the future.

We believe acquisitions, including our acquisitions of the HeRO® Graft and DFINE, Inc., will help us offer new products and services to existing call points. New product development has already been initiated, and we believe it will contribute to margin improvement and growth in the future.

We believe our distribution of products such as the SwiftNINJA® Steerable Microcatheter and the True Form™ Reshapable Guide Wire will provide unique innovative products with pull-through of existing products, as well as a broadening of our product portfolio.

Margin expansion proceeded with the help of new higher margin products and operating efficiency, as well as a targeted program of cost reductions.

As we enter 2017, we intend to integrate products from the Argon Medical Devices and Catheter Connections acquisitions. We believe these products will support our goal of expanding our value proposition to our hospital customers globally.

We continue to believe that additional opportunities and increased profitability will pave the way for increased shareholder value in the future.

Sincerely,

A handwritten signature in black ink, reading 'Fred P. Lampropoulos'.

FRED P. LAMPROPOULOS | CHAIRMAN & CEO

---

---

**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, 2016**

or

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**



**MERIT MEDICAL SYSTEMS, INC.**

(Exact name of registrant as specified in its charter)

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

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

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

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

(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: **(801) 253-1600**

Securities registered pursuant to Section 12(b) of the Act: **Common Stock, No Par Value, 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 ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐  
(Do not check if a  
smaller reporting company)

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant, on June 30,  
2016, 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, 2016), was approximately  
\$844,073,573. 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, 2017, the registrant had 44,651,196 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 24, 2017.

---

---



## TABLE OF CONTENTS

PART I	
Item 1.	Business . . . . . 3
Item 1A.	Risk Factors . . . . . 27
Item 1B.	Unresolved Staff Comments . . . . . 43
Item 2.	Properties . . . . . 43
Item 3.	Legal Proceedings . . . . . 44
Item 4.	Mine Safety Disclosures . . . . . 44
PART II	
Item 5.	Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities . . . . . 45
Item 6.	Selected Financial Data . . . . . 48
Item 7.	Management’s Discussion and Analysis of Financial Condition and Results of Operations . . . . . 48
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk . . . . . 60
Item 8.	Financial Statements and Supplementary Data . . . . . 63
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure . . . . . 107
Item 9A.	Controls and Procedures . . . . . 107
Item 9B.	Other Information . . . . . 111
PART III	
Item 10.	Directors, Executive Officers and Corporate Governance . . . . . 111
Item 11.	Executive Compensation . . . . . 111
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters . . . . . 111
Item 13.	Certain Relationships and Related Transactions, and Director Independence . . . . . 111
Item 14.	Principal Accountant Fees and Services . . . . . 111
PART IV	
Item 15.	Exhibits and Financial Statement Schedules . . . . . 111
Item 16.	Form 10-K Summary . . . . . 116
SIGNATURES . . . . . 117	

## 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, 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,” “seeks,” “believes,” “estimates,” “potential,” “forecasts,” “continue,” or other forms of these words or similar words or expressions, or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results will likely differ, and could differ materially, from those projected or assumed in the forward-looking statements. Prospective investors are cautioned not to unduly rely on any such 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 the following:

- risks relating to managing growth, particularly if accomplished through acquisitions, and the integration of acquired businesses;
- risks relating to protecting our intellectual property;
- claims by third parties that we infringe their intellectual property rights which could cause us to incur significant legal or licensing expenses and prevent us from selling our products;
- greater scrutiny and regulation by governmental authorities, including risks relating to the subpoena we received in October 2016 from the U.S. Department of Justice seeking information on our marketing and promotional practices;
- risks relating to our products being used in unapproved circumstances;
- risks relating to significant adverse changes in, or our failure to comply, with governing regulations;
- FDA regulatory clearances processes and any failure to obtain and maintain required regulatory clearances and approvals;
- failure to comply with export control laws, customs laws, sanctions laws and other laws governing our operations in the U.S. and other countries, which could subject us to civil or criminal penalties, other remedial measures and legal expenses;
- disruption of our critical information systems or material breaches in the security of our systems;

- restrictions and limitations in our debt agreements and instruments, which could affect our ability to operate our business and our liquidity;
- expending significant resources for research, development, testing and regulatory approval or clearance of our products under development and any failure to develop the products or obtain approvals for commercial use;
- violations of laws targeting fraud and abuse in the healthcare industry;
- risks relating to healthcare reform legislation negatively affecting our financial results, business, operations or financial condition;
- loss of key personnel;
- product liability claims;
- failure to report adverse medical events to the FDA, which may subject us to sanctions that may materially harm our business;
- failure to maintain or establish sales capabilities on our own or through third parties, which may result in our inability to commercialize any of our products in countries where we lack direct sales and marketing capabilities;
- our estimates on the addressable market for our product groups have not been established with precision, and may be smaller than we estimate;
- demands for price concessions resulting from consolidations in the healthcare industry, group purchasing organizations or public procurement policies;
- inability to compete in markets, particularly if there is a significant change in relevant practices or technology;
- fluctuations in foreign currency exchange rates negatively impacting our financial results;
- 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;
- inability to accurately forecast customer demand for our products or manage our inventory, including rapid increases in the demand for our products;
- changes in international and national economic and industry conditions;
- inability to generate sufficient cash flow to fund our debt obligations, capital expenditures, and ongoing operations;
- risks relating to our revenues being derived from a few products and medical procedures;
- volatility of the market price of our common stock;
- risks relating to work stoppage, transportation interruptions, severe weather and natural disasters;
- fluctuations in our effective tax rate adversely affecting our business, financial condition or results of operation;
- limits on reimbursement imposed by governmental and other programs;
- failure to comply with applicable environmental laws and regulations; and
- other factors referenced in our press releases and in our reports filed with the Securities and Exchange Commission (the “SEC”).

All subsequent forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by these cautionary statements. Our actual results will likely 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. If we do update or correct one or more forward-looking statements, investors and others should not conclude that we will make additional updates or corrections. Additional factors that may have a direct bearing on our operating results are described under Item 1A “Risk Factors” beginning on page 27.

## **DISCLOSURE REGARDING TRADEMARKS**

This report includes trademarks, tradenames and service marks that are our property or the property of other third parties. Solely for convenience, such trademarks and tradenames sometimes appear without any “TM” or “®” symbol. However, failure to include such symbols is not intended to suggest, in any way, that we will not assert our rights or the rights of any applicable licensor, to these trademarks and tradenames.

### **Item 1. *Business.***

#### ***The Company***

Merit Medical Systems, Inc. is a leading manufacturer and marketer of disposable medical devices used in a vast array of interventional, diagnostic and therapeutic medical procedures, particularly in cardiology, radiology and endoscopy. 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 customers, employees, shareholders, and communities when we focus outward and are determined to deliver an exceptional customer experience.

Merit Medical Systems, Inc. was founded in 1987 by Fred P. Lampropoulos, Kent W. Stanger, Darla Gill and William Padilla. Initially we focused our operations 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 expanded substantially, both through internal research and development projects and strategic acquisitions.

Our business strategy focuses on four target areas as follows:

- enhancing growth and profitability through research and development, sales model optimization, strategic acquisitions and alliances, 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, acquiring and delivering in peripheral, cardiac, interventional oncology and spine, and endoscopy product groups; and
- 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, market, and manufacture, through our own operations and contract manufacturers, approximately 180 innovative medical products (classified into more than 20,000 individual product catalog numbers) 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; neurointerventional radiology and surgery; vascular, general and thoracic surgery; electrophysiology; cardiac rhythm management; interventional pulmonology; interventional nephrology; orthopaedic spine surgery; interventional oncology and 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.

We currently conduct our business through two business segments: cardiovascular and endoscopy. Within those business segments, we offer products focused in four core product groups: peripheral intervention, cardiac intervention, interventional oncology and spine, and endoscopy. A number of our products are marketed within each product group; accordingly, we do not maintain separate measures of profitability by product group. Based on industry data and our internal market information, we estimate that the addressable market opportunities (in terms of annual net sales), that we are targeting with our current or newly-released product portfolios, for each of our business segments are as follows:

- Cardiovascular: \$5.11 billion (global)
- Endoscopy: \$411 million (U.S. domestic)

However, we operate in a competitive environment with many companies seeking to address the same market opportunities. Additionally, these opportunities may evolve significantly as a result of changes in customer preferences or the macroeconomic and regulatory environments in which we operate. For these and other reasons, we cannot guarantee the degree to which we will be able to realize increased net sales as a result of these, or any other, opportunities. For information relating to our business segments, see Note 12 to our consolidated financial statements set forth in Item 8 of this report.

During the year ended December 31, 2016, net sales generated by our top ten selling products accounted for approximately 39% of our total net sales. Sales of our inflation devices accounted for approximately 12%, 14% and 16% of our net sales for the years ended December 31, 2014, 2015 and 2016, respectively.

### **Peripheral Intervention**

We strive to provide our customers, the healthcare providers, with superior products designed to alleviate patient suffering from peripheral vascular and non-vascular diseases. These technologies support the minimally invasive diagnosis and treatment of diseases in peripheral vessels and organs throughout the body excluding the heart. Our Peripheral Intervention product line is organized into product portfolios as follows: Access, Angiography, Intervention, Drainage & Biopsy and Complete Procedural Solutions.

#### *Peripheral Access Portfolio*

We offer a broad line of devices used to gain and maintain vascular access. These products include access systems such as the micropuncture family kits consisting of the PAK™ (pedal access kit), the



MAK™ (mini access kit) and the S-MAK™ (stiff MAK). Additionally, our extensive line of Prelude® sheath introducers and related products provide clinicians with smooth, convenient, and less traumatic access to the patient's vasculature. 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 lines 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 December 2016, we entered into a strategic partnership with Bluegrass Vascular Technologies, and we acquired the global distribution rights with respect to the Surfacar® Inside-Out® Access Catheter System. The Surfacar system, which recently received CE mark approval, is an innovative Inside-Out approach to restore access to the right internal jugular vein and to preserve treatment options in hemodialysis patients with occluded veins. Additionally, the Surfacar system aligns with our existing peripheral access portfolio.

In February 2016, we acquired the HeRO® (Hemodialysis Reliable Outflow) Graft from CryoLife, Inc. ("Cryolife"). The HeRO Graft is a fully subcutaneous vascular access system intended for use in maintaining long-term vascular access for chronic hemodialysis patients who have failing fistulas, grafts or are catheter dependent due to a central venous blockage. The Super HeRO Adapter and its accompanying HeRO Ally™ Revision Kit are the newest addition to our growing HeRO family of dialysis devices. This technology offers surgeons the safety and efficiency of the original HeRO graft, but with more graft options to choose from, including early cannulation grafts, which can eliminate the need for a bridging catheter.

The CentrosFLO® Long-Term Hemodialysis Catheters anchor our chronic dialysis line. With its self-centering distal tip design, the CentrosFLO is designed to maintain long-term patency, as shown by retrospective and prospective studies published in 2016. We also offer the ProGuide™ Chronic Dialysis Catheter, a "workhorse" catheter for chronic dialysis.

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

### *Angiography Portfolio*

We market an extensive line of diagnostic and hydrophilic guide wires for use in angiography procedures. Our diagnostic guide wires are used to traverse the vascular anatomy and aid in placing catheters and therapeutic devices to their target location. Our Merit Laureate® Hydrophilic Guide Wire has a consistent, lubricious coating intended to promote rapid advancement through the vasculature, provide additional assistance for crossing difficult lesions, and facilitate smooth catheter exchanges by minimizing friction. Additionally, our pre-coated, high-performance InQwire® Diagnostic Guide Wires are lubricious and available in a wide range of configurations designed to meet clinicians' diagnostic needs.

We have strengthened our angiography portfolio with the addition of the SPINR™ high-performance guidewire controller. The SPINR is a mechanical torque device used to access distal anatomy by navigating tortuous vessels, crossing old lesions, and working through fresh blockages. This guidewire controller bridges the gap between manual torque devices and electromechanical torque devices.

The diagnosis and treatment of peripheral arterial disease is paramount to ensuring appropriate patient care and helping patients achieve an enduring, productive lifestyle. The Performa® and Impress® Diagnostic Catheter product lines are designed to provide solutions for traversing difficult peripheral vasculature during angiographic procedures. These catheters work in tandem with our guide

wires to aid in the diagnosis of peripheral artery disease and can be used to facilitate transradial access, a procedure which uses the wrist artery as the access entry point for peripheral procedures rather than the more traditional femoral artery approach.

### *Intervention Portfolio*

We market an extensive line of products designed to treat blood clots that obstruct the flow of blood in arteries and veins. 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, as well as native dialysis fistula and synthetic grafts. We offer standard and low-profile ASAP® Aspiration Catheters, which offer clinicians two options for the safe and efficient removal of fresh, soft emboli and thrombi from vessels.

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 recanalization of both arterial and venous chronic occlusions. 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.

For more than two decades, we have offered inflation devices designed to accurately measure pressures during balloon and stent deployment. We offer the basixTOUCH™ Inflation Device for one-handed preparation and priming for faster preparation time. Many procedures today require high pressures. For these procedures, we are proud to offer the basixTOUCH40™.

Its 40 ATM (standard atmosphere) pressure capacity allows inflation of high pressure interventional balloons. Additionally, the BasixCompak™ Inflation Device and the Blue Diamond™ Digital Inflation Device feature an angled gauge for better viewing.

In 2016, we introduced the Advocate™ Peripheral Angioplasty Balloon product line intended for balloon dilation or percutaneous transluminal angioplasty of the iliac, femoral, popliteal, infra-popliteal and renal arteries. The Advocate's ThinTek™ technology produces a thin-walled, yet strong balloon material allowing improved crossability, superior tracking and pushability, and improved rewrap.

### *Drainage & Biopsy Portfolio*

We have a broad line of drainage access products. Our One-Step™ Drainage Catheter, Safety Paracentesis Procedure Tray and Thoracentesis and Paracentesis Set are designed to provide clinicians with safe, convenient and cost-effective methods for removing unwanted fluid accumulation. Our Valved One-Step™ Centesis Catheters are designed with an integrated self-sealing valve to minimize the risk of air entering the pleural space and to prevent fluid leakage during thoracentesis and paracentesis procedures.

The ReSolve® Locking Drainage Catheter offers a convenient locking mechanism that we believe enhances patient comfort. A range of catheter fixation devices are also available including the StayFIX® Fixation Device and the Revolution™ Catheter Securement Device, which were designed to save time, enhance patient comfort and improve cost-effectiveness. We provide a wide selection of accessories that complement our drainage catheters, including tubing sets and drainage bags. For non-vascular applications, the mini access kit (MAK-NV™) is designed for easy visualization and quick access into the drainage area. For enhanced visibility, the kit features an echo-enhanced needle and radiopaque marker tip on the introducer.

In January 2017, we launched the CorVocet™ Biopsy System. This exciting new product is designed to cut full-core of tissue, providing large specimens for pathological examination. Its sleek lines, light weight, and ergonomic grip help facilitate one-handed priming, positioning, and deployment, which is especially beneficial during image-guided procedures.

#### *Complete Procedural Solutions*

We offer a variety of pre-arranged kits, trays and packs to meet our customers' specific needs. We work closely with our customers to create a customized assortment of products designed to meet their needs and improve patient outcomes. Our Vein Closure Tray™ is one example of how we can help streamline procedural efficiency and reduce costs by combining the clinical tools needed in one convenient package.

Merit Disposal Depot™ waste bags fully contain fluid waste for easy disposal and come in many configurations for connecting directly to a manifold or for convenient placement on a back table.

In response to the growing demand for hemostasis valves that provide for minimized blood loss and reduced exposure to blood, we have made available a full line of hemostasis valves in a variety of sizes and options that allow hospitals and physicians to choose products that reflect their procedural preferences.

#### **Cardiac Intervention**

We manufacture and sell a variety of products designed to aid in the treatment of various cardiac conditions specific to interventional cardiology and electrophysiology including cardiac rhythm management and lead management.

Two key program drivers in cardiac intervention during 2016 were the Think Radial™ Program and Think Interventional CRT™, which stands for cardiac resynchronization therapy. Think Radial is a global education program that provides clinicians with the training and tools to commence or further their practice of the transradial approach. The transradial approach 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 2016, we hosted several Think Radial training courses at our facilities for interventional cardiologists and interventional radiologists from across the U.S., Europe, and Canada.

The Think Interventional CRT therapy training program showcases a new interventional approach to implanting left ventricle leads. This approach utilizes new products and offers techniques to electrophysiologists who are relatively new to telescoping support catheters, subclavian vein venoplasty, and using snares to provide guidewire support. In 2016, our Think Interventional CRT training programs globally assisted with the training and education of electrophysiologists from across the U.S., Europe, and Canada.

Our Cardiac Intervention product group is organized under product portfolios which include: Access, Angiography, Hemostasis, Intervention, Custom Procedural Solutions, and Electrophysiology.

#### *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 is 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.



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 these procedures. We believe that these catheters offer physicians superior torque, high shaft strength for pushability and a large inner diameter for improved flow rates during a variety of angiographic procedures. Our MIV™ Radial Ventriculogram Pigtail Catheter addresses the difficulty in accessing the left ventricle from the radial artery, which occurs when using standard femoral approach catheters.

#### *Cardiac Hemostasis Portfolio*

Catheterization for diagnostic and interventional cardiology procedures generally takes 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 now offer the PreludeSYNC™ hemostasis device, as well as our legacy Safeguard Radial™ device. These devices compete in a fast-growing segment within the interventional cardiology and radial compression markets. The PreludeSYNC was designed to address the market need for improved patient comfort and clinician use without compromising safety. To accomplish this, the device has a soft band with a secure hook and loop closure. To improve patient experience, the device comes packaged with creative, unique designs printed directly on the band, which is a first of its kind for our company.

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 our 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 and peripheral artery 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 line of inflation devices designed to accurately measure pressures during balloon and stent deployment. The basixTOUCH™ Inflation Syringe reduces preparation time through its single-handed preparation and priming features. 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 gain access to the heart. Our line of Concierge® Guiding Catheters has an advanced braiding technology and proprietary polymer-blend shaft, which allow for an increased lumen size while maintaining exceptional support.

Pericardiocentesis is a procedure through 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.

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 (“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 minimize errors 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 to make the clinical setting safer for the clinician, staff and patient.

#### *Electrophysiology Portfolio*

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

Cardiac rhythm management (“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 2016, we launched the Prelude SNAP™ Hydrophilic Sheath, which is a hydrophilic coated splittable, hemostatic sheath providing the same features and benefits as our Prelude SNAP™ but with a hydrophilic coating for improved insertion. 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 abnormal electrical activities of the heart. Common EP 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.

### **Interventional Oncology & Spine**

In July 2016, we acquired DFINE, Inc., which was headquartered in San Jose, California (“DFINE”). In connection with the acquisition, we formed a new product group, Interventional Oncology & Spine. The DFINE acquisition added a line of vertebral augmentation products for the treatment of vertebral compression fractures (“VCF”) as well as medical devices used to treat metastatic spine tumors. Our Interventional Oncology & Spine product group has been developed to enable greater focus on the broad range of products and is segmented into five portfolios: VCF, ablation, oncology, embolotherapy, and delivery systems.

#### *Vertebral Compression Fractures Portfolio*

VCFs occur when a vertebra cracks, fractures or collapses due to osteoporosis or cancer. VCFs can be extremely painful and have debilitating effects on a patient’s quality of life. Using our StabiliT® System, physicians treat VCFs by inserting small instruments through the skin into the fractured vertebra. Bone cement is injected through a hollow needle into the fractured bone. Our StabiliT® System is a comprehensive treatment system and includes access instruments, osteotomes, introducers, bone cement and corresponding mixing and delivery systems.

#### *Ablation Portfolio*

We offer our STAR® Tumor Ablation System to cancer patients for the palliative treatment of painful metastatic tumors. Targeted radiofrequency ablation using the STAR System offers patients pain relief and improved quality of life in a minimally invasive treatment. This procedure requires an articulating radiofrequency, or RF, device to be placed through the skin into the vertebral body and inserted directly into the tumor to ablate the tumor. Thermocouples embedded in the RF device allow for constant monitoring of the temperature directly in the ablation zone, which is a key feature when performing ablations near vital structures like the spinal cord. The STAR system includes ablation instruments, introducers, osteotomes and our MetaSTAR® RF Generator.

#### *Oncology Portfolio*

In the United States, we sell QuadraSphere® Microspheres for the treatment of hypervascularized tumors, including hepatoma and arteriovenous malformations. Malignant hepatoma, also known as hepatocellular carcinoma (“HCC”), is a common cancer and the third leading cause of cancer deaths worldwide. QuadraSphere Microspheres are precisely calibrated and designed to offer controlled, targeted embolization, treating HCC by stopping the blood flow to the tumors.

In Europe, as well as Brazil, Russia, and other emerging markets, we offer HepaSphere™ Microspheres for delivery of chemotherapy drugs in the treatment of primary and metastatic liver cancer.

#### *Embolotherapy Portfolio*

We offer Embosphere® Microspheres to treat hypervascularized tumors, including symptomatic uterine fibroids, and arteriovenous malformations in the United States as well as Europe and other international markets. Additionally, in certain markets outside of the U.S., we offer Embosphere Microspheres for hemostatic embolization and embolization of the prostatic arteries for the treatment of symptomatic benign prostatic hyperplasia.



We also offer embolic particles, namely our Bearing nsPVA®, globally for the treatment of hypervascularized tumors, including symptomatic uterine fibroids and vascular malformations.

#### *Delivery Systems Portfolio*

To enhance the ability to safely perform procedures in small vessels, we manufacture a variety of microcatheters for the controlled and selective infusion of diagnostic, embolic, or therapeutic agents into vessels. In 2016, we introduced our newest microcatheter, the SwiftNINJA®, which articulates up to 180 degrees in opposing directions. This articulating feature allows physicians to treat diseases that in the past would have been too difficult to access due to challenging patient anatomies. We continue to offer our Merit Maestro® Microcatheter, which has a swan neck design that allows physicians to “seat” the catheter in the vessel. The SwiftNINJA can be used for the controlled and selective infusion of diagnostic, embolic, or therapeutic materials into vessels. It is compatible with many key configurations of Embosphere®, Quadrasphere®, HepaSphere Bearing nsPVA®, and other competitive embolic products.

#### **Endoscopy**

Our endoscopy division, Merit Endotek, integrates advanced non-vascular stent technology with balloon dilators, inflation devices, guide wires, procedure kits, and other devices that are used by endoscopists in interventional gastroenterology and interventional pulmonology, 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 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 AEROMini® fully covered bronchial stent was launched in 2015 and features a low-profile delivery system designed to provide additional flexibility, and 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 available for sale outside the United States.

Merit Endotek’s biliary stent systems are marketed under the Alimaxx-B® brand name. Alimaxx-B stent systems are used by interventional gastroenterologists to palliate symptoms associated with malignant tumors affecting the bile duct. Additionally, we sell a plastic biliary stent that is used to restore patency and relieve symptoms associated with strictures and blockages within the biliary system. These stents are often used to “stage” treatment of malignant tumors such as pancreatic cancer and other serious conditions.

Merit Endotek’s esophageal balloon dilator, the Elation® Fixed Wire Balloon Dilator, was introduced late in 2015, and is intended for use in adult and adolescent populations to endoscopically dilate strictures of the esophagus. In 2016, we added a wire-guided balloon dilator, intended for use in the alimentary tract, to the Elation product line. These devices 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 procedures, we offer a variety of kits and accessories, including 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 operate a hypotube manufacturing facility in Galway, Ireland, which provides advanced laser cutting and ablation, passivation, cleaning and other hypotube manufacturing processes. Our Merit Hypotube™ is used as the catheter shaft in percutaneous transluminal coronary angioplasty and percutaneous transluminal angioplasty balloon catheters, as well as functional guide wires.

Our sensor division manufactures and sells microelectromechanical systems sensor components consisting of piezoresistive pressure sensors in various forms, including bare silicon die, die mounted on ceramic substrates, and fully calibrated components for numerous applications both inside and outside the healthcare industry.

### ***Marketing and Sales***

**Target Market/Industry.** Our principal target markets are peripheral intervention, cardiac intervention, interventional oncology and endoscopy. Within these markets our products are used in the following clinical areas: diagnostic and interventional cardiology; interventional radiology; neurointerventional radiology and surgery; vascular, general and thoracic surgery; electrophysiology; cardiac rhythm management; interventional pulmonology; interventional nephrology; orthopaedic spine surgery; interventional oncology and 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.

**Marketing Strategy.** As part of our product 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, peer-to-peer education, and patient outreach. We work closely with major centers involving our primary target markets in the areas of training, therapy awareness programs, clinical studies and ongoing research.

We also offer products to service the 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 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.

**Product Development Strategy.** Our product development 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; neurointerventional radiology and surgery; vascular, general and thoracic surgery; electrophysiology; cardiac rhythm management; interventional pulmonology; interventional nephrology; orthopaedic spine surgery; interventional oncology and pain management; outpatient access centers; computed tomography; ultrasound; and interventional gastroenterology. Suggestions for new products and product improvements may also come from engineers, marketing, sales people, physicians and technicians who perform clinical procedures.

When we believe 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 conceive, design, develop and introduce new products.

**U.S. and International Sales.** Sales of our products in the U.S. accounted for approximately 61% of our net sales in each of the years ended December 31, 2016, 2015 and 2014. In the U.S., we have a dedicated, direct sales organization primarily focused on selling to end-user physicians, hospitals and clinics, major buying groups and integrated healthcare networks.

Internationally, we employ sales representatives and contract with independent dealer organizations and custom procedure tray manufacturers to distribute our products worldwide, including territories in Europe, Africa, the Middle East, Asia, South and Central America, Oceania, and Canada. In 2016, our international sales grew approximately 9% over our 2015 international sales, and accounted for



approximately 39% of our net sales. China represents our most significant international sales market with net sales of approximately \$59.9 million, \$50.7 million, and \$40.7 million for the years ended December 31, 2016, 2015 and 2014, respectively. 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 have a global direct sales force of more than 280 employees located in the following geographic regions:

- United States—128 employees;
- Europe, Middle East and Africa—78 employees; and
- Asia Pacific, Canada, Latin America—80 employees.

Our largest non-U.S. market is China, which represented approximately ten percent of our net sales in 2016. We maintain a distribution center and administrative office in Beijing. We also have small sales offices in Shanghai, Guangzhou, and Hong Kong. We sell our products through more than 400 distributors in mainland China, who are responsible for reselling the products, primarily to hospitals. We employ over 50 sales people throughout China who work with our distributors to promote the clinical advantages of our products to clinicians and other decision makers at hospitals. Under this “modified direct” sales approach, our salespeople are involved with promoting the advantages of our products to clinicians and other customers, while the distributors handle sales transactions and address issues related to fulfillment and inventory management.

In Europe, the Middle East, and Africa, we have both corporate (i.e., direct) and modified corporate sales operations. Our corporate sales operations are based in 16 European countries, including the largest markets of the UK, France, Germany, and most recently Spain, where the Company transitioned from a long-standing distributor to a corporate sales structure near the end of 2016.

Our direct sales personnel are principally engaged in our Cardiac Intervention, Peripheral Intervention and Interventional Oncology and Spine product groups. Each division operates clinical education programs, often directed by leading subject matter personnel, who provide technical instruction on techniques and therapies to physicians, nurses, and technologists. We are currently conducting education programs specific to radial access, spinal intervention, surgical grafts, and electrophysiology.

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 applicable anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act, as well as all applicable laws and regulations in their respective countries.

In 2016, we began conversions from distributor-based sales models to direct sales models in Australia and Canada. We now supply hundreds of healthcare providers directly in Australia and Canada from Merit-operated distribution centers in those countries. We also began negotiations in 2016 with our long-time exclusive distribution partner in Japan to assume distribution responsibilities for most of our product lines in Japan. We expect this conversion to begin later this year. These distributor-to-direct sales conversions generally involve eliminating a distributor from the sales channel, either by acquiring the distributor or terminating the distribution relationship. Our goal with conversion is to obtain improved product pricing and more direct access to the end users of our products within these sales channels.

We consider training to be a critical factor in the success of our sales force. Members of our sales force are trained by our clinical marketers, our staff professionals, consulting physicians, and senior field trainers in their respective territories.

**OEM Sales.** Our global original equipment manufacturer (“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 products from other companies and sold under a Merit or third-party label. Products sold by our OEM division can be customized and enhanced to customer specifications, including packaging, labeling and a variety of physical modifications. Our 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, orthopaedic 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, or 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 2016, our U.S. sales force made sales accounting for approximately 45% of our net sales directly to U.S. hospitals and sales accounting for approximately six percent of our net 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 10% of our 2016 net sales. The remaining 39% of our 2016 net sales was attributable to sales 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 net sales during the year ended December 31, 2016.

### ***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 2016, 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 \$45.2 million, \$40.8 million, and \$36.6 million in 2016, 2015 and 2014, respectively.

We continue to develop new products and make improvements to our existing products utilizing many different sources. Our Chief Executive Officer and Executive Vice President of Global Research & 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

- Jackson Township, New Jersey
- Malvern, Pennsylvania
- Paris, France
- Pearland, Texas
- San Jose, California
- 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.

Given the specialization of our manufacturing personnel and processes in our Utah and Ireland facilities, we possess the capability to strategically shift the manufacture of more technologically-advanced products to those facilities, and utilize the manufacturing capacity of our other facilities for more commoditized products. The actual determination of manufacturing location will be based upon multiple factors, including technological capabilities, market demand, acquisition and integration activities and economic and competitive conditions.

Merit Sensors develops and markets silicon pressure sensors and presently supplies substantial portions of the sensors we utilize in our digital inflation devices and blood pressure transducers.

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

Our products are manufactured at several facilities, including facilities located in South Jordan and West Jordan, Utah; Malvern, Pennsylvania; Galway, Ireland; Venlo, The Netherlands; Paris, France; Pearland, Texas; Tijuana, Mexico; Joinville, Brazil; 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 product 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*

The medical products industry is highly competitive. Many of our competitors are much larger than us and have access to greater resources. We also compete with smaller companies that sell single or limited numbers of products in specific product lines or geographies. We compete globally in several market areas, including diagnostic and interventional cardiology; interventional radiology; neurointerventional radiology and surgery; vascular, general and thoracic surgery; electrophysiology; cardiac rhythm management; interventional pulmonology; interventional nephrology; orthopaedic spine surgery; interventional oncology and 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, clinical outcomes, 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, general surgery, thoracic surgery and pulmonology markets, we compete with large international, multi-divisional medical supply companies such as Cordis Corporation (Cardinal Health), Boston Scientific Corporation, Medtronic, C.R. Bard, Abbott Teleflex, Cook Incorporated, and Terumo Corporation. Medium-size companies we compete with include Vascular Solutions, B. Braun, Olympus Medical, Edwards Lifesciences, Argon Medical Devices, CONMED, AngioDynamics, Medcomp, and ICU Medical.

Based on available industry data, with respect to the number of procedures performed, we believe we are a leading provider of digital inflation technology in the world. In addition, we believe we are one of the market leaders in the United States for analog inflation devices. We believe we are a market leader in the United States for control syringes, waste-disposal systems, tubing and manifolds. We anticipate the recent and planned additions to our product lines will help us 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.

In the vertebral augmentation market, our main competitors are Medtronic and Stryker. In April 2016, Stryker acquired CareFusion, which had been a key competitor in this space. Both Medtronic and Stryker offer products to treat vertebral compression fractures, but only Medtronic offers products to treat metastatic spine tumors.

Within the field of uterine fibroid embolization, or UFE, we believe we are a market share leader. 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***

We rely on a combination of patents, trade secrets, trademarks, copyrights and confidentiality agreements to protect our intellectual property. 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, 2016, we owned or had a license to more than 800 U.S. and international patents and patent applications. Additionally, we hold exclusive and non-exclusive licenses to a variety of third-party technologies covered by patents and patent applications. In the aggregate, our intellectual property assets are critical to our business, but no single patent, trademark or other intellectual property asset is of material importance to our business.

The Merit® name and logo are trademarks in the U.S. and other countries. In addition to the Merit name and 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. As of December 31, 2016, we owned over 250 U.S. and foreign trademark registrations and trademark applications.

There is substantial litigation regarding patents and other intellectual property rights in the medical device industry. At any given time, we may be involved as either, or both, a plaintiff and a defendant in patent infringement actions. 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. In addition, intellectual property litigation is costly and may consume significant time of employees and management.

### ***Regulation***

**U.S. Regulation.** The Food and Drug Administration (“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 criminal prosecution. Such actions could have a material adverse effect on our business, financial condition or results of operations.

In October 2016, we received a subpoena from the U.S. Department of Justice seeking information on certain of our marketing and promotional practices. We are in the process of responding to the subpoena, which we anticipate will continue during 2017. The investigation is ongoing and at this time

we are unable to predict its scope, duration or outcome. Investigations such as this may result in the imposition of, among other things, significant damages, injunctions, fines or civil or criminal claims or penalties against our company or individuals.

**Overview of FDA Regulation of Devices.** The FDCA establishes a risk-based classification system for medical devices and applies regulatory controls commensurate with the risk posed by a device:

- Class I devices are those for which safety and effectiveness can be reasonably assured by adherence to the FDA's general regulatory controls, which include compliance with the applicable portions of the FDA's Quality System Regulations (QSRs), facility registration and product listing, reporting of certain adverse medical events and malfunctions, and compliance with FDA's restrictions against misbranding and adulteration. While most Class I devices are exempt from the 510(k) premarket notification process, some Class I devices also require 510(k) clearance by the FDA.
- Class II devices are subject to the FDA's general controls, including the design control requirements of the QSRs, and any other special controls deemed necessary by the FDA to provide reasonable assurance of the safety and effectiveness of the device. Premarket review and clearance by the FDA for Class II devices are accomplished through the 510(k) premarket notification procedure.
- Class III devices are those deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or those devices deemed not substantially equivalent to a legally marketed predicate device. Class III devices include those devices for which FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of the device.

**FDA Premarket Review.** In general, we cannot introduce a new medical device into the market until we obtain market clearance through a 510(k) premarket notification or approval through a premarket approval ("PMA") application. Some devices, typically lower-risk devices, are subject to specific exemptions from premarket review. In addition, in limited cases devices may come to the market through alternative procedures, such as a *de novo* classification request or humanitarian device exemption.

To obtain 510(k) clearance, a device manufacturer must submit a premarket notification to the FDA demonstrating that the device is substantially equivalent to another legally marketed predicate device. A predicate device is a device that has been cleared through the 510(k) process; a device that was legally marketed prior to May 28, 1976; a device that has been downclassified by the FDA to Class I or Class II; or a device that FDA has previously determined to be exempt from the 510(k) process. To be substantially equivalent, the notification must show that the new device has the same intended use and the same technology as the predicate device, or, if the new device has different technology, that the device is as safe and effective as the predicate device and does not raise different questions of safety and effectiveness. Performance testing is generally required to demonstrate substantial equivalence, and, for some devices, clinical data may be required. The standards and data requirements necessary for the clearance of a new device may be unclear or may be subject to change. In addition, FDA may publish or adopt special controls it deems necessary to provide a reasonable assurance of the safety and effectiveness of a device, which might include standards for the testing and clearance of a new device. 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 the submission of a *de novo* classification request or PMA application for the device.

A *de novo* classification is an alternate pathway to classify novel devices that are low to moderate risk but for which no substantially equivalent predicate device exists. Clearance of a *de novo* request generally takes six months to one year from the time of submission of the *de novo* request, although it can take longer.

A PMA application is required for Class III devices. The application must demonstrate that there is reasonable assurance that the device is safe and effective for its intended use based on valid scientific evidence. 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. 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 devices. 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.

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. 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. For clinical trials involving a device that does not present a significant risk, the sponsor is not required to obtain approval of an IDE, but the sponsor must obtain the review and approval of an institutional review board. Both significant risk and non-significant risk trials are subject to additional FDA regulations, including a requirement to obtain informed consent and reporting and recordkeeping requirements. We, the FDA, or the 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.

The FDA clearance and approval processes for medical devices are expensive, uncertain and lengthy. There can be no assurance that we will be able to obtain necessary regulatory clearances or approvals for any product on a timely basis or at all. Delays in receipt of or failure to receive such clearances or approvals, the loss of previously received clearances or approvals, or the failure to comply with existing or future regulatory requirements could have a material adverse effect on our business, financial condition or results of operations. In addition, if the FDA discovers that an applicant has submitted false or misleading information, the FDA may refuse to review submissions until certain requirements are met pursuant to its Application Integrity Policy, which specifies procedures that FDA personnel should follow to ensure the integrity of data and information in applications submitted for FDA review and approval.

We are currently conducting a clinical trial 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, including inconclusive or negative results of our trials or those conducted by our competitors or other third parties. 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.** Certain modifications to our marketed devices, including certain manufacturing changes, product enhancements and product line extensions, require new 510(k) clearance or approval of a PMA supplement. For devices marketed under an approved PMA, we must submit a PMA supplement to FDA for review and approval prior to making a change to the device that affects the safety or effectiveness of the device, including changes to the design, manufacturing or labeling of the device. Likewise, for 510(k)-cleared devices, we must obtain new FDA 510(k) clearance when there is a major change or modification in the intended use or indications for use or a change or modification of the device that could significantly affect the safety or effectiveness of the device. In some cases, clinical data may be required to support a PMA supplement or 510(k) premarket notification for a device modification. The FDA may determine that a modified device is not substantially equivalent to the marketed 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 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, record keeping, personnel training, supplier qualification, design controls, complaint handling, 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. If 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. If the FDA determines that our promotional materials constitute promotion of an uncleared or unapproved use, or otherwise violate the FDCA, it could request that we modify our promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a notice of violation, a warning letter, injunction, seizure, civil fines or criminal penalties. Allegations of off-label promotion can also result in enforcement action by federal, state, or foreign enforcement authorities and trigger significant civil or criminal penalties, including exclusion from the Medicare and Medicaid programs and liability under the False Claims Act, discussed further below.

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 or misleading 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.

In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims.

**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. Additionally, the laws of the United States require imported articles to have their labels accurately marked with the appropriate country of origin, the violation of which may result in confiscation, fines and penalties.

**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 QSR at the time of the last FDA inspection.

Additionally, the export of our products to certain countries is subject to restrictions due to trade and economic sanctions imposed by the United States, the European Union and other governments and organizations. The U.S. Departments of Justice, Commerce, State and Treasury and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of economic sanctions laws, export control laws, and other federal statutes and regulations, including those established by the Office of Foreign Assets Control (“OFAC”). Under these laws and regulations, as well as other export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses and may seek to impose modifications to business practices, including cessation of business activities in sanctioned countries or with sanctioned persons or entities.

**Additional Postmarket Requirements.** Medical device manufacturers are also subject to other postmarket requirements, including product listing and establishment regulations, compliance with FDA’s requirements for unique device identifiers, reports of corrections and removals and other requirements. Medical Device Reporting (“MDR”) requirements of the FDA, vigilance reporting requirements under the European Medical Devices Directive and similar regulations in other foreign markets, require manufacturers to report to the FDA or an equivalent foreign regulatory body any incident in which their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur. Our obligation to report under the MDR

regulations is triggered on the date on which we become aware of an adverse event and the nature of the event. If we fail to comply with our MDR reporting obligations, the FDA could issue warning letters or untitled letters, take administrative actions, commence criminal prosecution, impose civil monetary penalties, revoke our device clearances, seize our products, or delay the clearance of our future products.

The FDA regularly inspects companies to determine compliance with the QSRs and other postmarket requirements. Failure to comply with statutory requirements and the FDA's regulations can result in an FDA Form 483 (which is issued by the FDA at the conclusion of an inspection when an investigator has observed any conditions that may constitute violations), public warning letters, monetary penalties against a company or its officers and employees, suspension or withdrawal of regulatory approvals, operating restrictions, total or partial suspension of production, injunctions, product recalls, product detentions, refusal to provide export certificates, seizure of products and criminal prosecution.

**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"). Adoption of the new regulations is anticipated in 2017 and is expected to include a three-year transition period. The new regulations are not expected to change fundamentally the regulatory framework for medical devices in the EEA. However, among other things, the new regulations are likely to include stricter clinical evidence requirements, impose additional reporting obligations on manufacturers of high risk devices, and require manufacturers to appoint an individual with responsibility for regulatory compliance. 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 that are covered and reimbursed by governmental payers, such as Medicare, and or private health plans. In general, these third-party payers cover a medical device and/or related procedure only when the payer determines that healthcare outcomes are supported by medical evidence and the device or procedure is medically necessary for the diagnosis or treatment of the patient's illness or injury. Even if a device has received clearance or approval for marketing by the FDA, there is no certainty that third-party payers will cover and reimburse for the cost of the device and related procedures. Because of increasing cost-containment pressures, some private payers in the U.S. and government payers in foreign countries may also condition payment on the cost-effectiveness of the device or procedure. 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 healthcare providers such as hospitals and physicians cannot obtain adequate coverage and reimbursement for our products or the procedures in which they are used, this may affect demand for our products and 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 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 imposed on medical device manufacturers a 2.3% excise tax on U.S. sales of certain medical devices, which adversely affected our gross profit and earnings for our marketed products in 2015. At the end of 2015, the excise tax was suspended for the 2016 and 2017 tax years. The tax will automatically be reinstated beginning on January 1, 2018 absent further legislation action to extend the suspension or repeal the tax. We cannot predict whether any such action will be taken and whether the suspension will continue past 2017.

Judicial challenges to, as well as legislative and executive initiatives to modify, limit, or repeal, the PPACA have been initiated and continue. For instance, in January 2017, President Trump issued an executive order which, among other things, stated that one of the priorities of the current administration is to seek prompt repeal of the PPACA and instructed all executive departments and branches to exercise their authority and discretion to minimize the economic and regulatory burdens of the PPACA to the maximum extent permitted by law. In light of such challenges to, and efforts to repeal or modify, the PPACA, we cannot predict what healthcare programs and regulations will be implemented or changed at the federal or state level in the United States, or the effect that any future legislation or regulation may have on our operations.

The 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. Other jurisdictions outside the United States have also begun adopting similar physician transparency laws. 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 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 corruptly offering, paying, or promising to pay anything of value to foreign officials for the purpose of obtaining or maintaining business. The FCPA also requires that we maintain fair and accurate books and records and devise and maintain an adequate system of internal accounting controls. Among other requirements to implement compliance, we are required to train our U.S. and international employees, and to train and monitor foreign third parties with whom we contract, e.g., distributors, to ensure compliance with these anti-corruption laws. Failing to comply with the FCPA or any other 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 statutory exemptions or 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 to procure their business. Settlements of these government cases have involved significant fines and 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. Most 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 the Federal Claims Act and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines and imprisonment.

**Privacy and Security.** The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the Health Information Technology for Economic and Clinical Health Act (the "HITECH Act"), and 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. Additionally, many state laws regulate the use and disclosure of health information and require notification in the event of breach of such information.

Although we do not believe we are a "covered entity" under HIPAA and do not meet the definition of "Business Associate, we are committed to maintaining the security and privacy of patients' health information and believe that we meet the expectations of the HIPAA rules in all material respects. However, to the extent we become subject to HIPAA, whether through a change in our business model or an enforcement action brought by the U.S. government, we would be directly subject to a broader range of requirements under HIPAA, HITECH, the rules issued thereunder and their respective 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.

### ***Seasonality***

Our worldwide sales have not historically reflected a significant degree of seasonality; however, customer purchases have historically been lower during the third quarter of the year, as compared to other quarters. This reflects, among other factors, lower demand during summer months in countries in the northern hemisphere.

### ***Employees***

As of December 31, 2016, we employed 4,150 people. None of our U.S. employees are subject to collective bargaining agreements; however, certain of our European employees are subject to such agreements. We believe our employee relations are generally good. Although our European employees will likely continue to be subject to collective organizing and bargaining activities, we do not expect such activities to materially affect our future operations.

### ***Recent Developments***

On January 31, 2017, we acquired substantially all the assets, including intellectual property covered by approximately 40 patents and pending applications, and assumed certain liabilities, of Catheter Connections, Inc. (“Catheter Connections”), in exchange for a payment for \$38 million. Catheter Connections, which is based in Salt Lake City, Utah, developed and marketed the DualCap® System, an innovative family of disinfecting products designed to protect patients from intravenous infections resulting from infusion therapy.

On January 31, 2017, we completed the acquisition of the critical care division of Argon Medical Devices, Inc. (“Argon”). As part of the acquisition, we acquired several Argon subsidiaries located in Singapore, Japan and Europe, a manufacturing facility in Singapore, as well as approximately 100 registered trademarks and other intellectual property, and inventory located in the United States. The products within the acquired critical care division include pressure monitoring transducers and various catheters. The transaction consideration was valued at approximately \$10 million.

Because the acquisitions of the Catheter Connections assets and the critical care division of Argon were completed in 2017, the financial condition and results of operations presented herein are those of Merit and its subsidiaries prior to the completion of these acquisitions, and do not include the financial condition or results of operations of Catheter Connections or the critical care division of Argon.

### ***Available Information***

We file annual, quarterly and current reports and other information with the SEC. These materials can be inspected and copied at the SEC’s Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Copies of these materials may also be obtained by mail at prescribed rates from the SEC’s

Public Reference Room at the above address. Information about the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of the SEC's Internet website is [www.sec.gov](http://www.sec.gov).

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

#### ***Financial Information About Foreign and Domestic Sales***

For financial information relating to our foreign and domestic sales see Note 12 to our consolidated financial statements set forth in Item 8 of this report.

#### **Item 1A. Risk Factors.**

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

***We may be unable to successfully manage growth, particularly if accomplished through acquisitions, and the integration of acquired businesses may present significant challenges that could harm our operations.***

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 acquisition of DFINE, Inc. in 2016. 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. For instance, prior to its acquisition, DFINE was not profitable or cash flow positive and, as such, we have sought to make DFINE operations accretive to our results of operations by, among other things, substantially reducing the number of employees at DFINE, restructuring our sales and marketing operations, and consolidating a significant portion of the manufacturing activities related to the DFINE products. These and other efforts to integrate DFINE, as well as efforts to integrate future acquisitions, may be hampered by delays, the loss of certain employees, suppliers or customers, proceedings resulting from employment terminations, culture clashes, unbudgeted costs, and other issues at certain levels, which may occur at levels that are more severe or prolonged than anticipated.

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, including regulatory, infringement, product liability, discrimination or other legal claims or issues. 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 may not be able to effectively protect our intellectual property, which could harm our business and financial condition.***

Our ability to remain competitive is dependent, in part, upon our ability to protect our intellectual property rights and 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. Additionally, these measures may not prevent competitors from duplicating our products or gaining access to our proprietary information and technology. Third parties may copy all or portions of our products or otherwise use our intellectual property without authorization, and we may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, vendors, former employees and current employees, despite the existence of nondisclosure and confidentiality agreements and other contractual restrictions, all of which could have an adverse effect on our business, operations, or financial condition.

Third parties may also develop similar or superior technology independently or by designing around our patents. In addition, the laws of some foreign countries do not offer the same level of protection for our intellectual property as the laws of the U.S. Further, no assurances can be given that any patent application we have filed or will file will result in a patent being issued, or that any existing or future patents will afford adequate or meaningful protection against competitors or against similar technologies. All of our patents will eventually expire and some of our patents, including patents protecting significant elements of our technology, will expire within the next several years.

Filing, prosecuting and defending our intellectual property in all countries throughout the world may be prohibitively expensive. Litigation may be necessary in the future to enforce our intellectual property rights, protect our trade secrets or to determine the validity and scope of proprietary rights claimed by others. Any such lawsuits that we might initiate could be expensive, take significant time and divert management's attention from our business. Litigation also puts our patents at risk of being invalidated or interpreted narrowly. Additionally, we may provoke third parties to assert claims against us. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patent and other intellectual property protection which makes it difficult to stop infringement. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially valuable.

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

Our commercial success will depend in part on not infringing or violating the intellectual property rights of others. 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. We may not be aware of whether our products do or will infringe existing or future patents or the intellectual property rights of others. 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, distract management from day-to-day operations and harm our brand or reputation, which in turn could harm our business or results of operations. If we are not successful in defending such claims, we could be required to stop selling, delay shipments of, or redesign, our products, discontinue the use of related trademarks, technologies or designs, pay monetary amounts as damages, enter into royalty or licensing arrangements or satisfy indemnification obligations that we have with some of our customers. Royalty or licensing arrangements that we may seek in such circumstances may not be available to us on commercially reasonable terms or at all and we may not be able to redesign applicable products in a way to avoid infringing the intellectual property rights of others. We have made and expect to continue 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.

***The medical device industry is experiencing greater scrutiny and regulation by governmental authorities. Moreover, in October 2016, we received a subpoena from the U.S. Department of Justice seeking information on our marketing and promotional practices. If governmental authorities determine that we have violated laws or regulations, including in respect of our marketing or promotional practices, our company or our employees may be subject to various penalties, including civil or criminal penalties.***

Our medical devices and business activities are subject to rigorous regulation by the FDA and other federal, state and foreign governmental authorities. These authorities and members of Congress have been increasing their scrutiny of 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. If we fail to comply with applicable regulatory requirements, we may be subjected to a wide variety of sanctions and enforcement actions, including warning letters that require corrective action, injunctions, product seizures or recalls, suspension of product manufacturing, revocation of approvals, exclusion from participation in government healthcare programs, civil fines, and criminal penalties.

In October 2016, we received a subpoena from the U.S. Department of Justice seeking information on certain of our marketing and promotional practices. Although we are in the process of responding to the subpoena, we may not be able to resolve this matter, or similar matters that may arise in the future, without our company or employees incurring significant fines, penalties, or other adverse civil or criminal consequences. Even if we are successful in resolving the pending matter without such consequences, we have incurred, and anticipate that we will continue to incur, substantial costs in connection with the matter. The pending matter, or other governmental proceedings, could significantly impact our reputation and divert management's attention and resources from growing our business, which in turn could harm our business, results of operations, financial condition and ability to obtain financing on reasonable terms or at all.

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 on our operations.

***Use of our products in unapproved circumstances could expose us to liabilities.***

The marketing approvals from the FDA and other regulators of certain of our products are, or are expected to be, limited to specific uses. We are prohibited from marketing or promoting any unapproved use of our product. However, physicians may use these products in ways or circumstances other than those strictly within the scope of the regulatory approval. Although the product training we

provide to physicians and other healthcare professionals is limited to approved uses, some physicians may be using our products in procedures that are not included in the clearance or approval of the products. Consequently, claims may be asserted by the FDA or other enforcement agencies that we are not in compliance with applicable laws or regulations, or have improperly promoted our products for uncleared or unapproved uses. The FDA or such other agencies 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.

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

We have extensive global operations, which necessitate that we seek various regulatory approvals for our products in the jurisdictions where our products are sold. Different regulatory requirements for product approvals and our need to comply with different regulatory regimes could impact our business.

Substantially all of our products are “devices,” as defined in the FDCA, and the manufacture, distribution, record keeping, labeling and advertisement of substantially all of our products are subject to regulation by the FDA in the United States and 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, ISO standards and similar requirements of foreign countries, which may cover, among others, the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipment of medical devices. Failure to comply with such requirements, or later discovery of previously unknown problems with our products or our third-party manufacturers’ manufacturing processes, including any failure to take satisfactory corrective action in response to an adverse QSR inspection, could result in total or partial suspension of production or distribution, a regulatory agency’s refusal to grant pending or future clearances or approvals for our products, withdrawal or suspension of regulatory clearances or approvals, clinical holds, warning letters or untitled letters or refusal to permit the import or export of our products.

***The FDA regulatory clearance process is expensive, time-consuming and uncertain, and the failure to obtain and maintain required regulatory clearances and approvals could prevent us from commercializing our products.***

Before we can introduce a new device or a new use of or a claim for a cleared device in the United States, we must generally obtain market clearance from the FDA through the 510(k) premarket notification process or through a PMA application, unless an exemption for lower-risk devices or an alternative procedure, such as a de novo classification request or a humanitarian device exemption, applies. The FDA clearance and approval processes for medical devices are expensive, uncertain and time-consuming.

To obtain 501(k) clearance, a device manufacturer must submit a premarket notification to the FDA demonstrating that the device is substantially equivalent to another legally marketed predicate device. To be substantially equivalent, the notification must show that the new device has the same intended use and the same technology as the predicate device, or, if the new device has different technology, that the device is as safe and effective as the predicate device and does not raise different questions of safety and effectiveness. Performance testing is generally required to demonstrate substantial equivalence, and, for some devices, clinical data may be required. The standards and data requirements necessary for the clearance of a new device may be unclear or may be subject to change. In addition, the FDA may publish or adopt special controls it deems necessary to provide a reasonable assurance of the safety and effectiveness of a device, which might include standards for the testing and clearance of a new device. In addition to the time required to conduct clinical trials, if necessary, it usually takes between three months and one year from the date a 510(k) notification is submitted to

obtain clearance, 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 the submission of a de novo classification request or PMA application for the device.

A de novo classification is an alternate pathway to classify novel devices that are low to moderate risk but for which no substantially equivalent predicate device exists. Clearance of a de novo request generally takes six months to one year from the time of submission of the de novo request, although it can take longer.

A PMA application is required for Class III devices. The application must demonstrate that there is reasonable assurance that the device is safe and effective for its intended use based on valid scientific evidence. The PMA application process generally takes several years to complete and is expensive, as it typically includes, among other things, human clinical trials, manufacturing facility inspection, bench tests, and laboratory and animal studies, which can be costly to conduct. The FDA may also require additional testing or clinical trials prior to approval or as a condition of approval. Even if the FDA approves the PMA application, it may nevertheless 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.

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 such trials in the U.S.. 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. For clinical trials involving a device that does not present a significant risk, the sponsor is not required to obtain approval of an IDE, but the sponsor must obtain the review and approval of an institutional review board. Both significant risk and non-significant risk trials are subject to additional FDA regulations, including a requirement to obtain informed consent and reporting and recordkeeping requirements. We, the FDA, or the 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.

We are also required to seek FDA clearance for certain manufacturing changes, product enhancements and product line extensions, which may require new 510(k) clearance or approval of a PMA supplement. For devices marketed under an approved PMA, we must submit a PMA supplement to FDA for review and approval prior to making a change to the device that affects the safety or effectiveness of the device, including changes to the design, manufacturing or labeling of the device. Likewise, for 510(k)-cleared devices, we must obtain new FDA 510(k) clearance when there is a major change or modification in the intended use or indications for use or a change or modification of the device that could significantly affect the safety or effectiveness of the device. In some cases, clinical data may be required to support a PMA supplement or 510(k) premarket notification for a device modification.

The FDA requires every manufacturer to make the determination regarding the need for a new 510(k) submission or a PMA supplement in the first instance, but the FDA may review the manufacturer's decisions not to seek a new 510(k) or PMA supplement. We may make changes to our cleared products without seeking additional clearances or approvals if we believe such clearances or approvals are not necessary. However, the FDA may disagree and determine that such a modified device is not substantially equivalent to the marketed device or may require additional information, including clinical data, to be submitted before a determination is made, in which case we may be required to delay the introduction and marketing of our modified products, redesign our products, conduct clinical trials to support any modifications and pay significant regulatory fines or penalties. In

addition, the FDA may not approve or clear our products for the indications that are necessary or desirable for successful commercialization.

There is no assurance that we will be able to obtain the necessary regulatory clearances or approvals for any product on a timely basis or at all. Further, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared products on a timely basis. Delays in receipt of, or failure to obtain, regulatory clearances for any product enhancements or new products we develop would result in delayed or no realization of revenue from such product enhancements or new products and in substantial additional costs, which could decrease our profitability.

In addition, we are required to continue to comply with applicable FDA and other regulatory requirements once we have obtained clearance for a product. We cannot assure you that we will successfully maintain the clearances we have received or may receive in the future. In addition, our existing clearances can be revoked if any issues arise that bring into question our products' safety or effectiveness. The loss of previously received clearances or approvals, or the failure to comply with existing or future regulatory requirements could also have a material adverse effect on our business.

***We are subject to export control laws, customs laws, sanctions laws and other laws governing our operations in the U.S. and other countries. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, which could adversely affect our business, results of operations and financial condition.***

Our global operations expose us to trade and economic sanctions and other restrictions imposed by the United States, the European Union and other governments and organizations. The U.S. Departments of Justice, Commerce, State and Treasury and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of economic sanctions laws, export control laws, and other federal statutes and regulations, including those established by OFAC. Under these laws and regulations, as well as other export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to business practices, including cessation of business activities in sanctioned countries or with sanctioned persons or entities and modifications to compliance programs, which may increase compliance costs, and may subject us to fines, penalties and other sanctions. A violation of these laws or regulations could adversely impact our business, results of operations and financial condition.

***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 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.***

In connection with our acquisition of DFINE, we entered into a Second Amended and Restated Credit Agreement, dated July 6, 2016, with the lenders who are or may become party thereto, Wells Fargo Bank, National Association, as administrative agent, swingline lender and a lender, and Wells Fargo Securities, LLC, as sole lead arranger and sole bookrunner, which was amended on September 28, 2016 (as amended, the “Second Amended Credit Agreement”). The Second Amended 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.

We have pledged substantially all of our assets as collateral for the Second Amended Credit Agreement. Our breach of any covenant in the Second Amended Credit Agreement, not otherwise cured, waived or amended, could result in a default under that agreement and could trigger acceleration of the underlying obligations. Any default under the Second Amended Credit Agreement could adversely affect our ability to service our debt and to fund our planned capital expenditures and ongoing operations. The administrative agent and lenders under the Second Amended Credit Agreement have available to them the remedies typically available to lenders and secured parties, including the ability to foreclose on the collateral we have pledged. Any default under the Second Amended Credit Agreement would at a minimum harm our ability to service our debt and to fund our prospective capital expenditures and ongoing operations. It could lead to an acceleration of indebtedness and foreclosure on our assets.

The Second Amended Credit Agreement provides for a total potential borrowing base of \$425.0 million, which is \$100.0 million more than the aggregate amount we were permitted to borrow under our prior credit agreement. Under the terms of the Second Amended Credit Agreement, it may be more difficult for us to comply with leverage ratios and other restrictive covenants in the Second Amended Credit Agreement, compared to our prior credit agreement. We may also have less cash available for operations and investments in our business, as we will be required to use additional cash to satisfy the minimum payment obligations associated with this increased indebtedness.

***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, in some cases, preclinical and 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, including inconclusive or negative results of our trials or those conducted by our competitors or other third parties. Any clinical trials we undertake in the future will likely be subject to these and similar risks. 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 harm 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 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.

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

The PPACA was enacted into law in March 2010, 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 was suspended for the 2016 and 2017 tax years, during the year ended December 31, 2015 we incurred \$4.3 million related to this tax, which reduced our gross profit by 0.8%. We cannot predict whether the suspension will be continued beyond 2017. In addition, the costs of compliance with the PPACA's 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.

Judicial challenges to, as well as legislative and executive initiatives to modify, limit, or repeal, the PPACA have been initiated and continue. For instance, in January 2017, President Trump issued an executive order which, among other things, stated that one of the priorities of the current administration is to seek prompt repeal of the PPACA and instructed all executive departments and branches to exercise their authority and discretion to minimize the economic and regulatory burdens of the PPACA to the maximum extent permitted by law.

We also currently market, and intend to continue to market, our products in Europe. To market our products in the Member States of the European Economic Area ("EEA") under the CE conformity mark, our devices are required to comply with the essential requirements, including a completion of a conformity assessment procedure which varies in severity based on the type and classification of the medical device, of the EU Medical Devices Directives (Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended). Since 2012, the European authorities have been working on a reform of the E.U. regulatory framework for medical devices. A final proposal for a new regulation (the "Medical Devices Regulation") has been agreed upon by the European Commission and the European Parliament in June 2016 and is expected to be formally approved and enter into force in the first half of 2017 and become applicable three years thereafter. The adoption of the Medical Devices Regulation may, however, be materially delayed. In its current form it would, among other things, impose additional reporting requirements on manufacturers of high risk medical devices, impose an obligation on manufacturers to appoint a "qualified person" responsible for regulatory compliance, and provide for more strict clinical evidence requirements. These new rules and procedures may result in increased regulatory oversight of any future high-risk devices that we may develop and this may, in turn, increase the costs, time and requirements that need to be met in order to maintain or place such devices on the EEA market.

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, or uncertainty with respect to potential changes, that lower reimbursements for our products or reduce medical procedure volumes could harm 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 harm 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.

***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 or death 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. Product liability claims may be brought by individuals or by groups seeking to represent a class. We have previously faced claims by patients claiming injuries from our products. To date, these claims have not resulted in material harm to 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 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, reduce our revenue, divert management's attention from our business, and harm our reputation.

***Our products may cause or contribute to adverse medical events that we are required to report to the FDA, and if we fail to do so, we may be subject to sanctions that may materially harm our business.***

Our products are subject to medical device reporting ("MDR") regulations, which require us to report to the FDA any incident in which our products may have caused or contributed to a death or serious injury, or in which our products malfunctioned and, if the malfunction were to recur, it could likely cause or contribute to a death or serious injury. Our obligation to report under the MDR regulations is triggered on the date on which we become aware of an adverse event and the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or if the product characteristic that caused the adverse event is removed in time from our products. If we fail to comply with our MDR reporting obligations, the FDA could issue warning letters or untitled letters, take administrative actions, commence criminal prosecution, impose civil monetary penalties, revoke our device clearances, seize our products, or delay the clearance of our future products.

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 harmed.

***We lack direct sales and marketing capabilities in many countries, and are wholly dependent on our distributors for the commercialization of our products in these countries. If we are unable to maintain or establish sales capabilities on our own or through third parties, we may not be able to commercialize any of our products in those countries.***

We have no or limited direct sales or marketing capabilities in some of the regions and countries in which our products are sold, including, among others, China, Russia and Japan. We have entered

into distribution agreements with third parties to market and sell our products in those countries in which we do not have a direct sales force and in those countries in which we utilize a “modified direct” sales approach. If we are unable to maintain or enter into such distribution arrangements on acceptable terms, or at all, we may not be able to successfully commercialize our products in certain countries. Moreover, to the extent that we enter into distribution arrangements with other companies, our revenues, if any, will depend on the terms of any such arrangements and the efforts of others. These efforts may turn out not to be sufficient and our third-party distributors may not effectively sell our products. In addition, although our contract terms require our distributors to comply with all applicable laws regarding the sale of our products, including anti-competition, anti-corruption, anti-money laundering and sanctions laws, we may not be able to ensure proper compliance. If our distributors fail to effectively market and sell our products in full compliance with applicable laws, our results of operations and business could be impacted.

Our employees, independent contractors, consultants, manufacturers and distributors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, manufacturers and distributors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates healthcare laws and regulations of the FDA and other federal, state and international authorities, manufacturing standards, and laws that require the true, complete and accurate reporting of financial information or data. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties.

***The size of the market for our product groups has not been established with precision, and may be smaller than we estimate.***

Our estimates of the annual total addressable market for our cardiovascular and endoscopy market segments are based on a number of internal and third-party estimates, including published industry data. While we believe these factors have historically provided and may continue to provide us with effective tools in estimating the total market for our products, these estimates may not be correct and the conditions supporting our estimates may change at any time, thereby reducing the predictive accuracy of the underlying factors we consider in our analysis. As a result, our estimates of the annual total addressable market for our products may prove to be incorrect. If the actual number of patients who would benefit from our products and the annual total addressable market for our products is smaller than we have estimated, our sales growth may be impaired and our business adversely impacted.

***Consolidation in the healthcare industry, group purchasing organizations or public procurement policies could lead to demands for price concessions, which may impact our ability to sell our products at prices necessary to support our current business strategies.***

Healthcare costs have risen significantly over the past decade, which has resulted in or led to numerous cost reform initiatives by legislators, regulators and third-party payers. Cost reform has triggered a consolidation trend in the healthcare industry to aggregate purchasing power, which may create more requests for pricing concessions in the future. Additionally, group purchasing organizations,

independent delivery networks, public procurement policies and large single accounts may continue to use their market power to consolidate purchasing decisions for hospitals and healthcare service providers. We expect that market demand, government regulation, third-party coverage and reimbursement policies and societal pressures will continue to change the healthcare industry worldwide, resulting in further business consolidations and alliances among our customers, which may exert further downward pressure on the prices of our products.

***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 competitors 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 increasingly subject to market risk relating to foreign currency. Those fluctuations could have a negative impact on our margins and financial results. For example, during 2016 and 2015, the exchange rate between all applicable foreign currencies and the U.S. Dollar resulted in a decrease in our net sales of approximately \$4.9 million and \$11.3 million, respectively.

For the year ended December 31, 2016, approximately \$154.3 million, or 26%, of our net sales were denominated in foreign currencies, with our Euro-denominated sales representing our largest single currency risk. If the rate of exchange between foreign currencies declines against the U.S. Dollar, we may not be able to increase the prices we charge our customers for products whose prices are denominated in 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 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 of the healthcare industry and the cost-containment efforts of our customers and third-party payers, 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 harmed.

***We may be unable to accurately forecast customer demand for our products and manage our inventory, including rapid increases in the demand for our products, particularly if the increase may not be sustained.***

To ensure adequate supply, we must forecast our inventory needs and place orders with our suppliers based on estimates of future demand for particular products. Our ability to accurately forecast demand for our products could be negatively affected by many factors, including our failure to accurately manage our expansion strategy and customer acceptance of new products, product introductions by our competitors, an increase or decrease in customer demand for our products or for products of our competitors, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions. Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which would impact our gross margin. Conversely, if we underestimate customer demand for our products, our manufacturing facilities may not be able to deliver products to meet our order requirements, which could damage our reputation and customer relationships.

In particular, due to regulatory issues experienced by a competitor during the year ended December 31, 2016 we experienced an increase in demand for certain of our products. We do not know whether this increase will be short-term, medium-term or sustained, nor can we presently estimate the amount of the increase. As a result of this increase, demand for those products may exceed our inventory and manufacturing capacity. In response to the development, we have increased capacity at some of our existing facilities; however, this increase may not be sufficient to meet demand and could place stress on our human and other resources. It may also place stress on our relationships with third-party suppliers. In the short term, we cannot outsource this manufacturing because our products need to be manufactured to exact specifications, in a clean environment and by a manufacturer that satisfies certain regulatory requirements. This is forcing us to make allocation decisions among existing and new customers. We may be unable to efficiently manage this increase in demand for certain products. In addition, such products are lower margin products and the increase in sales of the products may reduce our gross margins. Failure to efficiently manage the situation could result in the loss of skilled employees or damage our existing supply relationships. A rapid increase in production may also lead to failures in our internal controls, including those related to quality, operations, or financial reporting. Any such failures on our part may result in long-term declines in our profitability and results of operations.

***International and national economic and industry conditions constantly change, and could harm 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, including, for instance, potential changes to the economic relationship between the United States and Mexico, China, and other countries in which we operate as a result of the new U.S. administration, and other changes and developments that we cannot anticipate, each of which could harm our business and results of operations. 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 harm our business or results of operations. Our customers may experience financial difficulties or be unable to borrow money to fund their operations, which may harm 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.

In particular, the new U.S. Administration has called for and may introduce substantial changes to fiscal, healthcare, trade and tax policies and legislation, which may include comprehensive tax reform and changes to existing trade agreements, including, but not limited to, the North American Free Trade Agreement (“NAFTA”). Such changes may have a significant impact on our operations and financial results. In particular, the potential enactment of tariffs on goods imported into the U.S., including but not limited to, goods imported from Mexico where we manufacture many of our products that we sell internationally, could adversely affect our gross profit margins. If enacted, any legislation by the U.S. federal government that restricts trade, such as tariffs, trade barriers, and other protectionist or retaliatory measures taken by governments in Europe, Asia, and other regions, could adversely impact our ability to sell products and services internationally. We cannot predict the impact, if any, of these changes to our business. If economic conditions worsen or fail to improve, changes in legislation impact the relationship between the U.S. and Mexico and other countries in which we operate or the continuity of NAFTA and other trade agreements, or new legislation is passed related to the healthcare system, fiscal or tax policies, customer demand may not materialize to the levels we require to achieve our anticipated financial results, which could have a material adverse effect on our business, financial condition, results of operations, or cash flows.

On June 23, 2016, the United Kingdom held a referendum in which voters approved an exit from the European Union (“Brexit”). As a result of the referendum, negotiations are under way to determine the future terms of the United Kingdom’s relationship with the European Union, including the terms of trade. It is possible that there will be greater restrictions on the movement of goods and people between the United Kingdom and the European Union countries and increased regulatory complexities, which could affect our ability to sell products in certain European Union countries and in the United Kingdom. Brexit could adversely affect European and worldwide economic and market conditions and could further contribute to instability in global financial and foreign exchange markets, including volatility in the value of the British pound and Euro, to which we have significant exposure. In addition, other European countries may seek to conduct referenda with respect to continuing membership with the European Union. We do not know to what extent such changes will impact our business.

All of the above developments, and others that we cannot anticipate, could adversely affect our business, operations and financial results.

***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 and medical procedures.***

A significant portion of our revenues is attributable to sales of our inflation devices. During the year ended December 31, 2016, sales of our inflation devices (including inflation devices sold in custom kits and through OEM channels) accounted for approximately 12% of our net sales. 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.

***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 harmed by natural disasters or significant human events, such as a war, civil unrest, terrorist attack, riot, strike, slowdown, or similar events. Any disruption in our manufacturing or transportation could materially harm 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. Relevant authorities may also disagree with tax positions we have taken and assess further taxes. Proposals for broad reform of the existing United States corporate tax system are under evaluation by various legislative and administrative bodies. In addition, further changes in the tax laws of foreign jurisdictions could arise, including as a result of recommendations issued by the Organisation for Economic Cooperation and Development, or the OECD, which could, if implemented, result in substantial changes to numerous long-standing tax positions and principles. These contemplated changes, to the extent adopted by OECD members or other countries, could increase tax uncertainty and may adversely affect our provision for income taxes. 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.

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

We sell our products to hospitals and other healthcare providers around the world that typically receive reimbursement for the services provided to patients from third-party payers such as government programs (e.g., Medicare and Medicaid in the U.S.) and private insurance programs. The ability of our customers to obtain appropriate reimbursement for the cost of our products from governmental and private third-party payers is critical to our business. Limits on reimbursement imposed by such programs may adversely affect the ability of hospitals and others to purchase our products, which could adversely affect our business and results of operations.

Third-party payers, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In general, a third-party payer covers a medical procedure only when the plan administrator is satisfied that the product or procedure is reasonable and necessary to the patient's treatment; however, the cost-effectiveness of the treatment may also be a condition. In addition, in the United States, no uniform policy of coverage and reimbursement for procedures using our products exists among third-party payers. Therefore, coverage and reimbursement for procedures using our products can differ significantly from payer to payer. In addition, payers continually review new and existing technologies for possible coverage and can, without notice, deny or reverse coverage or alter pre-authorization requirements for new or existing products and procedures. We cannot provide assurance that we will be successful in any efforts we may potentially undertake to reverse such non-coverage decisions. If we are not successful in reversing non-coverage policies, or if third-party payers that currently cover or reimburse certain procedures reverse or limit their coverage of such procedures in the future, or if other third-party payers issue similar policies, our business could be adversely impacted.

Further, we believe that future coverage and reimbursement may be subject to increased restrictions, such as additional preauthorization requirements, both in the United States and in international markets. Third-party coverage and reimbursement for procedures using our products or any of our products in development for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could have an adverse impact on our business.

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

We manufacture and assemble certain products that require the use of hazardous materials that are subject to various national, federal, state and local laws and regulations governing the protection of the environment, health and safety. While the cost of compliance with such laws and regulations has not had a material adverse effect on our results of operations historically, compliance with future regulations may require additional capital investments. Additionally, because we use hazardous and other regulated materials in our manufacturing processes, we are subject to certain risks of future liabilities, lawsuits and claims resulting from any substances we manufacture, dispose of or release. Any accidental release may have an adverse effect on our business, operations or financial condition. We cannot predict what additional environmental, health and safety legislation or regulations will be enacted or become effective in the future or how existing or future laws or regulations will be administered or interpreted with respect to our operations, capital expenditures, results of operations or competitive position. Compliance with more stringent laws or regulations or adverse changes in the interpretation of existing laws or regulations by government agencies could have a material adverse effect on our business, operations or financial condition, and could require substantial expenditures.

**Item 1B. *Unresolved Staff Comments.***

None.

**Item 2. *Properties.***

Our world headquarters is located in South Jordan, Utah, with our principal office for European operations located in Galway, 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 Bangalore, India; Beijing, Hong Kong, GuangZhou and Shanghai, China; Buccinasco, Italy; Dubai, UAE; Melbourne, Australia; Moscow, Russia; Ontario, Canada; Rockland, Massachusetts; São Paulo, Brazil; Selangor, Malaysia; Seoul, Republic of Korea; Tokyo, Japan; and Versailles, France. 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; Joinville, Brazil; Venlo, The Netherlands; and Singapore. 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; San Jose, California and Venlo, The Netherlands.

The following is an approximate summary of our facilities as of December 31, 2016 (in square feet):

	<u>Owned</u>	<u>Leased</u>	<u>Total</u>
U.S. ....	544,525	446,314	990,839
International .....	232,356	347,390	579,746
Total .....	<u>776,881</u>	<u>793,704</u>	<u>1,570,585</u>

The operations associated with our cardiology segment utilize all of our facilities. The operations associated with our endoscopy segment are conducted from our facilities located in South Jordan, Utah and Pearland and Dallas, Texas.

In 2016, we took occupancy of a leased warehouse in Ontario, Canada, totaling approximately 12,000 square feet, to facilitate our direct sales operations in Canada. We also lease a research and development facility in San Jose, California, totaling approximately 34,000 square feet which we



acquired through our acquisition of DFINE in July 2016. The DFINE facility lease is scheduled to expire on August 31, 2019.

In connection with our acquisition of the Argon critical care division in January 2017, we acquired a manufacturing and warehouse facility in Singapore and an office in Tokyo, Japan. The Singapore facility, which totals approximately 68,000 square feet, is located on property leased from a Singapore governmental agency. The Singapore land lease is scheduled to expire on August 30, 2019. The Argon Tokyo office is approximately 2,600 square feet and its lease is scheduled to expire on November 22, 2017.

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 business, we are involved in various claims and litigation matters. These claims and litigation matters may include actions involving product liability, intellectual property, contract disputes, and employment or other matters that are significant to our business. Based upon our review of currently available information, we do not believe that any such actions are likely to be, individually or in the aggregate, materially adverse to our business, financial condition, results of operations or liquidity.

In October 2016, we received a subpoena from the U.S. Department of Justice seeking information on certain of our marketing and promotional practices. We are in the process of responding to the subpoena, which we anticipate will continue during 2017. We have incurred, and anticipate that we will continue to incur, substantial costs in connection with the matter. The investigation is ongoing and at this stage we are unable to predict its scope, duration or outcome. Investigations such as this may result in the imposition of, among other things, significant damages, injunctions, fines or civil or criminal claims or penalties against our company or individuals.

In the event of unexpected further developments, it is possible that the ultimate resolution of any of the foregoing matters, or other similar matters, if resolved in a manner unfavorable to us, 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.

## 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.

<u>For the year ended December 31, 2016</u>	<u>High</u>	<u>Low</u>
First Quarter . . . . .	\$19.49	\$15.47
Second Quarter . . . . .	\$20.59	\$17.94
Third Quarter . . . . .	\$25.08	\$19.61
Fourth Quarter . . . . .	\$26.85	\$20.70
 <u>For the year ended December 31, 2015</u>	 <u>High</u>	 <u>Low</u>
First Quarter . . . . .	\$19.96	\$15.20
Second Quarter . . . . .	\$22.15	\$18.28
Third Quarter . . . . .	\$26.42	\$21.00
Fourth Quarter . . . . .	\$25.50	\$17.60

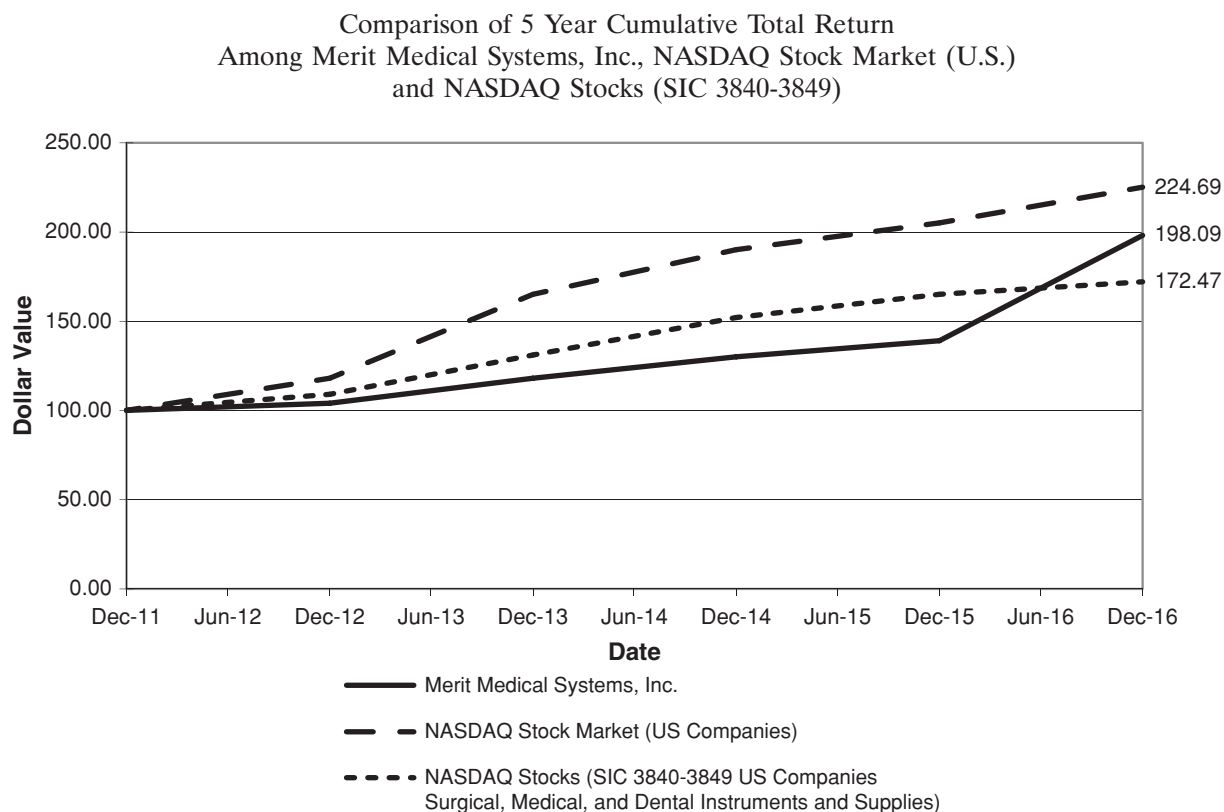
As of February 24, 2017, the number of shares of Common Stock outstanding was 44,651,196 held by approximately 119 shareholders of record, not including shareholders whose shares are held in securities position listings.

#### *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 Second Amended Credit Agreement contains covenants prohibiting the declaration and distribution of a cash dividend at any time prior to the termination of the Second Amended Credit Agreement.

## 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, 2011 to December 31, 2016.



	12/2011	12/2012	12/2013	12/2014	12/2015	12/2016
Merit Medical Systems, Inc. . . . .	\$100	\$104	\$118	\$130	\$139	\$198
NASDAQ Stock Market (U.S. Companies) . . . . .	100	118	165	190	205	225
NASDAQ Stocks (SIC 3840-3849 U.S. Companies)	100	109	131	152	165	172

The stock performance graph assumes for comparison that the value of the Common Stock and of each index was \$100 on December 31, 2011 and that all dividends were reinvested. Past performance is not necessarily an indicator of future results.

NOTE: Performance graph data is complete through last fiscal year. 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 2017. Used with permission. All rights reserved.

***Securities Authorized for Issuance Under Equity Compensation Plans***

The following table contains information regarding our equity compensation plans as of December 31, 2016 (in thousands):

<b>Plan category</b>	<b>Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)</b>	<b>Weighted-average exercise price of outstanding options, warrants and rights (b)</b>	<b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)</b>
Equity compensation Plans approved by security holders . . . . .	<u>2,817</u> (1)(3)	<u>\$15.32</u>	<u>1,854</u> (2)(3)

- 
- (1) Consists of 2,816,538 shares of Common Stock subject to the options granted under the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan.
- (2) Consists of 150,718 shares available to be issued under the Merit Medical Systems, Inc. Non-Qualified Employee Stock Purchase Plan and 1,702,792 shares available to be issued under the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan.
- (3) See Note 11 to our consolidated financial statements set forth in Item 8 of this report for additional information regarding these plans.

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

	2016	2015	2014	2013	2012
<b>OPERATING DATA:</b>					
Net Sales . . . . .	\$603,838	\$542,149	\$509,689	\$449,049	\$394,288
Cost of Sales . . . . .	338,813	306,368	284,467	254,682	212,296
Gross Profit . . . . .	265,025	235,781	225,222	194,367	181,992
<b>Operating Expenses:</b>					
Selling, general, and administrative . . . . .	184,398	156,348	147,894	128,642	122,106
Research and development . . . . .	45,229	40,810	36,632	33,886	27,795
Intangible asset impairment charge . . . . .	—	—	1,102	8,089	—
Contingent consideration expense (benefit) . .	61	80	(572)	(4,094)	—
Acquired in-process research and development . . . . .	461	1,000	—	—	2,450
Total operating expenses . . . . .	230,149	198,238	185,056	166,523	152,351
Income from Operations . . . . .	34,876	37,543	40,166	27,844	29,641
<b>Other Income (Expense):</b>					
Interest income . . . . .	81	272	217	255	226
Interest expense . . . . .	(8,798)	(6,229)	(8,829)	(8,044)	(604)
Other income (expense) . . . . .	(773)	(386)	18	(216)	(1,645)
Other income (expense)—net . . . . .	(9,490)	(6,343)	(8,594)	(8,005)	(2,023)
Income Before Income Taxes . . . . .	25,386	31,200	31,572	19,839	27,618
Income Tax Expense . . . . .	5,265	7,398	8,598	3,269	7,908
Net Income . . . . .	\$ 20,121	\$ 23,802	\$ 22,974	\$ 16,570	\$ 19,710
<b>Earnings Per Common Share:</b>					
Diluted . . . . .	\$ 0.45	\$ 0.53	\$ 0.53	\$ 0.39	\$ 0.46
<b>Average Common Shares:</b>					
Diluted . . . . .	44,862	44,511	43,409	42,884	42,610
<b>BALANCE SHEET DATA:</b>					
Working capital . . . . .	\$155,092	\$116,093	\$116,910	\$100,321	\$ 88,992
Total assets . . . . .	942,803	778,728	747,165	728,283	705,309
Long-term debt, less current portion . . . . .	314,373	197,593	214,490	238,854	227,566
Stockholders' equity . . . . .	498,189	466,103	435,259	405,706	381,577

**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 operations should be read in conjunction with the Consolidated Financial Statements and related Notes thereto, which are included in Item 8 of this report.

**Overview**

We design, develop, manufacture and market single-use medical products for interventional and diagnostic procedures. For financial reporting purposes, we report our operations in two operating segments: cardiovascular and endoscopy. Our cardiovascular segment consists of cardiology and radiology devices, which assist in diagnosing and treating coronary arterial disease, peripheral vascular disease and other non-vascular diseases and includes embolotherapeutic, cardiac rhythm management("CRM"), electrophysiology ("EP"), and interventional oncology and spine devices. 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, 2016, we reported sales of approximately \$603.8 million, up approximately \$61.7 million or 11.4%, over 2015 sales of approximately \$542.1 million.

Gross profit as a percentage of sales increased to 43.9% for the year ended December 31, 2016 as compared to 43.5% for the year ended December 31, 2015.

Net income for the year ended December 31, 2016 was approximately \$20.1 million, or \$0.45 per share, as compared to \$23.8 million, or \$0.53 per share, for the year ended December 31, 2015.

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, 2016. In 2016, international sales were approximately \$233.5 million, or 39% of our net sales, up 9% from 2015.

We believe the following new products will help us continue our growth objectives in 2017:

- CorVocet™ Biopsy System
- SwiftNINJA® Steerable Microcatheter
- Elation® GI & Pulmonary Balloons
- TWISTER® PLUS Rotatable Retrieval Device
- PreludeEASE™ Hydrophilic Sheath Introducer
- PreludeSync™ Radial Compression Device
- HeRO® Graft
- Super HeRO®
- True Form™ Guide Wires
- Heartspan® Transseptal Sheath
- Amplatz Guide Wires
- Merit PAK™ Pedal Access
- Critical Care Products acquired from Argon
- Dual Cap® Disinfection and Protection acquired from Catheter Connections

We believe these new products will strengthen our product portfolio and help us achieve greater market penetration, which, if successful, is expected to drive top-line growth.

We anticipate that our business will be impacted in 2017 by the following trends, each resulting from the development of our business model, as well as changes in the business and regulatory environment in which we operate:

- We anticipate continued international expansion through the transition from a distributor-based sales model to a modified direct sales model, which is already in place in a number of markets, including China. We believe this transition will improve revenue growth opportunities by providing us with greater control over the sales channel and improving gross margins, as we move from a wholesale channel to a retail channel. On the other hand, the transition may result

in increased costs, primarily as a result of increased compensation expenses for existing and new sales personnel.

- We also anticipate we will continue to expand product registrations of existing products and introduce new products in new and emerging markets, in an effort to increase the breadth of our product portfolio offered in international markets, thereby supporting revenue growth and margin expansion. Improvement in gross margin remains a key priority for management, through the management of product mix, continued improvement of operational performance and continued new product introductions. However, any reversal in the aforementioned trends could have a negative impact on our future revenue and gross margin.
- Our revenue growth has been driven by, and we expect our revenue to continue to increase in the future as a result of, the introduction of new products, continued international expansion, and increased physician awareness of our products, among other factors. Any reversal in these trends could have a negative impact on our future revenue. In addition, we have continuously expanded our sales and marketing infrastructure to help us drive and support revenue growth and we intend to continue this expansion.
- Our revenue may fluctuate, from quarter to quarter, as well as within each quarter, due to a variety of factors, including the seasonality of demand for our products, foreign exchange fluctuations, the timing of new product introductions, competitor product introductions, and associated physician evaluations and competitor pricing changes.
- Our gross margin has been, and we expect it will continue to be, affected by a variety of factors, including product sales mix, geographic sales mix and prices, launch of new products, the impact of distributor relationships and our focus on expanding to a modified direct sales model, production volumes, manufacturing costs and product yields, and the implementation of cost-reduction strategies. As we continue to expand through acquisitions, the acquisitions may be gross margin dilutive. Our gross margins could be negatively affected to the extent that the products acquired have gross margins that differ from ours. For example, the gross margin for Argon is less than our current gross margin. However, improvement in gross margin remains a key priority for management, through the control of product mix, continued improvement of operational performance and continued introductions of new product.
- The integration of recently completed acquisitions may increase our operating expenses, and it may take time to realize expected revenue from acquisitions. While we expect to integrate our acquired businesses successfully, the expected synergies may not materialize.
- We continue to experience a variety of financial risks including changes in foreign currency exchange rates, especially when our acquisitions increase the proportion of our revenue from international sales; risks associated with our variable floating rate borrowings, which could negatively affect us in an increasing interest rate environment; and the potentially substantial changes to fiscal, healthcare, trade and tax policies and legislation, which may include comprehensive tax reform and changes to existing trade agreements, including, but not limited to, NAFTA, as well as healthcare reform, including the potential repeal of certain provisions of the PPACA.

Our management utilizes a range of financial and non-financial key performance indicators to manage our business. The financial indicators we use include ratio of revenue to market growth, product mix, gross margin improvement, operating expense leverage, net income growth, working capital and cash flow metrics, capital allocation and return on investment. The non-financial indicators we use include various quality system and operational utilization metrics.

### Results of Operations

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

	2016	2015	2014
Net sales . . . . .	100%	100%	100%
Gross profit . . . . .	43.9	43.5	44.2
Selling, general and administrative expenses . . . . .	30.5	28.8	29.0
Research and development expenses . . . . .	7.5	7.5	7.2
Acquired in-process research and development . . . . .	0.1	0.2	—
Intangible asset impairment charge . . . . .	—	—	0.2
Contingent consideration expense (benefit) . . . . .	—	—	(0.1)
Income from operations . . . . .	5.8	6.9	7.9
Income before income taxes . . . . .	4.2	5.8	6.2
Net income . . . . .	3.3	4.4	4.5

Listed below are the sales by product category within each business segment for the years ended December 31, 2016, 2015 and 2014 (in thousands):

	% Change	2016	% Change	2015	% Change	2014
<b>Cardiovascular</b>						
Stand-alone devices . . . . .	25%	\$193,517	8%	\$155,414	15%	\$143,712
Custom kits and procedure trays . . . . .	3%	119,392	5%	116,368	7%	111,076
Inflation devices . . . . .	1%	73,919	1%	73,373	10%	72,538
Catheters . . . . .	15%	110,939	11%	96,833	17%	87,550
Embolization devices . . . . .	2%	46,035	3%	45,025	31%	43,855
CRM/EP . . . . .	8%	36,446	3%	33,902	17%	32,975
Total . . . . .	11%	580,248	6%	520,915	14%	491,706
<b>Endoscopy</b>						
Endoscopy devices . . . . .	11%	23,590	18%	21,234	6%	17,983
Total . . . . .	11%	\$603,838	6%	\$542,149	14%	\$509,689

**Cardiovascular Sales.** Our cardiovascular sales for the year ended December 31, 2016 were approximately \$580.2 million, up 11.4%, when compared to the corresponding period for 2015 of approximately \$520.9 million. Sales for the year ended December 31, 2016 were favorably affected by increased sales of our stand-alone devices (particularly our infusion bag, Map™, and Ensnare® products, as well as new sales from our acquisitions of the Hero Graft device and the DFINE product line) of approximately \$38.1 million, up 24.5%, catheters (particularly our Impress® product line, Performa® vessel-sizing catheters, and our Maestro® microcatheters) of approximately \$14.1 million, up 14.6%, and custom kits and procedure trays of approximately \$3.0 million, up 2.6%. 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 sales in 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% .

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 0.8% in 2016 compared to 2015, decreased sales 2.0% in 2015 compared to 2014, and increased sales 0.1% in 2014 compared to 2013. 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, 2016 were approximately \$23.6 million, up 11.1%, when compared to sales in 2015 of approximately \$21.2 million. This increase was primarily related to an increase in sales of our EndoMAXX™ fully covered esophageal stent, as well as the introduction of our Elation® Balloon Dilator. 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.

International Sales. International sales for the year ended December 31, 2016 were approximately \$233.5 million, or 39% of net sales, up 9% from the same period in 2015. International sales for the year ended December 31, 2015 were approximately \$214.0 million, or 39% of net 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 net sales, up 19.6% from the same period in 2013. The increase in our international sales during 2016 was primarily related to a year-over-year sales increase in China of approximately \$9.2 million, or 18.2%, as well as sales in our new direct markets in Canada, Australia, and Russia. The increase in our international sales during 2015 was primarily related to year-over-year sales increases in China of approximately of \$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 of \$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%.

Gross Profit. Our gross profit as a percentage of sales was 43.9%, 43.5%, and 44.2% in 2016, 2015 and 2014, respectively. The increase in gross margin for 2016, as compared to 2015 was primarily related to our increased focus on higher margin products and the suspension of the medical device tax in the United States, which was partially offset by increased amortization as part of the DFINE acquisition. 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.

*Selling, General and Administrative Expenses.* Our selling, general and administrative expenses increased approximately \$28.1 million, or 17.9%, in 2016 compared to 2015; \$8.5 million, or 5.7%, in 2015 compared to 2014; and approximately \$19.3 million, or 15.0%, in 2014 compared to 2013. Selling, general and administrative expenses as a percentage of sales were 30.5%, 28.8%, and 29.0% in 2016, 2015 and 2014, respectively.

The increase in selling, general, and administrative expenses for the year ended December 31, 2016 compared to the year ended December 31, 2015 was primarily related to headcount additions, \$1.0 million of expenses incurred in responding to an inquiry from the U.S. Department of Justice, \$4.5 million of acquisition and integration-related costs and \$10.3 million of severance costs primarily related to the DFINE acquisition, which were partially offset by a decrease in our foreign-currency-based expenses of approximately \$1.6 million due to fluctuations in the exchange rates between the U.S. Dollar and various foreign currencies.

The increase in selling, general, and administrative expenses for the year ended December 31, 2015 was primarily related to 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 foreign-currency-based expenses of approximately \$6.0 million due to fluctuations in the exchange rates between the U.S. Dollar and various foreign currencies.

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.

*Research and Development Expenses.* Research and development (“R&D”) expenses increased by 10.8% to approximately \$45.2 million in 2016, compared to approximately \$40.8 million in 2015. The increase in R&D expenses for the year ended December 31, 2016 was largely due to hiring of additional research and development personnel to support various new product developments. 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 R&D 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 R&D expenses for the year ended December 31, 2014 was primarily due to headcount additions to support new product development. Our research and development expenses as a percentage of sales were 7.5%, 7.5% and 7.2% for 2016, 2015, and 2014, respectively. 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 foreseeable future with average gross margins that are higher than our historical gross margins.

In addition, during the year ended December 31, 2016 and 2015, we incurred in-process research and development charges of approximately \$461,000 and \$1.0 million, respectively.



Our operating profits by business segment for the years ended December 31, 2016, 2015 and 2014 were as follows (in thousands):

	<u>2016</u>	<u>2015</u>	<u>2014</u>
<b>Operating Income</b>			
Cardiovascular . . . . .	\$30,120	\$34,052	\$38,601
Endoscopy . . . . .	4,756	3,491	1,565
Total operating income . . . . .	<u>\$34,876</u>	<u>\$37,543</u>	<u>\$40,166</u>

*Cardiovascular Operating Income.* Our cardiovascular operating income for the year ended December 31, 2016 was approximately \$30.1 million, compared to operating income of approximately \$34.1 million for the year ended December 31, 2015. This decrease was primarily related to headcount additions, \$1.0 million of expenses incurred in responding to an inquiry from the U.S. Department of Justice, \$4.5 million of acquisition and integration-related costs and \$10.3 million of severance costs primarily related to the DFINE acquisition, which were partially offset by a decrease in our foreign-currency-based expenses of approximately \$1.6 million due to fluctuations in the exchange rates between the U.S. Dollar and various foreign currencies. 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.

*Endoscopy Operating Income.* Our endoscopy operating income for the year ended December 31, 2016 was approximately \$4.8 million, compared to approximately \$3.5 million for the year ended December 31, 2015. This increase was primarily the result of higher sales, improved gross margins, and lower SG&A expenses as a percentage of sales, partially offset by increased R&D expenses as a percentage of sales. 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.

*Effective Tax Rate.* Our effective income tax rate for 2016, 2015 and 2014 was 20.7%, 23.7%, and 27.2%, respectively. The decrease in the effective income tax rate for 2016 compared to 2015 and 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.

*Other Expense.* Our other expense for the years ended December 31, 2016, 2015 and 2014 was approximately \$9.5 million, \$6.3 million, and \$8.6 million, respectively. The increase in other expenses for 2016 over 2015 was principally the result of increased interest expense related to higher debt balances as a result of our acquisition of DFINE, as well as losses on fluctuations in foreign exchange rates. 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.

**Net Income.** Our net income for 2016, 2015 and 2014 was approximately \$20.1 million, \$23.8 million, and \$23.0 million, respectively. The decrease in net income for 2016, when compared to 2015, was primarily due to acquisition and severance costs, as well as increased interest expense related to higher debt balances related to the DFINE acquisition, which were partially offset by a higher gross margin percentage and a lower effective tax rate. 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.

**Total Assets.** Total assets utilized in our cardiovascular segment were approximately \$932.9 million as of December 31, 2016, compared to approximately \$768.0 million as of December 31, 2015. Total assets utilized in our endoscopy segment were approximately \$9.9 million as of December 31, 2016, compared to approximately \$10.8 million as of December 31, 2015.

**Off-Balance Sheet Arrangements.** We do not have any off-balance sheet arrangements that have had, or are reasonably likely in the future to have, an effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

### ***Liquidity and Capital Resources***

#### **Capital Commitments and Contractual Obligations**

The following table summarizes our capital commitments and contractual obligations as of December 31, 2016, as well as the future periods in which such payments are currently anticipated to become due:

<b>Contractual Obligations</b>	<b>Payment due by period (in thousands)</b>				
	<b>Total</b>	<b>Less than 1 Year</b>	<b>1 - 3 Years</b>	<b>4 - 5 Years</b>	<b>After 5 Years</b>
Long-term debt . . . . .	\$325,000	\$10,000	\$27,500	\$287,500	\$ —
Interest on long-term debt(1) . . . . .	34,787	7,748	15,697	11,342	—
Operating leases . . . . .	69,931	10,168	17,223	9,804	32,736
Royalty obligations . . . . .	333	50	100	85	98
Total contractual cash . . . . .	<u>\$430,051</u>	<u>\$27,966</u>	<u>\$60,520</u>	<u>\$308,731</u>	<u>\$32,834</u>

- (1) Interest payments on our variable long-term debt were forecasted using the LIBOR forward curves plus a base of 1.00% during 2017 and 0.7% thereafter based on the terms of our Second Amended Credit Agreement. Interest payments on a portion of our long-term debt were forecasted using a fixed rate of 1.983% and 2.12% as a result of our interest rate swaps (see Note 8 to our consolidated financial statements set forth in Item 8 of this report).

As of December 31, 2016, we had approximately \$683,000 of contingent consideration liability, \$438,000 of unrecognized tax positions, and \$9.2 million of deferred compensation payable that have been recognized as liabilities that have not been included in the contractual obligations table due to uncertainty as to when such amounts may be settled.

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

### **Cash Flows**

At December 31, 2016 and 2015, we had cash and cash equivalents of approximately \$19.2 million and \$4.2 million respectively, of which \$18.4 million and \$3.7 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, 2016 and 2015, we had cash and cash equivalents of approximately \$9.5 million and \$1.7 million, respectively, held by our subsidiary in China.

*Cash flows provided by operating activities.* Cash provided by operating activities during the years ended December 31, 2016 and 2015 was primarily the result of net income excluding non-cash items offset by shifts in working capital. Our working capital as of December 31, 2016, 2015 and 2014 was approximately \$155.1 million, \$116.1 million and \$116.9 million respectively. The increase in working capital as of December 31, 2016 compared to December 31, 2015 was primarily the result of increases in cash, trade receivables and inventories, as well as a decrease in trade payables, which were partially offset by an increase in accrued expenses. The decrease in working capital as of December 31, 2015 compared to December 31, 2014 was primarily the result of a decrease in cash, trade receivables and other receivables, as well as an increase in trade payables and accrued expenses, which were partially offset by an increase in inventories. As of December 31, 2016 and 2015, we had a current ratio of 2.76 to 1 and 2.32 to 1, respectively.

During the year ended December 31, 2016, our inventory balance increased approximately \$14.7 million, from approximately \$106.0 million as of December 31, 2015 to approximately \$120.7 million as of December 31, 2016. The increase in the inventory balance was due to several factors, including increased sales, the acquisition of DFINE, and the opening of new direct-sales markets in Canada, Australia, and Russia. 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 month inventory turns for the period ended December 31, 2016 decreased to 2.99, compared to 3.10 for the twelve-month period ended December 31, 2015.

*Cash flows provided by (used in) financing activities.* Cash provided by financing activities for the year ended December 31, 2016 was approximately \$121.1 million, compared to cash used in financing activities of approximately \$10.2 million for the year ended December 31, 2015, a change of approximately \$131.3 million. This change was primarily the result of increased debt financing related to acquisitions, principally our acquisitions of DFINE and the HeRO Graft device and other related assets, as well as reduced proceeds from the issuance of common stock, during the year ended December 31, 2016, compared to the year ended December 31, 2015.

The Second Amended Credit Agreement provides for a term loan of \$150 million and a revolving credit commitment up to an aggregate amount of \$275 million, which includes a reserve of \$25 million to make swingline loans from time to time. The term loan is payable in quarterly installments in the amounts provided in the Second Amended Credit Agreement until the maturity date of July 6, 2021, at which time the term and revolving credit loans, together with accrued interest thereon, will be due and payable. 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.

Revolving credit loans denominated in dollars and term loans made under the Second Amended Credit Agreement bear interest, at our election, at either a Base Rate or Eurocurrency Base Rate (as such terms are defined in the Second Amended Credit Agreement) plus the applicable margin, which increases as our Consolidated Total Leverage Ratio (as defined in the Second Amended Credit Agreement) increases. Revolving credit loans denominated in an Alternative Currency (as defined in the Second Amended Credit Agreement) bear interest at the Eurocurrency rate plus the applicable margin. Swingline loans bear interest at the base rate plus the applicable margin. Upon an event of default, the interest rate may be increased by 2.0%. The revolving credit commitment will also carry a commitment fee of 0.15% to 0.40% per annum on the unused portion.

The Second Amended Credit Agreement is collateralized by substantially all our assets. The Second Amended Credit Agreement contains covenants, representations and warranties and other terms customary for loans of this nature. The Second Amended Credit Agreement requires that we maintain certain financial covenants, as follows:

	<u>Covenant Requirement</u>
Consolidated Total Leverage Ratio(1)	
Through March 31, 2017 . . . . .	4.5 to 1.0
April 1, 2017 through June 30, 2017 . . . . .	4.0 to 1.0
July 1, 2017 through December 31, 2017 . . . . .	3.75 to 1.0
January 1, 2018 through March 31, 2018 . . . . .	3.5 to 1.0
April 1, 2018 and thereafter . . . . .	3.25 to 1.0
Consolidated EBITDA(2) . . . . .	1.25 to 1.0
Consolidated Net Income(3) . . . . .	\$—
Facility Capital Expenditures(4) . . . . .	\$30 million

- (1) Maximum Consolidated Total Leverage Ratio (as defined in the Second Amended Credit Agreement) as of any fiscal quarter end.
- (2) Minimum ratio of Consolidated EBITDA (as defined in the Second Amended Credit Agreement and adjusted for certain expenditures) to Consolidated Fixed Charges (as defined in the Second Amended Credit Agreement) for any period of four consecutive fiscal quarters.
- (3) Minimum level of Consolidated Net Income (as defined in the Second Amended Credit Agreement) for certain periods, and subject to certain adjustments.
- (4) Maximum level of the aggregate amount of all Facility Capital Expenditures (as defined in the Second Amended Credit Agreement) in any fiscal year.

Additionally, the Second Amended Credit Agreement contains customary events of default and affirmative and negative covenants for transactions of this type. As of December 31, 2016, we believe we were in compliance with all covenants set forth in the Second Amended Credit Agreement.

As of December 31, 2016, we had outstanding borrowings of approximately \$325.0 million under the Second Amended Credit Agreement, with available borrowings of approximately \$95.0 million, based on the leverage ratio required pursuant to the Second Amended Credit Agreement. Our interest rate as of December 31, 2016 was a fixed rate of 3.12% on \$45.0 million and 2.98% on \$130.0 million as a result of interest rate swaps (see Note 8) and a variable floating rate of 2.77% on \$150.0 million. 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, variable floating rate of 1.74% on \$65.8 million and a variable floating rate of 2.12% on approximately \$6.8 million.

*Cash flows used in investing activities.* Our cash flow used in investing activities for the year ended December 31, 2016 was approximately \$159.1 million, compared to approximately \$62.0 million for the year ended December 31, 2015, an increase of approximately \$97.1 million. This increase was primarily a result of more cash paid for acquisitions during the year ended December 31, 2016, compared to the year ended December 31, 2015, principally the cash paid in the acquisitions of DFINE and the HeRO Graft device (see Note 2 of the notes to our consolidated financial statements). 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.

Capital expenditures for property and equipment were approximately \$32.8 million, \$51.0 million, and \$34.2 million for the years ended December 31, 2016, 2015 and 2014, respectively. Historically, we have incurred significant expenses in connection with facility construction, production automation, product development and the introduction of new products. We anticipate that we will spend approximately \$35 million in 2017 for buildings, property and equipment.

We currently believe that our existing cash balances, anticipated future cash flows from operations, equipment financing and borrowings under the Second Amended Credit Agreement will be adequate to fund our current and currently planned future operations for the next twelve months and the foreseeable future.

#### *Critical Accounting Policies and Estimates*

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

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



Forecasted unit demand is derived from our historical experience of product sales and production raw material usage. If market conditions become less favorable than those projected by our management, additional inventory write-downs may be required. During the years ended December 31, 2016, 2015 and 2014, we recorded obsolescence expense of approximately \$3.9 million, \$2.8 million, and \$2.3 million, respectively, and wrote off approximately \$2.8 million, \$2.5 million, and \$2.4 million, respectively. Based on this historical trend, we believe that our inventory balances as of December 31, 2016 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 guideline public company market-based approach and a discounted cash flow income-based approach. 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. 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 2016, which was completed during the third quarter of 2016, 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 the year ended December 31, 2014, 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. There were no significant adjustments for the years ended December 31, 2016 and 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 related to those assets during the year ended December 31, 2014. These adjustments reduced operating income for the year ended December 31, 2014 by approximately \$228,000, or approximately \$141,000, 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.

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

Our principal market risk relates to changes in the value of the Euro (EUR), Chinese Yuan Renminbi (CNY), and British Pound (GBP) relative to the value of the U.S. Dollar (USD). We also have a limited market risk relating to the Hong Kong Dollar (HKD), Mexican Peso (MXN), Australian Dollar (AUD), Canadian Dollar (CAD), Brazilian Real (BRL), Swiss Franc (CHF), Swedish Krona (SEK), and Danish Krone (DKK). Our consolidated financial statements are denominated in, and our principal currency is, the U.S. Dollar. For the year ended December 31, 2016, a portion of our net sales (approximately \$154.3 million, representing approximately 26% of our aggregate net sales), 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 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 \$4.5 million dollars. Conversely, a weakening U.S. dollar against the Chinese Yuan Renminbi of 10%

would increase net income by approximately \$4.5 million dollars. During the year ended December 31, 2016, exchange rate fluctuations of foreign currencies against the U.S. Dollar resulted in a decrease in our gross revenues of approximately \$4.9 million, or 0.8%, and an increase in gross margin of approximately \$3.3 million, or 1.2% (or approximately 200 basis points in gross margin percentage), primarily as a result of unfavorable impacts to revenue due to sales denominated in CNY and GBP, partially offset by favorable impacts due to increases in manufacturing costs from our facility in Tijuana, Mexico denominated in MXN.

We forecast our net exposure in various receivables and payables to fluctuations in value of various currencies, and we enter into foreign currency forward contracts to mitigate that exposure. As of December 31, 2016, we had entered into the following foreign currency forward contracts (which were not designated as hedging instruments) related to those balance sheet accounts (amounts in thousands and in local currencies):

<u>Currency</u>	<u>Symbol</u>	<u>Forward Notional Amount</u>
Euro . . . . .	EUR	20,657
British Pound . . . . .	GBP	975
Chinese Yuan Renminbi . . . . .	CNY	16,615
Mexican Peso . . . . .	MXN	19,125
Brazilian Real . . . . .	BRL	5,100
Australian Dollar . . . . .	AUD	4,150
Hong Kong Dollar . . . . .	HKD	11,000
Swiss Franc . . . . .	CHF	230
Swedish Krona . . . . .	SEK	3,035
Canadian Dollar . . . . .	CAD	4,320

We also forecast our net exposure related to sales and expenses denominated in foreign currencies. As of December 31, 2016, we had entered into foreign currency forward contracts, which qualified as cash flow hedges, with the following notional amounts (in thousands and in local currencies):

<u>Currency</u>	<u>Symbol</u>	<u>Forward Notional Amount</u>
Euro . . . . .	EUR	11,065
Swiss Franc . . . . .	CHF	1,303
Danish Krone . . . . .	DKK	8,795
British Pound . . . . .	GBP	3,115
Mexican Peso . . . . .	MXN	76,525
Swedish Krona . . . . .	SEK	13,165

See Note 8 to our consolidated financial statements for a discussion of our foreign currency forward contracts.

As discussed in Note 7 to our consolidated financial statements set forth in Item 8 of this report, as of December 31, 2016, we had outstanding borrowings of approximately \$325.0 million under the Second Amended 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, 2016, a notional amount of \$45.0 million remained on the interest rate swap agreement, which expires on December 19, 2017. On August 5, 2016, we entered into a pay-fixed, receive-variable interest rate swap having an initial notional amount of \$42.5 million with Wells Fargo to fix the one-month LIBOR rate at 1.12%. The notional amount of this interest rate swap increases quarterly by an amount equal to the decrease of the hedge entered into on December 19, 2012, up to the amount of \$175 million. The interest rate swap is scheduled to expire on July 6, 2021. These instruments are intended to reduce our

exposure to interest rate fluctuations and were not entered into for speculative purposes. Excluding the amount that is subject to a fixed rate under the interest rate swap and assuming the current level of borrowings remained the same, it is estimated that our interest expense and income before income taxes would change by approximately \$1.5 million annually for each one percentage point change in the average interest rate under these borrowings.

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

**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, 2016 and 2015, 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, 2016. 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, 2016 and 2015, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, 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, 2016, 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 March 1, 2017, expressed an unqualified opinion on the Company’s internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Salt Lake City, Utah  
March 1, 2017



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

	<b>2016</b>	<b>2015</b>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents . . . . .	\$ 19,171	\$ 4,177
Trade receivables—net of allowance for uncollectible accounts—2016—\$1,587 and 2015—\$1,297 . . . . .	80,521	70,292
Employee receivables . . . . .	198	217
Other receivables . . . . .	5,445	6,799
Inventories . . . . .	120,695	105,999
Prepaid expenses and other assets . . . . .	6,226	5,634
Prepaid income taxes . . . . .	2,525	2,955
Deferred income tax assets . . . . .	8,219	7,025
Income tax refund receivables . . . . .	423	905
Total current assets . . . . .	<u>243,423</u>	<u>204,003</u>
<b>PROPERTY AND EQUIPMENT:</b>		
Land and land improvements . . . . .	19,379	19,307
Buildings . . . . .	139,119	136,595
Manufacturing equipment . . . . .	178,110	158,775
Furniture and fixtures . . . . .	43,433	39,301
Leasehold improvements . . . . .	30,413	27,561
Construction-in-progress . . . . .	28,180	26,292
Total property and equipment . . . . .	<u>438,634</u>	<u>407,831</u>
Less accumulated depreciation . . . . .	<u>(162,061)</u>	<u>(140,053)</u>
Property and equipment—net . . . . .	<u>276,573</u>	<u>267,778</u>
<b>OTHER ASSETS:</b>		
Intangible assets:		
Developed technology—net of accumulated amortization—2016—\$52,843 and 2015—\$38,497 . . . . .	135,358	69,861
Other—net of accumulated amortization—2016—\$30,048 and 2015—\$26,603 . . . . .	47,339	39,493
Goodwill . . . . .	211,927	184,472
Deferred income tax assets . . . . .	171	—
Other assets . . . . .	28,012	13,121
Total other assets . . . . .	<u>422,807</u>	<u>306,947</u>
<b>TOTAL</b> . . . . .	<u><u>\$ 942,803</u></u>	<u><u>\$ 778,728</u></u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Trade payables . . . . .	\$ 30,619	\$ 37,977
Accrued expenses . . . . .	44,947	37,846
Current portion of long-term debt . . . . .	10,000	10,000
Advances from employees . . . . .	572	589
Income taxes payable . . . . .	2,193	1,498
Total current liabilities . . . . .	<u>88,331</u>	<u>87,910</u>
<b>LONG-TERM DEBT</b> . . . . .	<u>314,373</u>	<u>197,593</u>
<b>DEFERRED INCOME TAX LIABILITIES</b> . . . . .	<u>25,981</u>	<u>10,985</u>
<b>LIABILITIES RELATED TO UNRECOGNIZED TAX BENEFITS</b> . . . . .	<u>438</u>	<u>768</u>
<b>DEFERRED COMPENSATION PAYABLE</b> . . . . .	<u>9,211</u>	<u>8,500</u>
<b>DEFERRED CREDITS</b> . . . . .	<u>2,550</u>	<u>2,721</u>
<b>OTHER LONG-TERM OBLIGATIONS</b> . . . . .	<u>3,730</u>	<u>4,148</u>
Total liabilities . . . . .	<u>444,614</u>	<u>312,625</u>
<b>COMMITMENTS AND CONTINGENCIES (Notes 2, 7, 8, 9 and 13)</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Preferred stock—5,000 shares authorized as of December 31, 2016 and 2015; no shares issued		
Common stock, no par value; shares authorized—2016 and 2015—100,000; issued and outstanding as of December 31, 2016—44,645 and December 31, 2015—44,267 . . . . .	206,186	197,826
Retained earnings . . . . .	293,885	273,764
Accumulated other comprehensive loss . . . . .	(1,882)	(5,487)
Total stockholders' equity . . . . .	<u>498,189</u>	<u>466,103</u>
<b>TOTAL</b> . . . . .	<u><u>\$ 942,803</u></u>	<u><u>\$ 778,728</u></u>

See notes to consolidated financial statements.

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF INCOME**  
(In thousands, except per share amounts)

	<u>2016</u>	<u>2015</u>	<u>2014</u>
NET SALES . . . . .	\$603,838	\$542,149	\$509,689
COST OF SALES . . . . .	338,813	306,368	284,467
GROSS PROFIT . . . . .	<u>265,025</u>	<u>235,781</u>	<u>225,222</u>
OPERATING EXPENSES:			
Selling, general and administrative . . . . .	184,398	156,348	147,894
Research and development . . . . .	45,229	40,810	36,632
Intangible asset impairment charges . . . . .	—	—	1,102
Contingent consideration expense (benefit) . . . . .	61	80	(572)
Acquired in-process research and development . . . . .	461	1,000	—
Total operating expenses . . . . .	<u>230,149</u>	<u>198,238</u>	<u>185,056</u>
INCOME FROM OPERATIONS . . . . .	<u>34,876</u>	<u>37,543</u>	<u>40,166</u>
OTHER INCOME (EXPENSE):			
Interest income . . . . .	81	272	217
Interest expense . . . . .	(8,798)	(6,229)	(8,829)
Other income (expense)—net . . . . .	<u>(773)</u>	<u>(386)</u>	<u>18</u>
Other expense—net . . . . .	<u>(9,490)</u>	<u>(6,343)</u>	<u>(8,594)</u>
INCOME BEFORE INCOME TAXES . . . . .	25,386	31,200	31,572
INCOME TAX EXPENSE . . . . .	5,265	7,398	8,598
NET INCOME . . . . .	<u>\$ 20,121</u>	<u>\$ 23,802</u>	<u>\$ 22,974</u>
EARNINGS PER COMMON SHARE:			
Basic . . . . .	<u>\$ 0.45</u>	<u>\$ 0.54</u>	<u>\$ 0.53</u>
Diluted . . . . .	<u>\$ 0.45</u>	<u>\$ 0.53</u>	<u>\$ 0.53</u>
AVERAGE COMMON SHARES:			
Basic . . . . .	<u>44,408</u>	<u>44,036</u>	<u>43,143</u>
Diluted . . . . .	<u>44,862</u>	<u>44,511</u>	<u>43,409</u>

See notes to consolidated financial statements.

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**  
(In thousands)

	<u>2016</u>	<u>2015</u>	<u>2014</u>
Net income . . . . .	\$20,121	\$23,802	\$22,974
Other comprehensive income (loss):			
Cash Flow Hedges . . . . .	4,784	(571)	(630)
Less income tax benefit (expense) . . . . .	(1,861)	222	245
Foreign currency translation adjustment . . . . .	878	(3,037)	(3,160)
Less income tax benefit (expense) . . . . .	(196)	311	190
Total other comprehensive income (loss) . . . . .	<u>3,605</u>	<u>(3,075)</u>	<u>(3,355)</u>
Total comprehensive income . . . . .	<u><u>\$23,726</u></u>	<u><u>\$20,727</u></u>	<u><u>\$19,619</u></u>

See notes to consolidated financial statements.

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
(In thousands)

	Total	Common Stock Shares	Amount	Retained Earnings	Accumulated Other Comprehensive Income (Loss)
BALANCE—January 1, 2014 . . . . .	\$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 . . . . .	<u>435,259</u>	<u>43,614</u>	<u>187,709</u>	<u>249,962</u>	<u>(2,412)</u>
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 . . . . .	<u>466,103</u>	<u>44,267</u>	<u>197,826</u>	<u>273,764</u>	<u>(5,487)</u>
Net income . . . . .	20,121			20,121	
Other comprehensive income . . . . .	3,605				3,605
Excess tax benefits from stock-based compensation . . . . .	669		669		
Stock-based compensation expense . . . .	2,506		2,506		
Options exercised . . . . .	4,923	362	4,923		
Issuance of common stock under Employee Stock Purchase Plans . . . . .	694	34	694		
Shares surrendered in exchange for payment of payroll tax liabilities . . . .	(86)	(4)	(86)		
Shares surrendered in exchange for exercise of stock options . . . . .	(346)	(14)	(346)		
BALANCE—December 31, 2016 . . . . .	<u>\$498,189</u>	<u>44,645</u>	<u>\$206,186</u>	<u>\$293,885</u>	<u>\$(1,882)</u>

See notes to consolidated financial statements.

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)

	<u>2016</u>	<u>2015</u>	<u>2014</u>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net income . . . . .	\$ 20,121	\$ 23,802	\$ 22,974
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization . . . . .	43,755	37,425	35,929
Losses (gains) on sales and/or abandonment of property and equipment . . . . .	530	(23)	916
Write-off of patents and intangible assets . . . . .	101	141	1,427
Acquired in-process research and development . . . . .	461	1,000	—
Amortization of deferred credits . . . . .	(170)	(171)	(175)
Amortization of long-term debt issuance costs . . . . .	952	987	987
Deferred income taxes . . . . .	(962)	3,450	3,870
Excess tax benefits from stock-based compensation . . . . .	(669)	(2,124)	(576)
Stock-based compensation expense . . . . .	2,506	2,243	1,460
Changes in operating assets and liabilities, net of effects from acquisitions:			
Trade receivables . . . . .	(6,816)	(5,872)	(13,599)
Employee receivables . . . . .	15	(52)	46
Other receivables . . . . .	1,146	387	(3,042)
Inventories . . . . .	(3,656)	(13,113)	(9,396)
Prepaid expenses . . . . .	271	(696)	(58)
Prepaid income taxes . . . . .	404	(1,788)	(41)
Income tax refund receivables . . . . .	406	(784)	11
Other assets . . . . .	(3,763)	(362)	(1,388)
Trade payables . . . . .	(6,835)	14,766	5,326
Accrued expenses . . . . .	3,245	5,656	6,137
Advances from employees . . . . .	(3)	217	142
Income taxes payable . . . . .	1,451	2,199	1,083
Liabilities related to unrecognized tax benefits . . . . .	597	536	(76)
Deferred compensation payable . . . . .	712	(135)	802
Other long-term obligations . . . . .	(200)	1,769	566
Total adjustments . . . . .	33,478	45,656	30,351
Net cash provided by operating activities . . . . .	53,599	69,458	53,325
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Capital expenditures for:			
Property and equipment . . . . .	(32,837)	(50,959)	(34,181)
Intangible assets . . . . .	(2,217)	(1,956)	(1,714)
Proceeds from sale-leaseback transactions . . . . .	—	2,017	5,521
Proceeds from sale of cost method investment . . . . .	1,089	—	—
Proceeds from the sale of property and equipment . . . . .	19	1,247	98
Cash paid in acquisitions, net of cash acquired . . . . .	(125,161)	(12,368)	(5,927)
Net cash used in investing activities . . . . .	(159,107)	(62,019)	(36,203)

See notes to consolidated financial statements.



**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)**  
(In thousands)

	<u>2016</u>	<u>2015</u>	<u>2014</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from issuance of common stock . . . . .	\$ 5,271	\$ 6,668	\$ 8,146
Proceeds from issuance of long-term debt . . . . .	219,505	152,375	144,018
Payments on long-term debt . . . . .	(102,098)	(169,272)	(169,392)
Excess tax benefits from stock-based compensation . . . . .	669	2,124	576
Long-term debt issuance costs . . . . .	(1,948)	—	—
Contingent payments related to acquisitions . . . . .	(218)	(1,212)	(67)
Payment of taxes related to an exchange of common stock . . . . .	(86)	(918)	(249)
Net cash provided by (used in) financing activities . . . . .	<u>121,095</u>	<u>(10,235)</u>	<u>(16,968)</u>
EFFECT OF EXCHANGE RATES ON CASH . . . . .	<u>(593)</u>	<u>(382)</u>	<u>(258)</u>
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS . . . . .	14,994	(3,178)	(104)
<b>CASH AND CASH EQUIVALENTS:</b>			
Beginning of year . . . . .	<u>4,177</u>	<u>7,355</u>	<u>7,459</u>
End of year . . . . .	<u>\$ 19,171</u>	<u>\$ 4,177</u>	<u>\$ 7,355</u>
<b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION</b>			
Cash paid during the year for:			
Interest (net of capitalized interest of \$460, \$325 and \$389, respectively) . . . . .	<u>\$ 8,872</u>	<u>\$ 6,273</u>	<u>\$ 9,014</u>
Income taxes . . . . .	<u>\$ 2,318</u>	<u>\$ 3,409</u>	<u>\$ 3,289</u>
<b>SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES</b>			
Property and equipment purchases in accounts payable . . . . .	<u>\$ 2,398</u>	<u>\$ 3,199</u>	<u>\$ 2,896</u>
Receivable due for sale of equipment . . . . .	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,256</u>
Cost method investment converted to intangible asset in acquisition in lieu of additional cash payment . . . . .	<u>\$ —</u>	<u>\$ 1,010</u>	<u>\$ —</u>
Contingent receivable in exchange for sale of cost method investment . . . . .	<u>\$ 711</u>	<u>\$ —</u>	<u>\$ —</u>
Acquisition purchases in accrued expenses and other long-term obligations . . . . .	<u>\$ —</u>	<u>\$ 1,300</u>	<u>\$ 1,000</u>
Merit common stock surrendered (14, 185 and 127 shares, respectively) in exchange for exercise of stock options . . . . .	<u>\$ 346</u>	<u>\$ 3,802</u>	<u>\$ 1,941</u>

See notes to consolidated financial statements.

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**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 medical device products which assist in diagnosing and treating coronary artery disease, peripheral vascular disease and other non-vascular diseases and includes embolotherapeutic, cardiac rhythm management, electrophysiology, and interventional oncology and spine devices. 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.

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, Canada, Western Europe, Australia, Brazil, Russia, 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 for impairment on an annual basis as of July 1 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 guideline public company market-based approach and a discounted cash flow income-based approach. 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.

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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

Customer lists . . . . .	5 - 14 years
Developed technology . . . . .	8 - 15 years
Distribution agreements . . . . .	3 - 12 years
License agreements and trademarks . . . . .	4 - 15 years
Covenants not to compete . . . . .	7 - 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, 2016, 2015 and 2014, 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, 2016, 2015 and 2014 was approximately \$24.5 million, \$22.6 million, and \$21.0 million, respectively.

**Deferred Compensation.** We have a deferred compensation plan that permits certain management employees to defer a portion of their salary until the future. We established a Rabbi trust to finance obligations under the plan with corporate-owned variable life insurance contracts. The cash surrender value totaled approximately \$9.9 million and \$8.8 million at December 31, 2016 and 2015, respectively, which is included in other assets in our consolidated balance sheets. We have recorded a deferred compensation payable of approximately \$9.2 million and \$8.5 million at December 31, 2016 and 2015, respectively, to reflect the liability to our employees under this plan.

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

**Other Assets.** Other assets consist of our deferred compensation plan cash surrender value discussed above, unamortized debt issuance costs, 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 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, 2016, 2015 and 2014. 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.

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

**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 in 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, 2016, 2015 and 2014 was approximately \$2.5 million, \$2.2 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 accounted for approximately 3% of net sales for each of the years ended December 31, 2016, 2015 and 2014.

**Foreign Currency.** The financial statements of our foreign subsidiaries are measured using local currencies as the functional currency, with the exception of our subsidiaries in 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 interest rate swaps to hedge changes in the benchmark interest rate related to our



**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

Second Amended 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 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, 2016, accumulated other comprehensive income (loss) included approximately \$2.9 million (net of tax of \$(1.9) million) related to cash flow hedges and (\$4.8) million (net of tax of \$318,000) related to foreign currency translation. 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.

**Recently Issued Financial Accounting Standards.** In January 2017, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2017-04, *Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*, which eliminates the requirement to determine the fair value of individual assets and liabilities of a reporting unit to measure goodwill impairment. Under these amendments, goodwill impairment testing will be performed by comparing the fair value of the reporting unit with its carrying amount and recognizing an impairment charge for the amount by which the carrying amount exceeds the reporting unit’s fair value. The new standard is effective for annual and interim goodwill impairment tests in fiscal years beginning after December 15, 2019, and should be applied on a prospective basis. Early adoption is permitted for annual or interim goodwill impairment testing performed after January 1, 2017. We plan to early adopt ASU 2017-01 effective January 1, 2017.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*, which provides guidance to entities to assist with evaluating when a set of transferred assets and activities is a business and provides a screen to determine when a set is not a business. Under the new guidance, when substantially all of the fair value of gross assets acquired (or disposed of) is concentrated in a single identifiable asset, or group of similar assets, the assets acquired would not represent a business. Also, to be considered a business, an acquisition would have to include an input and a substantive process that together significantly contribute to the ability to produce outputs. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017, and should be applied on a prospective basis to any transactions occurring within the period of adoption. Early adoption is permitted for interim or annual periods in which the financial statements have not been issued. We plan to early adopt ASU 2017-01 effective January 1, 2017.

In October 2016, the FASB issued ASU No. 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other than Inventory*, which requires the recognition of the income tax consequences of an intra-entity transfer of an asset, other than inventory, when the transfer occurs. ASU 2016-16 will be effective for us on January 1, 2018. We are currently evaluating the impact of adopting ASU 2016-16 on our consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, which addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. ASU 2016-15 will be

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

effective for us on January 1, 2018 with early adoption permitted. We do not presently anticipate that the adoption of ASU 2016-15 will have a material impact on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, which requires companies to record excess tax benefits and deficiencies in income rather than the current requirement to record them through equity. ASU 2016-09 also allows companies the option to recognize forfeitures of share-based awards when they occur rather than the current requirement to make an estimate upon the grant of the awards. ASU 2016-09 will be effective for us on January 1, 2017. Early adoption of ASU 2016-09 will be permitted in any interim or annual period, with any adjustments reflected as of the beginning of the fiscal year of adoption. We do not anticipate that the adoption of ASU 2016-09 will have a material impact on our financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*, which eliminates the current tests for lease classification under U.S. GAAP and requires lessees to recognize the right-of-use assets and related lease liabilities on the balance sheet for all leases greater than one year in duration. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. ASU 2016-02 provides that lessees (for capital and operating leases) and lessors (for sales-type, direct financing, and operating leases) must apply a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The modified retrospective approach would not require any transition accounting for leases that expired before the earliest comparative period presented. Lessees and lessors may not apply a full retrospective transition approach. We are assessing the impact that ASU 2016-02 is anticipated to have on our consolidated financial statements. We currently expect that most of our operating lease commitments will be subject to the new standard and recognized as lease liabilities and right-of-use assets upon our adoption of ASU 2016-02.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments—Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*, which amends the guidance regarding the classification and measurement of financial instruments. Changes to the current guidance primarily affect the accounting for equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. In addition, ASU 2016-01 clarifies guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. ASU 2016-01 will be effective for us on January 1, 2018. Early adoption is not permitted except for the provision to record fair value changes for financial liabilities under the fair value option resulting from instrument-specific credit risk in other comprehensive income. Upon adoption of ASU 2016-01, an entity should apply the amendments by means of a cumulative-effect adjustment to the balance sheet at the beginning of the first reporting period in which the guidance is effective. We do not presently anticipate that the adoption of ASU 2016-01 will have a material impact on our financial statements.

In November 2015, the FASB issued ASU 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*, which will require all deferred tax assets and deferred tax liabilities to be presented as noncurrent within a classified balance sheet. ASU 2015-17 will be effective for us as of January 1, 2017, with early application permitted. ASU 2015-17 may be applied either prospectively to all deferred tax assets and liabilities or retrospectively to all periods presented. We have elected not to

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

early adopt ASU 2015-17. We do not anticipate that the adoption of ASU 2015-17 will have a material impact on our financial statements.

In July 2015, the FASB issued ASU 2015-11, *Simplifying the Measurement of Inventory*. ASU 2015-11 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 ASU 2015-11 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 May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, to update the financial reporting requirements for revenue recognition. Topic 606 outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. The guidance is based on the principle that an entity should recognize revenue to depict the transfer of 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 guidance also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to fulfill a contract. This guidance is effective for us beginning on January 1, 2018, and entities have the option of using either a full retrospective or a modified retrospective approach for the adoption of the new standard. We have not yet reached a final conclusion on whether we will adopt this new standard on a prospective or retrospective basis.

We are concluding the assessment phase of implementing this guidance. We have evaluated each of the five steps in Topic 606, which are as follows: 1) Identify the contract with the customer; 2) Identify the performance obligations in the contract; 3) Determine the transaction price; 4) Allocate the transaction price to the performance obligations; and 5) Recognize revenue when (or as) performance obligations are satisfied. Our preliminary conclusion is that we expect to identify similar performance obligations under ASC Topic 606 as compared with deliverables and separate units of account previously identified. As a result, we expect the timing of our revenue to remain the same in comparison to the current revenue recognition guidance. There are also certain considerations related to internal control over financial reporting that are associated with implementing Topic 606. We are currently evaluating our control framework for revenue recognition and identifying any changes that may need to be made in response to the new guidance. Disclosure requirements under the new guidance in Topic 606 have been significantly expanded in comparison to the disclosure requirements under the current guidance. Designing and implementing the appropriate controls over gathering and reporting the information required under Topic 606 is currently in process.

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. ACQUISITIONS**

On December 19, 2016, we paid \$5.0 million for 1,251,878 shares of common stock and a distribution agreement with Bluegrass Vascular Technologies, Inc. (“Bluegrass”). The common stock, which represents an ownership interest of approximately 19.5%, has been accounted for as a cost method investment of \$4.0 million reflected within other assets in the accompanying consolidated balance sheets because we are not able to exercise significant influence over the operations of Bluegrass. The distribution agreement intangible asset was valued at \$1.0 million and will be amortized over a period of three years.

On July 6, 2016, we acquired all of the issued and outstanding shares of DFINE Inc. (“DFINE”). The DFINE acquisition added a line of vertebral augmentation products for the treatment of vertebral compression fractures (“VCF”) as well as medical devices used to treat metastatic spine tumors. We made an initial payment of \$97.5 million to certain DFINE stockholders on July 6, 2016 and paid approximately \$578,000 related to a net working capital adjustment subject to review by Merit and the preferred stockholders of DFINE. We accounted for the acquisition as a business combination. In the three-month period ended December 31, 2016, we negotiated the final net working capital adjustment resulting in a reduction to the purchase price of approximately \$1.1 million. As a result, we recorded measurement period adjustments to reduce inventories by approximately \$89,000, reduce property and equipment by approximately \$109,000, reduce goodwill by approximately \$1.2 million, reduce accrued expenses by approximately \$407,000 and increase the associated deferred tax liabilities by approximately \$113,000. Under GAAP, measurement period adjustments are recognized on a prospective basis in the period of change, instead of restating prior periods. There was no impact to reported earnings in connection with these measurement period adjustments.

Acquisition-related costs during the year ended December 31, 2016, which are included in selling, general, and administrative expenses in the accompanying consolidated statements of income, were approximately \$1.6 million. 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, 2016, our net sales of DFINE products were approximately \$13.5 million. It is not practical to separately report the earnings related to the DFINE acquisition, as we cannot split out sales costs related to DFINE products, principally because our sales representatives are selling multiple products (including DFINE products) in the cardiovascular business segment.

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. ACQUISITIONS (Continued)**

The purchase price was allocated to the net tangible and intangible assets acquired and liabilities assumed, based on estimated fair values, as follows (in thousands):

<b>Assets Acquired</b>	
Trade receivables . . . . .	\$ 4,054
Other receivables . . . . .	6
Inventories . . . . .	8,585
Prepaid expenses . . . . .	630
Property and equipment . . . . .	1,630
Other long-term assets . . . . .	145
Intangibles	
Developed technology . . . . .	67,600
Customer lists . . . . .	2,400
Trademarks . . . . .	4,400
Goodwill . . . . .	24,818
Total assets acquired . . . . .	114,268
<b>Liabilities Assumed</b>	
Trade payables . . . . .	(1,790)
Accrued expenses . . . . .	(5,298)
Deferred income tax liabilities—current . . . . .	(701)
Deferred income tax liabilities—noncurrent . . . . .	(10,844)
Total liabilities assumed . . . . .	(18,633)
<b>Net assets acquired, net of cash received of \$1,327 . . . . .</b>	<b><u>\$ 95,635</u></b>

The gross amount of trade receivables we acquired in the acquisition was approximately \$4.3 million, of which approximately \$224,000 was expected to be uncollectible or returned. With respect to the DFINE assets, we are amortizing developed technology over fifteen years and customer lists on an accelerated basis over nine 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 fifteen years from the acquisition date. The total weighted-average amortization period for these acquired intangible assets is 14.8 years.

The following table summarizes our consolidated results of operations for the years ended December 31, 2016 and 2015, as well as unaudited pro forma consolidated results of operations as



**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. ACQUISITIONS (Continued)**

though the acquisition had occurred on January 1, 2015 (in thousands, except per common share amounts):

	2016		2015	
	As Reported	Pro Forma	As Reported	Pro Forma
Net Sales . . . . .	\$603,838	\$621,463	\$542,149	\$575,541
Net Income . . . . .	20,121	9,825	23,802	3,135
Earnings per common share:				
Basic . . . . .	\$ 0.45	\$ 0.22	\$ 0.54	\$ 0.07
Diluted . . . . .	\$ 0.45	\$ 0.22	\$ 0.53	\$ 0.07

The unaudited pro forma information set forth above is for informational purposes only and includes adjustments related to amortization expense of 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 DFINE acquisition had occurred on January 1, 2015, or results that may be obtained in any future period.

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, Georgia (“CryoLife”). The HeRO Graft is a fully subcutaneous vascular access system intended for use in maintaining long-term vascular access for chronic hemodialysis patients who have failing fistulas, grafts or are catheter dependent due to a central venous blockage. The purchase price was \$18.5 million, which was paid in full during 2016. We accounted for this acquisition as a business combination. The purchase price was allocated as follows (in thousands):

<b>Assets Acquired</b>	
Inventories . . . . .	\$ 2,455
Property and equipment . . . . .	290
Intangibles	
Developed technology . . . . .	12,100
Trademarks . . . . .	700
Customers Lists . . . . .	400
Goodwill . . . . .	2,555
<b>Total assets acquired . . . . .</b>	<b>\$18,500</b>

We are amortizing the developed HeRO Graft technology asset over ten years, the related trademarks over 5.5 years, and the associated customer lists over 12 years. We have estimated the weighted average life of the intangible HeRO Graft assets acquired to be approximately 9.82 years. Acquisition-related costs related to the HeRO Graft device and other related assets during the year ended December 31, 2016, which are 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, 2016, our net sales of the products acquired from CryoLife were approximately \$7.1 million. It is not practical to separately report the earnings related to the products acquired from CryoLife, as we cannot split out sales costs related to those products, principally because

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. ACQUISITIONS (Continued)**

our sales representatives are selling multiple products (including the HeRO Graft device) in the cardiovascular business segment. The pro forma consolidated results of operations acquired from CryoLife are not presented, as we believe the pro forma financial effect of the transaction is not significant.

During 2016, we paid approximately \$3.0 million for 2,965,000 preferred limited liability company units of Cagent Vascular, LLC, a medical device company (“Cagent”), which represents an ownership interest of approximately 19.9% and has been accounted for as cost method investment reflected within other assets in the accompanying consolidated balance sheets because we are not able to exercise significant influence over the operations of Cagent.

On December 4, 2015, we entered into a license agreement with ArraVasc Limited, an Irish 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. During the year ended December 31, 2016, we paid an additional \$1.5 million as the milestones set forth in the license agreement were met during that period. We accounted for the transaction as an asset purchase and intend to amortize the license agreement intangible 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. 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 in Xablecath is approximately 14% and is accounted for as a cost-method investment reflected within other assets in the accompanying consolidated balance sheets. 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 and paid in the first quarter of 2016. We also recorded \$270,000 of contingent consideration related to royalties payable to Quellent pursuant to the asset purchase 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

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. ACQUISITIONS (Continued)**

\$60,000 to goodwill. We are amortizing the developed technology intangible asset over 13 years. The pro forma consolidated results of operations are not presented, as we believe the pro forma financial effect of the transaction is not significant.

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. As of December 31, 2016, we have paid cash of \$400,000, have a current liability recorded in accrued expenses of \$200,000 for the payment that will be due in less than a year and have a long-term obligation of \$400,000 recorded for the payments 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 are amortizing 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 paid an additional \$400,000 in the year-ended December 31, 2016, which was recorded to the customer list intangible asset, because Teleflex met certain obligations under the agreement. There are no additional payments due under this agreement. We are amortizing 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 (“Catheter Connections”), which we had originally entered into on August 21, 2012 for Catheter Connection’s MaleCap Solo technology. The amendment provides exclusive rights for certain aspects of Catheter Connection’s DualCap disinfecting cap technology. The purchase price of \$250,000 was allocated to a distribution agreement asset, which we are amortizing over ten years.

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 additional 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

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. ACQUISITIONS (Continued)**

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. The purchase price was allocated as follows: \$200,000 to a distribution agreement asset, which we are amortizing over a period of three years and \$6.3 million to a license agreement asset, which we are amortizing 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 are amortizing 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 as a cost-method investment. We made a refundable advance to G Medix of \$350,000 in 2013 that was credited against the final purchase amount, resulting in a \$1.45 million cash payment to G Medix during 2014. G Medix develops catheter-based therapeutic devices.

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 certain acquisitions is expected to be deductible for income tax purposes.

**3. INVENTORIES**

Inventories at December 31, 2016 and 2015, consisted of the following (in thousands):

	<u>2016</u>	<u>2015</u>
Finished goods . . . . .	\$ 63,852	\$ 59,170
Work-in-process . . . . .	11,008	8,540
Raw materials . . . . .	45,835	38,289
Total . . . . .	<u>\$120,695</u>	<u>\$105,999</u>

**4. GOODWILL AND INTANGIBLE ASSETS**

The changes in the carrying amount of goodwill for the years ended December 31, 2016 and 2015, are as follows (in thousands):

	<u>2016</u>	<u>2015</u>
Goodwill balance at January 1 . . . . .	\$184,472	\$184,464
Effect of foreign exchange . . . . .	82	(52)
Additions as the result of acquisitions . . . . .	27,373	60
Goodwill balance at December 31 . . . . .	<u>\$211,927</u>	<u>\$184,472</u>

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**4. GOODWILL AND INTANGIBLE ASSETS (Continued)**

As of December 31, 2016, we had recorded \$8.3 million of accumulated goodwill impairment charges. All of the goodwill balance as of December 31, 2016 and 2015, is related to our cardiovascular segment.

Other intangible assets at December 31, 2016 and 2015, consisted of the following (in thousands):

	<b>2016</b>		
	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net Carrying Amount</b>
Patents . . . . .	\$14,130	\$ (3,165)	\$10,965
Distribution agreements . . . . .	6,626	(3,527)	3,099
License agreements . . . . .	20,695	(3,422)	17,273
Trademarks . . . . .	12,380	(3,330)	9,050
Covenants not to compete . . . . .	1,028	(936)	92
Customer lists . . . . .	22,261	(15,401)	6,860
Royalty agreements . . . . .	267	(267)	—
Total . . . . .	<u>\$77,387</u>	<u>\$(30,048)</u>	<u>\$47,339</u>

	<b>2015</b>		
	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net Carrying Amount</b>
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 . . . . .	<u>\$66,096</u>	<u>\$(26,603)</u>	<u>\$39,493</u>

Aggregate amortization expense for the years ended December 31, 2016, 2015 and 2014 was approximately \$19.3 million, \$14.8 million and \$14.9 million, respectively.



**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**4. GOODWILL AND INTANGIBLE ASSETS (Continued)**

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 did not record any impairment charges during the years ended December 31, 2016 and 2015. During the third quarter of 2014, 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 recorded an impairment charge for Ostial of approximately \$1.1 million, which was offset by approximately \$874,000 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, 2016 (in thousands):

<u>Year Ending December 31</u>	
2017 .....	\$21,800
2018 .....	21,229
2019 .....	20,826
2020 .....	19,732
2021 .....	13,296

**5. INCOME TAXES**

For the years ended December 31, 2016, 2015 and 2014, income before income taxes is broken out between U.S. and foreign-sourced operations and consisted of the following (in thousands):

	<u>2016</u>	<u>2015</u>	<u>2014</u>
Domestic .....	\$ 6,174	\$ 9,470	\$16,961
Foreign .....	19,212	21,730	14,611
Total .....	<u>\$25,386</u>	<u>\$31,200</u>	<u>\$31,572</u>

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**5. INCOME TAXES (Continued)**

The components of the provision for income taxes for the years ended December 31, 2016, 2015 and 2014, consisted of the following (in thousands):

	<u>2016</u>	<u>2015</u>	<u>2014</u>
Current expense (benefit):			
Federal . . . . .	\$1,933	\$ (17)	\$1,316
State . . . . .	492	747	768
Foreign . . . . .	3,802	3,218	2,644
Total current expense . . . . .	<u>6,227</u>	<u>3,948</u>	<u>4,728</u>
Deferred expense (benefit):			
Federal . . . . .	(144)	3,250	4,078
State . . . . .	(195)	294	(119)
Foreign . . . . .	(623)	(94)	(89)
Total deferred (benefit) expense . . . . .	<u>(962)</u>	<u>3,450</u>	<u>3,870</u>
Total income tax expense . . . . .	<u>\$5,265</u>	<u>\$7,398</u>	<u>\$8,598</u>

The difference between the income tax expense reported and amounts computed by applying the statutory federal rate of 35.0% to pretax income for the years ended December 31, 2016, 2015 and 2014, consisted of the following (in thousands):

	<u>2016</u>	<u>2015</u>	<u>2014</u>
Computed federal income tax expense at statutory rate of 35% . . . . .	\$ 8,885	\$10,920	\$11,050
State income taxes . . . . .	193	698	438
Tax credits . . . . .	(1,164)	(1,019)	(888)
Production activity deduction . . . . .	(53)	—	—
Foreign tax rate differential . . . . .	(3,717)	(3,564)	(1,958)
Uncertain tax positions . . . . .	597	536	(76)
Deferred compensation insurance assets . . . . .	(307)	182	(81)
Transaction-related expenses . . . . .	274	—	—
Other—including the effect of graduated rates . . . . .	557	(355)	113
Total income tax expense . . . . .	<u>\$ 5,265</u>	<u>\$ 7,398</u>	<u>\$ 8,598</u>

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**5. INCOME TAXES (Continued)**

Deferred income tax assets and liabilities at December 31, 2016 and 2015, consisted of the following temporary differences and carry-forward items (in thousands):

	<u>2016</u>	<u>2015</u>
Deferred income tax assets:		
Allowance for uncollectible accounts receivable . . . . .	\$ 645	\$ 531
Accrued compensation expense . . . . .	6,203	5,534
Inventory differences . . . . .	1,065	2,043
Net operating loss carryforwards . . . . .	27,742	11,434
Deferred revenue . . . . .	73	118
Stock-based compensation expense . . . . .	2,738	2,532
Federal research and development credit carryforward . . . . .	3,524	2,355
Foreign tax credits . . . . .	364	600
Other . . . . .	6,984	5,754
Total deferred income tax assets . . . . .	<u>49,338</u>	<u>30,901</u>
Deferred income tax liabilities:		
Prepaid expenses . . . . .	(782)	(841)
Property and equipment . . . . .	(25,108)	(24,467)
Intangible assets . . . . .	(35,773)	(6,495)
Other . . . . .	(1,480)	(1,077)
Total deferred income tax liabilities . . . . .	<u>(63,143)</u>	<u>(32,880)</u>
Valuation allowance . . . . .	<u>(3,786)</u>	<u>(1,981)</u>
Net deferred income tax assets (liabilities) . . . . .	<u><u>\$(17,591)</u></u>	<u><u>\$ (3,960)</u></u>
Reported as:		
Deferred income tax assets—Current . . . . .	\$ 8,219	\$ 7,025
Deferred income tax assets—Long-term . . . . .	171	—
Deferred income tax liabilities—Current . . . . .	—	—
Deferred income tax liabilities—Long-term . . . . .	<u>(25,981)</u>	<u>(10,985)</u>
Net deferred income tax liabilities . . . . .	<u><u>\$(17,591)</u></u>	<u><u>\$ (3,960)</u></u>

The long-term deferred income tax balances are not netted as they represent deferred amounts applicable to different taxing jurisdictions. Deferred income tax balances reflect the temporary differences between the carrying amounts of assets and liabilities and their tax basis 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, non-US net operating loss carryforwards, and capital loss carryforwards for which we believe it is more likely than not that the deferred tax assets will not be realized. The valuation allowance increased by approximately \$1.8 million, \$378,000, and \$240,000 during the years ended December 31, 2016, 2015 and 2014, 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.

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**5. INCOME TAXES (Continued)**

As of December 31, 2016 and 2015, we had U.S federal net operating loss carryforwards of approximately \$76.4 million and \$32.7 million, respectively, which were generated by DFINE, Inc. and Biosphere Medical, Inc. prior to our acquisition of these companies. The increase in our net operating loss carryforwards during 2016 relates to our acquisition of DFINE, Inc. in July 2016. These net operating loss carryforwards, which expire at various dates through 2035, 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 19 years. We utilized a total of approximately \$6.2 million and \$6.0 million in U.S. federal net operating loss carryforwards during the years ended December 31, 2016 and 2015, respectively.

As of December 31, 2016, we had \$3.0 million of non-U.S. net operating loss carryforwards, which have no expiration date. As of December 31, 2015, we had \$0 of non-U.S. net operating loss carryforwards. Non-U.S. net operating loss carryforwards utilized during the year ended December 31, 2016 and 2015 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 2013. In foreign jurisdictions, we are no longer subject to income tax examinations for years before 2010.

Although we believe our estimates are reasonable, the final outcomes of these matters may be different from those which we have reflected in our historical income tax provisions and accruals. Such differences could have a material 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, 2016, including interest and penalties, was approximately \$2.8 million, of which approximately \$2.8 million would favorably impact our effective tax rate if recognized. Approximately \$2.3 million of the total liability at December 31, 2016 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, 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. As of December 31, 2016 and 2015, we had accrued approximately \$216,000 and \$187,000 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, 2016, 2015 and 2014 we added interest and penalties of approximately \$30,000, \$6,000 and \$42,000, respectively, to 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 \$500,000.

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**5. INCOME TAXES (Continued)**

A reconciliation of the beginning and ending amount of liabilities associated with uncertain tax benefits for the years ended December 31, 2016, 2015 and 2014, consisted of the following (in thousands):

<u>Tabular Roll-forward</u>	<u>2016</u>	<u>2015</u>	<u>2014</u>
Unrecognized tax benefits, opening balance . . . . .	\$1,982	\$1,736	\$2,129
Gross increases in tax positions taken in a prior year . . . . .	77	187	142
Gross increases in tax positions taken in the current year . . . . .	856	763	309
Lapse of applicable statute of limitations . . . . .	(366)	(704)	(844)
Unrecognized tax benefits, ending balance . . . . .	<u>\$2,549</u>	<u>\$1,982</u>	<u>\$1,736</u>

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, 2016 and 2015, consisted of the following (in thousands):

	<u>2016</u>	<u>2015</u>
Payroll taxes . . . . .	\$ 2,406	\$ 2,369
Payroll . . . . .	7,733	4,971
Bonuses . . . . .	4,470	5,283
Commissions . . . . .	974	790
Vacation . . . . .	8,846	7,748
Royalties . . . . .	1,806	1,499
Value-added tax . . . . .	2,046	1,797
Other accrued expenses . . . . .	16,666	13,389
Total . . . . .	<u>\$44,947</u>	<u>\$37,846</u>

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

On July 6, 2016, we entered into a Second Amended and Restated Credit Agreement (as amended on September 28, 2016, the “Second Amended Credit Agreement”), with Wells Fargo Bank, National Association, as administrative agent, swingline lender and a lender, and Wells Fargo Securities, LLC, as sole lead arranger and sole bookrunner. In addition to Wells Fargo Bank, National Association, Bank of America, N.A., U.S. Bank, National Association, and HSBC Bank USA, National Association, are parties to the Second Amended Credit Agreement as lenders. The Second Amended Credit Agreement amends and restates in its entirety Merit’s previously outstanding Amended and Restated Credit Agreement and all amendments thereto.



**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**7. REVOLVING CREDIT FACILITY AND LONG-TERM DEBT (Continued)**

The Second Amended Credit Agreement provides for a term loan of \$150 million and a revolving credit commitment up to an aggregate amount of \$275 million, which includes a reserve of \$25 million to make swingline loans from time to time. The term loan is payable in quarterly installments in the amounts provided in the Second Amended Credit Agreement until the maturity date of July 6, 2021, at which time the term and revolving credit loans, together with accrued interest thereon, will be due and payable. 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.

In summary, principal balances under our long-term debt as of December 31, 2016 and 2015, consisted of the following (in thousands):

	<u>2016</u>	<u>2015</u>
Term loan . . . . .	\$145,000	\$ 64,962
Revolving credit loans . . . . .	180,000	142,631
Less debt issuance costs . . . . .	(627)	—
Total long-term debt . . . . .	324,373	207,593
Less current portion . . . . .	10,000	10,000
Long-term portion . . . . .	<u>\$314,373</u>	<u>\$197,593</u>

Revolving credit loans denominated in dollars and term loans made under the Second Amended Credit Agreement bear interest, at our election, at either a Base Rate or Eurocurrency Base Rate (as such terms are defined in the Second Amended Credit Agreement) plus the applicable margin, which increases as our Consolidated Total Leverage Ratio (as defined in the Second Amended Credit Agreement) increases. Revolving credit loans denominated in an Alternative Currency (as defined in the Second Amended Credit Agreement) bear interest at the Eurocurrency rate plus the applicable margin. Swingline loans bear interest at the base rate plus the applicable margin. Upon an event of default, the interest rate may be increased by 2.0%. The revolving credit commitment will also carry a commitment fee of 0.15% to 0.40% per annum on the unused portion.

The Second Amended Credit Agreement is collateralized by substantially all our assets. The Second Amended Credit Agreement contains covenants, representations and warranties and other

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**7. REVOLVING CREDIT FACILITY AND LONG-TERM DEBT (Continued)**

terms customary for loans of this nature. The Second Amended Credit Agreement requires that we maintain certain financial covenants, as follows:

	<u>Covenant Requirement</u>
Consolidated Total Leverage Ratio(1)	
Through March 31, 2017 .....	4.5 to 1.0
April 1, 2017 through June 30, 2017 .....	4.0 to 1.0
July 1, 2017 through December 31, 2017 .....	3.75 to 1.0
January 1, 2018 through March 31, 2018 .....	3.5 to 1.0
April 1, 2018 and thereafter .....	3.25 to 1.0
Consolidated EBITDA(2) .....	1.25 to 1.0
Consolidated Net Income(3) .....	\$—
Facility Capital Expenditures(4) .....	\$30 million

- (1) Maximum Consolidated Total Leverage Ratio (as defined in the Second Amended Credit Agreement) as of any fiscal quarter end.
- (2) Minimum ratio of Consolidated EBITDA (as defined in the Second Amended Credit Agreement and adjusted for certain expenditures) to Consolidated Fixed Charges (as defined in the Second Amended Credit Agreement) for any period of four consecutive fiscal quarters.
- (3) Minimum level of Consolidated Net Income (as defined in the Second Amended Credit Agreement) for certain periods, and subject to certain adjustments.
- (4) Maximum level of the aggregate amount of all Facility Capital Expenditures (as defined in the Second Amended Credit Agreement) in any fiscal year.

Additionally, the Second Amended Credit Agreement contains customary events of default and affirmative and negative covenants for transactions of this type. As of December 31, 2016, we believe we were in compliance with all covenants set forth in the Second Amended Credit Agreement.

Future minimum principal payments on our long-term debt as of December 31, 2016, are as follows (in thousands):

<u>Years Ending December 31</u>	<u>Future Minimum Principal Payments</u>
2017 .....	10,000
2018 .....	12,500
2019 .....	15,000
2020 .....	17,500
2021 .....	270,000
Total future minimum principal payments .....	<u>\$325,000</u>

As of December 31, 2016, we had outstanding borrowings of approximately \$325.0 million under the Second Amended Credit Agreement, with available borrowings of approximately \$95.0 million, based on the leverage ratio required pursuant to the Second Amended Credit Agreement. Our interest

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**7. REVOLVING CREDIT FACILITY AND LONG-TERM DEBT (Continued)**

rate as of December 31, 2016 was a fixed rate of 3.12% on \$45.0 million and 2.98% on \$130.0 million as a result of interest rate swaps (see Note 8), and a variable floating rate of 2.77% on \$150.0 million. 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, variable floating rate of 1.74% on \$65.8 million and a variable floating rate of 2.12% on approximately \$6.8 million.

**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 interest rate swaps 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 hedging instruments are recorded in earnings throughout the term of the derivative.

**Interest Rate Risk.** 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 Second Amended Credit Agreement that is solely due to changes in the benchmark interest rate.

*Derivatives Designated as Cash Flow Hedges*

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 Second Amended Credit Agreement. The interest rate swap is scheduled to expire on December 19, 2017.

On August 5, 2016, we entered into a pay-fixed, receive-variable interest rate swap having an initial notional amount of \$42.5 million with Wells Fargo to fix the one-month LIBOR rate at 1.12%. The variable portion of the interest rate swap is tied to the one-month LIBOR rate (the benchmark interest rate). On a monthly basis, 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. The notional amount of the

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**8. DERIVATIVES (Continued)**

interest rate swap increases quarterly by an amount equal to the decrease of the hedge entered into on December 19, 2012, up to the amount of \$175.0 million. The interest rate swap is scheduled to expire on July 6, 2021.

At December 31, 2016 and 2015, our interest rate swaps qualified as cash flow hedges. The fair value of our interest rate swaps at December 31, 2016 was an asset of approximately \$5.0 million, which was partially offset by approximately \$1.9 million in deferred taxes. The fair value of our interest rate swap at December 31, 2015 was an asset of approximately \$2,000, which was offset by approximately \$1,000 in deferred taxes.

**Foreign Currency Risk.** We operate on a global basis and are exposed to the risk that our financial condition, results of operations, and cash flows could be adversely affected by changes in foreign currency exchange rates. To reduce the potential effects of foreign currency exchange rate movements on net earnings, we enter into derivative financial instruments in the form of foreign currency exchange forward contracts with major financial institutions. Our policy is to enter into foreign currency derivative contracts with maturities of up to two years. We are primarily exposed to foreign currency exchange rate risk with respect to transactions and balances denominated in Euros, British Pounds, Chinese Yuan Renminbi, Mexican Pesos, Brazilian Reals, Australian Dollars, Hong Kong Dollars, Swiss Francs, Swedish Krona, Canadian Dollars, and Danish Krone. We do not use derivative financial instruments for trading or speculative purposes. We are not subject to any credit risk contingent features related to our derivative contracts, and counterparty risk is managed by allocating derivative contracts among several major financial institutions.

*Derivatives Designated as Cash Flow Hedges*

For derivative instruments that are designated and qualify as cash flow hedges, the effective portion of the gain or loss on the derivative instrument is reported as a component of other comprehensive income (loss) and reclassified into earnings in the same line item associated with the forecasted transaction and in the same period or periods during which the hedged transaction affects earnings. The remaining gain or loss on the derivative instrument in excess of the cumulative change in the present value of future cash flows of the hedged item, if any (i.e., the ineffectiveness portion) or hedge components excluded from the assessment of effectiveness, are recognized in earnings during the current period. We entered into forward contracts on various foreign currencies to manage the risk associated with forecasted exchange rates which impact revenues, cost of sales, and operating expenses in various international markets. The objective of the hedges is to reduce the variability of cash flows associated with the forecasted purchase or sale of the associated foreign currencies.

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**8. DERIVATIVES (Continued)**

We enter into approximately 100 cash flow foreign currency hedges every month. As of December 31, 2016, we had entered into foreign currency forward contracts, which qualified as cash flow hedges, with the following notional amounts (in thousands and in local currencies):

<u>Currency</u>	<u>Symbol</u>	<u>Forward Notional Amount</u>
Euro . . . . .	EUR	11,065
Swiss Franc . . . . .	CHF	1,303
Danish Krone . . . . .	DKK	8,795
British Pound . . . . .	GBP	3,115
Mexican Peso . . . . .	MXN	76,525
Swedish Krona . . . . .	SEK	13,165

*Derivatives Not Designated as Cash Flow Hedges*

We forecast our net exposure in various receivables and payables to fluctuations in the value of various currencies, and we enter into foreign currency forward contracts to mitigate that exposure. We enter into approximately 20 foreign currency fair value hedges every month. As of December 31, 2016, we had entered into foreign currency forward contracts related to those balance sheet accounts with the following notional amounts (in thousands and in local currencies):

<u>Currency</u>	<u>Symbol</u>	<u>Forward Notional Amount</u>
Euro . . . . .	EUR	20,657
British Pound . . . . .	GBP	975
Chinese Yuan Renminbi . . . . .	CNY	16,615
Mexican Peso . . . . .	MXN	19,125
Brazilian Real . . . . .	BRL	5,100
Australian Dollar . . . . .	AUD	4,150
Hong Kong Dollar . . . . .	HKD	11,000
Swiss Franc . . . . .	CHF	230
Swedish Krona . . . . .	SEK	3,035
Canadian Dollar . . . . .	CAD	4,320

**Balance Sheet Presentation of Derivatives.** As of December 31, 2016 and 2015, all derivatives, both those designated as hedging instruments and those that were not designated as hedging instruments, were recorded gross at fair value on our consolidated balance sheets. We are not subject to any master netting agreements.

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**8. DERIVATIVES (Continued)**

The fair value of derivative instruments on a gross basis is as follows (in thousands):

	As of December 31, 2016		As of December 31, 2015	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
<i><b>Derivatives designated as hedging instruments</b></i>				
<i>Assets</i>				
Interest rates swaps . . . . .	Other assets (long-term)	\$4,991	Other assets (long-term)	\$ 2
Foreign currency forward contracts . . . . .	Prepaid expenses and other assets	116	N/A	—
Foreign currency forward contracts . . . . .	Other assets (long-term)	18	N/A	—
<i>Liabilities</i>				
Foreign currency forward contracts . . . . .	Accrued Expenses	(275)	N/A	—
Foreign currency forward contracts . . . . .	Other long-term obligations	(18)	N/A	—
<i><b>Derivatives not designated as hedging instruments</b></i>				
<i>Assets</i>				
Foreign currency forward contracts . . . . .	Prepaid expenses and other assets	\$ 220	Other Receivables	\$ 115
<i>Liabilities</i>				
Foreign currency forward contracts . . . . .	Accrued Expenses	(171)	Accrued Expenses	(278)



**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**8. DERIVATIVES (Continued)**

**Income Statement Presentation of Derivatives**

*Derivatives Designated as Cash Flow Hedges*

Derivative instruments designated as cash flow hedges had the following effects, before income taxes, on other comprehensive income and net earnings in our consolidated statements of earnings, consolidated statements of comprehensive income and consolidated balance sheets (in thousands):

	Amount of Gain/(Loss) recognized in OCI				Amount of Gain/ (Loss) reclassified from AOCI		
	Year ended December 31,				Year ended December 31,		
	2016	2015	2014		2016	2015	2014
				<i>Location in statements of income</i>			
<i>Derivative instrument</i>							
<i>Interest rate swaps . . . . .</i>	\$4,989	\$(571)	\$(630)	<i>Interest Expense . . . . .</i>	\$718	\$1,103	\$587
<i>Foreign currency forward contracts . . . . .</i>	68	—	—	<i>Revenue . . . . .</i>	21	—	—
<i>Foreign currency forward contracts . . . . .</i>	(273)	—	—	<i>Cost of goods sold . . . . .</i>	(26)	—	—

The net amount recognized in earnings during the years ended December 31, 2016, 2015 and 2014 due to ineffectiveness and amounts excluded from the assessment of hedge effectiveness were not significant.

As of December 31, 2016, approximately \$205,000, or \$125,000 after taxes, was expected to be reclassified from accumulated other comprehensive income to earnings in revenue and cost of sales over the succeeding twelve months. As of December 31, 2016, approximately \$91,000, or \$56,000 after taxes, was expected to be reclassified from accumulated other comprehensive income to earnings in interest expense over the succeeding twelve months.

*Derivatives Not Designated as Hedging Instruments*

The following gains/(losses) from these derivative instruments were recognized in our consolidated statements of income for the years presented (in thousands):

		Year ended December 31,		
		2016	2015	2014
<i>Derivative Instrument</i>	<i>Location in statements of income</i>			
Foreign currency forward contracts . . . . .	Other expense	\$69	\$(302)	\$8

See Note 16 for more information about our derivatives.

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**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, 2016, 2015 and 2014, approximated \$11.4 million, \$10.7 million and \$8.1 million, respectively.

The future minimum lease payments for operating leases as of December 31, 2016, consisted of the following (in thousands):

<u>Years Ending December 31</u>	<u>Operating Leases</u>
2017 .....	\$10,168
2018 .....	9,062
2019 .....	8,161
2020 .....	5,100
2021 .....	4,704
Thereafter .....	32,736
Total minimum lease payments .....	<u>\$69,931</u>

**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. We did not enter into any new sale and leaseback transactions during the year ended December 31, 2016. The lease agreements from the sale and leaseback transactions are accounted for as operating leases. Under the terms of the lease agreements, we have agreed to operate and maintain the equipment. The lease term of the agreements is seven years.

**Irish Government Development Agency Grants.** As of December 31, 2016, we had entered into several grant agreements with the Irish Government Development Agency. 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, 2016 and 2015, was approximately \$2.5 million and \$2.7 million, respectively. During the years ended December 31, 2016, 2015 and 2014, approximately \$170,000, \$171,000 and \$175,000, 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, 2016, the total amount of grants that could be subject to refund was approximately \$3.7 million, and the remaining grant liability period was two 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, contract disputes, and employment or other matters that are significant to our business. Based upon our review of currently available information, we do not believe that any such actions are likely to

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**9. COMMITMENTS AND CONTINGENCIES (Continued)**

be, individually or in the aggregate, materially adverse to our business, financial condition, results of operations or liquidity.

In October 2016, we received a subpoena from the U.S. Department of Justice seeking information on certain of our marketing and promotional practices. We are in the process of responding to the subpoena, which we anticipate will continue during 2017. We have incurred, and anticipate that we will continue to incur, substantial costs in connection with the matter. The investigation is ongoing and at this stage we are unable to predict its scope, duration or outcome. Investigations such as this may result in the imposition of, among other things, significant damages, injunctions, fines or civil or criminal claims or penalties against our company or individuals.

In the event of unexpected further developments, it is possible that the ultimate resolution of any of the foregoing matters, or other similar matters, if resolved in a manner unfavorable to us, 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):

	<u>Net Income</u>	<u>Shares</u>	<u>Per Share Amount</u>
Year ended December 31, 2016:			
Basic EPS . . . . .	\$20,121	44,408	<u>\$0.45</u>
Effect of dilutive stock options and warrants . . . . .		<u>454</u>	
Diluted EPS . . . . .	<u>\$20,121</u>	<u>44,862</u>	<u>\$0.45</u>
Year ended December 31, 2015:			
Basic EPS . . . . .	\$23,802	44,036	<u>\$0.54</u>
Effect of dilutive stock options and warrants . . . . .		<u>475</u>	
Diluted EPS . . . . .	<u>\$23,802</u>	<u>44,511</u>	<u>\$0.53</u>
Year ended December 31, 2014:			
Basic EPS . . . . .	\$22,974	43,143	<u>\$0.53</u>
Effect of dilutive stock options and warrants . . . . .		<u>266</u>	
Diluted EPS . . . . .	<u>\$22,974</u>	<u>43,409</u>	<u>\$0.53</u>

For the years ended December 31, 2016, 2015 and 2014, approximately 727,000, 423,000 and 1,292,000, respectively, of stock options were not included in the computation of diluted earnings per share because their effect would have been anti-dilutive.

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**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, 2016, a total of approximately 1.7 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, 2016, the total number of shares of Common Stock that remained available to be issued under our non-qualified plan was approximately 151,000 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, 2016, 2015 and 2014, consisted of the following (in thousands):

	<u>2016</u>	<u>2015</u>	<u>2014</u>
Cost of goods sold . . . . .	\$ 472	\$ 398	\$ 198
Research and development . . . . .	184	122	69
Selling, general, and administrative . . . . .	1,850	1,723	1,193
Stock-based compensation expense before taxes . . . . .	<u>\$2,506</u>	<u>\$2,243</u>	<u>\$1,460</u>

We recognize stock-based compensation expense (net of a forfeiture rate) for those awards which are expected to vest on a straight-line basis over the requisite service period. We estimate the forfeiture rate based on our historical experience and expectations about future forfeitures. As of December 31, 2016, the total remaining unrecognized compensation cost related to non-vested stock options, net of expected forfeitures, was approximately \$7.9 million and is expected to be recognized over a weighted average period of 3.45 years.

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

	<u>2016</u>	<u>2015</u>	<u>2014</u>
Risk-free interest rate . . .	1.15% - 1.40%	1.53% - 1.66%	1.53% - 1.97%
Expected option life . . . . .	5.0 years	5.0 years	5.0 - 5.5 years
Expected dividend yield . .	—%	—%	—%
Expected price volatility . .	34.28% - 37.06%	33.72% - 35.11%	34.52% - 36.90%

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

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**11. EMPLOYEE STOCK PURCHASE PLAN, STOCK OPTIONS AND WARRANTS. (Continued)**

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, 2016, 2015 and 2014, approximately 880,000, 618,000 and 666,000 stock-based compensation grants were made, respectively, for a total fair value of approximately \$5.2 million, \$3.7 million and \$2.8 million, net of estimated forfeitures, respectively.

The table below presents information related to stock option activity for the years ended December 31, 2016, 2015 and 2014 (in thousands):

	<u>2016</u>	<u>2015</u>	<u>2014</u>
Total intrinsic value of stock options exercised . . . . .	\$3,648	\$7,548	\$3,505
Cash received from stock option exercises . . . . .	4,577	6,227	7,697
Excess tax benefit from the exercise of stock options . . . .	669	2,124	576

Changes in stock options for the year ended December 31, 2016, consisted of the following (shares and intrinsic value in thousands):

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Remaining Contractual Term (in years)</u>	<u>Intrinsic Value</u>
Beginning balance . . . . .	2,408	\$14.26		
Granted . . . . .	880	17.43		
Exercised . . . . .	(362)	13.61		
Forfeited/expired . . . . .	(109)	14.52		
Outstanding at December 31 . . . . .	2,817	15.32	4.4	\$31,476
Exercisable . . . . .	1,033	13.64	2.7	13,274
Ending vested and expected to vest . . . . .	2,718	15.27	4.4	30,512

The weighted average grant-date fair value of options granted during the years ended December 31, 2016, 2015 and 2014 was \$5.94, \$5.98 and \$4.27, respectively.

The following table summarizes information about stock options outstanding at December 31, 2016 (shares in thousands):

<u>Range of Exercise</u>	<u>Options Outstanding</u>			<u>Options Exercisable</u>	
	<u>Number Outstanding</u>	<u>Weighted Average Remaining Contractual Life (in years)</u>	<u>Weighted Average Exercise Price</u>	<u>Number Exercisable</u>	<u>Weighted Average Exercise Price</u>
\$9.95 - \$13.16	772	3.70	\$12.11	393	\$12.23
\$13.75 - \$16.05	1,181	4.02	\$14.84	533	\$13.77
\$16.41 - \$20.27	747	5.54	\$18.35	103	\$18.06
\$21.71 - \$22.00	117	6.54	\$21.94	4	\$21.98
\$9.95 - \$22.00	<u>2,817</u>			<u>1,033</u>	

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**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 embolotherapeutic, cardiac rhythm management (“CRM”), electrophysiology (“EP”), and interventional oncology and spine 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, 2016, 2015 and 2014 (in thousands):

	<u>% Change</u>	<u>2016</u>	<u>% Change</u>	<u>2015</u>	<u>% Change</u>	<u>2014</u>
<b>Cardiovascular</b>						
Stand-alone devices . . . . .	25%	\$193,517	8%	\$155,414	15%	\$143,712
Custom kits and procedure trays . .	3%	119,392	5%	116,368	7%	111,076
Inflation devices . . . . .	1%	73,919	1%	73,373	10%	72,538
Catheters . . . . .	15%	110,939	11%	96,833	17%	87,550
Embolization devices . . . . .	2%	46,035	3%	45,025	31%	43,855
CRM/EP . . . . .	8%	36,446	3%	33,902	17%	32,975
Total . . . . .	11%	580,248	6%	520,915	14%	491,706
<b>Endoscopy</b>						
Endoscopy devices . . . . .	11%	23,590	18%	21,234	6%	17,983
Total . . . . .	11%	<u>\$603,838</u>	6%	<u>\$542,149</u>	14%	<u>\$509,689</u>

During the years ended December 31, 2016, 2015 and 2014, we had foreign sales of approximately \$233.5 million, \$214.0 million and \$198.3 million, respectively, or approximately 39%, 39% and 39%, respectively, of net sales, primarily in China, Japan, Germany, France, the United Kingdom and Russia. China represents our most significant international sales market with sales of approximately \$59.9 million, \$50.7 million, and \$40.7 million for the years ended December 31, 2016, 2015 and 2014, respectively. Foreign sales are attributed based on location of the customer receiving the product.

Our long-lived assets by geographic area at December 31, 2016, 2015 and 2014, consisted of the following (in thousands):

	<u>2016</u>	<u>2015</u>	<u>2014</u>
United States . . . . .	\$194,715	\$186,389	\$177,627
Ireland . . . . .	47,337	48,896	49,708
Other foreign countries . . . . .	34,521	32,493	16,836
Total . . . . .	<u>\$276,573</u>	<u>\$267,778</u>	<u>\$244,171</u>



**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**12. SEGMENT REPORTING AND FOREIGN OPERATIONS (Continued)**

Financial information relating to our reportable operating segments and reconciliations to the consolidated totals for the years ended December 31, 2016, 2015 and 2014, are as follows (in thousands):

	<u>2016</u>	<u>2015</u>	<u>2014</u>
<b>Net Sales</b>			
Cardiovascular . . . . .	\$580,248	\$520,915	\$491,706
Endoscopy . . . . .	23,590	21,234	17,983
Total net sales . . . . .	603,838	542,149	509,689
<b>Operating expenses</b>			
Cardiovascular . . . . .	218,659	187,492	175,152
Endoscopy . . . . .	11,490	10,746	9,904
Total operating expenses . . . . .	230,149	198,238	185,056
<b>Operating income (loss)</b>			
Cardiovascular . . . . .	30,120	34,052	38,601
Endoscopy . . . . .	4,756	3,491	1,565
Total operating income . . . . .	34,876	37,543	40,166
Total other expense—net . . . . .	(9,490)	(6,343)	(8,594)
Income tax expense . . . . .	5,265	7,398	8,598
Net income . . . . .	<u>\$ 20,121</u>	<u>\$ 23,802</u>	<u>\$ 22,974</u>

Total assets by business segment at December 31, 2016, 2015 and 2014, consisted of the following (in thousands):

	<u>2016</u>	<u>2015</u>	<u>2014</u>
Cardiovascular . . . . .	\$932,927	\$767,952	\$734,940
Endoscopy . . . . .	9,876	10,776	12,225
Total . . . . .	<u>\$942,803</u>	<u>\$778,728</u>	<u>\$747,165</u>

Total depreciation and amortization by business segment for the years ended December 31, 2016, 2015, and 2014 consisted of the following (in thousands):

	<u>2016</u>	<u>2015</u>	<u>2014</u>
Cardiovascular . . . . .	\$42,806	\$36,474	\$34,975
Endoscopy . . . . .	949	951	954
Total . . . . .	<u>\$43,755</u>	<u>\$37,425</u>	<u>\$35,929</u>

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**12. SEGMENT REPORTING AND FOREIGN OPERATIONS (Continued)**

Total capital expenditures for property and equipment by business segment for the years ended December 31, 2016, 2015 and 2014 consisted of the following (in thousands):

	<u>2016</u>	<u>2015</u>	<u>2014</u>
Cardiovascular . . . . .	\$32,613	\$50,927	\$33,660
Endoscopy . . . . .	224	32	521
Total . . . . .	<u>\$32,837</u>	<u>\$50,959</u>	<u>\$34,181</u>

**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 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 recorded expense of approximately \$1.8 million, \$1.5 million and \$1.5 million related to royalty payments to AP-HP for the years ended December 31, 2016, 2015 and 2014, respectively. These amounts are included as a current liability in accrued expenses in our consolidated balance sheets for the years indicated.

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, 2016, 2015 and 2014, totaled approximately \$2.3 million, \$2.0 million and \$1.8 million, respectively.

We also 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, 2016, 2015 and 2014, totaled approximately \$1.1 million, \$893,000 and \$912,000, respectively.

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**15. QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)**

Quarterly data for the years ended December 31, 2016 and 2015 consisted of the following (in thousands, except per share amounts):

	Quarter Ended			
	March 31	June 30	September 30	December 31
<b>2016</b>				
Net sales . . . . .	\$138,077	\$151,071	\$156,975	\$157,715
Gross profit . . . . .	60,100	66,854	67,815	70,256
Income from operations . . . . .	7,706	11,581	2,987	12,602
Income tax expense (benefit) . . . . .	1,555	2,572	(978)	2,116
Net income . . . . .	4,351	7,290	973	7,507
Basic earnings per common share . . . . .	0.10	0.16	0.02	0.17
Diluted earnings per common share . . . . .	0.10	0.16	0.02	0.17
<b>2015</b>				
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

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.

**16. FAIR VALUE MEASUREMENTS**

Our financial assets and (liabilities) carried at fair value measured on a recurring basis as of December 31, 2016 and 2015, consisted of the following (in thousands):

Description	Total Fair Value at December 31, 2016	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) . . . . .	\$4,991	\$—	\$4,991	\$—
Foreign currency contract assets, current and long-term(2) . . . . .	\$ 354	\$—	\$ 354	\$—
Foreign currency contract liabilities, current and long-term(3) . . . . .	\$ (464)	\$—	\$ (464)	\$—

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**16. FAIR VALUE MEASUREMENTS (Continued)**

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)	\$—

- (1) The fair value of the interest rate contracts is determined using Level 2 fair value inputs and is recorded as other assets or other long-term obligations in the consolidated balance sheets.
- (2) The fair value of the foreign currency contract assets (including those designated as hedging instruments and those not designated as hedging instruments) is determined using Level 2 fair value inputs and is recorded as prepaid and other assets or other long-term assets in the consolidated balance sheets.
- (3) The fair value of the foreign currency contract liabilities (including those designated as hedging instruments and those not designated as hedging instruments) is determined using Level 2 fair value inputs and is recorded as accrued expenses or other long-term obligations 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, 2016 and 2015, consisted of the following (in thousands):

	2016	2015
Beginning balance . . . . .	\$1,024	\$ 1,886
Contingent consideration liability recorded as the result of acquisitions (see Note 2) . . . . .	—	270
Fair value adjustments recorded to income during the period . . . .	(123)	80
Contingent payments made . . . . .	(218)	(1,212)
Ending balance . . . . .	<u>\$ 683</u>	<u>\$ 1,024</u>

As of December 31, 2016, approximately \$595,000 was included in other long-term obligations and approximately \$88,000 was included in accrued expenses in our consolidated balance sheet. 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. 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.

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**16. FAIR VALUE MEASUREMENTS (Continued)**

During the first quarter of 2016, we sold a cost method investment for cash and for the right to receive additional payments based on various contingent milestones. We determined the fair value of the contingent payments using Level 3 inputs defined under authoritative guidance for fair value measurements, and we recorded a contingent receivable asset, which as of December 31, 2016 had a value of approximately \$528,000. We record any changes in fair value to operating expenses as part of our cardiovascular segment in our consolidated statements of income. During the year ended December 31, 2016, we recorded a loss on the contingent receivable of approximately \$184,000. As of December 31, 2016, approximately \$367,000 was included in other long-term assets and approximately \$161,000 was included in other receivables as a current asset in our consolidated balance sheet.

The recurring Level 3 measurement of our contingent consideration liability and contingent receivable includes the following significant unobservable inputs at December 31, 2016 and 2015 (amounts in thousands):

Contingent consideration asset or liability	Fair value at December 31, 2016	Valuation technique	Unobservable inputs	Range
Revenue-based payments contingent liability . . . . .	\$683	Discounted cash flow	Discount rate Probability of milestone payment Projected year of payments	9.9% - 15% 100% 2017 - 2028
Contingent receivable asset . . . . .	\$528	Discounted cash flow	Discount rate Probability of milestone payment Projected year of payments	10% 57% 2017 - 2019
Contingent consideration liability	Fair value at December 31, 2015	Valuation technique	Unobservable inputs	Range
Revenue-based payments contingent liability . . . . .	\$874	Discounted cash flow	Discount rate Probability of milestone payment Projected year of payments	5% - 15% 100% 2016 - 2028
Other payments contingent liability . . . . .	\$150	Discounted cash flow	Discount rate Probability of milestone payment Projected year of payments	—% 100% 2016

The contingent consideration liability and contingent receivable are 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

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**16. FAIR VALUE MEASUREMENTS (Continued)**

a discounted cash flow model. Projected revenues are based on our most recent internal operational budgets and long-range strategic plans. 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. A decrease in the probability of any milestone payment may result in lower fair value measurements. Our determination of the fair value of the contingent consideration liability and contingent receivable 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.

During the years ended December 31, 2016, 2015 and 2014, we had losses of approximately \$101,000, \$141,000, and \$1.4 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 approximate 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.

**17. SUBSEQUENT EVENTS**

We have evaluated whether any subsequent events have occurred from December 31, 2016 to the time of filing of this report that would require disclosure in the consolidated financial statements. We note the following events below.

On February 1, 2017, we acquired certain products from Argon Medical Devices, Inc. and Catheter Connections, Inc. The combined transactions were financed with a combination of cash and existing credit facilities, which totaled \$48.0 million. We are currently evaluating the accounting treatment of these purchases, as well as performing the valuation of the assets acquired and the related purchase price allocation.



### ***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, 2016. Based on this evaluation, our principal executive officer and principal financial officer concluded that as of December 31, 2016, our disclosure controls and procedures were effective, at a reasonable assurance level, to ensure that information we are required to disclose in the reports we file or submit under the Exchange Act is (a) recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms and is (b) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

#### **MANAGEMENT’S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING**

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2016. 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)*. However, as permitted by SEC guidance, we have excluded DFINE from management’s assessment of internal control over financial reporting as of December 31, 2016. DFINE’s assets constituted approximately 4.6% of our total assets as of December 31, 2016 (excluding approximately \$96.6 million of goodwill and intangible assets, which were integrated into our systems and control environment). Additionally, DFINE’s operations contributed 2.2% of our 2016 net sales, and resulted in a net pre-tax loss in 2016 of approximately \$6.8 million (excluding approximately \$2.7 million of amortization of intangible assets, which was integrated into our systems and control environment).

Based on the criteria discussed above and our management’s assessment, our management concluded that, as of December 31, 2016, our internal control over financial reporting was effective.

#### **CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING**

Except as set forth below, during the quarter ended December 31, 2016, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934).

On July 6, 2016, we completed our acquisition of DFINE. We are currently integrating the policies, processes, employees, technology and operations of DFINE. Management does not currently expect a material change to our internal controls over financial reporting as we fully integrate DFINE into our operations.

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

## 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, 2016, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. As described in Management’s Report on Internal Control over Financial Reporting, management excluded DFINE from its assessment of internal control over financial reporting, which was acquired on July 6, 2016, and whose financial statements constitutes approximately 4.6% of total assets (excluding approximately \$96.6 million of goodwill and intangible assets, which was integrated into the Company’s systems and control environment), 2.2% of net sales, and resulted in a net pre-tax loss of approximately \$6.8 million (excluding approximately \$2.7 million of amortization of intangible assets, which was integrated into the Company’s systems and control environment) of the consolidated financial statement amounts as of and for the year ended December 31, 2016. Accordingly, our audit did not include the internal control over financial reporting at DFINE. 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, 2016, 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, 2016 of the Company and our report dated March 1, 2017 expressed an unqualified opinion on those financial statements and financial statement schedule.

/s/ DELOITTE & TOUCHE LLP

Salt Lake City, Utah

March 1, 2017

**Item 9B. Other Information.**

None.

**PART III**

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

The information required by these items is incorporated by reference to our definitive proxy statement relating to our Annual Meeting of Shareholders scheduled for May 24, 2017. We anticipate that our definitive proxy statement will be filed with the SEC not later than 120 days after December 31, 2016, 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—Financial Statements . . . . .	63
Consolidated Balance Sheets as of December 31, 2016 and 2015 . . . . .	64
Consolidated Statements of Income for the Years Ended December 31, 2016, 2015, and 2014 . . .	65
Consolidated Statements of Comprehensive Income for the Years Ended December 31, 2016, 2015 and 2014 . . . . .	66
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2016, 2015 and 2014 . . . . .	67
Consolidated Statements of Cash Flows for the Years Ended December 31, 2016, 2015 and 2014 .	68
Notes to Consolidated Financial Statements . . . . .	70
Report of Independent Registered Public Accounting Firm—Internal Control . . . . .	109

(2) Financial Statement Schedule.

—Schedule II—Valuation and qualifying accounts

**Years Ended December 31, 2016, 2015 and 2014**  
**(In thousands)**

<u>Description</u>	<u>Balance at Beginning of Year</u>	<u>Additions Charged to Costs and Expenses(a)</u>	<u>Deduction(b)</u>	<u>Additions due to Acquisitions(c)</u>	<u>Balance at End of Year</u>
<b>ALLOWANCE FOR UNCOLLECTIBLE ACCOUNTS:</b>					
<b>2014</b> .....	(840)	(83)	30	—	(893)
<b>2015</b> .....	(893)	(607)	203	—	(1,297)
<b>2016</b> .....	(1,297)	(404)	322	(208)	(1,587)

- (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.
- (c) This amount includes additional allowance recorded as a result of acquisitions made during the years presented.

**Years Ended December 31, 2016, 2015 and 2014**  
**(In thousands)**

<u>Description</u>	<u>Balance at Beginning of Year</u>	<u>Additions Charged to Costs and Expenses(d)</u>	<u>Deduction</u>	<u>Balance at End of Year</u>
<b>TAX VALUATION ALLOWANCE:</b>				
<b>2014</b> .....	(1,363)	(240)	—	(1,603)
<b>2015</b> .....	(1,603)	(378)	—	(1,981)
<b>2016</b> .....	(1,981)	(1,805)	—	(3,786)

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



(b) Exhibits:

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

	Description	Exhibit No.
2.1	Agreement and Plan of Merger by and among Merit, MMS Transaction Co., a wholly-owned subsidiary of Merit, DFine Inc., certain preferred stockholders and Shareholder Representative Services LLC as a stockholder representative*	[Form 10-Q filed August 8, 2016, and Form 10-Q/A filed September 2, 2016, Exhibit No. 2.1]
3.1	Amended and Restated Articles of Incorporation dated February 28, 2017	Filed herewith.
3.2	Second Amended and Restated Bylaws*	[Form 8-K filed December 16, 2015]
4.1	Specimen Certificate of the Common Stock*	[Form S-18 filed October 19, 1989, Exhibit No. 10]
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]
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]

	Description	Exhibit No.
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	Separation Agreement and Release of All Claims of Greg Barnett dated November 3, 2015*†	[Form 10-K for year ended December 31, 2015, Exhibit No. 10.23]
10.16	Separation Agreement and Release of All Claims of Rashelle Perry dated December 1, 2015*†	[Form 10-K for year ended December 31, 2015, Exhibit No. 10.24]
10.17	Separation Agreement and Release of All Claims of Kent W. Stanger dated January 4, 2016*†	
10.18	Second Amended and Restated Credit Agreement dated as of July 6, 2016 by and among Merit Medical Systems, Inc., Wells Fargo Bank, National Association, Well Fargo Securities, LLC and the lenders named therein*	[Form 10-Q for quarter ended June 30, 2016, Exhibit No. 10.1]
10.19	Form of Indemnification Agreement, dated June 13, 2016, between the Company and each of the following individuals: Fred P. Lampropoulos, Kent W. Stanger, Nolan E. Karras, A. Scott Anderson, Richard W. Edelman, Franklin J. Miller, M.D., Michael E. Stillabower, M.D., F. Ann Millner, Ed. D., Bernard J. Birkett, Ronald A. Frost, Joseph C. Wright, Justin J. Lampropoulos, and Brian G. Lloyd*†	[Form 10-Q for quarter ended June 30, 2016, Exhibit No. 10.2]
10.20	Form of Employment Agreement, dated May 26, 2016 between the Company and each of the following individuals: Bernard J. Birkett, Ronald A. Frost, Joseph C. Wright, Justin J. Lampropoulos, and Brian G. Lloyd*†	[Form 10-Q for quarter ended June 30, 2016, Exhibit No. 10.3]
10.21	Employment Agreement, dated May 26, 2016 between the Company and Fred P. Lampropoulos*†	[Form 10-Q for quarter ended June 30, 2016, Exhibit No. 10.4]

	<b>Description</b>	<b>Exhibit No.</b>
10.22	Third Amendment to the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan dated February 13, 2015†	Filed herewith
10.23	Merit Medical Systems, Inc., Restatement of the 1996 Employee Stock Purchase Plan dated July 1, 2000†	Filed herewith
10.24	First Amendment to the Merit Medical Systems, Inc., 1996 Employee Stock Purchase Plan dated April 1, 2001†	Filed herewith
10.25	Second Amendment to the Merit Medical Systems, Inc., 1996 Employee Stock Purchase Plan dated January 1, 2006†	Filed herewith
10.26	Third Amendment to the Merit Medical Systems, Inc., 1996 Employee Stock Purchase Plan dated April 7, 2006†	Filed herewith
10.27	Fourth Amendment to the Merit Medical Systems, Inc., 1996 Employee Stock Purchase Plan dated February 13, 2015†	Filed herewith
10.28	Indemnification Agreement, dated July 23, 2016, between the Company and David M. Liu†	Filed herewith
10.29	First Amendment to Second Amended and Restated Credit Agreement, dated September 28, 2016	Filed herewith
21	Subsidiaries of Merit Medical Systems, Inc.	Filed herewith
23.1	Consent of Independent Registered Public Accounting Firm	Filed herewith
31.1	Certification of Chief Executive Officer	Filed herewith
31.2	Certification of Chief Financial Officer	Filed herewith
32.1	Certification of Chief Executive Officer	Filed herewith
32.2	Certification of Chief Financial Officer	Filed herewith

	Description	Exhibit No.
101	The following materials from the Merit Medical Systems, Inc. Annual Report on Form 10-K for the fiscal year ended December 31, 2016, 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

**Item 16. Form 10-K Summary.**

None.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, on March 1, 2017.

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 March 1, 2017.

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

**EXECUTIVE OFFICERS**

**Fred P. Lampropoulos**  
Chairman, Chief Executive Officer

**Bernard J. Birkett**  
Chief Financial Officer, Treasurer

**Brian G. Lloyd**  
Chief Legal Officer, Corporate Secretary

**Ronald A. Frost**  
Chief Operating Officer

**Justin J. Lampropoulos**  
Executive Vice President Global Sales,  
Marketing and Strategy

**Joseph C. Wright**  
President, International

**BOARD OF DIRECTORS**

**Fred P. Lampropoulos**  
Chairman, Chief Executive Officer  
Merit Medical Systems, Inc.

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

**Richard W. Edelman**  
Private Investor

**Nolan E. Karras**  
Chairman and Chief Executive Officer  
The Karras Company, Inc.

**David M. Liu, MD**  
Clinical Associate Professor, Faculty of Medicine,  
University of British Columbia

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

**F. Ann Millner, Ed. D.**  
Regents Professor in Health Administrative Services  
Weber State University

**Kent W. Stanger**  
Former Chief Financial Officer  
Merit Medical Systems, Inc.

**Michael E. Stillabower, M.D.**  
Director, Cardiovascular Clinic Trials  
Christiana Care Health System  
Clinical Associate Professor of Medicine  
Jefferson Medical College

**CORPORATE OFFICES**

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

**INDEPENDENT ACCOUNTANTS**

Deloitte & Touche LLP

**LEGAL COUNSEL**

**Parr Brown Gee & Loveless**  
Corporate and Securities Counsel

**Stoel Rives LLP**  
Intellectual Property Counsel

**Workman Nydegger**  
Intellectual Property Counsel

**FORM 10-K**

Merit Medical Systems, Inc. filed an Annual Report on Form 10-K with the Securities and Exchange Commission for the fiscal year ended December 31, 2016. A copy may be obtained by written request from Anne-Marie Wright at Merit's corporate office in South Jordan, Utah.

**ANNUAL MEETING**

All shareholders are invited to attend Merit's Annual Meeting of Shareholders on Wednesday, May 24, 2017, at 3:00 p.m. at Merit's corporate offices in South Jordan, Utah.

**STOCK TRANSFER AGENT/REGISTRAR**

Zions Bank, a division of ZB, N.A.  
P. O. Box 30880  
Salt Lake City, Utah 84130

**MARKET INFORMATION**

Merit's common stock is traded on the NASDAQ Global Select Market System under the symbol "MMSI." As of February 24, 2017, the number of shares of Common Stock outstanding was 44,651,196 held by approximately 119 shareholders of record, not including shareholders whose shares are held in securities position listings. The following chart sets forth the high and low closing sale prices for Merit's common stock for the last two years:

2015	HIGH	LOW	2016	HIGH	LOW
First Quarter	\$19.96	\$15.20	First Quarter	\$19.49	\$15.47
Second Quarter	\$22.15	\$18.28	Second Quarter	\$20.59	\$17.94
Third Quarter	\$26.42	\$21.00	Third Quarter	\$25.08	\$19.61
Fourth Quarter	\$25.50	\$17.60	Fourth Quarter	\$26.85	\$20.70

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

**MARKET INFORMATION**

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

**FOR MORE INFORMATION, CONTACT**

**Bernard J. Birkett**  
Chief Financial Officer, Treasurer  
Merit Medical Systems, Inc.  
(801) 253-1600

This report includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. All statements other than statements of historical fact are forward-looking statements for purposes of these provisions. Merit assumes no obligation to update any forward-looking statement. Although Merit believes the expectations reflected in the forward-looking statements contained herein are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results will likely differ, and may differ materially, from those projected or assumed in the forward-looking statements. Merit's future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including factors referenced in Merit's press releases and filings with the Securities and Exchange Commission. A number of the factors that may have a direct bearing on Merit's financial condition and operating results are described under "Risk Factors" beginning on page 27 of Merit's Annual Report on Form 10-K, filed with the U.S. Securities and Exchange Commission on March 1, 2017.





**VISION. GROWTH. PROFITABILITY.™**

**MERIT MEDICAL SYSTEMS, INC.**

1600 West Merit Parkway, South Jordan, Utah 84095

+1 (801) 253-1600 [www.merit.com](http://www.merit.com)