MERIT MEDICAL SYSTEMS INC
Form 10-K
March 01, 2019
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iso4217:EUR iso4217:HKD iso4217:BRL mmsi:hedge

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
for the fiscal year ended December 31, 2018

or

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

MERIT MEDICAL SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

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

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

Securities registered pursuant to Section 12(b) of the Act: **Common Stock, No Par Value,** registered on the NASDAQ Global Select Market
Securities registered pursuant to Section 12(g) of the Act: **None**

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

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

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

Indicate by check mark whether the registrant has submitted electronically 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 such files). Yes x No o

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

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

Large Accelerated Filer x	Accelerated Filer o	Non-Accelerated Filer o (Do not check if a smaller reporting company)	Smaller Reporting Company o	Emerging Growth Company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant on June 29, 2018, which is the last business day of the registrant's most recently completed second fiscal quarter (based upon the closing sale price of $51.20 of the registrant's common stock on the NASDAQ National Market System on June 29, 2018), was approximately $2.5 billion. Shares of common stock held by each officer and director of the registrant and by each person who may be deemed to be an affiliate have been excluded.

As of February 26, 2019, the registrant had 54,902,835 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the following document are incorporated by reference in Part III of this Report: the registrant's definitive proxy statement relating to the Annual Meeting of Shareholders scheduled for May 23, 2019.

Table of Contents

TABLE OF CONTENTS

Table of Contents

PART I

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

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This report includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, 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 form 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 physicians' use of our products in unapproved circumstances;
- FDA regulatory clearance processes and any failure to obtain and maintain required regulatory clearances and approvals;
- international regulatory clearance processes and any failure to obtain and maintain required regulatory clearances and approvals;
- disruption of our security of information technology systems to operate our business, our critical information systems or a breach in the security of our systems;

- the effect of evolving U.S. and international laws and regulations regarding privacy and data protection;
- uncertainties about when, how or if the United Kingdom will withdraw from the European Union;
- risks relating to significant adverse changes in, or our failure to comply, with governing regulations;
- restrictions and limitations in our debt agreements and instruments, which could affect our ability to operate our business and our liquidity;
- uncertainties relating to the LIBOR calculation and potential phasing out of LIBOR after 2021;

Table of Contents

- expending significant resources for research, development, testing and regulatory approval or clearance of our products under development and any failure to develop the products, any failure of the products to be effective or any failure to obtain approvals for commercial use;
- violations of laws targeting fraud and abuse in the healthcare industry;
- risks relating to healthcare legislation negatively affecting our financial results, business, operations or financial condition;
- loss of key personnel;
- termination or interruption of, or a failure to monitor, our supply relationships or increases in the price of our component parts, finished products, third-party services or raw materials, particularly petroleum-based products;
- product liability claims;
- failure to report adverse medical events to the FDA or other governmental authorities, 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;
- employees, independent contractors, consultants, manufacturers and distributors engaging in misconduct or other improper activities, including noncompliance;
- the addressable market for our product groups being smaller than our estimates;
- consolidation in the healthcare industry, group purchasing organizations or public procurement policies leading to demands for price concessions;
- our 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;
- inability to accurately forecast customer demand for our products or manage our inventory;
- international and national economic and industry conditions constantly changing;
- changes in general economic conditions, geopolitical conditions, U.S. trade policies and other factors beyond our control;
- 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;
- 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;

- 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;
- volatility of the market price of our common stock and potential dilution from future equity offerings; and

Table of Contents

- 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 22.

Table of Contents

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 "™" 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.

Our Company

Merit Medical Systems, Inc. is a leading manufacturer and marketer of proprietary disposable medical devices used in interventional, diagnostic and therapeutic procedures, particularly in cardiology, radiology, oncology, critical care and endoscopy. We strive 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 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. 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 through strategic acquisitions.

Business Strategy

Our business strategy focuses on five target areas as follows:

- enhancing global growth and profitability through research and development, sales model optimization, cost discipline and operational focus;
- optimizing our operational capability through lean processes, cost effective environments and asset utilization;
- targeting high-growth, high-return opportunities by understanding, innovating and delivering in our core product groups;
- maintaining a highly disciplined, customer-focused enterprise guided by strong core values to globally address unmet or underserved healthcare needs, and
- creating sustainability of our business for our employees, shareholders and community.

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.

Products

We design, develop, market and manufacture, through our own operations and contract manufacturers, medical products that offer a high level of quality, value and safety to our customers, as well as the patients they serve. Our products are used in the following clinical areas: diagnostic and interventional cardiology; interventional radiology; neurointerventional radiology; vascular, general and thoracic surgery; electrophysiology; cardiac rhythm management; interventional pulmonology; interventional nephrology; orthopaedic spine surgery; interventional oncology; pain management; outpatient access centers; intensive care; computed tomography; ultrasound; and interventional gastroenterology. During the years ended December 31, 2018, 2017 and 2016, net sales generated by our top ten selling products accounted for approximately 33%, 37% and 39%, respectively of our total net sales. Sales of our inflation devices (including our Big60® device sold within our endoscopy segment and kits and packs which include inflation devices, but also include other products) accounted for approximately 10.8%, 11.4% and 12.7% of our net sales for the years ended December 31, 2018, 2017 and 2016, respectively.

Table of Contents

The success of our products is enhanced by the extensive experience of our management team in the healthcare industry, our experienced direct sales force and distributors, our ability to provide custom procedural solutions such as kits, trays and procedural packs at the request of our customers and our dedication to offering facility-unique solutions in the markets we serve worldwide.

Our products are offered for sale in six core product groups: peripheral intervention, cardiac intervention, cardiovascular and critical care, interventional oncology and spine, breast cancer localization and guidance, and endoscopy. A number of our products are marketed within multiple product groups; 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 core product groups are as follows:

- Peripheral Intervention: $3.1 billion (global)
- Cardiac Intervention: $1.8 billion (global)
- Cardiovascular and Critical Care: $5.5 billion (global)
- Interventional Oncology and Spine: $1.4 billion (global)
- Breast Cancer Localization and Guidance: $1 billion (global)
- Endoscopy: $484 million (U.S. domestic)

We currently conduct our business through two financial reporting segments: cardiovascular (which includes our peripheral intervention, cardiac intervention, interventional oncology and spine, cardiovascular and critical care, and breast cancer localization and guidance product groups) and endoscopy. For information relating to our business segments, see Note 13 to our consolidated financial statements set forth in Item 8 of this report.

Peripheral Intervention

Our peripheral intervention products 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 Solutions. The main products we offer under these portfolios are identified below.

We offer a broad line of medical devices used to gain and maintain vascular access. These products include our micropuncture kits, angiographic needles, our family of Prelude® sheath introducers and a wide range of guide wires and safety products. Additionally, we offer hemodialysis and peritoneal dialysis catheters and grafts which provide dialysis access options across a continuum of disease states. Our principal dialysis and graft offerings include:

- our HeRO® (Hemodialysis Reliable Outflow) Graft, a fully subcutaneous vascular access system, which is intended for use in maintaining long-term vascular access for chronic hemodialysis patients,
- our CentrosFLO® Long-Term Hemodialysis Catheter and ProGuide® Chronic Dialysis Catheter,
- our peritoneal dialysis catheters, accessories and implantation kits, and
- our Surfacer® Inside-Out® Access Catheter System, an innovative approach to restore access and to preserve treatment options for hemodialysis patients with occluded veins. The Surfacer Inside-Out is sold through our distribution agreement with BlueGrass Vascular Technologies.

Our angiography products are used to identify blockages and other disease states in the blood vessel. Our angiography products include:

-

our extensive line of Merit Laureate® Hydrophilic Guide Wires, a smooth-surface guide wire designed to minimize friction and promote rapid catheter exchanges,

- our InQwire® Diagnostic Guide Wires and InQwire® Amplatz guide wires, and
- our Performa® and Impress® Diagnostic Catheters, designed for traversing difficult to access peripheral blood vessels.

Table of Contents

Our intervention products are chiefly used to remove blood clots, retrieve foreign bodies in blood vessels and assist with placing balloons and stents to treat arterial disease.

On May 18, 2018, we entered into a distribution agreement with QXMédical, LLC ("QXMédical") for the exclusive global distribution rights to the Q50® PLUS Stent Graft Balloon Catheter. The Q50 PLUS is used in abdominal and thoracic endovascular aneurysm repair procedures to repair abdominal aortic aneurysms and thoracic aortic aneurysms.

On December 14, 2018 we acquired the intellectual property rights, inventory and certain other assets of Vascular Insights, LLC ("Vascular Insights"). The primary assets are the ClariVein® IC and ClariVein OC specialty infusion and occlusion catheter systems utilized in more than 120,000 cases to treat superficial venous disease, particularly below the knee and in venous leg ulcers. In addition to our Q50 PLUS, ClariVein IC and ClariVein OC specialty infusion and occlusion catheter systems, our intervention offerings include:

- our Advocate™ Percutaneous Transluminal Angioplasty ("PTA") Catheter and Dynamis AV™ PTA Dilatation Catheter, used to correct failing or thrombosed dialysis fistulae,
- our Fountain® Infusion System and Mistique® Infusion Catheters, used to treat arterial and hemodialysis graft occlusions and deep vein thrombosis,
- our low profile and standard ASAP® Aspiration Catheters, a safe and efficient catheter used to remove fresh, soft emboli and thrombi from vessels,
- our extensive line of EN Snare® and One Snare® Endovascular Snare Systems, snares designed to manipulate, capture and retrieve foreign material in the body,
- our line of inflations devices, including our basixTOUCH™ Inflation Device, BasixCompak™ Inflation Device and Blue Diamond™ Digital Inflation Device, designed to accurately measure pressures during balloon and stent deployment. and
- our new high-pressure basixTOUCH40™ Inflation Device, introduced in 2018, which features a quick-release handle with a 40-atmosphere pressure capacity.

Our drainage products are used to drain fluids from body cavities to relieve pain and discomfort and lessen trauma. On February 14, 2018, we expanded our drainage product line through our acquisition of the divestment assets of Becton, Dickinson and Company ("BD") in connection with BD’s recently completed acquisition of C.R. Bard, Inc. ("Bard") in which we acquired the Aspira® Pleural Effusion Drainage and Aspira® Peritoneal Drainage Systems. The Aspira system provides a compassionate home treatment option for end-stage cancer patients with malignant pleural effusion or malignant ascites, allowing patients to spend more time at home by eliminating the need for frequent hospital visits to treat their symptoms. In the same acquisition, we acquired soft tissue core needle biopsy products sold under the trade names Achieve® Programmable Automatic Biopsy System, Temno® Biopsy System and Tru-Cut® Biopsy Needles.

In addition to our Aspira® products, we offer a broad line of drainage access products. Our drainage access products include:

- our One-Step™ and Valved One-Step™ Drainage Catheters, sold individually and in kits, for emergency drainage procedures, quickly removing unwanted fluid accumulation,
- our ReSolve® Locking and Non-Locking Drainage Catheters, Resolve Biliary Catheter and related products including tubing sets and drainage bags, and
- our Revolution™ Catheter Securement Device and StayFIX® Fixation Device, used to stop migration, movement and accidental removal of a percutaneous catheter.

In addition to the soft tissue core needle biopsy products we acquired from BD, our biopsy product offerings also include:

- our innovative CorVocet® Biopsy System, introduced in 2018, for soft tissue biopsy procedures, designed to cut a full-core of tissue, providing large specimens for pathological examination, and
- our Madison™, Huntington™, Kensington™, Preston™ and Westbrook™ bone and spine biopsy products, now fully launched the U.S.

Our solutions products conveniently package an assortment of peripheral intervention products in trays, packs and kits.

Cardiac Intervention Products

We manufacture and sell a variety of products designed to treat various heart conditions. Our cardiac intervention product group is organized under the following product portfolios: Access, Angiography, Hemostasis, Intervention, and Electrophysiology and Cardiac Rhythm Management. The main products we offer under these portfolios are identified below.

Table of Contents

Our cardiac intervention access products used to gain access to the heart include:

- our Merit Advance® needles, arm boards with radiation scatter protection, scalpels and guide wires, and
- our family of Prelude Introducer Sheaths, for both radial and femoral access, features our new Prelude Ideal™ Hydrophilic Sheath Introducer, introduced in 2018, an ultra-thin wall introducer sheath that provides more room for the insertion of catheters and other devices in the radial artery.

Our angiography products identify blocked or narrowed coronary arteries and overlap with our peripheral intervention angiography products. Our angiography product offerings include:

- our InQwire® Guide Wires and complete line of manifolds, syringes, and stopcocks,
- our Performa® Diagnostic Catheter, known for its superior torque, high shaft strength for pushability and a large inner diameter for improved flow rates; and
- our MIV™ Radial Ventriculogram Pigtail Catheter, a catheter specifically designed for radial artery access.

Our hemostasis products assist clinicians in obtaining and maintaining hemostasis or stopping the flow of blood following arterial catheterization. Our cardiac intervention hemostasis product offerings include:

- our SafeGuard Pressure Assisted Device and Safeguard Radial Compression Device, a comfortable hemostasis device which delivers adjustable active compression and enables immediate pressure adjustment and
- our new and innovative PreludeSYNC™ Hemostasis Device and PreludeSYNC Distal, introduced in early 2019, a comfortable hemostasis device with colorful band designs.

Our cardiac intervention products for coronary catheterization procedures include:

- our new FLO40XR™ and FLO50™ Hemostasis Valves, introduced in 2018, and our full line of hemostasis valves including the MAP™ Merit Angioplasty Packs, Honor®, PhD™, AccessPLUS™, Access-9™, DoublePlay™, MBA™ and the Passage®,
- our new basixTAU™ Inflation Device, introduced in 2018, which features a fold-out handle, reducing physician fatigue by reducing the rotational force applied by physicians when performing multiple inflation procedures, along with our legacy inflation devices, including our BasixCompak™, Blue Diamond™ and BasixTouch™,
- our pericardiocentesis kits, which combines the necessary medical devices for pericardial drainage procedures,
- our Ostial PRO® Stent Positioning System, a stent alignment tool for precise stent implantation in aorto-ostial lesions,
- our ConcierGE® Guiding Catheters with a large inner lumen and soft tip used to gain access to the heart, and
- our Merit SureCross® Support Catheters, support catheters used to reach and cross tight, difficult lesions.

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. Electrophysiology is the study of diagnosing and treating abnormal electrical activities of the heart. We offer innovative solutions in the rapidly-expanding cardiac rhythm management and electrophysiology markets including:

- our Worley™ Advanced LV Delivery System, used to aid in the insertion and implantation of left ventricular pacing leads, shown to reduce lead implant failures, improve target lead location and reduce procedure times,
- our HeartSpan® Transseptal Needle, for left-heart access procedures, exceptionally responsive with transparent handle allowing direct visualization, and
- our newest generation HeartSpan® Steerable Sheath Introducer, introduced in 2018, featuring a neutral position indicator and tactile click to help physicians identify curve orientation.

Cardiovascular and Critical Care

Our cardiovascular and critical care products treat patients with life-threatening diseases, protect healthcare providers from exposure to bloodborne pathogens and provide medical devices designed for efficiency and effectiveness, improving a patient's experience, while simplifying the challenges of clinical care.

Our cardiovascular product offering includes:

- our DualCap® Disinfection Protection System, which protects and disinfects needleless valves with isopropyl alcohol, designed to reduce healthcare-associated infections in hospitals,
- our Medallion® Syringes, a medication syringe, available in assorted colors for easy medication identification,

Table of Contents

- our Pen and Label Medication Labeling Systems, for labeling syringes, bowls and other medical containers,
- our ShortStop® Temporary Sharps Holders, to hold needles and prevent accidental needlestick injuries to hospital staff, and
- our family of BackStop® Disposable Basins, for holding contaminated fluid waste, for safe and quick waste elimination.

Blood pressure monitoring products are vital to critical care. Our extensive portfolio of monitoring devices and fluid management devices provide valuable information to physicians to assist and accelerate patient recovery, which include:

- our Meritrans DTXPLUS® Pressure Transducers, used to identify a patient's blood pressure and cardiovascular status,
- our Safedraw® Closed Arterial Blood Sampling System, for easy blood sampling, which reduces unnecessary blood discard,
- our RadialFlo™ Arterial Catheter, introduced in 2018, which controls blood flow with an integral switch and is silicone-coated for smooth insertion,
- our TRAM® Manifolds with an integral pressure transducer to measure blood pressures, and
- our Careflow® Central Venous and Arterial Catheters for high flow rate infusions.

Interventional Oncology and Spine

Our interventional oncology and spine products treat vertebral compression fractures, metastatic spinal tumors, liver cancer, uterine fibroids, benign prostatic hyperplasia, arteriovenous malformations and hemostatic embolization for certain markets outside of the U.S. Our interventional oncology and spine product line is organized into product portfolios as follows: Delivery Systems, Embolotherapy, Spine Ablation and Vertebral Compression Fracture. The main products we offer under these portfolios are identified below.

Our delivery systems portfolio includes a variety of microcatheters and guide wires for targeted access, control and selective infusion of diagnostic, embolic, or therapeutic agents into vessels. Our interventional oncology delivery systems include:

- our new Merit Pursue™ Microcatheter, introduced in 2018, a small microcatheter designed for pushability and trackability through small and tortuous vessels,
- our SwiftNINJA® Steerable Microcatheter, an advanced microcatheter with a 180-degree articulating tip, sold through our exclusive worldwide distribution agreement (excluding Japan) with Sumitomo Bakelite Co., Ltd.,
- our Merit Maestro® Microcatheter, designed for small vessels, providing reliable embolization,
- our True Form™ Reshapable Guide Wire, which can be shaped and reshaped multiple times, reducing the need for multiple guide wires, and
- our Tenor® Steerable Guide Wire, which facilitates navigation in challenging anatomy during embolic procedures.

Our embolotherapy products treat disease by blocking or slowing the flow of blood into the arteries or delivering chemotherapy drugs in the treatment of primary and metastatic liver cancer. In 2017, we received FDA approval for prostatic artery embolization ("PAE") providing a non-surgical treatment option for millions of men who suffer from BPH or benign prostatic hyperplasia. Our embolotherapy products include:

- our Embosphere® Microspheres, a highly studied, round embolic for consistent and predictable results,
- our new EmboCube™, introduced in 2018, a pre-loaded syringe filled with gelatin foam which speeds up procedure preparation,
- our Bearing nsPVA® Embolization Particles, non-spherical embolic particles,
- our QuadraSphere® Microspheres, a precisely calibrated embolic for controlled, targeted embolization, and
- our HepaSphere™ Microspheres, offered outside of the U.S., for the treatment of primary and metastatic liver cancer.

Our spine systems are used to treat painful vertebral compression fractures caused by osteoporosis or cancer by injecting a bone cement through a small hole in the skin into a fractured vertebra. Our vertebral compression fracture products include:

- our StabiliT® Vertebral Augmentation System, which treats pathological fractures by delivering bone cement with a consistent viscosity using radio-frequency energy,
- our StabiliT MX Vertebral Augmentation System, using our industry-leading inflation devices to deliver bone cement,
- our StabiliT VP Vertebroplasty System, which combines a simple cement preparation and controlled delivery of high-viscosity cement, and

Table of Contents

- our Osseoflex® products, which are part of our unique brand of directional devices that allow users to navigate and target specific anatomy within the spine. Our Osseoflex products include access kits, steerable needles, steerable and straight balloons, as well as cement mixing and delivery systems.

Our tumor ablation portfolio is represented by the STAR™ Tumor Ablation System. The STAR system is designed to provide palliative treatment of painful metastatic spinal tumors in cancer patients by targeted radiofrequency ablation.

Cianna Medical

On November 13, 2018, we completed the acquisition of Cianna Medical, Inc. ("Cianna Medical"), a privately held company dedicated to the innovative treatment of early-stage breast cancer. Following the Cianna Medical acquisition, we began selling our SAVI® Brachytherapy Breast Radiation and our SAVI SCOUT® Radar Localization System , a wire-free breast tumor localization system, designed to produce audible and visual indicators surgeons can use to mark cancerous tissue during lumpectomy and biopsy procedures.

Endoscopy

Our endoscopy division, Merit Endotek™, markets products for gastrointestinal and pulmonary conditions. On April 6, 2018 our endoscopy product offering was expanded to include the NvisionVLE® Imaging System through a worldwide distribution agreement with NinePoint Medical, Inc. This innovative system uses an optical signal acquisition and processing method to create high-resolution cross-sectional images and mark tissue visible under white light endoscopy, designed to help clinicians evaluate 100% of the tissue allowing targeted biopsies in the esophagus.

We offer a variety of non-vascular stents to treat pulmonary and gastrointestinal disease including:

- our AERO®, AEROmini® and AERO DV® Fully Covered Tracheobronchial Stents, for the treatment of tracheobronchial strictures produced by malignant neoplasms,
- our Alimaxx-ES™ and EndoMAXX®, Fully Covered Esophageal Stents, intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors and for occlusion of esophageal fistulae, and
- our Alimaxx-B® biliary stent systems, intended for the palliation of malignant strictures in the biliary tree.

We offer dilation balloons to endoscopically dilate strictures. Our balloon dilators products include:

- our Elation® Fixed Wire and Wire Guided Balloon Dilators, intended for use in the alimentary tract,
- our newly-added Elation Pulmonary Balloon Dilator, for the dilation of strictures of the trachea and bronchi, and
- our BIG60® Inflation Device, a 60-mL syringe and gauge designed to inflate and deflate non-vascular balloon dilators while monitoring and displaying inflation pressures up to 12 atmospheres.

We also offer a variety of kits and accessories for endoscopy and bronchoscopy procedures, including:

- our MAXXWIRE™ Guide Wire, used to position catheters and other interventional devices within the gastrointestinal tract and the tracheobronchial tree,
- our Brighton® Bipolar Probe, used to provide hemostasis throughout the gastrointestinal tract,
- our BiliQUICK™ Cholangiography Rapid Refill Continuous Injection Kit, a combination kit designed to deliver contrast media quickly and efficiently,
- our TIO™ Three-in-One, a combination oral airway, bite block and oxygen administration device,
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- our BAL (bronchoalveolar lavage) Convenience Kit™, designed to save time and improve specimen quality during bronchoalveolar lavage procedures, and
- our Aspira® Drainage System, acquired from BD, sold in partnership with our peripheral intervention sales team.

Specialty Procedure Products

We provide coating services for medical tubes and wires under original equipment manufacturer ("OEM") brands in addition to many of the products identified above. 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.

Table of Contents

Customers and clinicians often have unique needs when performing procedures, and we work closely with customers to create standard and customized trays, packs, and kits to enable clinicians to more effectively perform clinical procedures.

We also manufacture and sell 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.

Table of Contents

Marketing and Sales

Target Market/Industry. Our principal target markets are peripheral intervention, cardiac intervention, interventional oncology, critical care and endoscopy. Within these markets our products are used in the following clinical areas: diagnostic and interventional cardiology; interventional radiology; neurointerventional radiology; vascular, general and thoracic surgery; electrophysiology; cardiac rhythm management; interventional pulmonology; interventional nephrology; orthopedic spine surgery; interventional oncology; pain management; breast cancer surgery, outpatient access centers; intensive care; 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 U.S. 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. Breast cancer is the most commonly diagnosed cancer in women and is the second leading cause of cancer death among women. 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 core technology and accessory products.

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 healthcare facilities and physicians involving our primary target markets in the areas of training, therapy awareness programs, clinical studies and ongoing research.

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. To stay abreast of customer needs, we frequently seek suggestions from health care professionals working in the fields of medicine in which we offer, or are developing, products. Suggestions for new products and product improvements may also come from engineers, marketing and sales personnel, 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 56%, 58% and 61% of our net sales for the years ended December 31, 2018, 2017 and 2016, respectively. 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, the Middle East, Africa, Asia, Oceania, Central and South America and Canada. In 2018, our international sales grew approximately

26% over our 2017 international sales, and accounted for approximately 44% of our net sales. China represents our most significant international sales market with net sales of approximately $92.7 million, $73.4 million, and $59.9 million for the years ended December 31, 2018, 2017 and 2016, respectively. With the recent and planned additions to our product lines, we believe our international sales will continue to increase.

Our largest non-U.S. market is China, which represented approximately 10.5% of our net sales in 2018. 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 500 distributors in mainland China, who are responsible for reselling the products, primarily to hospitals. We employ sales personnel 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. With respect to our business activities in the rest of the Asia-Pacific region, in 2018 we continued to increase our sales presence and related new business development activities.

Table of Contents

In Europe, the Middle East and Africa, we have both direct and modified direct sales operations. Our corporate sales operations are active throughout the region, including the largest markets of the UK, France, Germany, Russia and Turkey.
Our direct sales personnel are principally engaged in each of our product groups. Marketing teams responsible for each product group operate 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 store 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 Australia and Canada, we have both a direct sales force and distributors and we operate distribution centers in those countries. In connection with our acquisition of the critical care division of Argon, we have implemented a modified direct sales approach (similar to the approach we are pursuing in China) to market and sell the majority of our products in Japan.
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 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 customer 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 physicians, technicians and nurses. Hospitals and acute care facilities in the U.S. 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 U.S., 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 2018, 38% of our net sales to U.S. hospitals and clinics were derived through our direct sales force and approximately 8% 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 2018 net sales. The remaining 44% of our 2018 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 2%, 2% and 3% of net sales during the years ended December 31, 2018, 2017 and 2016, respectively.

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 2018, our commitment to innovation led to the introduction of several new products, improvements to our existing products and expansion of our product lines, as well as enhancements and new

equipment in our research and development facilities.

We continue to develop new products and make improvements to our existing products utilizing many different sources. Our Chief Executive Officer and our 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:

- Aliso Viejo and San Jose, California
- Dallas and Pearland, Texas

Table of Contents

- Jackson Township, New Jersey
- Malvern, Pennsylvania
- South Jordan and West Jordan, Utah
- Galway, Ireland
- Paris, France
- Singapore
- Tijuana, Mexico
- 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") 13485:2016 certification for our facilities in California, Pennsylvania, Texas, Utah, Ireland, France, Mexico, The Netherlands and Singapore. We have also received ISO 9001:2015 certification for our coatings facility in Venlo, The Netherlands and our Merit Sensor Systems, Inc. ("Merit Sensors") facility in South Jordan, Utah. Merit Sensors develops and markets silicon pressure sensors and presently supplies a substantial portion of the sensors we utilize in our digital inflation devices and blood pressure sensors.

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.

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.

We have packaging and manufacturing facilities located in Chester, Virginia; Galway, Ireland; Joinville, Brazil; Malvern, Pennsylvania; Melbourne, Australia; Paris, France; Pearland, Texas; Singapore; South Jordan and West Jordan, Utah; Tijuana, Mexico; and Venlo, The Netherlands. See Item 2. "Properties."

We have distribution centers located in Auckland, New Zealand; Bangalore, India; Beijing and Hong Kong, China; Chester, Virginia; Johannesburg, South Africa; Joinville, Brazil; Maastricht, The Netherlands; Malvern, Pennsylvania; Melbourne, Australia; Toronto, Canada; Podolsk, Russia; Seoul, South Korea; South Jordan, Utah; Tijuana, Mexico; and Tokyo, Japan. Additionally, in early 2019 we opened a distribution center in London, United Kingdom.

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. We seek to develop and have relationships with potential back-up suppliers for materials and components in the event of supply interruptions. Additionally, there are a limited number of third parties that supply sterilization services for our medical devices. There are no assurances that we will not experience supply or sterilization service disruptions in the future. If we are unable to obtain raw materials or sterilization services, we may have to suspend product manufacturing which could

materially harm our ability to meet customer demand.

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; vascular, general and thoracic surgery; electrophysiology; cardiac rhythm management; interventional pulmonology; interventional nephrology; orthopedic spine surgery; interventional oncology; pain management; outpatient access centers; intensive care; computed tomography; ultrasound; and interventional gastroenterology.

Table of Contents

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, interventional radiology, gastroenterology, endoscopy, general surgery, thoracic surgery and pulmonology markets we compete with large international, multi-divisional medical supply companies such as Cordis Corporation (a Cardinal Health company); Boston Scientific Corporation ("Boston Scientific") (including the operations previously conducted by BTG plc); Medtronic plc ("Medtronic"); Abbott Laboratories; Teleflex Incorporated; Becton, Dickinson and Company ("BD"); Cook Medical Incorporated ("Cook Medical"); Guerbet Company; Stryker Corporation ("Stryker"); 3M Company; ICU Medical, Inc. and Terumo Corporation ("Terumo"). Medium-size companies we compete with include B. Braun Melsungen AG; UreSil LLC; Olympus Corporation; Edwards Lifesciences; Argon Medical Devices, Inc.; ConMed Corporation; AngioDynamics, Inc.; Medical Components, Inc. and U.S. Endoscopy.

Within the breast cancer therapy space, we believe we are a market leader in the U.S. in wire-free breast tumor localization. Currently, we compete with Leica Biosystems Nussloch GmbH and Hologic, Inc.

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 U.S. for analog inflation devices. We believe we are a market leader in the U.S. for control syringes, waste-disposal systems, tubing and manifolds. Although we believe our recent and planned additions to these product lines will help us compete even more effectively in both the U.S. and international markets, we cannot give any 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 our 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. 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 ("UFE") and PAE, we believe we are a market share leader. Based on both research and clinical studies conducted on our product for UFE and PAE, 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 embolotherapy product has been Embosphere Microspheres. In the microsphere and embolic particle market we compete with Boston Scientific (including the operations previously conducted by BTG plc); Cook Medical; Terumo; and Pfizer Inc.

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 application. As of December 31, 2018, we owned or had a license to more than 1,500 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

Table of Contents

our trademark registrations varies from country to country; in the U.S. we generally can maintain our trademark rights and renew any trademark registrations for as long as the trademarks are in use. As of December 31, 2018, we owned over 400 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 a plaintiff or a defendant, as well as a counter-claimant or counter-defendant, in patent, trademark, and other intellectual property infringement actions. If a court rules against us in any intellectual property 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 may 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 2019. 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 the 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 the FDA's restrictions against misbranding and adulteration. While most Class I devices are exempt from the 510(k) premarket notification process (assuming they are within the limitations of the exemption), 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. While most Class II devices require premarket review and clearance by the FDA through the 510(k) premarket notification procedure, some Class II devices are exempt from the 510(k) premarket notification process (assuming they are within the limitations of the exemption).

- 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 the 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 down-classified by the FDA to Class I or Class II; or a device that the 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

Table of Contents

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. 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 the 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 the FDA personnel should follow to ensure the integrity of data and information in applications submitted for FDA review and approval.

Clinical Trials. We conduct clinical trials to obtain PMA approval or 510(k) clearance from the FDA and to obtain CE Marking approval and other international equivalents. In order for us to obtain the desired regulatory approvals, we will need to complete the trial(s) and submit positive clinical data to the regulatory authority. 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, if there is a change in the standard of care or available competing therapies, or depending on other factors, we will likely not be able to complete the trial(s). Even if we complete the clinical trial(s), the regulatory authority may require us to undertake additional testing, or the trial results may not be sufficient to obtain regulatory approval 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 regulatory authority approval of the product use claimed in a clinical trial, we will not be able to sell, distribute or promote the subject product for the indicated treatment of the specific disease or condition.

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

Table of Contents

supplement. For devices marketed under an approved PMA, we must submit a PMA supplement to the 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.

Foreign jurisdictions have similar requirements that necessitate submission and review when changes are made to currently available devices, including product line extensions. These requirements vary between regions and are subject to ongoing change by their respective regulatory bodies. Prior review and approval in these regions may be required 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. In some cases, clinical data may be required. The process to obtain approval of a modified devices could significantly delay its introduction.

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 quality system 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 U.S., the importer must file an entry notice and bond with the U.S. 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 U.S. 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 are subject to foreign countries' import requirements and the exporting requirements of the exporting countries’ regulating bodies, as applicable. In particular, international sales of medical devices manufactured in the U.S. that are not approved or cleared by the FDA for use in the U.S., or are banned or deviate from lawful performance standards, are subject to FDA export requirements and we may not be able to export such products.

Table of Contents

Foreign countries often require, among other things, an FDA certificate for products for export, also called a Certificate to Foreign Government. To obtain this certificate from the FDA, the device manufacturer must apply to the FDA. The FDA certifies that the product has been granted clearance or approval in the U.S. 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 U.S., the European Union (the "EU") 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 Post-Market Requirements. Medical device manufacturers are also subject to other post-market requirements in multiple jurisdictions, including product listing, establishment registration, Unique Device Identification ("UDI"), reports of corrections and removals and other requirements. Medical Device Reporting required by the FDA, medical device 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 a complaint 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 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. Other regulatory authorities could take similar actions within their jurisdictions.

The FDA regularly inspects companies to determine compliance with the QSRs and other post-market 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. Other regulatory authorities, including EU Notified Bodies, regularly audit companies to determine compliance with ISO 13485 and their respective regulations. They may take similar actions as FDA within their jurisdictions.

Foreign Regulations. Medical device laws and regulations are also in effect in many countries outside of the U.S. 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.

The regulatory framework for medical devices in the European Economic Area underwent a significant revision in 2017, which has introduced new regulatory requirements to obtain CE Mark approval. The new Medical Device Regulations ("MDR") include a three-year transition period which is scheduled to end in May 2020. The MDR includes increasingly stringent requirements in multiple areas, such as pre-market clinical evidence (some of which are now in effect), review of high-risk devices, labeling and post-market surveillance. Under the MDR, pre-market clinical data will now be required to obtain CE Mark approval for high-risk, new and modified medical devices. We believe these new requirements have the potential to be expensive and time-consuming to implement and maintain and could 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 or a similar foreign regulatory agency, there is no certainty that third-party payers will cover

Table of Contents

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 ("Affordable Care Act") has changed the way healthcare in the U.S. 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 Affordable Care Act 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. The U.S. Congress suspended the excise tax for the 2016-2018 tax years and recently extended the suspension until January 1, 2020. We cannot predict whether any new action will be taken and whether the suspension will continue past 2020. If the excise tax is not repealed or further suspended, it will likely adversely impact our future results of operations.

Additionally, the long-term viability of the Affordable Care Act, and its impact on our business and results of operations, remains uncertain. For instance, in December 2017, the U.S. enacted the Tax Cuts and Jobs Act, which, among other things, eliminated the tax penalty for not obtaining health coverage (beginning in 2019). Additionally, members of the U.S. Congress have suggested other changes that may impact individual insurance marketplaces. These and other legislative and executive initiatives may significantly change the scope and impact of the Affordable Care Act and, in turn, the medical device industry. See Note 6 of the notes to our consolidated financial statements for further information on the Tax Cuts and Jobs Act.

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 U.S. have also adopted or 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-corruption laws are in place in the U.S. and in many jurisdictions throughout the world. In the U.S., 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. Anti-corruption laws present particular challenges in the medical device industry because in many countries including China, hospitals are state-owned or operated by the government, and doctors and other hospital employees are considered foreign government officials. 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. In addition, the Chinese government has also sponsored anti-corruption campaigns from time to time, which could have a chilling effect on any future marketing efforts by us to new hospital customers. There have been occurrences in which certain hospitals have denied access to sales representatives from medical device companies because the hospitals wanted to avoid the

perception of corruption. If this attitude becomes widespread among our potential customers, our ability to promote our products to hospitals may be adversely affected.

As we expand our operations in China and other jurisdictions internationally, we will need to increase the scope of our compliance programs to address the risks relating to the potential for violations of the FCPA and other anti-corruption laws. Our compliance programs will need to include policies addressing not only the FCPA, but also the provisions of a variety of anti-corruption laws in multiple foreign jurisdictions, including China, provisions relating to books and records that apply to us as a public company, and include effective training for our personnel and relevant third-parties.

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.”

Table of Contents

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 continue their enforcement efforts on the sales and marketing activities of pharmaceutical, medical device and other healthcare companies, including the pursuit of 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 Affordable Care Act, 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 U.S. 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.

Labor Standards Laws. We are also subject to corporate social responsibility ("CSR") laws and regulations which require us to monitor the labor standards in our supply chain, including the California Transparency in Supply Chains Act, the UK Modern Slavery Act, and U.S. Federal Acquisition Regulations regarding Combating Trafficking in Persons. These CSR laws and regulations may impose additional processes and supplier management systems and have led certain key customers to impose additional requirements on medical device companies, including audits, as a prerequisite to selling products to such customers, which could result in increased costs for our products, the termination or suspension of certain suppliers, and reductions in our margins and profitability.

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.

The EU has adopted a single EU privacy regulation, the General Data Protection Regulation (“GDPR”), which went into effect May 25, 2018. The GDPR extends the scope of the EU data protection law to all companies processing personal data in the context of the activities of an establishment of a controller or a processor in the EU, regardless of whether the processing takes place in the EU or not. In addition, it applies to the processing of personal data of data subjects who are in the EU by a controller or processor not established in the EU, where the processing activities are related to: (a) the offering of goods or services, irrespective of whether a payment of the data subject is required, to such data subjects in the EU; or (b) the monitoring of their behavior as far as their behavior takes place within the EU. The GDPR provides for a harmonization of the data protection regulations throughout

Table of Contents

the EU. It imposes a strict data protection compliance regime with severe penalties of up to the greater of 4% of worldwide sales or €20 million and includes new rights such as the "portability" of personal data. Although the GDPR will apply across the EU without a need for local implementing legislation, it contains a number of opener clauses enabling the EU member states to provide for additional legislation. In addition, local data protection authorities will still have the ability to interpret the GDPR, which has the potential to create inconsistencies on a country-by-country basis. We have implemented changes to our business practices to comply with the GDPR.

We post on our websites our privacy policies and practices regarding the collection, use and disclosure of user data. Any failure, or perceived failure, by us to comply with our posted privacy policies or with any applicable regulatory requirements or orders, or privacy, data protection, information security or consumer protection-related privacy laws and regulations in one or more jurisdictions, could result in proceedings or actions against us by governmental entities or others, including class action privacy litigation in certain jurisdictions, subject us to significant fines, penalties, judgments and negative publicity, require us to change our business practices, increase the costs and complexity of compliance, and adversely affect our business. Data protection, privacy and information security have become the subject of increasing public, media and legislative concern. If our customers were to reduce their use of our products and services as a result of these concerns, our business could be materially harmed. As noted above, we are also subject to the possibility of security and privacy breaches, which themselves may result in a violation of these privacy laws.

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.

Environmental Sustainability Practices

We are engaged and passionate about continually innovating solutions to produce the highest quality medical products while reducing our global environmental footprint. Each year, we track and measure our environmental performance, holding ourselves accountable and continually looking for ways to improve.
We have designed programs to reduce waste including:

- our major program to reduce film thickness in kit packaging, without compromising on quality,
- our transition to re-usable pallets and methods to move products in bulk containers, significantly reducing intra-company shipping materials,

- our packaging design, which allows our products to ship to customers in its original packaging, eliminating the need for additional shipping materials, such as boxes and plastic bubble wrap,
- our transition from paper to electronic work orders in our facilities worldwide, from which we expect to reduce our paper usage by approximately 2.8 million pieces and 20,000 plastic sleeves annually,
- our GreenChoice™ program for our kits and packs, which now gives our customers the option to choose eco product alternatives—such as trays and natural fiber towels—that can be included in their order,
- our Employee Recycling Program, in which our employees recycle as many materials as we can, including paper, cardboard, food and beverage containers, scrap metal, and pallets,

Table of Contents

- our partnership with companies who can use our plastic waste that surrounds a finished molded part and our investment in a line of fully compostable “to-go” containers made from plant starch and sugarcane and our program to transition to reusable cutlery at all of our dining facilities worldwide, reducing the amount of cutlery and plates waste sent to landfills.

LEED Certification

We have been awarded Silver LEED (Leadership in Energy and Environmental Design) certification for our Bean Building, the newest addition to our Salt Lake City campus.

Employees

As of December 31, 2018, we employed 5,783 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

None.

Available Information

We file annual, quarterly and current reports and other information with the SEC. These materials can be inspected and copied at the SEC’s Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Copies of these materials may also be obtained by mail at prescribed rates from the SEC’s Public Reference Room at the above address. Information about the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of the SEC’s Internet website is www.sec.gov.

We make available, free of charge, on our Internet website, located at www.merit.com, our most recent Annual Report on Form 10-K, our most recent Quarterly 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 2 and Note 13 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, sales and other personnel, and on our financial, product design, marketing, distribution, technology 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.

Table of Contents

Over the past several years, we have completed a series of significant acquisitions and, at any given time, we may be considering a number of potential further acquisitions and strategic transactions, certain of which may also be significant. 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, including sales models related to capital equipment. Our 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, which may occur at levels that are more severe or prolonged than anticipated. Additionally, past and future acquisitions may increase the risks of competition we face by, among other things, extending our operations into industry segments and product lines where we have few existing customers or qualified sales personnel and limited expertise. For example, although we acquired certain tunneled home drainage catheter and soft tissue core needle biopsy products from BD in February 2018, BD retained other products that directly compete with the products we acquired. As BD is a larger company with a more well-established market presence in such product lines, we may be unable to realize expected benefits from the acquisition in the timeframe anticipated or at all. Further, as a result of several of our completed acquisition and other strategic transactions, we are selling capital equipment, in addition to our historical sales of disposable medical devices. The sale of capital equipment may create additional risks and potential liability, which may negatively affect our business, operations or financial condition.

We have incurred, and will likely continue to incur, significant expenses in connection with negotiating and consummating various acquisition and other strategic transactions, and we may inherit significant liabilities in connection with prospective acquisitions or other strategic transactions, 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 or other transaction. If we do not adequately identify targets for, or manage issues related to, our future acquisition and strategic transactions, such transactions 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 patent, trademark, copyright and trade secret laws. However, 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 countries throughout the world may be impractical and 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 patents and other intellectual property protections, 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

Table of Contents

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 such 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 and 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 subject to extensive 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 domestic and foreign legislators continue to scrutinize 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, as well as foreign counterparts, 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 clearances and 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 uncleared or 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 or clearance. The use of our products for unauthorized purposes could arise from our sales personnel or distributors violating our policies by providing information or recommendations about such unauthorized uses. 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, fines or other civil or criminal actions.

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 U.S., we must generally obtain clearance from the FDA through the 510(k) premarket notification process or approval through a PMA application, unless an exemption from premarket review or an alternative procedure, such as a *de novo* risk-based classification or a humanitarian

Table of Contents

device exemption, applies. The FDA clearance and approval processes for medical devices are expensive, uncertain and time-consuming.

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 IDE application with the FDA prior to commencing such trials in the U.S. Submission of an IDE application does not ensure that the IDE will become effective. If the IDE application is approved, there can be no assurance that 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 FDA 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, reporting and recordkeeping requirements, and other 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.

Changes to 510(k) cleared or PMA approved devices, including manufacturing changes, product enhancements and product line extensions, may require a new 510(k) clearance or approval of a PMA supplement. For devices marketed under an approved PMA, we must submit a PMA supplement to the 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 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 determine such clearances or approvals are not necessary and document the basis for that conclusion. However, the FDA may disagree with our determination 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 or approval for a product. We cannot assure that we will successfully maintain the clearances or approvals we have received or may receive in the future. 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.

Our products are generally subject to regulatory requirements in foreign countries in which we sell those products. We will be required to expend significant resources to obtain regulatory approvals or clearances of our products, and there may be delays and uncertainty in obtaining those approvals or clearances.

In order to sell our products in foreign countries, generally we must obtain regulatory approvals and comply with the regulations of those countries. These regulations, including the requirements for approvals or clearances and the time required for regulatory review, vary from country-to-country.

The European Union, or EU, requires that manufacturers of medical devices obtain the right to affix the CE mark, for compliance with the Medical Device Directive (93/42/EEC), as amended, to medical devices before selling them in member countries of the EU. The CE mark is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. In order to obtain the authorization to affix the CE mark to products, a manufacturer must obtain certification that its processes and products meet certain European quality standards.

Table of Contents

In April 2017, the EU adopted the MDR to replace the Medical Device Directive (93/42/EEC), as amended. The MDR will apply after a three-year transition period and imposes stricter requirements for the marketing and sale of medical devices and grants Notified Bodies increased post-market surveillance authority.

Complying with and obtaining regulatory approval in foreign countries have caused or may cause us to experience more uncertainty, risk, expense and delay in commercializing products in certain foreign jurisdictions, which could adversely impact our net sales, market share and operating profits from our international operations.

We rely on the proper function, availability and security of information technology systems to operate our business, and a material disruption of critical information systems or a material breach in the security of our systems may adversely affect our business and customer relationships.

We rely on information technology systems (including technology from third party providers) to process, transmit, and store electronic information in our day-to-day operations, including sensitive personal information and proprietary or confidential information. 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 code, 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 have prevented or will prevent security breaches, any of which could have a significant impact on our business, reputation and financial condition, particularly attacks that result in our intellectual property and other confidential information being accessed or stolen.

We rely on third-party vendors to supply and support certain aspects of our information technology systems. These third-party systems could also become vulnerable to cyber-attacks, malicious intrusions, breakdowns, interference or other significant disruptions, and may contain defects in design or manufacture or other problems that could result in system disruption or compromise the information security of our own systems. In addition, we continue to grow in part through business and product acquisitions and, as a result, may face risks associated with defects and vulnerabilities in the systems operated by the other parties to those transactions, or difficulties or other breakdowns or disruptions in connection with the integration of the acquired businesses and products into our information technology systems.

Cyber-attacks could also result in unauthorized access to our systems and products, including personal information of individuals, which could trigger notification requirements, encourage actions by regulatory bodies, result in adverse publicity, prompt us to offer credit support products or services to affected individuals and lead to class action or other civil litigation. 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, lose customers, be subject to fraud, breach our agreements with or duties toward customers, physicians, other health care professionals and employees, be subject to regulatory sanctions or penalties, incur expenses or lose revenues, sustain damage to our reputation or suffer other adverse consequences. Unauthorized tampering, adulteration or interference with our products may also create issues with product functionality that could result in a loss of data, risk to patient safety, and product recalls or field actions. Any of these events could have a material adverse effect on our business, operations or financial condition.

Our business is subject to complex and evolving U.S. and international laws and regulations regarding privacy and data protection. Many of these laws and regulations are subject to change and uncertain interpretation and could result in claims, changes to our business practices, penalties, increased cost of operations, or declines in user growth or engagement, or otherwise harm our business.

The U.S. and many other countries in which we conduct our operations have adopted laws and regulations protecting certain data, including medical and personal data, and requiring data holders and controllers to implement administrative, logical and technical controls and procedures in order to protect the privacy of such data. Internationally, some countries have also passed laws and regulations that require individually identifiable data on their citizens to be maintained on local servers and that may restrict transfer or processing of that data. In addition, regulatory authorities around the world are considering a number of additional proposals concerning data protection. These laws and regulations have been, and may continue to be, inconsistent with each other, requiring different approaches in different jurisdictions. In addition, the interpretation and application of medical and personal data protection laws and regulations in the U.S., Europe, China and elsewhere are often uncertain and in flux. Further, we have incurred, and will likely continue to incur, significant expense in connection with our efforts to comply with those laws and regulations. It is possible that these laws and regulations may be interpreted and applied in a manner that is inconsistent with our data practices. These legislative and regulatory proposals, if adopted, and such interpretations could, in addition to the possibility of fines, result in an order requiring that we change our data practices, which could have an adverse effect on our business and

Table of Contents

results of operations. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices in a manner adverse to our business.

Recent legal developments in Europe have created compliance uncertainty regarding certain transfers of personal data from the EU to the U.S. and other non-EU jurisdictions. For example, the GDPR, which came into application in the EU on May 25, 2018, applies to our activities conducted from an establishment in the EU or related to products and services that we offer to EU users. The GDPR created a range of new compliance obligations, which could cause us to change our business practices, and significantly increases financial penalties for noncompliance (including possible fines of up to 4% of global annual turnover for the preceding financial year or €20 million (whichever is higher) for the most serious infringements).

The pending exit of the United Kingdom from the European Union, and current uncertainty about when, how or if such exit will occur could harm our business and results of operations in Europe and elsewhere.

On June 23, 2016, the United Kingdom held a referendum in which voters approved an exit from the EU, commonly referred to as "Brexit." As a result of the referendum, negotiations are under way to determine the future terms of the United Kingdom's relationship with the EU, including the terms of trade. As it stands, the United Kingdom is scheduled to depart the EU on March 30, 2019, but the terms of its withdrawal and the nature of its future relationship with the EU are still being decided. Due to stalled negotiations between the United Kingdom and the EU, and political opposition in the United Kingdom, it is possible that Brexit will not occur in March 2019 or at all. Whether or not Brexit occurs, as a result of the disruption in the relationship between the United Kingdom and other EU countries, it is possible that there will be greater restrictions and additional costs on the movement of goods and people between the United Kingdom and the EU countries and increased regulatory complexities, which could affect our ability to sell products in certain EU countries and in the United Kingdom. Currently, all of our European production is in EU countries outside of the United Kingdom. However, during the fiscal year ended December 31, 2018, approximately 2.0% of our world-wide revenues arose from sales into the United Kingdom. Disruptions arising from the exit of the United Kingdom from the EU, or from stalled or failed negotiations between the United Kingdom and the EU, could result in various trade barriers limiting or prohibiting our ability to export or sell our products into the United Kingdom.

In the fiscal year ended in December 31, 2018, approximately 13.0% of our world-wide revenue arose from sales into EU countries, other than the United Kingdom. Brexit could adversely affect the economy of EU countries, which could adversely affect our sales into those countries. In addition, Brexit could also harm 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 the Euro, to which we have significant exposure. In addition, other European countries may seek to conduct referenda with respect to continuing membership with the EU. The uncertainties surrounding Brexit, and the possibility that Brexit could result in restrictions on trade and related tariffs between the United Kingdom and the rest of the EU, could result in additional costs, reduced demand, adverse currency fluctuations and otherwise harm our business and operations.

In late 2018 we opened a warehouse and distribution facility in Reading, England, principally in an effort to address the potential impact of Brexit on our ability to market, sell and distribute our products in the United Kingdom. We have incurred, and will continue to incur, substantial expenses in connection with the leasing, improvement and commencement of operations associated with the new Reading facility. In part due to the continued uncertainty regarding the timing and consequences of Brexit, there can be no assurance regarding the effect our Reading facility will have on our business, operations or financial condition.

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 U.S. 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. Costs to comply with regulations, including, for instance, regulations for medical devices enacted by the EU in May 2017 and effective in 2020, and costs associated with remediation can be significant. Additionally, 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,

Table of Contents

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 clearances, approvals, clinical holds, warning letters or untitled letters or refusal to permit the import or export of our products.

The agreements and instruments governing our debt contain restrictions and limitations that could significantly affect our ability to operate our business, as well as significantly affect our liquidity.

We have entered into a Second Amended and Restated Credit Agreement with Wells Fargo Bank, National Association, as administrative agent, swingline lender and a lender, Wells Fargo Securities, LLC, as sole lead arranger and sole bookrunner and the lenders who are or may become party thereto, which was amended on September 28, 2016, March 20, 2017, December 13, 2017 and March 28, 2018. 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. It could lead to an acceleration of indebtedness and foreclosure on our assets.

As currently amended, the Second Amended Credit Agreement provides for potential borrowings of up to $447.5 million. Such increased borrowing limits may make it more difficult for us to comply with leverage ratios and other restrictive covenants in the Second Amended 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.

Uncertainty relating to the LIBOR calculation method and potential phasing out of LIBOR after 2021 may adversely affect the interest rates under our Credit Agreement.

Certain of the interest rates applicable to our Second Amended Credit Agreement, and applicable to hedging instruments we have purchased to offset interest rate risk under our Second Amended Credit Agreement, are LIBOR-based. On July 27, 2017, the U.K. Financial Conduct Authority (the "FCA") announced that it will no longer persuade or compel banks to submit rates for the calculation of LIBOR rates after 2021. Actions by the FCA, other regulators or law enforcement agencies may result in changes to the method by which LIBOR is calculated. At this time, it is not possible to predict the effect of any such changes or any other reforms to LIBOR that may be enacted in the United Kingdom or elsewhere. Uncertainty as to the nature of such potential changes may adversely affect the trading market for LIBOR-based securities, including the floating rates applicable to our Second Amended Credit Agreement and related hedges. It is possible that the changes in how LIBOR is calculated, changes in the trading market for LIBOR-based securities or actions of the FCA and other government entities may cause unexpected increases in LIBOR rates or a breakdown in the LIBOR systems. If these issues arise, we could experience increased interest rates or uncertainty with respect to the calculation of interest on our Second Amended Credit Agreement and other instruments, which could harm our operations.

We will be required to expend significant resources for research, development, testing and regulatory approval or clearance of our products under development, and these products may not be developed successfully or approved for commercial use.

Most of our products under development will require significant additional research, development, engineering and, 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.

Table of Contents

We are currently conducting one clinical trial in an effort to obtain approval from the FDA that would enable us to expand our efforts to commercialize the QuadraSphere Microspheres. EU regulations do not currently require such applications for these classes of medical device. In order for us to obtain FDA approval to promote the use of QuadraSphere Microspheres for the purposes indicated in our clinical trial, we will need to complete the trial and submit positive clinical data to the FDA. If we cannot enroll study subjects in sufficient numbers to complete the necessary study, if there is a disruption in the supply of materials for the trial or if any other factors preclude us from completing the trial in a timely manner, we will likely not be able to complete the trial. Even if we complete the clinical trial, the FDA may require us to undertake additional testing, or the trial results may not be sufficient to obtain FDA approval for other reasons, 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 studied 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 U.S.

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.

The Affordable Care Act affects, and potentially affects, our business in many ways, and both its existence and repeal (or partial repeal) could have a material adverse effect on our business, operations or financial condition.

The Affordable Care Act was enacted into law in March 2010 and imposes on medical device manufacturers a 2.3% excise tax on U.S. sales of certain medical devices. Although this tax has been suspended until January 1, 2020, during the year ended December 31, 2015 we paid $4.3 million related to this tax. We cannot predict whether the suspension will be continued beyond January 1, 2020. If the excise tax is not repealed or further suspended, it will likely adversely impact our future results of operations. In addition, the costs of compliance with the Affordable Care Act'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.

Additionally, the long-term viability of the Affordable Care Act, and its impact on our business and results of operations, remains uncertain. For instance, in December 2017, the U.S. enacted the Tax Cuts and Jobs Act, which, among other things, eliminated the tax penalty for not obtaining health coverage (beginning in 2019). In December 2018, a federal district judge ruled that the Affordable Care Act is unconstitutional (but suspended implementation of such ruling), as a result of the elimination of the tax penalty for not obtaining health coverage. This ruling is subject to

appeal. The adoption of Affordable Care Act increased the number of U.S. residents with health insurance and has contributed to an overall increase in medical spending in the U.S. If the Affordable Care Act is repealed as a result of court decision or otherwise, it may reduce the demand for our products in the U.S. On the other hand, the elimination of the Affordable Care Act could result in the elimination of certain costly reporting and disclosure requirements.

Over the long term, any repeal of the Affordable Care Act could increase the likelihood that new medical reform legislation would be adopted. We are uncertain whether any such changes would benefit, or harm, our business and results of operations. Any changes in health care laws in the U.S. could result in additional requirements and costs on our operations and harm our revenue by limiting the number of products sold or the price at which we can sell our products. Uncertainty about the status of health care law also harms our ability to plan for the future and build out our operational and compliance systems.

We are dependent upon key personnel.

Table of Contents

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.

Termination or interruption of, or a failure to monitor, our supply relationships and 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, parts, products and services are 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, liability concerns, 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.

We are also subject to corporate social responsibility, or CSR, laws and regulations which require us to monitor the labor standards in our supply chain, including the California Transparency in Supply Chains Act, the UK Modern Slavery Act, and U.S. Federal Acquisition Regulations regarding Combating Trafficking in Persons. These CSR labor laws and regulations may impose additional processes and supplier management systems and have led certain key customers to impose additional requirements on medical device companies, including audits, as a prerequisite to selling products to such customers, which could result in increased costs for our products, the termination or suspension of certain suppliers, and reductions in our margins and profitability.

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.

Our products may be subject to product liability claims and warranty 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.

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

Table of Contents

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.

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 or other governmental authorities, 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 regulations, which require us to report to the FDA information that reasonably suggests one of our products may have caused or contributed to a death or serious injury, or one of our products malfunctioned and, if the malfunction were to recur, this device or a similar device that we market would be likely to cause or contribute to a death or serious injury. Our obligation to report under the medical device reporting regulations is triggered on the date on which we become aware of information that reasonably suggests a reportable adverse event occurred. 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 medical device reporting obligations, the FDA could issue warning letters or untitled letters, take administrative actions, commence criminal prosecution, impose civil monetary penalties, demand or initiate a product recall, seize our products, or delay the clearance of our future products.

We lack direct sales and marketing capabilities in many countries, and are 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, Japan, Russia and India. 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, and a global anti-corruption policy, 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 cardiac intervention, peripheral intervention, interventional oncology and spine, and cardiovascular and critical care and endoscopy product groups 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

Table of Contents

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. Even if the markets are as large as projected, there is no assurance that our market share or aggregate sales will increase as a result of the size of addressable markets.

Consolidation in the healthcare industry, group purchasing organizations or public procurement policies could lead to demands for price concessions, which may harm 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 U.S., 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. During 2018, 2017 and 2016, the exchange rate between all applicable foreign currencies and the U.S. Dollar resulted in an increase in net sales of approximately $5.2 million, an increase of approximately $0.6 million and a decrease of approximately $4.9 million, respectively.

For the year ended December 31, 2018, approximately $284.8 million, or 32.3%, 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.

We may be unable to accurately forecast customer demand for our products and manage our inventory.

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.

Table of Contents

Our forecasts of customer demand and related decisions that we make about production levels may take into account potential opportunities created by regulatory issues, supply disruptions or other challenges experienced by our competitors. We generally do not know the extent and cannot predict the duration of these challenges experienced by our competitors. As a result, our estimates about related increased demand for our products are inherently uncertain and subject to change. If our estimates incorrectly forecast the extent or duration of this increased demand, or the product types to which it relates, our revenues, margins and earnings could be adversely affected.

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 U.S. and Mexico, China, and other countries in which we operate as a result of the current 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 our customers on acceptable terms, if at all. An inability of our customers to obtain financing necessary to purchase our products could harm our business and results of operations.

Changes in general economic conditions, geopolitical conditions, U.S. trade policies and other factors beyond our control may adversely impact our business and operating results.

Our operations and performance depend significantly on global, regional and U.S. economic and geopolitical conditions. During, and following, the U.S. presidential election in 2016, there has been discussion and dialogue regarding potential significant changes to U.S. trade policies, legislation, treaties and tariffs, including the North American Free Trade Agreement ("NAFTA") as well as trade policies and tariffs affecting China. At this time, it is unknown whether and to what extent new legislation will be passed into law, pending or new regulatory proposals will be adopted, international trade agreements will be negotiated, or the effect that any such action would have, either positively or negatively, on our industry or our Company. If any new legislation and/or regulations are implemented, or if existing trade agreements are renegotiated, it may be inefficient and expensive for us to alter our business operations in order to adapt to or comply with such changes. Such operational changes could have a material adverse effect on our business, financial condition, results of operations or cash flows.

In addition to changes in U.S. trade policy, a number of other economic and geopolitical factors both in the U.S. and abroad could have a material adverse effect on our business, financial condition, results of operations or cash flows, which could ultimately result in:

- a global or regional economic slowdown in any of our market segments;
- postponement of spending, in response to tighter credit, financial market volatility and other factors;
- effects of significant changes in economic, monetary and fiscal policies in the U.S. and abroad including significant income tax changes, currency fluctuations and inflationary pressures;
- rapid material escalation of the cost of regulatory compliance and litigation;
- changes in government policies and regulations affecting the Company or its significant customers;
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- industrial policies in various countries that favor domestic industries over multinationals or that restrict foreign companies altogether;
- difficulties protecting intellectual property;
- longer payment cycles;
- credit risks and other challenges in collecting accounts receivable; and
- the impact of each of the foregoing on outsourcing and procurement arrangements.

In addition, any changes in U.S. trade policy could trigger retaliatory actions by affected countries, such as China, resulting in a “trade war.” A trade war could result in increased costs for raw materials we use in our manufacturing and could result in foreign governments imposing tariffs on products that we export outside the U.S. or otherwise limiting our ability to sell our products abroad. These events could result in increased costs, lower margins and lower demand than we have assumed in our projected financial results, which could have a material adverse effect on our business, financial condition, results of operations, or cash flows.

Table of Contents

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 U.S., the EU 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. 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.

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, 2018, sales of our inflation devices (including our Big60® device sold within our endoscopy segment and kits and packs which include inflation devices, but also include other products) accounted for approximately 10.8% 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.

We are subject to work stoppage, transportation, severe weather, natural disasters and related risks.

We manufacture products at various locations in the U.S. 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. On December 22, 2017, the U.S. government enacted comprehensive federal tax legislation commonly referred to as the Tax Cuts and Jobs Act of 2017, or TCJA. The TCJA makes changes to the corporate tax rate, business-related deductions

Table of Contents

and taxation of foreign earnings, among others, that will generally be effective for taxable years beginning after December 31, 2017. These changes could have a material impact on the value of our U.S. deferred tax assets, result in significant one-time charges in the current or future taxable years and increase our future U.S. tax expense. We continue to evaluate the TCJA and its requirements, as well as its application to our business and its impact on our effective tax rate. At this stage, it is unclear how many U.S. states will incorporate these federal law changes, or portions thereof, into their tax codes. The implementation by us of new practices and processes designed to comply with, and benefit from, the TCJA and its rules and regulations could require us to make substantial changes to our business practices, allocate additional resources, and increase our costs, which could negatively affect our business, results of operations and financial condition. 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 U.S., 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 U.S. 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 U.S. 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.

The market price of our common stock has been, and may continue to be, volatile.

Table of Contents

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 risk factors. 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 capital markets generally.

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 distribution and customer service facility located in Maastricht, the Netherlands. In addition, we lease commercial space in Bangalore, India; Beijing, Hong Kong, GuangZhou and Shanghai, China; Buccinasco, Italy; Dubai, UAE; Melbourne, Australia; Moscow, Russia; Toronto, Canada; Rockland, Massachusetts; São Paulo, Brazil; Selangor, Malaysia; Seoul, Republic of Korea; Tokyo, Japan; Johannesburg, South Africa; Reading, United Kingdom; Ho Chi Minh City, Vietnam, Taipei, Taiwan; Auckland, New Zealand; Jakarta, Indonesia; Jackson Township, New Jersey; Carrolton, Texas; and Versailles, France. Our principal manufacturing and packaging facilities are located in Chester, Virginia; Galway, Ireland; Joinville, Brazil; Malvern, Pennsylvania; Melbourne, Australia; Paris, France; Pearland, Texas; Singapore; South Jordan and West Jordan, Utah; Tijuana, Mexico; and Venlo, The Netherlands. Our research and development activities are conducted principally at facilities located in South Jordan and West Jordan, Utah; Pearland and Dallas, Texas; Malvern, Pennsylvania; Jackson Township, New Jersey; San Jose, California; Galway, Ireland; Paris, France; Singapore; and Venlo, The Netherlands.

The following is a summary of the approximate square footage of our facilities as of December 31, 2018:

	Owned	Leased	Total
U.S.	552,207	499,074	1,051,281
International	344,181	456,957	801,138
Total	896,388	956,031	1,852,419

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

We are currently constructing an additional manufacturing facility at our South Jordan, Utah, headquarters, totaling approximately 136,000 square feet and anticipate construction of the facility will be completed in February 2020.

In addition to routine leases, during 2018 we entered into leases for properties in Johannesburg, South Africa, and Reading, United Kingdom, for customer service offices and distribution warehouses in each location.

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 addition to the foregoing matters, 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 2019. 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, civil or criminal claims or penalties against our company or individuals.

Table of Contents

It is possible that the ultimate resolution of any of the foregoing matters, or other 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.

Table of Contents

PART II

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

Market Price for the Common Stock

Our common stock is traded on the NASDAQ Global Select Market under the symbol "MMSI."

As of February 26, 2019, the number of shares of our common stock outstanding was 54,902,835, held by approximately 105 shareholders of record, not including shareholders whose shares are held in securities position listings.

Performance

The following graph compares the performance of our 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, 2013 to December 31, 2018.

	12/2013	12/2014	12/2015	12/2016	12/2017	12/2018
Merit Medical Systems, Inc.	$ 100	$ 110	$ 118	$ 168	$ 274	$ 355
NASDAQ Stock Market (U.S. Companies)	100	115	124	136	146	143
NASDAQ Stocks (SIC 3840-3849 U.S. Companies)	100	114	127	132	185	209

The stock performance graph assumes for comparison that the value of our common stock and of each index was $100 on December 31, 2013 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 2019. Used with permission. All rights reserved.

Table of Contents

Securities Authorized for Issuance Under Equity Compensation Plans

The following table contains information regarding our equity compensation plans as of December 31, 2018 (in thousands, except weighted-average price):

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation Plans approved by security holders	3,507 (1),(3)	$ 26.30	3,005 (2),(3)

(1) Consists of 3,306,660 shares of common stock subject to the options granted under the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan and 200,000 shares of common stock subject to the options granted under the Merit Medical Systems, Inc. 2018 Long-Term Incentive Plan.
(2) Consists of 105,207 shares available to be issued under the 1996 Merit Medical Systems, Inc. Non-Qualified Employee Stock Purchase Plan and 2,900,000 shares available to be issued under the Merit Medical Systems, Inc. 2018 Long-Term Incentive Plan.
(3) See Note 12 to our consolidated financial statements set forth in Item 8 of this report for additional information regarding these plans.

Table of Contents

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

	2018	2017	2016	2015	2014
OPERATING DATA:					
Net Sales	$882,753	$727,852	$603,838	$542,149	$509,689
Cost of Sales	487,983	401,599	338,813	306,368	284,467
Gross Profit	394,770	326,253	265,025	235,781	225,222
Operating Expenses:					
Selling, general, and administrative	276,018	229,134	184,398	156,348	147,894
Research and development	59,532	51,403	45,229	40,810	36,632
Intangible asset impairment charge	657	809	—	—	1,102
Contingent consideration expense (benefit)	(698)	(298)	61	80	(572)
Acquired in-process research and development	644	12,136	461	1,000	—
Total operating expenses	336,153	293,184	230,149	198,238	185,056
Income from Operations	58,617	33,069	34,876	37,543	40,166
Other Income (Expense):					
Interest income	1,199	381	81	272	217
Interest expense	(10,360)	(7,736)	(8,798)	(6,229)	(8,829)
Gain on bargain purchase	—	11,039	—	—	—
Other income (expense)	63	(872)	(773)	(386)	18
Other income (expense)—net	(9,098)	2,812	(9,490)	(6,343)	(8,594)
Income Before Income Taxes	49,519	35,881	25,386	31,200	31,572
Income Tax Expense	7,502	8,358	5,265	7,398	8,598
Net Income	$42,017	$27,523	$20,121	$23,802	$22,974
Earnings Per Common Share:					
Diluted	$0.78	$0.55	$0.45	$0.53	$0.53
Average Common Shares:					
Diluted	53,931	50,101	44,862	44,511	43,409
BALANCE SHEET DATA:					
Working capital	$254,491	$200,501	$155,092	$116,093	$116,910
Total assets	1,620,012	1,111,811	942,803	778,728	747,165
Long-term debt, less current portion	373,152	259,013	314,373	197,593	214,490
Stockholders' equity	932,775	676,334	498,189	466,103	435,259

Table of Contents

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

The following discussion and analysis of our financial condition and results of 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 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, electrophysiology, critical care, Cianna Medical 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. Within those two operating segments, we offer products focused in six core product groups: peripheral intervention, cardiac intervention, interventional oncology and spine, cardiovascular and critical care, breast cancer localization and guidance and endoscopy.

For the year ended December 31, 2018, we reported sales of approximately $882.8 million, up approximately $154.9 million or 21.3%, over 2017 sales of approximately $727.9 million.

Gross profit as a percentage of sales decreased to 44.7% for the year ended December 31, 2018 as compared to 44.8% for the year ended December 31, 2017.

Net income for the year ended December 31, 2018 was approximately $42.0 million, or $0.78 per share, as compared to $27.5 million, or $0.55 per share, for the year ended December 31, 2017.

We continue to focus our efforts on expanding our presence in foreign markets, particularly Europe, Middle East and Africa ("EMEA"), China, Southeast Asia, Japan, Australia and Brazil, in an effort to expand our market opportunities. These efforts have increased our selling, general and administrative expenses, but we believe over time they will help us improve our profitability. Our international sales growth was strong for the year ended December 31, 2018. In 2018, international sales were approximately $386.3 million, or 44% of our net sales, up 26% from international sales of $307.1 million in 2017.

We believe our forecasted growth will be facilitated by recently introduced products such as the EmboCube™ Embolization Gelatin, the basixTAU™ Inflation Device, the Prelude Prestige™ Splittable Sheath Introducer, the Prelude Ideal™ Sheath Introducer, and the PreludeSYNC™ Radial Compression Device, among others.

We recently opened a new distribution center in Reading, England in an effort to address potential Brexit disruption, as well as a direct sales and distribution center in Johannesburg, South Africa. We believe the ability to provide essentially same-day service to our customers in those regions will enhance customer confidence and increase our growth prospects.

Table of Contents

Results of Operations

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

	2018	2017	2016
Net sales	100%	100%	100%
Gross profit	44.7	44.8	43.9
Selling, general and administrative expenses	31.3	31.5	30.5
Research and development expenses	6.7	7.1	7.5
Intangible asset impairment charges	0.1	0.1	—
Contingent consideration expense (benefit)	(0.1)	—	—
Acquired in-process research and development expenses	0.1	1.7	0.1
Income from operations	6.6	4.5	5.8
Income before income taxes	5.6	4.9	4.2
Net income	4.8	3.8	3.3

Listed below are the sales by product category within each operating segment for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	% Change	2018	% Change	2017	% Change	2016
Cardiovascular						
Stand-alone devices	31%	$361,613	44%	$275,456	23%	$191,127
Cianna Medical	n/a	6,292	—%	—	—%	—
Custom kits and procedure trays	7%	134,756	6%	126,089	2%	119,247
Inflation devices	16%	92,419	8%	79,875	1%	73,916
Catheters	22%	155,525	13%	127,747	17%	113,367
Embolization devices	1%	50,038	8%	49,532	2%	46,035
CRM/EP	17%	48,834	15%	41,914	8%	36,459
Total	21%	849,477	21%	700,613	11%	580,151
Endoscopy						
Endoscopy devices	22%	33,276	15%	27,239	12%	23,687
Total	21%	$882,753	21%	$727,852	11%	$603,838

Note: Certain product categories for 2017 and 2016 have been adjusted from prior disclosure to reflect changes in product classifications to be consistent with updates in the management of our product portfolios in 2018. Also note that Cianna Medical is a new category in 2018 as a result of the acquisition in November 2018 (see Note 3).

Cardiovascular Sales. Our cardiovascular sales for the year ended December 31, 2018 were approximately $849.5 million, up 21.2%, when compared to the corresponding period for 2017 of approximately $700.6 million. Sales for the year ended December 31, 2018 were favorably affected by increased sales of (a) our stand-alone devices (particularly our Map™ Merit Angioplasty Packs, PreludeSYNC™, guide wires, and Merit Laureate® Hydrophilic Guide Wire products, as well as sales from our acquisitions of the BD and Argon critical care division product lines, among others) of approximately $86.2 million, up 31.3%; (b) catheters (particularly our Prelude® Radial Introducer Sheath product line, our Merit Maestro® Microcatheters and our new Prelude Ideal™) of approximately $27.8 million, up 21.7%; and (c) our inflation devices (particularly our BASIXTouch™ and BasixCompak™ product lines and inflation kits sold through our OEM relationships) of approximately $12.5 million, up 15.7%.

Our cardiovascular sales for the year ended December 31, 2017 were approximately $700.6 million, up 20.8%, when compared to the corresponding period for 2016 of approximately $580.2 million. Sales for the year ended

December 31, 2017 were favorably affected by increased sales of (a) our stand-alone devices (particularly our Map™, Medallion®, guide wires, and HeRO® Graft products, as well as new sales from our acquisitions of the DFINE, Argon critical care division and Catheter Connections product lines) of approximately $84.3 million, up 44.1%; (b) catheters (particularly our SwiftNINJA® product line, Concierge® Guiding Catheters, Prelude® Radial Introducer Sheath product line, and our Merit Maestro®

Table of Contents

Microcatheters) of approximately $14.4 million, up 12.7%; and (c) our custom kits and procedure trays of approximately $6.8 million, up 5.7%, which includes sales from our acquisition of ITL Healthcare Pty Ltd. ("ITL").

Sales by our international direct sales forces are subject to foreign currency exchange rate fluctuations between the natural currency of a foreign country and the U.S. Dollar. Foreign currency exchange rate fluctuations increased sales 0.6% for the year ended December 31, 2018 compared to 2017 and increased sales 0.1% for the year ended December 31, 2017 compared to 2016. 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, 2018 were approximately $33.3 million, up 22.2%, when compared to sales in 2017 of approximately $27.2 million. This increase was primarily related to new sales from our distribution agreement with NinePoint Medical, Inc. and our acquisition of BD, as well as an increase in sales of our EndoMAXX™ fully covered esophageal stent and our Elation® balloon dilator. Our endoscopy sales for the year ended December 31, 2017 were approximately $27.2 million, up 15.0%, when compared to sales in 2016 of approximately $23.7 million. This increase was primarily related to an increase in sales of our EndoMAXX™ fully covered esophageal stent and our Elation® balloon dilator.

International Sales. International sales for the year ended December 31, 2018 were approximately $386.3 million, or 44% of net sales, up 26% from 2017. International sales for the year ended December 31, 2017 were approximately $307.1 million, or 42% of net sales, up 32% from 2016. The increase in our international sales during 2018 was primarily related to a year-over-year sales increase in China of approximately $19.4 million, or 26%, in Japan of approximately $12.8 million, or 38%, and in Australia of approximately $9.3 million, or 190% (primarily due to the acquisition of ITL). The increase in our international sales during 2017 was primarily related to a year-over-year sales increase in China of approximately $13.4 million, or 22%, the acquisition of the critical care division of Argon, and sales in modified direct markets added in 2017, namely South Korea, Japan and India, as well as continued growth in direct markets added in 2016, namely Canada, Australia and Russia.

Gross Profit. Our gross profit as a percentage of sales was 44.7%, 44.8%, and 43.9% for the years ended December 31, 2018, 2017 and 2016, respectively. The decrease in gross profit as a percentage of sales for 2018, as compared to 2017, was primarily related to increased amortization expense and mark-up of acquired inventory associated with current year acquisitions and unfavorable manufacturing variances associated with our operations in Australia, which was partially offset by improvements associated with changes in product mix. The increase in gross profit as a percentage of sales for 2017, as compared to 2016, was primarily related to changes in product mix and increased efficiencies gained from our operations team.

Selling, General and Administrative Expenses. Our selling, general and administrative expenses increased approximately $46.9 million, or 20.5%, for the year ended December 31, 2018 compared to 2017 and $44.7 million, or 24.3%, for the year ended December 31, 2017 compared to 2016. Selling, general and administrative expenses as a percentage of sales were 31.3%, 31.5% and 30.5% for the years ended December 31, 2018, 2017 and 2016, respectively.

The increase in selling, general, and administrative expenses for the year ended December 31, 2018 compared to the year ended December 31, 2017 was primarily related to $7.6 million of acquisition and integration-related costs (compared to $6.6 million in 2017), increased headcount, increased amortization of intangible assets and foreign market expansion, partially offset by decreased legal costs associated with responding to the pending subpoena from the U.S. Department of Justice ($5.6 million in 2018 compared to $12.6 million in 2017).

The increase in selling, general, and administrative expenses for the year ended December 31, 2017 compared to the year ended December 31, 2016 was primarily related to legal expenses of approximately $12.6 million incurred in

responding to the pending subpoena from the U.S. Department of Justice, $6.6 million of acquisition and integration-related costs, increased headcount, increased amortization, and foreign market expansion.

Research and Development Expenses. Research and development ("R&D") expenses increased by $8.1 million or 15.8% to approximately $59.5 million for the year ended December 31, 2018, compared to approximately $51.4 million in 2017. The increase in R&D expenses for the year ended December 31, 2018 was largely due to hiring additional research and development personnel to support various new core and acquired product developments. Research and development expenses increased by approximately $6.2 million or 13.7% to approximately $51.4 million for the year ended December 31, 2017, compared to approximately $45.2 million in 2016. The increase in R&D expenses for the year ended December 31, 2017 was largely due to hiring additional research and development personnel to support various new core and acquired product developments. Our research and development expenses as a percentage of sales were 6.7%, 7.1% and 7.5% for 2018,

Table of Contents

2017, and 2016, 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 years ended December 31, 2018, 2017 and 2016 we incurred in-process research and development charges of approximately $0.6 million, $12.1 million and $0.5 million, respectively. The decrease in our in-process research and development charges for the year ended December 31, 2018 was primarily driven by the acquisition of IntelliMedical and its intellectual property rights associated with a steerable guidewire system in 2017, as discussed in Note 3 of the notes to our consolidated financial statements.

Our operating profits by business segment for the years ended December 31, 2018, 2017 and 2016 were as follows (in thousands):

	2018	2017	2016
Operating Income			
Cardiovascular	$49,289	$24,819	$30,053
Endoscopy	9,328	8,250	4,823
Total operating income	$58,617	$33,069	$34,876

Cardiovascular Operating Income. Our cardiovascular operating income for the year ended December 31, 2018 was approximately $49.3 million, compared to cardiovascular operating income of approximately $24.8 million for the year ended December 31, 2017. This increase in cardiovascular operating income was primarily related to increased sales, lower R&D costs as a percentage of sales, the $11.9 million acquired in-process R&D charge from Intellimedical in 2017 which did not repeat in 2018, lower legal expenses incurred in responding to the pending subpoena from the U.S. Department of Justice ($5.6 million in 2018 compared to $12.6 million in 2017), partially offset by costs related to increased headcount, increased amortization of intangible assets, and costs associated with foreign market expansion. Our cardiovascular operating income for the year ended December 31, 2017 was approximately $24.8 million, compared to operating income of approximately $30.1 million for the year ended December 31, 2016. This decrease in cardiovascular operating income was primarily related to legal expenses of approximately $12.6 million incurred in responding to the pending subpoena from the U.S. Department of Justice, $6.6 million of acquisition and integration-related costs, increased headcount, increased amortization, and foreign market expansion.

Endoscopy Operating Income. Our endoscopy operating income for the year ended December 31, 2018 was approximately $9.3 million, compared to approximately $8.3 million for the year ended December 31, 2017. This increase was primarily the result of higher sales (due to the distribution agreement with NinePoint Medical, Inc. and the acquisition of BD). Our endoscopy operating income for the year ended December 31, 2017 was approximately $8.3 million, compared to approximately $4.8 million for the year ended December 31, 2016. This increase was primarily the result of higher sales, improved gross margins, and lower SG&A expenses as a percentage of sales.

Effective Tax Rate. Our effective income tax rate for the years ended December 31, 2018, 2017 and 2016 was 15.2%, 23.3%, and 20.7%, respectively. On December 22, 2017, the U.S. government enacted the TCJA, which significantly revises the U.S. corporate tax by, among other things, lowering the corporate tax rate and imposing a one-time repatriation tax on deemed repatriated earnings of foreign subsidiaries (“transition tax”). The decrease in the effective income tax rate for 2018 compared to 2017 was primarily the result of the reduced U.S. corporate tax rate and the favorable impact of the revision and completion of the transition tax calculation, partially offset by the unfavorable impact of the estimated withholding tax on unremitted foreign earnings. The increase in the effective income tax rate for 2017 compared to 2016 was primarily the result of increased tax expense due to the transition tax, partially offset by the favorable impact of the reduced tax rate on our net deferred tax liabilities.

Other Income (Expense). Our other income (expense) for the years ended December 31, 2018, 2017 and 2016 was approximately $(9.1) million, $2.8 million, and $(9.5) million, respectively. The change in other income (expense) for 2018 over 2017 was principally the result of increased interest expense due to higher average debt balances during 2018 and from the fact that the gain on bargain purchase related to the 2017 acquisition of the Argon critical care division of approximately $11.0 million did not repeat in 2018. The change in other income (expense) for 2017 over 2016 was principally the result of the gain on bargain purchase related to the acquisition of the Argon critical care division of approximately $11.0 million.

Net Income. Our net income for the years ended December 31, 2018, 2017 and 2016 was approximately $42.0 million, $27.5 million, and $20.1 million, respectively. The increase in net income for 2018, when compared to 2017, was

Table of Contents

primarily due to increased sales (both from acquisitions and organic growth), decreased R&D expenses as a percentage of sales, lower legal expenses incurred in responding to the pending subpoena from the U.S. Department of Justice ($5.6 million in 2018 compared to $12.6 million in 2017) and a lower effective tax rate in 2018 (in large part due to the TCJA), partially offset by slightly lower gross margins and increased interest expense due to higher average debt balances in 2018.

The increase in net income for the year ended December 31, 2017, when compared to 2016, was primarily due to increased sales, gross margin improvement and the gain on bargain purchase of approximately $11.0 million related to the acquisition of the Argon critical care division, which was partially offset by the acquired in-process research and development expenses of approximately $12.1 million attributable to the IntelliMedical acquisition, approximately $12.6 million of legal expenses incurred in responding to the pending subpoena from the U.S. Department of Justice, and approximately $6.6 million of acquisition and integration-related costs.

Total Assets. Total assets utilized in our cardiovascular segment were approximately $1.6 billion as of December 31, 2018, compared to approximately $1.1 billion as of December 31, 2017 and approximately $932.9 million as of December 31, 2016. Total assets utilized in our endoscopy segment were approximately $31.0 million as of December 31, 2018, compared to approximately $8.0 million as of December 31, 2017 and approximately $9.9 million as of December 31, 2016.

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, 2018, as well as the future periods in which such payments are currently anticipated to become due:

	Payment due by period (in thousands)				
Contractual Obligations	**Total**	**Less than 1 Year**	**1-3 Years**	**4-5 Years**	**After 5 Years**
Long-term debt	$395,500	$ 22,000	$373,500	$—	$ —
Interest on long-term debt (1)	39,843	11,063	28,780	—	—
Operating leases	102,495	13,421	21,314	15,006	52,754
Royalty obligations	7,236	804	1,442	1,350	3,640
Total contractual cash	$545,074	$ 47,288	$425,036	$16,356	$ 56,394

(1) Interest payments on our variable long-term debt were forecasted using the LIBOR forward curves plus a base of 1.00% 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 2.115% as a result of our interest rate swap (see Note 8 to our consolidated financial statements set forth in Item 8 of this report).

As of December 31, 2018, we had approximately $82.2 million of contingent consideration liabilities, $3.0 million of unrecognized tax positions, and $11.2 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 8 and 10 to our consolidated financial statements set forth in Item 8 below.

Cash Flows

At December 31, 2018 and 2017, we had cash and cash equivalents of approximately $67.4 million and $32.3 million respectively, of which approximately $57.3 million and $30.4 million, respectively, were held by foreign subsidiaries. The TCJA one-time repatriation tax liability effectively taxes the undistributed earnings previously deferred from U.S. income taxes. The TCJA eliminated certain material tax effects on the repatriation of cash to the U.S. Future repatriation of cash and other property held by our foreign subsidiaries will generally not be subject to U.S. federal income tax. As a result, after reevaluation of the permanent reinvestment assertion, we are no longer permanently reinvested with respect to our historic unremitted foreign earnings as of December 31, 2018.

Table of Contents

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, 2018 and 2017, we had cash and cash equivalents of approximately $18.6 million and $13.1million, respectively, held by our subsidiary in China.

Cash flows provided by operating activities. Cash provided by operating activities during the years ended December 31, 2018 and 2017 was primarily the result of net income excluding non-cash items, offset by shifts in working capital. Our working capital as of December 31, 2018, 2017 and 2016 was approximately $254.5 million, $200.5 million and $155.1 million, respectively. The increase in working capital as of December 31, 2018 compared to December 31, 2017 was primarily the result of increases in cash, trade receivables and inventories, which were partially offset by an increase in trade payables and accrued expenses. The increase in working capital as of December 31, 2017 compared to December 31, 2016 was primarily the result of increases in cash, trade receivables and inventories, which were partially offset by an increase in accrued expenses and the current portion of long-term debt. As of December 31, 2018 and 2017, we had a current ratio of 2.45 to 1 and 2.73 to 1, respectively.

During the year ended December 31, 2018, our inventory balance increased approximately $42.2 million, from approximately $155.3 million as of December 31, 2017 to approximately $197.5 million as of December 31, 2018. The increase in the inventory balance was due to several factors, including acquisitions and increased demand. During the year ended December 31, 2017, our inventory balance increased approximately $34.6 million, from approximately $120.7 million at December 31, 2016 to approximately $155.3 million at December 31, 2017. The increase in the inventory balance was due to several factors, including acquisitions, increased sales, and the opening of new modified direct sales markets in South Korea, India, and Japan. The trailing twelve month inventory turns for the period ended December 31, 2018 was 2.80, compared to 2.91 for the twelve-month period ended December 31, 2017.
Cash flows provided by financing activities. Cash provided by financing activities for the year ended December 31, 2018 was approximately $328.3 million compared to approximately $96.5 million for the year ended December 31, 2017, an increase of approximately $231.8 million. The increase in net cash provided from financing activities was primarily the result of an increase in the proceeds from the issuance of long-term debt (primarily driven by the acquisitions of BD and Cianna Medical), as well as cash provided from our public equity offering of 4,025,000 shares of common stock (from which we received net proceeds of approximately $205.0 million, which is net of approximately $12.0 million in underwriting discounts and commissions incurred and paid by us in connection with this equity offering). This was partially offset by increased payments on our long-term debt, as we used the proceeds of the equity offering to pay down debt balances.

Cash provided by financing activities for the year ended December 31, 2017 was approximately $96.5 million, compared to approximately $121.1 million for the year ended December 31, 2016, a change of approximately $24.6 million. The decrease in net cash provided from financing activities was primarily the result of a decrease in the proceeds from the issuance of long-term debt, which was partially offset by our public equity offering of 5,175,000 shares of common stock from which we received net proceeds of approximately $136.6 million, which is net of approximately $8.8 million in underwriting discounts and commissions and approximately $816,000 in other direct costs incurred and paid by us in connection with this equity offering.

The Second Amended Credit Agreement provides for a term loan of $150 million and a revolving credit commitment up to an aggregate amount of $375 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:

Table of Contents

	Covenant Requirement
Consolidated Total Leverage Ratio (1)	
January 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, 2018, we believe we were in compliance with all covenants set forth in the Second Amended Credit Agreement.

As of December 31, 2018, we had outstanding borrowings of approximately $388.5 million under the Second Amended Credit Agreement, with available borrowings of approximately $58.3 million, based on the leverage ratio required pursuant to the Second Amended Credit Agreement. Our interest rate as of December 31, 2018 was a fixed rate of 2.12% on $175.0 million as a result of an interest rate swap (see Note 9) and a variable floating rate of 3.52% on $213.5 million. We also had a variable rate of 3.39% on $7.0 million related to our collateralized debt facility with HSBC in China.

Our interest rate as of December 31, 2017 was a fixed rate of 2.68% on $175.0 million as a result of an interest rate swap (see Note 9) and a variable floating rate of 2.82% on $97.0 million. We also had a variable floating rate of 2.38% on approximately $7.0 million related to a collateralized debt facility with HSBC in China.

Cash flows used in investing activities. Our cash flow used in investing activities for the year ended December 31, 2018 was approximately $378.8 million compared to approximately $146.8 million for the year ended December 31, 2017, an increase of approximately $232.1 million. This increase was primarily a result of an increase of approximately $196.2 million in net cash paid for acquisitions (primarily BD and Cianna Medical) during the year ended December 31, 2018, compared to the year ended December 31, 2017 (see Note 3) and a $24.7 million increase in capital expenditures for property and equipment to fund our expanding operations.

Our cash flow used in investing activities for the year ended December 31, 2017 was approximately $146.8 million, compared to approximately $159.1 million for the year ended December 31, 2016, a decrease of approximately $12.3 million. This decrease was primarily a result of a decrease of approximately $19.6 million in net cash paid for acquisitions during the year ended December 31, 2017, compared to the year ended December 31, 2016 (see Note 3),

partially offset by a $5.8 million increase in capital expenditures for property and equipment.

Capital expenditures for property and equipment were approximately $63.3 million, $38.6 million, and $32.8 million for the years ended December 31, 2018, 2017 and 2016, 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 $60 to $65 million in 2019 for buildings, property and equipment.

We currently believe that our existing cash balances, anticipated future cash flows from operations 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. 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.

Table of Contents

Critical Accounting Policies and Estimates

The SEC has requested that all registrants address their most critical accounting policies. The SEC has indicated that a "critical accounting policy" is one which is both important to the representation of the registrant's financial condition and results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. We base our estimates on past experience and on various other assumptions our management believes to be reasonable under the circumstances, the results of which form the basis for making judgments about carrying values of assets and liabilities that are not readily apparent from other sources. Actual results will differ, and may differ materially from these estimates under different assumptions or conditions. Additionally, changes in accounting estimates could occur in the future from period to period. 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, 2018, 2017 and 2016, we recorded obsolescence expense of approximately $8.2 million, $6.1 million, and $3.9 million, respectively, and wrote off approximately $7.9 million, $2.9 million, and $2.8 million, respectively. Based on this historical trend, we believe that our inventory balances as of December 31, 2018 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. and international distributors, as well as 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 stock-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.

Valuation of Goodwill, Intangible Assets and Contingent Consideration. We allocate any excess purchase price over the fair value of the net tangible and identifiable intangible assets acquired in a business combination to goodwill. 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

Table of Contents

determination of a discount rate based on our weighted average cost of capital. During our annual test of goodwill balances in 2018, which was completed during the third quarter of 2018, 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 subject to amortization 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. In-process technology intangible assets, which are not subject to amortization until projects reach commercialization, are assessed for impairment at least annually and more frequently if events occur that would indicate a potential reduction in the fair value of the assets below their carrying value.

During the year ended December 31, 2018, we compared the carrying value of the amortizing intangible assets acquired in our July 2015 acquisition of certain assets from Quellent, LLC, all of which pertained to our cardiovascular segment, 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 Quellent 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 Quellent 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 Quellent of approximately $657,000.

During the year ended December 31, 2017, we compared the carrying value of the amortizing intangible assets acquired in our July 2015 acquisition of certain assets from Distal Access, LLC 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 Distal Access 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 Distal Access 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 Distal Access of approximately $809,000.

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 or other 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.

Table of Contents

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

Our principal market risk relates to changes in the value of the following currencies related to the U.S. Dollar (USD):
•Euro (EUR),
•Chinese Yuan Renminbi (CNY), and
•British Pound (GBP)

We also have a limited market risk relating to the following currencies (among others):
•Hong Kong Dollar (HKD),
•Mexican Peso (MXN),
•Australian Dollar (AUD),
•Canadian Dollar (CAD),
•Brazilian Real (BRL),
•Swiss Franc (CHF),
•Swedish Krona (SEK),
•Danish Krone (DKK),
•South Korean Won (KRW), and
•Japanese Yen (JPY).

Our consolidated financial statements are denominated in, and our principal currency is, the U.S. Dollar. For the year ended December 31, 2018, a portion of our net sales (approximately $284.8 million, representing approximately 32.3% 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, generally have a positive effect on our operating income. As we continue to expand our operations in China, we have been increasingly exposed to currency risk related to our CNY-denominated revenue. In general, a strengthening of the U.S. Dollar against CNY has a negative effect on our operating income. The following table presents the USD impact to reported operating income related to a hypothetical positive and negative 10% exchange rate fluctuation in the value of the U.S. Dollar relative to both the EUR and CNY:

(in thousands)	**USD Relative to Other Currency**	
	10% Strengthening	**10% Weakening**
Impact to Operating Income of:		
EUR	$4,600	$(4,600)
CNY	$(6,600)	$6,600

During the year ended December 31, 2018, exchange rate fluctuations of foreign currencies against the U.S. Dollar had the following impact on sales, cost of sales and gross profit (in thousands, except basis points):

	Year Ended December 31, 2018 Currency Impact to Reported Amounts	
	Increase/(Decrease)	Percent Increase/(Decrease)
Net Sales	5,163	0.59 %
Cost of Sales	5,260	1.09 %
Gross Profit (1)	(97)	(0.02)%

(1) Represents approximately 27 basis points decrease in gross margin percentage

The impact to sales for the year ended December 31, 2018 was primarily a result of favorable impacts due to sales denominated in CNY and EUR, partially offset by unfavorable impacts due to sales denominated in BRL. The impact to cost of sales was primarily a result of unfavorable impacts from EUR fluctuations related to manufacturing costs from our facilities in

Table of Contents

Europe denominated in EUR and unfavorable MXN fluctuations on our manufacturing costs from our facility in Tijuana, Mexico denominated in MXN.

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. As of December 31, 2018, 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):

Currency	Symbol	Forward Notional Amount
Australian Dollar	AUD	11,400
Brazilian Real	BRL	9,000
Canadian Dollar	CAD	2,300
Swiss Franc	CHF	269
Chinese Renminbi	CNY	63,200
Danish Krone	DKK	3,237
Euro	EUR	5,927
British Pound	GBP	2,358
Hong Kong Dollar	HKD	11,000
Japanese Yen	JPY	265,000
Korean Won	KRW	5,500,000
Mexican Peso	MXN	23,000
Swedish Krona	SEK	9,627
Singapore Dollar	SGD	8,500

We also forecast our net exposure related to sales and expenses denominated in foreign currencies. As of December 31, 2018, 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):

Currency	Symbol	Forward Notional Amount
Australian Dollar	AUD	3,000
Canadian Dollar	CAD	4,410
Swiss Franc	CHF	2,145
Chinese Renminbi	CNY	160,000
Danish Krone	DKK	17,225
Euro	EUR	20,310
British Pound	GBP	5,280
Japanese Yen	JPY	1,145,000
Korean Won	KRW	3,050,000
Mexican Peso	MXN	230,000
Swedish Krona	SEK	30,210

See Note 9 to our consolidated financial statements for a discussion of our foreign currency forward contracts.

As discussed in Note 8 to our consolidated financial statements set forth in Item 8 of this report, as of December 31, 2018, we had outstanding borrowings of approximately $388.5 million under the Second Amended Credit Agreement. Accordingly, our earnings and after-tax cash flow are affected by changes in interest rates. On August 5, 2016, we entered into a pay-fixed, receive-variable interest rate swap with Wells Fargo, which as of December 31, 2018 had a notional amount of $175 million, to fix the one-month LIBOR rate at 1.12%. The interest rate swap is scheduled to expire on July 6, 2021. This instrument is intended to reduce our exposure to interest rate fluctuations and was not entered into for speculative purposes. Excluding the amount that is subject to a fixed rate under the interest rate swap and assuming the current level of borrowings remained the same, it is estimated that our interest

expense and income before income taxes would change by approximately $2.1 million annually for each one percentage point change in the average interest rate under these borrowings.

Table of Contents

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

Table of Contents

Item 8. Financial Statements and Supplementary Data.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Merit Medical Systems, Inc. and subsidiaries (the "Company") as of December 31, 2018 and 2017, 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, 2018, and the related notes and the schedule listed in the Index at Item 15 (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the U.S. of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, 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, 2019, expressed an unqualified opinion on the Company's internal control over financial reporting.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ DELOITTE & TOUCHE LLP

Salt Lake City, Utah
March 1, 2019
We have served as the Company's auditor since 1988.

Table of Contents

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2018 AND 2017
(In thousands)

	2018	2017
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$67,359	$32,336
Trade receivables — net of allowance for uncollectible accounts — 2018 — $2,355 and 2017 — $1,769	137,174	105,536
Other receivables	11,879	9,429
Inventories	197,536	155,288
Prepaid expenses and other assets	11,326	9,096
Prepaid income taxes	3,627	3,225
Income tax refund receivables	933	1,211
Total current assets	429,834	316,121
PROPERTY AND EQUIPMENT:		
Land and land improvements	26,801	19,877
Buildings	151,251	147,356
Manufacturing equipment	221,029	197,651
Furniture and fixtures	54,765	49,528
Leasehold improvements	33,678	31,161
Construction-in-progress	53,491	32,896
Total property and equipment	541,015	478,469
Less accumulated depreciation	(209,563)	(185,649)
Property and equipment — net	331,452	292,820
OTHER ASSETS:		
Intangible assets:		
Developed technology — net of accumulated amortization — 2018 — $102,357 and 2017 — $87,147	387,420	167,771
Other — net of accumulated amortization — 2018 — $49,136 and 2017 — $38,127	79,566	59,553
Goodwill	335,433	238,147
Deferred income tax assets	3,001	2,359
Other assets	57,579	35,040
Total other assets	858,726	502,870
TOTAL	$1,620,012	$1,111,811

See notes to consolidated financial statements.

(continued)

Table of Contents

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2018 AND 2017
(In thousands)

	2018	2017
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$54,024	$34,931
Accrued expenses	96,173	58,932
Current portion of long-term debt	22,000	19,459
Income taxes payable	3,146	2,298
Total current liabilities	175,343	115,620
LONG-TERM DEBT	373,152	259,013
DEFERRED INCOME TAX LIABILITIES	56,363	23,289
LONG-TERM INCOME TAXES PAYABLE	392	4,846
LIABILITIES RELATED TO UNRECOGNIZED TAX BENEFITS	3,013	2,746
DEFERRED COMPENSATION PAYABLE	11,219	11,181
DEFERRED CREDITS	2,261	2,403
OTHER LONG-TERM OBLIGATIONS	65,494	16,379
Total liabilities	687,237	435,477
COMMITMENTS AND CONTINGENCIES (Notes 3, 8, 9, and 10)		
STOCKHOLDERS' EQUITY:		
Preferred stock — 5,000 shares authorized as of December 31, 2018 and 2017; no shares issued	—	—
Common stock, no par value; shares authorized — 2018 and 2017 - 100,000; issued and outstanding as of December 31, 2018 - 54,893 and December 31, 2017 - 50,248	571,383	353,392
Retained earnings	363,425	321,408
Accumulated other comprehensive income (loss)	(2,033)	1,534
Total stockholders' equity	932,775	676,334
TOTAL	$1,620,012	$1,111,811

See notes to consolidated financial statements. (concluded)

55

Table of Contents

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF INCOME
YEARS ENDED DECEMBER 31, 2018, 2017 AND 2016
(In thousands, except per share amounts)

	2018	2017	2016
NET SALES	$882,753	$727,852	$603,838
COST OF SALES	487,983	401,599	338,813
GROSS PROFIT	394,770	326,253	265,025
OPERATING EXPENSES:			
Selling, general and administrative	276,018	229,134	184,398
Research and development	59,532	51,403	45,229
Intangible asset impairment charges	657	809	—
Contingent consideration expense (benefit)	(698)	(298)	61
Acquired in-process research and development	644	12,136	461
Total operating expenses	336,153	293,184	230,149
INCOME FROM OPERATIONS	58,617	33,069	34,876
OTHER INCOME (EXPENSE):			
Interest income	1,199	381	81
Interest expense	(10,360)	(7,736)	(8,798)
Gain on bargain purchase	—	11,039	—
Other income (expense) - net	63	(872)	(773)
Other income (expense) — net	(9,098)	2,812	(9,490)
INCOME BEFORE INCOME TAXES	49,519	35,881	25,386
INCOME TAX EXPENSE	7,502	8,358	5,265
NET INCOME	$42,017	$27,523	$20,121
EARNINGS PER COMMON SHARE:			
Basic	$0.80	$0.56	$0.45
Diluted	$0.78	$0.55	$0.45
AVERAGE COMMON SHARES:			
Basic	52,268	48,805	44,408
Diluted	53,931	50,101	44,862

See notes to consolidated financial statements.

56

Table of Contents

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
YEARS ENDED DECEMBER 31, 2018, 2017 AND 2016
(In thousands)

	2018	2017	2016
Net income	$42,017	$27,523	$20,121
Other comprehensive income (loss):			
Cash flow hedges	64	901	4,784
Less income tax (expense)	(16)	(350)	(1,861)
Foreign currency translation adjustment	(3,606)	3,117	878
Less income tax (expense)	(9)	(252)	(196)
Total other comprehensive income (loss)	(3,567)	3,416	3,605
Total comprehensive income	$38,450	$30,939	$23,726

See notes to consolidated financial statements.

Table of Contents

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED DECEMBER 31, 2018, 2017 AND 2016
(In thousands)

		Common Stock		Retained	Accumulated Other Comprehensive
	Total	Shares	Amount	Earnings	Income (Loss)
BALANCE — January 1, 2016	$466,103	44,267	$197,826	$273,764	$ (5,487)
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	498,189	44,645	206,186	293,885	(1,882)
Net income	27,523			27,523	
Other comprehensive income	3,416				3,416
Stock-based compensation expense	4,075		4,075		
Options exercised	5,689	404	5,689		
Issuance of common stock under Employee Stock Purchase Plans	836	24	836		
Issuance of common stock, net of offering costs	136,606	5,175	136,606		
BALANCE — December 31, 2017	676,334	50,248	353,392	321,408	1,534
Net income	42,017			42,017	
Other comprehensive loss	(3,567)				(3,567)
Stock-based compensation expense	6,117		6,117		
Options exercised	10,634	690	10,634		
Issuance of common stock under Employee Stock Purchase Plans	1,087	22	1,087		
Issuance of common stock, net of offering costs	205,030	4,025	205,030		
Shares surrendered in exchange for payment of payroll tax liabilities	(2,616)	(49)	(2,616)		
Shares surrendered in exchange for exercise of stock options	(2,261)	(43)	(2,261)		
BALANCE — December 31, 2018	$932,775	54,893	$571,383	$363,425	$ (2,033)

See notes to consolidated financial statements.

Table of Contents

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2018, 2017 AND 2016
(In thousands)

	2018	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	$42,017	$27,523	$ 20,121
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	69,546	53,582	43,755
Gain on bargain purchase	—	(11,039)	—
Losses on sales and/or abandonment of property and equipment	625	427	530
Write-off of patents and intangible assets	814	988	101
Acquired in-process research and development	644	12,136	461
Amortization of deferred credits	(142)	(147)	(170)
Amortization of long-term debt issuance costs	804	685	952
Deferred income taxes	2,052	(1,304)	(962)
Excess tax benefits from stock-based compensation	—	—	(669)
Stock-based compensation expense	6,117	4,075	2,506
Changes in operating assets and liabilities, net of effects from acquisitions:			
Trade receivables	(27,522)	(12,844)	(6,816)
Other receivables	(2,754)	(3,557)	1,161
Inventories	(28,172)	(17,834)	(3,656)
Prepaid expenses and other current assets	(2,000)	(1,236)	271
Prepaid income taxes	(444)	(611)	404
Income tax refund receivables	232	(588)	406
Other assets	315	(3,735)	(3,763)
Trade payables	15,726	417	(6,835)
Accrued expenses	12,706	6,461	3,242
Income taxes payable	918	21	1,451
Long-term income taxes payable	(4,454)	4,846	—
Liabilities related to unrecognized tax benefits	267	(19)	597
Deferred compensation payable	39	1,970	712
Other long-term obligations	(801)	2,510	(200)
Total adjustments	44,516	35,204	33,478
Net cash provided by operating activities	86,533	62,727	53,599
CASH FLOWS FROM INVESTING ACTIVITIES:			
Capital expenditures for:			
Property and equipment	(63,324)	(38,623)	(32,837)
Intangible assets	(3,012)	(2,577)	(2,217)
Proceeds from sale of cost method investment	—	—	1,089
Proceeds from the sale of property and equipment	55	21	19
Issuance of notes receivable	(10,750)	—	—
Cash paid in acquisitions, net of cash acquired	(301,789)	(105,582)	(125,161)
Net cash used in investing activities	(378,820)	(146,761)	(159,107)

See notes to consolidated financial statements. (continued)

Table of Contents

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2018, 2017 AND 2016
(In thousands)

	2018	2017	2016
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock	$214,993	$143,810	$ 5,271
Offering costs	(366)	(816)	—
Proceeds from issuance of long-term debt	639,108	197,214	219,505
Payments on long-term debt	(522,608)	(243,214)	(102,098)
Excess tax benefits from stock-based compensation	—	—	669
Long-term debt issuance costs	—	(416)	(1,948)
Contingent payments related to acquisitions	(231)	(61)	(218)
Payment of taxes related to an exchange of common stock	(2,616)	—	(86)
Net cash provided by financing activities	328,280	96,517	121,095
EFFECT OF EXCHANGE RATES ON CASH	(970)	682	(593)
NET INCREASE IN CASH AND CASH EQUIVALENTS	35,023	13,165	14,994
CASH AND CASH EQUIVALENTS:			
Beginning of year	32,336	19,171	4,177
End of year	$67,359	$32,336	$ 19,171
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION			
Cash paid during the year for:			
Interest (net of capitalized interest of $647, $513 and $460, respectively)	$10,324	$7,707	$ 8,872
Income taxes	$8,692	$6,049	$ 2,318
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES			
Property and equipment purchases in accounts payable	$4,989	$1,992	$ 2,398
Contingent receivable in exchange for sale of equity investment	$—	$—	$ 711
Receivable for issuance of common stock associated with option exercises	$—	$137	$ —
Acquisition purchases in accrued expenses and other long-term obligations	$72,209	$10,488	$ —
Merit common stock surrendered (43, 0 and 14 shares, respectively) in exchange for exercise of stock options	$2,261	$—	$ 346

See notes to consolidated financial statements. (concluded)

Table of Contents

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2018, 2017 and 2016

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, critical care, 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. Within those two operating segments, we offer products focused in six core product groups: peripheral intervention, cardiac intervention, interventional oncology and spine, cardiovascular and critical care, breast cancer localization and guidance, and endoscopy.

We manufacture our products in plants located in the U.S., Mexico, The Netherlands, Ireland, France, Brazil, Australia, and Singapore. We export sales to dealers and have direct or modified direct sales forces in the U.S., Canada, Western Europe, Australia, Brazil, Russia, Japan, China, Malaysia, South Korea, UAE, India, New Zealand and South Africa (see Note 13). Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States. 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 ("U.S. GAAP") 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. Trade accounts receivable are recorded at the net invoice value and are not interest bearing. An allowance for uncollectible accounts receivable is recorded based on our historical bad debt experience and on management’s evaluation of our ability to collect individual outstanding balances. Once collection efforts have been exhausted and a receivable is deemed to be uncollectible, such balance is charged against the allowance for uncollectible accounts.

Inventories. We value our inventories at the lower of cost, at approximate costs determined on a first-in, first-out method, 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 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.

Finite-lived intangible assets including developed technology, customer lists, distribution agreements, license agreements, trademarks, covenants not to compete and patents are subject to amortization. Intangible assets are amortized over their estimated useful life on a straight-line basis, except for customer lists, which are generally amortized on an accelerated basis. Estimated useful lives are determined considering the period the assets are expected to contribute to future cash flows. We evaluate the recoverability of our finite-lived intangible assets periodically and take into account events or circumstances that warrant revised estimates of useful lives or that indicate impairment exists.

Table of Contents

In-process technology intangible assets, which are not subject to amortization until projects reach commercialization, are assessed for impairment at least annually and more frequently if events occur that would indicate a potential reduction in the fair value of the assets below their carrying value. An impairment charge would be recognized to the extent the carrying amount of the in-process technology exceeded its fair value.

Long-Lived Assets. We periodically review the carrying amount of our depreciable 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.

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, 2018, 2017 and 2016 was approximately $28.3 million, $26.8 million, and $24.5 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 $11.7 million and $11.7 million at December 31, 2018 and 2017, respectively, which is included in other assets in our consolidated balance sheets. We have recorded a deferred compensation payable of approximately $11.2 million and $11.2 million at December 31, 2018 and 2017, respectively, to reflect the liability to our employees under this plan.

Other Assets. Other assets consist of our deferred compensation plan cash surrender value discussed above, unamortized issuance costs on revolving debt, investments in privately-held companies, notes receivable issued to third-parties, a long-term income tax refund receivable, deposits related to various leases, and the long-term assets related to derivatives.

We analyze our investments to determine if they should be accounted for using the equity method based on our ability to exercise significant influence over operating and financial policies of the investment. Our share of earnings associated with equity method investments is reported within other income (expense) in our consolidated statements of income. Investments not accounted for under the equity method of accounting are accounted for under the cost method of accounting wherein impairment charges are recognized if circumstances suggest that the value of the investment has changed.

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 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. Revenue is recognized when a customer obtains control of promised goods based on the consideration we expect to receive in exchange for these goods. This core principle is achieved through the following steps:

Identify the contract with the customer. A contract with a customer exists when (i) we enter into an enforceable contract with a customer that defines each party's rights regarding the goods to be transferred and identifies the payment terms related to these goods, (ii) the contract has commercial substance and, (iii) we determine that collection of substantially all consideration for services that are transferred is probable based on the customer's intent and ability to pay the promised consideration. We do not

Table of Contents

have significant costs to obtain contracts with customers. For commissions on product sales, we have elected the practical expedient to expense the costs as incurred if the amortization period would have been one year or less.

Identify the performance obligations in the contract. Generally, our contracts with customers do not include multiple performance obligations to be completed over a period of time. Our performance obligations generally relate to delivering single-use medical products to a customer, subject to the shipping terms of the contract. Limited warranties are provided, under which we typically accept returns and provide either replacement parts or refunds. We do not have significant returns. We do not typically offer extended warranty or service plans.

Determine the transaction price. Payment by the customer is due under customary fixed payment terms, and we evaluate if collectability is reasonably assured. None of our contracts as of December 31, 2018 contained a significant financing component. Revenue is recorded at the net sales price, which includes estimates of variable consideration such as product returns, rebates, discounts, and other adjustments. The estimates of variable consideration are based on historical payment experience, historical and projected sales data, and current contract terms. Variable consideration is included in revenue only to the extent that it is probable that a significant reversal of the revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Taxes collected from customers relating to product sales and remitted to governmental authorities are excluded from revenues.

Allocate the transaction price to performance obligations in the contract. We typically do not have multiple performance obligations in our contracts with customers. As such, we generally recognize revenue upon transfer of the product to the customer's control at contractually stated pricing.

Recognize revenue when or as we satisfy a performance obligation. We generally satisfy performance obligations at a point in time upon either shipment or delivery of goods, in accordance with the terms of each contract with the customer. We do not have significant service revenue.

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, 2018, 2017 and 2016. In addition, we invoice our customers for taxes assessed by governmental authorities such as sales tax and value added taxes. We present these taxes on a net basis.

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

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

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

Income Taxes. 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.

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:

Table of Contents

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 stock-based payment transactions in accordance with ASC 718, *Compensation — Stock Compensation*. Under the provisions of ASC 718, stock-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, 2018, 2017 and 2016 was approximately $6.1 million, $4.1 million and $2.5 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 2%, 2%, and 3% of net sales for the years ended December 31, 2018, 2017 and 2016, respectively.

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.

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 Second Amended Credit Agreement described in Note 8. 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 9).

Accumulated Other Comprehensive Income (Loss). As of December 31, 2018, accumulated other comprehensive loss included approximately $3.5 million (net of tax of $(2.2) million) related to cash flow hedges and $(5.6) million (net of tax of $(9,000)) related to foreign currency translation. As of December 31, 2017, accumulated other comprehensive income included approximately $3.5 million (net of tax of $(2.2) million) related to cash flow hedges and $(1.9) million (net of tax of $0) related to foreign currency translation.

New Financial Accounting Standards.

Recently Adopted

In October 2016, the FASB issued Accounting Standards Update ("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 became effective for us as of January 1, 2018. The adoption of ASU 2016-16 did not have a material impact on our consolidated financial statements for the year ended December 31, 2018.

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 became effective for us on January 1, 2018. The adoption of ASU 2016-15 did not have a material impact on our consolidated financial statements for the year ended December 31, 2018.

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

Table of Contents

available-for-sale debt securities. We adopted ASU 2016-01 on January 1, 2018. The adoption of ASU 2016-01 did not have a material impact on our consolidated financial statements for the year ended December 31, 2018.

The FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which provides a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers. We adopted this ASU (and all subsequent ASUs that modified Topic 606) effective January 1, 2018 on a modified retrospective basis. Adoption of this standard did not result in significant changes to our accounting policies, business processes, systems or controls, or have a material impact on our financial position, results of operations or cash flows. As such, prior period amounts are not adjusted and continue to be reported under accounting standards then in effect, and we did not record a cumulative adjustment to the opening equity balance of retained earnings as of January 1, 2018. However, additional disclosures have been added in accordance with the requirements of Topic 606 and are reflected in Note 2.

Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842),* ("ASC 842"). The objective of the guidance in ASC 842 is to increase transparency and comparability among organizations by recognizing lease assets and liabilities in the balance sheet and disclosing key information. ASC 842 amends previous lease guidance to require a lessee to recognize a lease liability and a right-of-use asset on the entity's balance sheet for all leases with terms that exceed one year. ASC 842 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. ASC 842 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.

We have completed our assessment of all our leases, and we estimate that the impact of the adoption of ASC 842 will result in recognition of operating right-of-use assets and lease liabilities of approximately $80 million. We do not expect the adoption to have a material impact on our statements of operations or cash flows. ASC 842 allows for several practical expedients which permit the following: no reassessment of lease classification or initial direct costs; use of the standard's effective date as the date of initial application; and no separation of non-lease components from the related lease components and, instead, to account for those components as a single lease component if certain criteria are met. We expect to elect these practical expedients and adopt ASC 842 on January 1, 2019 using the effective date as our date of initial application. Therefore, financial information and disclosures under ASC 842 will not be provided for periods prior to January 1, 2019.

In February 2018, the FASB issued ASU 2018-02, *Income Statement-Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income,* which allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act enacted in December 2017. ASU 2018-02 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted. We do not believe that the adoption of ASU 2018-02 will have a material impact on our consolidated financial statements.

In August 2017, the FASB issued ASU 2017-12, *Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities*, which expands and refines hedge accounting for both financial and non-financial risk components, aligns the recognition and presentation of the effects of hedging instruments and hedge items in the financial statements, and includes certain targeted improvements to ease the application of current guidance related to the assessment of hedge effectiveness. ASU 2017-12 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted. We do not anticipate the impact of adopting

ASU 2017-12 will be material to our consolidated financial statements.

All other issued and not yet effective accounting standards are not relevant to our financial statements.

2. REVENUES

The following table presents sales by operating segment disaggregated based on type of product and geographic region for the years ended December 31, 2018, 2017 and 2016.

Table of Contents

	Year Ended December 31, 2018			Year Ended December 31, 2017			Year Ended December 31, 2016		
	United States	International	Total	United States	International	Total	United States	International	Total
Cardiovascular									
Stand-alone devices	$202,129	$ 159,484	$361,613	$148,620	$ 126,836	$275,456	$105,250	$ 85,877	$191,127
Cianna Medical	6,292	—	6,292	—	—	—	—	—	—
Custom kits and procedure trays	92,975	41,781	134,756	92,474	33,615	126,089	93,109	26,138	119,247
Inflation devices	31,717	60,702	92,419	31,848	48,027	79,875	35,506	38,410	73,916
Catheters	68,708	86,817	155,525	62,284	65,463	127,747	56,899	56,468	113,367
Embolization devices	20,433	29,605	50,038	22,374	27,158	49,532	24,075	21,960	46,035
CRM/EP	41,970	6,864	48,834	36,746	5,168	41,914	32,561	3,898	36,459
Total	464,224	385,253	849,477	394,346	306,267	700,613	347,400	232,751	580,151
Endoscopy									
Endoscopy devices	32,189	1,087	33,276	26,357	882	27,239	22,950	737	23,687
Total	$496,413	$ 386,340	$882,753	$420,703	$ 307,149	$727,852	$370,350	$ 233,488	$603,838

Note: Certain revenue categories for 2017 and 2016 have been adjusted from prior disclosures to reflect changes in product classifications to be consistent with updates in management of our product portfolios during 2018. Also note that Cianna Medical is a new category in 2018 as a result of the acquisition in November 2018 (see Note 3).

3. ACQUISITIONS

On December 14, 2018, we consummated an acquisition transaction contemplated by an asset purchase agreement with Vascular Insights, LLC and VI Management, Inc. (combined "Vascular Insights") and acquired Vascular Insight's intellectual property rights, inventory and certain other assets, including, the ClariVein® IC system and the ClariVein OC system. The ClariVein systems are specialty infusion and occlusion catheter systems with rotating wire tips designed for the controlled 360-degree dispersion of physician-specified agents to the targeted treatment area. We accounted for this acquisition as a business combination. The purchase consideration included an upfront payment of $40 million, and we are obligated to pay up to an additional $20 million based on achieving certain revenue milestones specified in 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. Acquisition-related costs associated with the Vascular Insights acquisition, which were included in selling, general and administrative expenses in our consolidated statements of income, were not material. Given the circumstances of this acquisition, which closed in December 2018, as well as the complexity of the transaction, the purchase price allocation disclosed herein is considered provisional at this time and subject to adjustment. We are in the process of finalizing the net working capital adjustment pursuant to the asset purchase agreement and the valuation of the acquired intangible assets and contingent consideration. The purchase price was preliminarily allocated as follows (in thousands):

Inventories	$1,308
Intangibles	
Developed technology	32,830
Customer list	840
Trademarks	1,410
Goodwill	21,832
Total assets acquired	**$58,220**

We are amortizing the developed technology intangible assets over 12 years, the related trademarks over nine years and the customer list on an accelerated basis over eight years. The total weighted-average amortization period for

these acquired intangible assets is approximately 11.8 years.

On November 13, 2018 we consummated an acquisition transaction contemplated by a merger agreement to acquire Cianna Medical, Inc. ("Cianna Medical"). The purchase consideration consisted of an upfront payment of $135 million plus an

Table of Contents

initial working capital adjustment of $1 million in cash, with potential earn-out payments of an additional $15 million for achievement of supply chain and scalability metrics, and up to an additional $50 million for achievement of sales milestones. Cianna Medical developed the first non-radioactive, wire-free breast cancer localization system. Its SCOUT® and SAVI® Brachy technologies are FDA-cleared and address unmet needs in the delivery of radiation therapy, tumor localization and surgical guidance. We accounted for this acquisition as a business combination. During the year ended December 31, 2018, our net sales of Cianna Medical products were approximately $6.3 million. It is not practical to separately report earnings related to the products acquired from Cianna Medical, as we cannot split out sales costs related solely to the products we acquired from Cianna Medical, principally because our sales representatives sell multiple products (including the products we acquired from Cianna Medical) in our cardiovascular business segment. Acquisition-related costs associated with the Cianna Medical acquisition, which are included in selling, general and administrative expenses in the accompanying consolidated statements of income, were approximately $3.5 million for the year ended December 31, 2018. The following table summarizes the preliminary purchase price allocated to the net assets acquired from Cianna Medical (in thousands):

Assets Acquired	
Trade receivables	$6,151
Inventories	5,803
Prepaid expenses and other assets	315
Property and equipment	1,047
Other long-term assets	14
Intangibles	
Developed technology	134,510
Customer lists	3,330
Trademarks	7,080
Goodwill	65,885
Total assets acquired	224,135
Liabilities Assumed	
Trade payables	(1,497)
Accrued expenses	(2,384)
Other long-term liabilities	(1,527)
Deferred tax liabilities	(30,363)
Total liabilities assumed	(35,771)
Total net assets acquired	$188,364

We are amortizing the developed technology intangible assets over 11 years, the related trademarks over ten years and the customer lists on an accelerated basis over eight years. The total weighted-average amortization period for these acquired intangible assets is approximately 10.7 years.

During July 2018, we purchased 1,786,000 preferred limited liability company units of Cagent Vascular, LLC, a medical device company ("Cagent"), for approximately $2.2 million. We had previously purchased 3,000,000 preferred limited liability company units for approximately $3.0 million during 2016 and 2017. Our investment has been recorded as an equity investment accounted for at cost and reflected within other assets in the accompanying consolidated balance sheets because we are not able to exercise significant influence over the operations of Cagent. Our total current investment in Cagent represents an ownership of approximately 19.5% of the outstanding stock.

On May 23, 2018, we entered into an asset purchase agreement with DirectACCESS Medical, LLC (“DirectACCESS”) to acquire its assets, including, certain product distribution agreements for the FirstChoice™ Ultra High Pressure PTA

Balloon Catheter. We accounted for this acquisition as a business combination. The purchase price for the assets was approximately $7.3 million. The sales and results of operations related to the acquisition have been included in our cardiovascular segment since the acquisition date and were not material. Acquisition-related costs associated with the DirectACCESS acquisition, which were included in selling, general and administrative expenses in our consolidated statements of income, were not material. The purchase price was preliminarily allocated as follows (in thousands):

Table of Contents

Inventories	$971
Intangibles	
Developed technology	4,840
Customer list	120
Trademarks	400
Goodwill	938
Total assets acquired	**$7,269**

We are amortizing the developed technology intangible asset over ten years, the related trademarks over ten years and the customer list on an accelerated basis over five years. The total weighted-average amortization period for these acquired intangible assets is approximately 9.9 years.

On May 18, 2018, we paid $750,000 for a distribution agreement with QXMédical, LLC ("QXMédical") for the Q50® PLUS Stent Graft Balloon Catheter. We accounted for this acquisition as an asset purchase. We are amortizing the distribution
agreement intangible asset over a period of ten years.

On April 6, 2018, we entered into long-term agreements with NinePoint Medical, Inc. (“NinePoint”), pursuant to which we (a) became the exclusive worldwide distributor for the NvisionVLE® Imaging System with Real-time Targeting™ using Optical Coherence Tomography (OCT) and (b) acquired an option to purchase up to 100% of the outstanding equity in NinePoint throughout a three-month period commencing 18 months subsequent to the agreement date, both in exchange for total consideration of $10 million. We accounted for this transaction as an asset purchase. In addition, we made a loan to NinePoint for $10.5 million with a maturity date of April 6, 2023, at which time the loan, together with accrued interest thereon, will be due and payable. The loan bears interest at a rate of 9.0% and is collateralized by NinePoint's rights, interest and title to the NvisionVLE® Imaging System and any other product owned or licensed by NinePoint utilizing OCT. This loan has been recorded as a note receivable within other long-term assets in our consolidated balance sheets.

We utilized the consolidation of variable interest entities guidance to determine whether or not NinePoint was a variable interest entity ("VIE"), and if so, whether we are the primary beneficiary of NinePoint. As of December 31, 2018, we concluded that NinePoint is a VIE based on the fact that the equity investment at risk in NinePoint is not sufficient to finance its activities. We have also determined that Merit is not the primary beneficiary of NinePoint as we do not have the power to direct NinePoint's most significant activities. Our exposure to loss related to our transaction with NinePoint is the carrying value of the amounts paid to and due from NinePoint. The results of operations related to the NinePoint distribution agreement have been included in our endoscopy segment since the acquisition date. During the year ended December 31, 2018, our net sales of NinePoint products were approximately $3.0 million. We believe the NinePoint products will enhance the product offerings of our Endotek operating segment and will be another step in our strategy to add therapy and disease-state products to our portfolio.

On February 14, 2018, we acquired certain divested assets from Becton, Dickinson and Company ("BD"), for an aggregate purchase price of $100.3 million. We also recorded a contingent consideration liability of $1.6 million related to milestone payments payable pursuant to the terms of the acquired contract with Sontina Medical LLC. The assets acquired include the soft tissue core needle biopsy products sold under the tradenames of Achieve® Programmable Automatic Biopsy System, Temno® Biopsy System, Tru-Cut® Biopsy Needles as well as Aspira® Pleural Effusion Drainage Kits, and the Aspira® Peritoneal Drainage System. We accounted for this acquisition as a business combination.

During the year ended December 31, 2018, our net sales of BD products were approximately $42.1 million. It is not practical to separately report earnings related to the products acquired from BD, as we cannot split out sales costs related solely to the products we acquired from BD, principally because our sales representatives sell multiple products (including the products we acquired from BD) in our cardiovascular business segment. Acquisition-related costs associated with the BD acquisition, which are included in selling, general and administrative expenses in the accompanying consolidated statements of income, were approximately $1.8 million for the year ended December 31, 2018. During the measurement period, which ended in December 2018, adjustments were made to finalize the allocation of purchase price related to intangible assets, goodwill and contingent liabilities. The following table summarizes the purchase price allocated to the assets acquired from BD (in thousands):

Table of Contents

Inventories	$5,804
Property and equipment	748
Intangibles	
Developed technology	74,000
Customer list	4,200
Trademarks	4,900
In-process technology	2,500
Goodwill	9,728
Total assets acquired	**$101,880**

We are amortizing the developed technology intangible assets over eight years, the related trademarks over nine years, and the customer lists on an accelerated basis over seven years. The total weighted-average amortization period for these acquired intangible assets is approximately 8 years.

On October 2, 2017 we acquired a custom procedure pack business located in Melbourne, Australia from ITL Healthcare Pty Ltd. ("ITL"), for an aggregate purchase price of $11.3 million. We accounted for this acquisition as a business combination. The following table summarizes the aggregate purchase price allocated to the assets acquired from ITL (in thousands):

Assets Acquired	
Trade receivables	$1,287
Other receivables	56
Inventories	1,808
Prepaid expenses and other assets	65
Property and equipment	1,053
Intangibles	
Customer lists	5,940
Goodwill	3,945
Total assets acquired	14,154
Liabilities Assumed	
Trade payables	(216)
Accrued expenses	(747)
Deferred tax liabilities	(1,901)
Total liabilities assumed	(2,864)
Total net assets acquired	$11,290

We are amortizing the customer list on an accelerated basis over seven years. Acquisition-related costs associated with the ITL acquisition, 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 years ended December 31, 2018 and 2017, our net sales of ITL products were approximately $8.0 million and $3.3 million, respectively. It is not practical to separately report the earnings related to the ITL acquisition, as we cannot split out sales costs related solely to the products we acquired from ITL, principally because our sales representatives sell multiple products (including the products we acquired from ITL) in our cardiovascular business segment.

On September 1, 2017, we acquired intellectual property rights associated with a steerable guidewire system from IntelliMedical Technologies Pty. Ltd. ("IntelliMedical"). We made an initial payment of approximately $11.9 million in September 2017, and we are obligated to pay up to an additional A$15.0 million (Australian dollars) if certain milestones set forth in the share purchase agreement with IntelliMedical are achieved. We are also required to pay royalties equal to 6% of net sales, commencing upon the first commercial sale of the product and throughout the term of the applicable patents. We accounted for this transaction as an asset purchase. The initial payment has been included in the accompanying consolidated statements of income as acquired

Table of Contents

in-process research and development expense for the year ended December 31, 2017, because both technological feasibility of the underlying research and development project had not yet been reached and such technology had no identified future alternative use as of the date of acquisition.

On August 4, 2017 we acquired from Laurane Medical S.A.S. ("Laurane") and its shareholders inventories and the intellectual property rights associated with certain manual bone biopsy devices, manual bone marrow needles and muscle biopsy kits for an aggregate purchase price of $16.5 million. We also recorded a contingent consideration liability of $5.5 million related to royalties potentially payable to Laurane's shareholders pursuant to the terms of an intellectual property purchase agreement. We accounted for this acquisition as a business combination. The following table summarizes the aggregate purchase price (including contingent royalty payment liabilities) allocated to the assets acquired from Laurane (in thousands):

Inventories	$594
Intangibles	
Developed technology	14,920
Customer list	120
Goodwill	6,366
Total net assets acquired	**$22,000**

We are amortizing the developed technology intangible asset over 12 years and the customer list on an accelerated basis over one year. The total weighted-average amortization period for these acquired intangible assets is 11.9 years. The sales and results of operations related to the acquisition have been included in our cardiovascular segment since the acquisition date and were not material. Acquisition-related costs associated with the Laurane acquisition, which are included in selling, general and administrative expenses in the accompanying consolidated statements of income, were not material.

On July 3, 2017, we acquired from Osseon LLC (“Osseon”) substantially all the assets related to Osseon’s vertebral augmentation products. We accounted for this acquisition as a business combination. The purchase price for the assets was approximately $6.8 million. Acquisition-related costs associated with the Osseon acquisition, 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 years ended December 31, 2018 and 2017, our net sales of Osseon products were approximately $2.1 million and $942,000, respectively. It is not practical to separately report the earnings related to the Osseon acquisition, as we cannot split out sales costs related solely to the products we acquired from Osseon, principally because our sales representatives sell multiple products (including the products we acquired from Osseon) in our cardiovascular business segment. The following table summarizes the purchase price allocated to the assets acquired (in thousands):

Inventories	$979
Property and equipment	58
Intangibles	
Developed technology	5,400
Customer list	200
Goodwill	203
Total net assets acquired	**$6,840**

We are amortizing the developed technology intangible asset over nine years and customer lists on an accelerated basis over eight years. The total weighted-average amortization period for these acquired intangible assets is approximately 9.0 years.

On July 1, 2017, we entered into an exclusive license agreement with Pleuratech ApS ("Pleuratech") to acquire the rights to manufacture and sell the KatGuide™ chest tube insertion tool. As of December 31, 2018, we had paid $2.0 million in connection with this agreement. We are obligated to pay an additional $5.0 million if certain milestones set forth in the license agreement are met. We are also required to pay royalties equal to 6% of net sales throughout the term of the license agreement. We accounted for this transaction as an asset purchase. We recorded the amount paid upon closing as a license agreement intangible asset, which we are amortizing over 15 years.

On June 16, 2017, we acquired from Lazarus Medical Technologies, LLC the patent rights and other intellectual property related to the Repositionable Chest Tube™ and related devices. As of December 31, 2018, we had paid $620,000 in connection

Table of Contents

with this agreement. We are also obligated to pay an additional $700,000 if certain milestones set forth in the purchase agreement are met. We are also required to pay royalties equal to 6% of net sales throughout the term of the purchase agreement. We accounted for this transaction as an asset purchase. We recorded the amount paid upon closing as a license agreement intangible asset, which we are amortizing over 15 years.

On May 23, 2017, we paid $2.5 million to acquire 182,000 shares of preferred stock of Fusion Medical, Inc. ("Fusion"), a developer of medical devices designed primarily for clot removal. The shares of preferred stock we acquired, which represent an ownership interest of approximately 19.5%, have been accounted for as an equity method investment of $2.5 million reflected within other assets in the accompanying consolidated balance sheets because we may be deemed to exercise significant influence over the operations of Fusion.

On May 19, 2017, we terminated our distribution agreement with Sheen Man Co., Ltd. and Sugan Co, Ltd., ("Sugan"), a Japanese medical device distributor and entered into a business purchase agreement, distribution agreement and a supply agreement with Sugan. Pursuant to these agreements, we acquired the customer list Sugan used in the distribution of our products in Japan. The purchase price is recorded as a customer list intangible asset of approximately $1.2 million. We are amortizing the customer list intangible asset on an accelerated basis over five years. In addition, we granted to Sugan the right to continue to distribute a limited number of our products, related to fluid administration, through December 31, 2021 and to manufacture and sell to Sugan certain contrast injector products during a term of four years, subject to extensions.

On May 1, 2017, we entered into an agreement and plan of merger with Vascular Access Technologies, Inc. ("VAT"), pursuant to which we acquired the SAFECVAD™ device. We accounted for this acquisition as a business combination. The purchase price for the business was $5.0 million. We also recorded $4.9 million of contingent consideration related to royalties potentially payable to VAT pursuant to the merger agreement. The following table summarizes the purchase price allocated to the net assets acquired and liabilities assumed (in thousands):

Intangibles	
Developed technology	$7,800
In-process technology	920
Goodwill	4,281
Deferred tax liabilities	(3,101)
Total net assets acquired	$9,900

We are amortizing the developed technology intangible asset over 15 years. The sales and results of operations related to the acquisition have been included in our cardiovascular segment since the acquisition date and were not material. Acquisition-related costs associated with the VAT acquisition, which are included in selling, general and administrative expenses in the accompanying consolidated statements of income, were not material.

On January 31, 2017, we acquired Argon’s critical care division, including a manufacturing facility in Singapore, the related commercial operations in Europe and Japan, and certain inventories and intellectual property rights within the U.S. We made an initial payment of approximately $10.9 million and received a subsequent reduction to the purchase price of approximately $797,000 related to a working capital adjustment according to the terms of the purchase agreement. We accounted for the acquisition as a business combination.

Acquisition-related costs associated with the acquisition of the Argon critical care division during the year ended December 31, 2017, which are included in selling, general and administrative expenses in the accompanying consolidated statements of income, were approximately $2.6 million. The results of operations related to this acquisition have been included in our cardiovascular segment since the acquisition date. During the years ended

December 31, 2018 and 2017, our net sales of the Argon critical care products were approximately $45.5 million and $41.2 million, respectively. It is not practical to separately report the earnings related to the Argon critical care acquisition, as we cannot split out sales costs related solely to the products we acquired from Argon, principally because our sales representatives sell multiple products (including the products we acquired from Argon) in our cardiovascular business segment.

The assets and liabilities in the purchase price allocation for the Argon critical care acquisition are stated at fair value based on estimates of fair value using available information and making assumptions our management believes are reasonable. The following table summarizes the purchase price allocated to the net tangible and intangible assets acquired and liabilities assumed (in thousands):

Table of Contents

Assets Acquired	
Cash and cash equivalents	$1,436
Trade receivables	8,351
Inventories	11,222
Prepaid expenses and other assets	1,275
Income tax refund receivable	165
Property and equipment	2,319
Deferred tax assets	202
Intangibles	
Developed technology	2,200
Customer lists	1,500
Trademarks	900
Total assets acquired	29,570
Liabilities Assumed	
Trade payables	(2,414)
Accrued expenses	(5,083)
Income taxes payable	—
Deferred income tax liabilities	(934)
Total liabilities assumed	(8,431)
Total net assets acquired	21,139
Gain on bargain purchase [(1)]	(11,039)
Total purchase price	$10,100

(1) The total fair value of the net assets acquired from Argon exceeded the purchase price, resulting in a gain on bargain purchase which was recorded within other income (expense) in our consolidated statements of income. We believe the reason for the gain on bargain purchase was a result of the divestiture of a non-strategic, slow-growth critical care business for Argon. It is our understanding that the divestiture allows Argon to focus on its higher growth interventional portfolio.

With respect to the Argon critical care assets, we are amortizing developed technology over seven years and customer lists on an accelerated basis over five years. While U.S. trademarks can be renewed indefinitely, we currently estimate that we will generate cash flow from the acquired trademarks for a period of five years from the acquisition date. The total weighted-average amortization period for these acquired intangible assets is 6.0 years.

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 payment of $38.0 million. Catheter Connections, 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. We accounted for this acquisition as a business combination.

Acquisition-related costs associated with the Catheter Connections acquisition during the year ended December 31, 2017, which are included in selling, general and administrative expenses in the accompanying consolidated statements

of income, were approximately $482,000. The results of operations related to this acquisition have been included in our cardiovascular segment since the acquisition date. During the years ended December 31, 2018 and 2017, our net sales of the products acquired from Catheter Connections were approximately $13.7 million and $10.0 million, respectively. It is not practical to separately report the earnings related to the products acquired from Catheter Connections, as we cannot split out sales costs related solely to those products, principally because our sales representatives sell multiple products (including the DualCap System) in the cardiovascular business segment. The purchase price was allocated as follows (in thousands):

Table of Contents

Assets Acquired	
Trade receivables	$958
Inventories	2,157
Prepaid expenses and other assets	85
Property and equipment	1,472
Intangibles	
Developed technology	21,100
Customer lists	700
Trademarks	2,900
Goodwill	8,989
Total assets acquired	38,361
Liabilities Assumed	
Trade payables	(338)
Accrued expenses	(23)
Total liabilities assumed	(361)
Net assets acquired	$38,000

We are amortizing the Catheter Connections developed technology asset over 12 years, the related trademarks over ten years, and the associated customer list over eight years. We have estimated the weighted average life of the intangible Catheter Connections assets acquired to be approximately 11.7 years.

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 U.S. 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 years ended December 31, 2018, 2017 and 2016, our net sales of DFINE products were

approximately $26.6 million, $27.0 million and $13.5 million, respectively. 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.

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):

Table of Contents

Assets Acquired	
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
Liabilities Assumed	
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)
Net assets acquired, net of cash received of $1,327	$95,635

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 15 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 15 years from the acquisition date. The total weighted-average amortization period for these acquired intangible assets is 14.8 years.

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):

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

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 9.8 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 years ended December 31, 2018, 2017 and 2016, our net sales of the products acquired from CryoLife were approximately $9.1 million, $8.6 million and $7.1 million, respectively. It is not practical to separately

Table of Contents

report the earnings related to the products acquired from CryoLife, as we cannot split out sales costs related to those products, principally because our sales representatives are selling multiple products (including the HeRO Graft device) in the cardiovascular business segment.

The following table summarizes our consolidated results of operations for the years ended December 31, 2018, 2017 and 2016, as well as unaudited pro forma consolidated results of operations as though the DFINE acquisition had occurred on January 1, 2015, the acquisition of the Argon critical care division had occurred on January 1, 2016 and the acquisition of Cianna Medical and Vascular Insights had occurred on January 1, 2017 (in thousands, except per common share amounts):

	2018		2017		2016	
	As Reported	Pro Forma	As Reported	Pro Forma	As Reported	Pro Forma
Net sales	$882,753	$928,336	$727,852	$768,571	$603,838	$664,366
Net income (loss)	42,017	20,699	27,523	(13,720)	20,121	23,054
Earnings per common share:						
Basic	$0.80	$0.40	$0.56	$(0.28)	$0.45	$0.52
Diluted	$0.78	$0.38	$0.55	$(0.27)	$0.45	$0.51

The unaudited pro forma information set forth above is for informational purposes only and includes adjustments related to the
step-up of acquired inventories, amortization expense of acquired intangible assets, stock-based compensation for cancelled or forfeited options, interest expense on long-term debt and changes in the timing of the recognition of the gain on bargain purchase. The pro forma information should not be considered indicative of actual results that would have been achieved if the acquisition of Cianna Medical and Vascular Insights had occurred on January 1, 2017, the acquisition of the Argon critical care division had occurred on January 1, 2016, or the acquisition of DFINE had occurred on January 1, 2015, or results that may be obtained in any future period. The pro forma consolidated results of operations do not include the acquisition of assets from BD because it was deemed impracticable to obtain information to determine net income associated with the acquired product lines which represent a small product line of a large, consolidated company without standalone financial information. The pro forma consolidated results of operations do not include the DirectACCESS, ITL, Laurane, Osseon, VAT, Catheter Connections or HeRO Graft acquisitions as we do not deem the pro forma effect of these transactions to be material.

The goodwill arising from the acquisitions discussed above consists largely of the synergies and economies of scale we hope to achieve from combining the acquired assets and operations with our historical operations (see Note 5). The goodwill recognized from certain acquisitions is expected to be deductible for income tax purposes.

Table of Contents

4. INVENTORIES

Inventories at December 31, 2018 and 2017, consisted of the following (in thousands):

	2018	2017
Finished goods	$117,703	$86,555
Work-in-process	14,380	12,799
Raw materials	65,453	55,934
Total	$197,536	$155,288

5. GOODWILL AND INTANGIBLE ASSETS

The changes in the carrying amount of goodwill for the years ended December 31, 2018 and 2017, are as follows (in thousands):

	2018	2017
Goodwill balance at January 1	$238,147	$211,927
Effect of foreign exchange	(1,304)	2,641
Additions as the result of acquisitions	98,590	23,579
Goodwill balance at December 31	$335,433	$238,147

Total accumulated goodwill impairment losses aggregated to $8.3 million as of December 31, 2018 and 2017. We did not have any goodwill impairments for the years ended December 31, 2018, 2017 and 2016. The total goodwill balance as of December 31, 2018 and 2017, is related to our cardiovascular segment.

Other intangible assets at December 31, 2018 and 2017, consisted of the following (in thousands):

	2018 Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patents	$19,378	$(5,012)	$14,366
Distribution agreements	8,012	(5,766)	2,246
License agreements	26,930	(7,411)	19,519
Trademarks	29,998	(6,586)	23,412
Covenants not to compete	1,028	(1,000)	28
Customer lists	39,936	(23,361)	16,575
In-process technology	3,420	—	3,420
Total	$128,702	$(49,136)	$79,566

Table of Contents

	2017 Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patents	$16,528	$(3,737)	$12,791
Distribution agreements	7,262	(4,686)	2,576
License agreements	23,783	(5,568)	18,215
Trademarks	16,224	(4,686)	11,538
Covenants not to compete	1,028	(968)	60
Customer lists	31,935	(18,482)	13,453
In-process technology	920	—	920
Total	$97,680	$(38,127)	$59,553

Aggregate amortization expense for the years ended December 31, 2018, 2017 and 2016 was approximately $41.2 million, $26.8 million and $19.3 million, respectively.

We evaluate long-lived assets, including amortizing intangible assets, for impairment whenever events or changes in circumstances indicate that their carrying amounts may not be recoverable. We perform the impairment analysis at the asset group for which the lowest level of identifiable cash flows are largely independent of the cash flows of other assets and liabilities. We compare the carrying value of the amortizing intangible assets acquired to the undiscounted cash flows expected to result from the asset group and determine whether the carrying amount is recoverable. We determine the fair value of our amortizing assets 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. During the years ended December 31, 2018 and 2017, we recorded impairment charges of $657,000, related to our July 2015 acquisition of certain assets from Quellent, LLC, and $809,000, related to our July 2015 acquisition of certain assets from Distal Access, LLC, respectively, all of which pertained to our cardiovascular segment. Some of the factors that influenced our estimated cash flows were slower than anticipated sales growth in the products acquired from our Quellent and Distal Access acquisitions and uncertainty about future sales growth. We did not record any impairment charges during the year ended December 31, 2016.

Estimated amortization expense for the developed technology and other intangible assets for the next five years consists of the following as of December 31, 2018 (in thousands):

Year Ending December 31	
2019	$58,035
2020	55,341
2021	48,084
2022	46,648
2023	45,417

6. INCOME TAXES

On December 22, 2017, U.S. federal tax legislation, commonly referred to as the Tax Cuts and Jobs Act (“TCJA”) was signed into law. Significant provisions that have impacted (and will in the future impact) our effective tax rate include the reduction in the corporate tax rate from 35% to 21%, effective in 2018; a one-time deemed repatriation (“transition tax”) on earnings of certain foreign subsidiaries that were previously tax deferred; and new taxes on certain foreign sourced earnings. At December 31, 2017, we had not completed our accounting for the tax effects of the TCJA;

however, in certain cases, as described below, we made reasonable estimates of the effects on our existing deferred tax balances and impact of the one-time transition tax. In accordance with SEC Staff Accounting Bulletin 118 (“SAB 118”), income tax effects of the TCJA may be refined upon obtaining, preparing, and/or analyzing additional information during the measurement period and such changes could be material. During the measurement period, provisional amounts may also be adjusted for the effects, if any, of interpretative guidance issued after December 31, 2017, by U.S. regulatory and standard-setting bodies.

As of December 31, 2017, we were able to determine a reasonable estimate and recognize the provisional impacts of the rate reduction on our existing deferred tax balances and the impact of the transition tax. The reduction in the U.S. corporate tax rate resulted in a net tax benefit of approximately $8.4 million related to the revaluation of our U.S. net deferred tax liability. The transition tax resulted in a one-time tax expense of approximately $10.6 million.

Table of Contents

As of December 31, 2018, we have revised these estimated amounts based upon further analysis of the TCJA and notices and regulations issued and proposed by the U.S. Department of Treasury and the Internal Revenue Service. We recognized an additional tax benefit of approximately $71,000 on the difference between the 2017 U.S. enacted tax rate of 35%, and the 2018 enacted tax rate of 21%. We recognized a tax benefit of approximately $3.3 million from the revised transition tax calculation, which included the completion of our calculation of the total post-1986 foreign earnings and profits ("E&P") of our foreign subsidiaries, and related foreign tax credits. We elected to pay our transition tax over the eight-year period provided by the TCJA.

For tax years beginning after December 31, 2017, the TCJA introduces new provisions of U.S. taxation of certain Global Intangible Low-Tax Income ("GILTI"). The FASB provided guidance that companies should make an accounting policy election to either treat taxes on GILTI as period costs or use the deferred method. We have elected to treat taxes on GILTI as period costs and recognized tax expense of approximately $347,000 in December 2018.

As of December 31, 2018, we have completed our accounting for the tax effects of the enactment of the TCJA; however, we continue to expect U.S. regulatory and standard-setting bodies to issue guidance and regulations that could have a material financial statement impact on our effective tax rate in future periods.

We have historically asserted indefinite reinvestment of the earnings of certain non-U.S. subsidiaries outside the U.S. The TCJA eliminated certain material tax effects on the repatriation of cash to the U.S. As such, future repatriation of cash and other property held by our foreign subsidiaries will generally not be subject to U.S. federal income tax. Therefore, after reevaluation of the permanent reinvestment assertion, we no longer consider our foreign earnings to be permanently reinvested as of December 31, 2018. As a result of the change in the assertion, during 2018 we recorded tax expense of approximately $5.6 million for foreign withholding taxes on unremitted foreign earnings as of December 31, 2018.

For the years ended December 31, 2018, 2017 and 2016, income before income taxes is broken out between U.S. and foreign-sourced operations and consisted of the following (in thousands):

	2018	2017	2016
Domestic	$21,084	$14,531	$6,174
Foreign	28,435	21,350	19,212
Total	$49,519	$35,881	$25,386

The components of the provision for income taxes for the years ended December 31, 2018, 2017 and 2016, consisted of the following (in thousands):

	2018	2017	2016
Current expense (benefit):			
Federal	$(1,132)	$3,849	$1,933
State	582	645	492
Foreign	6,000	5,168	3,802
Total current expense	5,450	9,662	6,227
Deferred expense (benefit):			
Federal	4,400	(314)	(144)
State	(667)	(216)	(195)
Foreign	(1,681)	(774)	(623)
Total deferred (benefit) expense	2,052	(1,304)	(962)

Total income tax expense	$7,502	$8,358	$5,265

The difference between the income tax expense reported and amounts computed by applying the statutory federal rate of 21.0% to pretax income for the year ended December 31, 2018, and 35% for years ended December 31, 2017 and 2016, consisted of the following (in thousands):

Table of Contents

	2018	2017	2016
Computed federal income tax expense at applicable statutory rate	$10,399	$12,559	$8,885
State income taxes	(59)	279	193
Tax credits	(1,734)	(1,377)	(1,164)
Production activity deduction	—	—	(53)
Foreign tax rate differential	(1,361)	(3,329)	(3,717)
Uncertain tax positions	267	(19)	597
Deferred compensation insurance assets	186	(479)	(307)
Transaction-related expenses	223	90	274
U.S. transition tax	(3,271)	10,612	—
TCJA remeasurement of deferred taxes	(71)	(8,383)	—
Stock-based payments	(4,278)	(2,264)	—
Bargain purchase gain	—	(1,570)	—
In-process research and development	—	1,486	—
Net GILTI	347	—	—
Foreign withholding tax	5,590	—	—
Other — including the effect of graduated rates	1,264	753	557
Total income tax expense	$7,502	$8,358	$5,265

Deferred income tax assets and liabilities at December 31, 2018 and 2017, consisted of the following temporary differences and carry-forward items (in thousands):

	2018	2017
Deferred income tax assets:		
Allowance for uncollectible accounts receivable	$ 606	$ 467
Accrued compensation expense	7,414	5,154
Inventory differences	1,269	2,505
Net operating loss carryforwards	20,226	15,741
Deferred revenue	46	58
Stock-based compensation expense	2,833	2,281
Other	9,243	8,986
Total deferred income tax assets	41,637	35,192
Deferred income tax liabilities:		
Prepaid expenses	(1,142)	(930)
Property and equipment	(20,045)	(20,352)
Intangible assets	(58,883)	(28,588)
Foreign withholding tax	(5,590)	—
Other	(4,350)	(1,830)
Total deferred income tax liabilities	(	