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

FORM 10-K

(Mark One)

☒ **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
for the fiscal year ended December 31, 2019
or

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**
for the transition period from _____ to _____ .
Commission File Number 0-18592

MERIT MEDICAL SYSTEMS, INC.
(Exact name of registrant as specified in its charter)

Utah	**87-0447695**
(State or other jurisdiction of incorporation or organization)	(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:

Title of each class	**Trading Symbol**	**Name of exchange on which registered**
Common Stock, no par value	MMSI	NASDAQ Global Select Market

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically 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 ☒ No ☐

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 ☒ Accelerated Filer ☐ Non-Accelerated Filer ☐ Smaller Reporting Company ☐ Emerging Growth Company ☐

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. ☐

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant on June 28, 2019, based upon the closing price of the common stock as reported by the NASDAQ Global Select Market on such date, was approximately $3.2 billion. As of February 27, 2020, the registrant had 55,216,906 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 our 2020 Annual Meeting of Shareholders.

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PART I

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

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This report includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements in this report, other than statements of historical fact, are "forward-looking statements" for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of our management for future operations, any statements concerning proposed new products or services, any statements regarding the integration, development or commercialization of the business or any assets acquired from other parties, any statements regarding future economic conditions or performance, and any statements of assumptions underlying any of the foregoing. All forward-looking statements included in this report are made as of the date hereof and are based on information available to us as of such date. We assume no obligation to update any forward-looking statement. In some cases, forward-looking statements can be identified by the use of terminology such as "may," "will," "expects," "plans," "anticipates," "intends," "seeks," "believes," "estimates," "potential," "forecasts," "continue," or other forms of these words or similar words or expressions, or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results will likely differ, and could differ materially, from those projected or assumed in the forward-looking statements. Prospective investors are cautioned not to unduly rely on any such forward-looking statements.

Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including the following:

- risks relating to managing growth, particularly if accomplished through acquisitions, and the integration of acquired businesses;
- risks relating to protecting our intellectual property;
- risks relating to the recent outbreak of a strain of coronavirus identified as "COVID-19" in China, and the spread of COVID-19 to countries around the world;
- 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;
- changes in general economic conditions, geopolitical conditions, U.S. trade policies and other factors beyond our control;
- constant changes in international and national economic and industry conditions;
- FDA regulatory clearance processes are expensive, time-consuming and uncertain and failure to obtain and maintain required regulatory clearances and approvals could prevent us from commercializing our products;
- international regulatory requirements and delays and failure to obtain and maintain required regulatory clearances and approvals;
- 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;
- consolidation in the healthcare industry, group purchasing organizations or public procurement policies leading to demands for price concessions;

- disruption of our information technology systems, our critical information systems or a breach in the security of our systems;
- changes in or 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;
- fluctuations in foreign currency exchange rates negatively impacting our financial results;
- 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;
- loss of key personnel;
- termination or interruption of, or a failure to monitor, our supply relationships or increases in the prices of our component parts, finished products, third-party services or raw materials, particularly petroleum-based products;
- limits on reimbursement imposed by governmental and other programs;
- 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 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;
- pursuit of litigation which affects our financial condition or results of operations;
- inability to compete in markets, particularly if there is a significant change in relevant practices or technology;
- inability to generate sufficient cash flow to fund our debt obligations, capital expenditures, and ongoing operations;
- uncertainties about the United Kingdom's ("UK") withdrawal from the European Union ("EU");
- uncertainties relating to the LIBOR calculation and the expected discontinuation of LIBOR after 2021;
- inability to accurately forecast customer demand for our products or manage our inventory;
- the addressable market for our product groups being smaller than our estimates;
- 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;
- risks relating to work stoppage, transportation interruptions, severe weather, natural disasters and outbreak of disease;
- fluctuations in our effective tax rate adversely affecting our business, financial condition or results of operation;
- risks relating to our revenues being derived from a few products and medical procedures;
- actions of activist shareholders being potentially disruptive and costly and causing change that conflicts with our strategic direction;
- effects of evolving U.S. and international laws and regulations regarding privacy and data protection;

- 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
- 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."

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, products 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 divisions;
- 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 and representative offices. 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, 2019, 2018 and 2017, net sales generated by our top ten selling products accounted for approximately 32%, 33% and 37%, respectively. 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 9.4%, 10.8% and 11.4% of our net sales for the years ended December 31, 2019, 2018 and 2017, respectively.

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: $3.3 billion (global)
- Cardiac Intervention: $2.1 billion (global)
- Cardiovascular and Critical Care: $3.5 billion (global)
- Interventional Oncology and Spine: $1.7 billion (global)
- Breast Cancer Localization and Guidance: $450 million (global)
- Endoscopy: $527 million (U.S. domestic)

We conduct our business through two financial reporting segments: Cardiovascular (which includes our Peripheral Intervention, Cardiac Intervention, Cardiovascular and Critical Care, Interventional Oncology and Spine 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.

The following section describes our principal product offerings by product group.

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 products are organized into product portfolios as follows: Access, Angiography, Intervention, Biopsy, Drainage and Solutions.

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. The principal Access Portfolio offerings in our Peripheral Intervention product group 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,
- CentrosFLO® Long-Term Hemodialysis Catheter and ProGuide® Chronic Dialysis Catheter,
- Broad offering of peritoneal dialysis catheters, accessories and implantation kits for home dialysis therapy, and
- 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 currently sold via our distribution agreement with BlueGrass Vascular Technologies.

The products in our Angiography Portfolio are used to identify blockages and other disease states in the blood vessel. The principal Angiography Portfolio offerings in our Peripheral Intervention product group include our:

- Extensive line of Merit Laureate® Hydrophilic Guide Wires, a smooth-surface guide wire designed to minimize friction and promote rapid catheter exchanges,
- InQwire® Diagnostic Guide Wires and InQwire® Amplatz guide wires,
- Performa® and Impress® Diagnostic Catheters, a catheter offering designed for traversing difficult to access peripheral blood vessels, and
- Performa Vessel Sizing Catheters for vessel measurement.

The products in our Intervention Portfolio are chiefly used to remove blood clots, retrieve foreign bodies in blood vessels and assist with placing balloons and stents to treat arterial disease. The principal Intervention Portfolio offerings in our Peripheral Intervention product group include our:

- ClariVein® Specialty Infusion Catheter, acquired in 2019, which is designed for controlled 360-degree dispersion of physician specified agents to the peripheral vasculature,
- Advocate™ Percutaneous Transluminal Angioplasty (“PTA”) Catheter and Dynamis AV™ PTA Dilatation Catheter, a line of catheters to correct failing or thrombosed dialysis fistulae,
- Q50X®, Q50® and Q50 Plus Stent Graft Balloon Catheters, a line of catheters that treat abdominal and thoracic endovascular aortic repair procedures and reinterventions,
- Fountain® Infusion System and Mistique® Infusion Catheters, a line of catheters that treat arterial and hemodialysis graft occlusions and deep vein thrombosis,
- EN Snare® and One Snare® Endovascular Snare Systems, a complete line of snares designed to manipulate, capture and retrieve foreign material in the body, and
- Inflation devices, including our basixTOUCH40™ and basixTOUCH™ Inflation Devices, BasixCompak™ Inflation Device and Blue Diamond™ Digital Inflation Device.

We offer an extensive line of soft tissue biopsy products, bone biopsy products and accessories to complement these products. The principal Biopsy Portfolio offerings in our Peripheral Intervention product group include our:

- Soft tissue core needle biopsy, bone biopsy and accessory products including our innovative CorVocet® Biopsy System for soft tissue biopsy procedures, designed to cut a full-core of tissue, providing large specimens for pathological examination,
- Achieve®, Temno® and TruCut® Soft Tissue Biopsy Devices, and
- Full offering of manual bone biopsy products including our Madison™, Huntington™, Kensington™, Preston™ and Westbrook™ biopsy products.

We offer a broad line of drainage products. The principal Drainage Portfolio offerings in our Peripheral Intervention product group include our:

- Aspira® Pleural Effusion Drainage and Aspira® Peritoneal Drainage Systems, a compassionate home treatment option for end-stage cancer, allowing patients to spend more time at home by eliminating the need for frequent hospital visits to treat their drainage needs,
- Family of ReSolve® Drainage Catheters, including our ReSolve ConvertX® Stent System and Mini™ Locking Drainage Catheter, introduced in 2019 and our related tubing sets and drainage bags,
- One-Step™ and Valved One-Step™ Drainage Catheters, sold individually and in kits, for quickly removing unwanted fluid accumulation, and
- Revolution™ Catheter Securement Device and StayFIX® Fixation Device, used to stop migration, movement and accidental removal of a percutaneous catheter.

Our Solutions Portfolio is comprised of standard and custom kit and pack solutions that include items needed for peripheral procedures, safety and waste management products, and hemostasis accessories. Our kit and pack solutions can optimize efficiency, and reduce cost and waste.

Cardiac Intervention

We manufacture and sell a variety of products designed to treat various heart conditions. Our Cardiac Intervention products are organized into product portfolios including: Access, Angiography, Hemostasis, Intervention, Interventional Fluid Management, Pressure Monitoring, Thermodilution & Pulmonary Artery Catheters and Electrophysiology and Cardiac Rhythm Management.

The principal Access Portfolio offerings in our Cardiac Intervention product group include our:

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

Angiography products identify blocked or narrowed coronary arteries and overlap with our peripheral intervention angiography products. The principal Angiography Portfolio offerings in our Cardiac Intervention product group include our:

- InQwire® Guide Wires and a complete line of manifolds, syringes, and stopcocks for fluid management and hemodynamic monitoring,
- Performa® Diagnostic Catheter, known for its superior torque, high shaft strength for pushability and a large inner diameter for improved flow rates, and
- Performa Ultimate™ Diagnostic Catheters and MIV™ Radial Ventriculogram Pigtail Catheter, specifically designed for radial artery procedures.

Our hemostasis products assist clinicians in obtaining and maintaining hemostasis or stopping the flow of blood following arterial catheterization. The principal Hemostasis Portfolio offerings in our Cardiac Intervention product group include our:

- PreludeSYNC™ Radial Compression devices, designed to reduce and stop blood flow and offered in a variety of colorful band designs. In 2019 we expanded our product line to include our PreludeSYNC Distal™ and PreludeSYNC EVO™, and
- SafeGuard® Pressure Assisted Device for the femoral artery and Safeguard Radial Compression Devices.

The principal Intervention Portfolio offerings in our Cardiac Intervention product group include our:

- Full line of hemostasis valves including the PhD™ Hemostasis Valve, launched in late 2019 in the United States and Japan; FLO40XR™ and FLO50™ Hemostasis Valves, introduced in 2018; and our full line of hemostasis valves including the Honor®, AccessPLUS™, Access-9™, DoublePlay™, MBA™ and Passage® valves,
- BasixTAU™ Inflation Device, introduced in late 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™, DiamondTouch™ and basixTOUCH™,
- ConcierGE® Guiding Catheters, featuring a large inner lumen and soft tip used to gain access to the heart,
- Merit SureCross® Support Catheters, designed to reach and cross tight, difficult lesions,
- Pericardiocentesis Kits, a combination of products containing devices used in pericardial drainage procedures, and
- Ostial PRO® Stent Positioning System, a stent alignment tool for precise stent implantation in aorto-ostial lesions.

Electrophysiology is the study of diagnosing and treating abnormal electrical activities of the heart. 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. The principal Electrophysiology and CRM Portfolio offerings in our Cardiac Intervention product group include our:

- Worley™ Advanced LV Delivery System, used to aid in the insertion and implantation of left ventricular pacing leads,
- HeartSpan® Transseptal Needle, for left-heart access procedures, and
- HeartSpan® Steerable Sheath Introducer, featuring a neutral position indicator and tactile click to help physicians identify curve orientation. In 2019 our product line was expanded to include new fixed curve shapes.

Cardiovascular and Critical Care

The products in our Cardiovascular and Critical Care product group treat patients with life-threatening disease, protect healthcare providers and patients from exposure to bloodborne pathogens and are designed for efficiency and effectiveness, improving a patient’s and clinician’s experience, while simplifying the challenges of care. The products in our Cardiovascular and Critical Care product group are organized under Interventional Fluid Management and Pressure Monitoring.

The principal Interventional Fluid Management portfolio offerings in our Cardiovascular and Critical Care product group include our:

- DualCap® Disinfection Protection System, a system of two caps designed to protect and disinfect needleless valves, reducing healthcare-associated infections,
- Medallion® Syringes, a medication syringe, available in assorted colors for easy medication identification,
- Pen and Label Medication Labeling Systems, for labeling syringes, bowls and other medical containers,
- ShortStop® Temporary Sharps Holders, to hold needles and prevent accidental needlestick injuries to hospital staff, and
- Family of BackStop® Disposable Basins, protective containers for holding fluid waste.

The principal Pressure Monitoring Portfolio offerings in our Cardiovascular and Critical Care product group include our:

- Meritrans DTXPLUS® Pressure Transducers, a disposable transducer to identify a patient's blood pressure and cardiovascular status,
- Safedraw® Closed Arterial Blood Sampling System, a closed in-line arterial blood sampling device,
- RadialFlo® Arterial Catheter, a catheter with an integral switch and silicone-coated for smooth insertion,
- TRAM® Manifolds, an integral pressure transducer to measure blood pressures, and
- Careflow™ Central Venous Catheter, a catheter used to administer medication or fluids.

Interventional Oncology and Spine

The products in our Interventional Oncology and Spine product group treat vertebral compression fractures, metastatic spinal tumors, liver cancer, uterine fibroids, symptomatic benign prostatic hyperplasia, arteriovenous malformations and hemostatic embolization. Our interventional oncology and spine product line is organized into product portfolios as follows: Delivery Systems, Embolotherapy, Spine Ablation, Angiography and Vertebral Compression Fracture.

The principal Delivery Systems Portfolio offerings in our Interventional Oncology and Spine product category include 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.,
- Merit Maestro® and Merit Pursue™ Microcatheters, a small microcatheter designed for pushability and trackability through small and tortuous vessels,
- True Form™ Reshapable Guide Wire, designed to be shaped and reshaped multiple times, reducing the need for multiple guide wires, and
- Tenor® Steerable Guide Wire, for navigating 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. The principal Embolotherapy Portfolio offerings for Interventional Oncology and Spine include our:

- EmboCube® Embolization Gelatin, a pre-loaded syringe filled with gelatin foam which speeds up procedure preparation,
- Torpedo™ Gelatin Foam, a uniform, pre-shaped gelatin foam loaded into a cartridge,
- Embosphere® Microspheres, a highly studied, round embolic for consistent and predictable results, and
- HepaSphere™ Microspheres, a drug-eluting bead offered outside of the U.S., for the treatment of primary and metastatic liver cancer.

The principal Spine Ablation Portfolio offerings for Interventional Oncology and Spine are used to treat painful vertebral compression fractures caused by osteoporosis or cancer by injecting bone cement through a small hole in the skin into a fractured vertebra and include our:

- STAR™ Tumor Ablation System, designed to provide palliative treatment of painful metastatic spinal tumors in cancer patients by targeted radiofrequency ablation,
- Arcadia™ Steerable and straight balloons, designed to achieve controlled, precise, targeted cavity creation in vertebral augmentation procedures, and
- StabiliT® MX Vertebral Augmentation System, which uses our insufflation devices to deliver bone cement.

Breast Cancer Localization and Guidance

The products in our Breast Cancer Localization and Guidance product group are dedicated to the innovative treatment of early-stage breast cancer. Our primary products in this product group include our:

- SCOUT® Radar Localization System, a nonradioactive, wire-free tumor localization system that facilitates successful surgical removal of marked lesions and lymph nodes. The system consists of a reflector, placed by radiologists to mark a suspicious lesion or lymph node, which a surgeon later detects using the SCOUT Console and Surgical Guide to locate and remove the reflector and targeted tissue during lumpectomy, targeted axillary dissection, and excisional biopsy procedures. SCOUT® reduces workflow inefficiencies and improves the patient experience, and
- SAVI® Brachytherapy, a precise, targeted approach to Accelerated Partial Breast Irradiation with lower toxicities and reduced treatment duration.

In 2019 we launched several new oncology products including:

- SCOUT and SAVI PinkPak™ Procedure Kits, to support workflow and convenience, by providing the supplies and tools needed for procedures in a single package,
- Tapered Sheath for the SCOUT Surgical Guide, a sheath that provides improved fit and longer length to cover the reusable SCOUT Guide during surgical procedures, and
- SCOUT Ultrasound Delivery System, a single-handed delivery system for placing the SCOUT Reflector under ultrasound guidance.

Endoscopy

The products in our Endoscopy Division, Merit Endotek™, are directed to gastrointestinal, pulmonary and thoracic surgery departments.

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

- AERO®, AEROmini® and AERO DV® Fully Covered Tracheobronchial Stents, for the treatment of tracheobronchial strictures produced by malignant neoplasms,
- Alimaxx-ES™ and EndoMAXX® Fully Covered Esophageal Stents, for maintaining esophageal luminal patency in certain esophageal strictures, and
- Alimaxx-B® Biliary Stent Systems, for the palliation of malignant strictures in the biliary tree.

We offer dilation balloons to endoscopically dilate strictures. Our balloon dilator portfolio includes our:

- Elation® Fixed Wire, Wire Guided and new 5-stage Balloon Dilators, intended for use in the alimentary tract,
- Elation Pulmonary Balloon Dilator, for the dilation of strictures of the trachea and bronchi, and
- 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 offer NvisionVLE® Imaging System with Real-time Targeting™, an advanced imaging system, to identify abnormalities in the esophagus and bile duct for tissue biopsy or resection. The NvisionVLE® is sold under our worldwide distribution agreement with NinePoint Medical, Inc. (“NinePoint”).

We also offer a variety of kits and accessories for endoscopy and bronchoscopy procedures.

Specialty Procedure Products

In 2019 we acquired Fibrovein®, a pharmaceutical product and detergent-based sclerosant licensed for the treatment of varicose veins. Fibrovein is a sterile aqueous injection of Sodium Tetradecyl Sulfate, an anionic detergent, and has been used in the treatment of varicose veins since 1946.

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 including guide wire components, coated mandrels/stylets and coated needles.

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.

Acquisitions

On June 14, 2019, we acquired Brightwater Medical Inc., ("Brightwater"). Brightwater's primary product, the ConvertX® Nephroureteral Stent System is a single use device that replaces a series of devices and procedures used to treat severe obstructions of the ureter. The system is designed to be implanted once and converted from a nephroureteral catheter to a nephroureteral stent without requiring sedation or local anesthesia. Brightwater recently received FDA clearance for the ConvertX® Biliary Stent System.

On August 1, 2019, we entered into a share purchase agreement to acquire Fibrovein Holdings Limited, the owner of 100% of the capital stock of STD Pharmaceutical Products Limited, a private company located in the UK ("STD Pharmaceutical"). Its primary product is Fibrovein, a pharmaceutical product and detergent-based sclerosant.

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 competitive 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 58%, 56% and 58% of our net sales for the years ended December 31, 2019, 2018 and 2017, 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, Mexico and Canada. In 2019, our international sales grew approximately 8.5% over our 2018 international sales and accounted for approximately 42% of our net sales. China represents our most significant international sales market, with net sales of approximately $113.3 million, $92.7 million, and $73.4 million for the years ended December 31, 2019, 2018 and 2017, respectively. With the recent and planned additions to our product lines, investments in resources, and movement to a "modified direct" sales approach, where 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, we believe our international sales will continue to increase.

Our largest non-U.S. market is China, which represented approximately 11.4% of our net sales in 2019. 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 utilize the "modified direct" sales approach in China, employing 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.

The recent emergence of a novel strain of coronavirus, specifically identified as "COVID-19," in the city of Wuhan and the Hubei province of China has resulted in certain emergency measures to combat the spread of the virus, including extension of the Lunar New Year holidays, implementation of travel bans and closure of factories and businesses in China. While the full impact of the COVID-19 outbreak is unknown at this time, a significant reduction in medical procedures in China could have a material impact on our operations and operating results in China and other areas of the world, as well as our overall financial condition, For further discussion of risks and uncertainties associated with COVID-19, refer to disclosure under the heading "*The outbreak of COVID-19 has negatively impacted our business and operations in China, as well as other countries around the world, and may materially and adversely impact our business, operations and financial results*" set forth in Item 1A "Risk Factors".

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 Germany, France, the UK and Russia.

Our direct sales personnel are principally engaged in each of our divisions. Marketing teams responsible for each division 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-corruption laws, such as the U.S. Foreign Corrupt Practices Act, as well as all applicable laws and regulations in their respective countries.

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 2019, 40% of our net sales were to U.S. hospitals and clinics through our direct sales force and approximately 9% of our net sales were 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 9% of our 2019 net sales. The remaining 42% of our 2019 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 2% of net sales during the years ended December 31, 2019, 2018 and 2017, 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 2019, 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 California, Pennsylvania, Texas, Utah, Ireland, France, and Singapore.

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, Virginia, 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 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 Pennsylvania, Texas, Virginia, Utah, Mexico, Brazil, Ireland, France, The Netherlands, Australia, and Singapore. See Item 2. "Properties."

We have distribution centers located in Virginia, Utah, Canada, Brazil, The Netherlands, UK, South Africa, Russia, South Korea, India, New Zealand, Japan, China and Australia.

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.

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. 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.

Our primary competitors in our Peripheral Intervention market are Teleflex Incorporated ("Teleflex"), Cook Medical Incorporated ("Cook Medical"), Medtronic plc ("Medtronic"), Boston Scientific Corporation ("Boston Scientific"), and Becton, Dickinson and Company ("BD"). Our primary competitors in our Cardiac Intervention market are Teleflex, Medtronic, Abbott Laboratories, Boston Scientific, and Terumo Corporation. Our primary competitors in our Cardiovascular and Critical Care market are Teleflex, BD, Argon Medical Devices, Inc. ("Argon"), Abbott Laboratories, Cook Medical, and Boston Scientific. Our primary competitors in our Interventional Oncology and Spine market are Medtronic, Stryker, and Johnson & Johnson. Our primary competitors in our Breast Cancer Localization and Guidance market are BD, Hologic, Argon and Cook Medical. Our primary competitors in our Endoscopy market are Getinge AB, Boston Scientific, Cook Medical, and Olympus Corporation.

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.

Sources and Availability of Raw Materials

Raw materials essential to our business are generally purchased worldwide and are normally available in quantities adequate to meet the needs of our business. Where there are exceptions, the temporary unavailability of those raw materials would not likely have a material adverse effect on our financial results.

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 rights to patents and 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, 2019, we owned approximately 1,600 U.S. and international patents and patent applications. Additionally, we hold exclusive and non-exclusive licenses to a variety of third-party technologies covered by patents and patent applications. In the aggregate, our intellectual property assets are critical to our business, but no single patent, trademark or other intellectual property asset is of material importance to our business.

The Merit® name and logo are trademarks in the U.S. and other countries. In addition to the Merit name and logo, we have used, registered or applied for registration of other specific trademarks and service marks to help distinguish our products, technologies and services from those of our competitors in the U.S. and foreign countries. See “Products” above. The duration of our trademark registrations varies from country to country; in the U.S. we can generally maintain our trademark rights and renew any trademark registrations for as long as the trademarks are in use. As of December 31, 2019, we owned approximately 500 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

Regulatory Approvals. Our products and operations are global and are subject to regulations by the U.S. Food and Drug Administration (“FDA”) and various other federal and state agencies, as well as by foreign governmental agencies. These agencies enforce laws and regulations that control the design, development, testing, clinical trials, manufacturing, labeling, storage advertising, marketing and distribution, and market surveillance of our medical products.

The time required to obtain approval by the FDA and other foreign governmental agencies can be lengthy and the requirements may differ. In particular, marketing of medical devices in the European Union (“EU”) is subject to compliance with Council Devices Directive 93/92/EEC (“MDD”). In May 2017, the EU adopted Regulation (EU) 2017/745 (“MDR”), which will repeal and replace the MDD with effect from May 26, 2020. Under transitional provisions, medical devices with notified body certificates issued under the MDD prior to May 26, 2020 may continue to be placed on the market for the remaining validity of the certificate, until May 27, 2024 at the latest. After the expiry of any applicable transitional period, only devices that have been CE marked under the MDR may be placed on the market in the EU. 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.

U.S. and global counter-part 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.

In November 2019, we were granted a Breakthrough Device Designation by the FDA for the Merit Wrapsody™ Endovascular Stent Graft System and we are pursuing regulatory approval in the EU and elsewhere. Human clinical trials of a medical device are often required for regulatory clearance or approval for devices and are expensive, time-consuming and uncertain.

Quality System Requirements. The Federal Food, Drug and Cosmetic Act ("FDCA") and its counterpart non-U.S. laws require us to comply with quality system regulations ("QSR") pertaining to all aspects of our product design and manufacturing processes, including requirements for packaging, labeling, record keeping, personnel training, supplier controls, 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, or could restrict our ability to obtain new product approvals or certificates from the FDA that are necessary for export of our products to foreign countries. Any of these results 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 laws. 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, including FDA cleared 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.

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 have responded to the subpoena, as well as additional related requests. The investigation is ongoing and at this stage we are unable to predict its scope, duration or outcome. Investigations such as this may result in the imposition of, among other things, significant damages, injunctions, fines or civil or criminal claims or penalties against our company or individuals.

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. 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.

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 is subject to restrictions due to trade and economic sanctions 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 ("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 or other post-market requirements, the FDA could issue warning letters or untitled letters, take administrative actions, commence criminal prosecution, impose civil monetary penalties, revoke our device approvals or clearances, seize our products, or delay the approval or 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, import refusals, refusal to provide export certificates, seizure of products and/or 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 the FDA within their jurisdictions.

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 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.

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 offering, paying, or promising to pay anything of value to foreign officials for the purpose of obtaining or maintaining an improper business advantage. 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.

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 Anti-Kickback Statute prohibits persons and entities from, among other things, knowingly and willfully offering or paying remuneration, directly or indirectly, to induce the purchase, order, lease, or recommendation of a good or service for which payment may be made in whole or part under a federal healthcare program such as Medicare or Medicaid, unless the arrangement fits within one of several statutory exemptions or regulatory "safe harbors." The definition of remuneration has been broadly interpreted to include anything of value, including, for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash and waivers of payments. Violations can result in significant penalties, imprisonment and exclusion from Medicare, Medicaid and other federal healthcare programs. Exclusion of a manufacturer would preclude any federal healthcare program from paying for the manufacturer's products. Under the Affordable Care Act, a violation of the Anti-Kickback Statute is deemed to be a violation of the False Claims Act. which is discussed in more detail below. A party's failure to fully satisfy the obligations of a regulatory "safe harbor" provision may result in increased scrutiny by government enforcement authorities.

Government officials continue their vigorous 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 federal Anti-Kickback Statute, many states have their own anti-kickback laws. Often, these laws closely follow the language of the federal law, although they do not always have the same exceptions or safe harbors. In some states, these anti-kickback laws apply with respect to all payers, including commercial health insurance companies.

False Claims Laws. 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. 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.

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. 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 to our consolidated financial statements set forth in Item 8 of this report 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. Several other jurisdictions, including China, outside the U.S. have also adopted or begun adopting similar 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.

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. Many state laws also 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 Act, 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 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. For example, California’s Consumer Protection Act went into effect on January 1, 2020, giving consumers the right to demand certain information and actions from companies who collect personal information. This enhanced scrutiny and legal requirements could results in costly compliance efforts and potentially result in fines, harm to reputation, or other consequences. 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.

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, Social, and Governance (“ESG”) Practices

The majority of our products are disposable medical devices and are generally disposed of after a single use due primarily to the risks of exposing patients to bloodborne pathogens capable of transmitting disease or other potentially infectious materials. Additionally, sterilization conditions differ and repeated sterilization may adversely affect the quality of the plastic used in many of our products and this may result in the failure of our product to function properly if used in multiple medical procedures. Consequently, many of our used products will likely end up in a medical waste disposal facility at the end of their usefulness. Despite this obstacle, we continue to look for ways to deliver sustainable long-term growth. Our sustainability practices are an integral component of our business strategy and our sustainability activities are reviewed and approved by senior management and our Board of Directors.

We have a number of programs designed to reduce waste, improve efficiency, and protect the environment including our:

- goal to achieve ISO 14001 certification in most of our facilities world-wide (ISO 14001 is the international standard that specifies requirements for an effective environmental management system);
- employee gardens that promote pollination and provide farm-to-table nutrition for our employees at our headquarters in South Jordan, Utah;
- transition to re-usable pallets and methods to move products in bulk containers, reducing intra-company shipping materials;
- reduction in packaging materials by reducing film thickness and using original product packaging where possible;
- transition from paper to electronic work orders in our manufacturing facilities worldwide, which we expect to reduce our paper usage by at least 2.8 million pieces and 20,000 plastic sleeves annually;
- expansion of recycling programs where our employees recycle materials, including food waste, paper, cardboard, food and beverage containers, scrap metal, and pallets, and re-use of our plastic scrap waste leftover from our manufacturing process of our molded parts;

- investment in a line of fully compostable “to-go” containers made from plant starch and sugarcane, and our program to transition to reusable dishes and cutlery at all our cafeterias;
- car charging stations and car-pooling preferential parking to incentivize employees to reduce their carbon footprint; and
- efficient heating and cooling systems that operate on variable efficiency drives, increasing our energy efficiency at our headquarters in South Jordan, Utah and our transition to Light Emitting Diode (“LED”) lighting in our manufacturing facilities.

In 2019 we provided in-kind donations of our medical devices to support nine medical or humanitarian missions and we worked closely with non-profit organizations in the United States to provide our medical devices for use in medical procedures primarily in Africa, the Caribbean, and Central America. We plan on continuing this practice in 2020.

Employees

As of December 31, 2019, we employed 6,355 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. 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.

Our Internet address is www.merit.com. On our Investor Relations website, www.merit.com/investors, we make available, free of charge, a variety of information for investors. Our goal is to maintain the Investor Relations website as a portal through which investors can easily find or navigate to pertinent information about us, including:

- Our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after we electronically file that material with or furnish it to the SEC.
- Press releases on our quarterly earnings and other pertinent information, including product launches and participation in upcoming investor conferences.
- Corporate governance information including our corporate governance guidelines, committee charters, and codes of business conduct and ethics.

Additionally, we provide electronic and paper copies of such filings free of charge upon request.

The information on www.merit.com is not, and will not be deemed, a part of this Report or incorporated into any other filings we make with the SEC.

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 our growth. To manage growth effectively, our management will need to continue to implement changes in certain aspects of our business, improve our information systems, infrastructure and operations to respond to increased demand, attract and retain qualified personnel, and develop, train, and manage an increasing number of employees. Growth has placed, and will likely continue to place, an increasing strain on our management, sales and other personnel, and on our financial, product design, marketing, distribution, technology and other resources. Given the pace of our recent growth, we have experienced operational challenges, and we could experience additional challenges in the future. Any failure to manage growth effectively could have a material adverse effect on our business, operations or financial condition.

Over the past several years, we have completed a series of significant acquisitions and, in the future we may consider other potential 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 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. For example, our December 2018 acquisition of Vascular Insights, LLC and VI Management, Inc. (combined “Vascular Insights”) presented a number of challenges, as demand for the acquired ClariVein® products was lower than we initially anticipated, partially as a result of excess inventory held by a number of distributors and customers at the time of our acquisition. Although sales of the ClariVein products have increased in each of the quarters since the acquisition, we could face other challenges associated with completed or prospective acquisitions, which we may not currently anticipate.

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 and value targets for, or manage issues related to, acquisitions and strategic transactions, such transactions may not produce the anticipated benefits and 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 to produce competing products. We seek to protect our intellectual property rights through a combination of confidentiality and license agreements, and through registrations under 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 intellectual property by consultants, vendors, former employees and current employees. Despite our efforts to restrict such unauthorized disclosure or use through nondisclosure agreements and other contractual restrictions, we may not be able to enforce these contractual provisions or we may incur substantial costs enforcing our legal rights.

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.

The outbreak of COVID-19 has negatively impacted our business and operations in China, as well as other countries around the world, and may materially and adversely impact our business, operations and financial results.

The recent outbreak of COVID-19 in China has negatively impacted our business and operations within the affected regions. Although the information we have received is preliminary and the situation is dynamic, we currently expect the adverse impact of COVID-19 on our net worldwide sales during the first quarter of 2020 to be in the range of $14 million to $19 million. Notwithstanding that preliminary estimate, if COVID-19 continues to spread and/or the precautionary measures being taken continue for a prolonged period of time, our business in China, as well as other regions around the world could be materially impacted, having a material adverse effect on our business, operations and financial results. The extent to which the COVID-19 outbreak impacts our results will depend on future developments that are uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact.

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

Our commercial success will depend in part on not infringing or violating the intellectual property rights of others. From time to time, third parties may claim that we have infringed their intellectual property rights, including claims regarding patents, copyrights, trademarks, and trade secrets. We may not be aware of whether our products do or will infringe existing or future patents or the intellectual property rights of others. Because of constant technological change in the medical device industry in which we compete, the extensive patent coverage of existing technologies, and the rapid rate of issuance of new patents, it is possible that the number of these claims may grow. In addition, former employers of

our former, current, or future employees may assert claims that such employees have improperly disclosed to us the confidential or proprietary information of 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.

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. In recent years, 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"). In January 2020, after passing the House and Senate, President Trump signed the United States Mexico Canada Agreement ("USMCA"). Mexico had already ratified the USMCA, but before it can take effect, Canada must also ratify the USMCA. At this time, it is unknown whether Canada will ratify the USMCA, new legislation will be passed into law, pending or new regulatory proposals will be adopted, other 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 the USMCA is fully ratified, 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.

Recently, the outbreak of the COVID-19 in China has impacted certain business operations within the affected regions. Throughout the year ended December 31, 2019, our sales in China increased, and in the absence of this outbreak, we expected such growth in China to continue into the future. We currently expect the adverse impact on our net sales during the first quarter of 2020 to be in the range of $14 million to $19 million. Moreover, if the COVID-19 outbreak continues to spread for a prolonged period of time, our business in China could continue to be adversely impacted, having a material adverse effect on our results of operations.

In addition to changes in U.S. trade policy and the COVID-19 outbreak, 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;
- industrial policies in various countries that favor domestic industries over multinationals or that restrict foreign companies altogether;
- difficulties protecting intellectual property;
- new or stricter trade policies and tariffs affecting China;

- 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.

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. Because of these conditions, 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.

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, unless an exemption from premarket review or an alternative procedure, such as a *de novo* risk-based classification or a humanitarian device exemption, applies. The FDA clearance and approval processes for medical devices are expensive, uncertain and time-consuming.

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 provide assurance 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 EU requires that manufacturers of medical devices obtain the right to affix the CE mark, for compliance with the Council Directive (93/42/EEC) ("MDD"), 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.

In May 2017, the EU adopted Regulation (EU) 2017/745 ("MDR"), which will repeal and replace the MDD with effect from May 26, 2020. Under transitional provisions, medical devices with notified body certificates issued under the MDD prior to May 26, 2020 may continue to be placed on the market for the remaining validity of the certificate, until May 27, 2024 at the latest. After the expiry of any applicable transitional period, only devices that have been CE marked under the MDR may be placed on the market in the EU. 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.

Complying with and obtaining regulatory approval in foreign countries, including compliance with the MDR, have caused and will likely continue to cause us to experience more uncertainty, risk, expense and delay in commercializing products in certain foreign jurisdictions, which could have a material adverse impact our net sales, market share and operating profits from our international operations.

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, import or export prohibitions, exclusion from participation in government healthcare programs, civil fines and/or 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. We have responded to the subpoena, as well as additional related requests. The

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

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 has created more requests for pricing concessions and is expected to continue in the future. Additionally, many of our customers belong to group purchasing organizations or integrated delivery networks that use their market power to consolidate purchasing decisions for these hospitals and healthcare service providers. These customers are often able to obtain lower prices and more favorable terms because of the potential sales volume they represent, which can lead to lower revenues and require us to take on additional liability. 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 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.

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, the MDR, 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, 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.

On July 31, 2019 we entered into a Third Amended and Restated Credit Agreement (“Third Amended Credit Agreement”), with Wells Fargo Bank, National Association, as administrative agent and a lender, and Wells Fargo Securities, LLC, BOFA Securities, Inc., HSBC Bank USA, National Association, and U.S. Bank National Association as joint lead arrangers and joint bookrunners, and Bank of America, N.A., HSBC Bank USA, National Association and U.S. Bank National Association as co-syndication agents. In addition, Bank of America, N.A., HSBC Bank USA, National Association, U.S. Bank, National Association, BMO Harris Bank, N.A., and MUFG Union Bank, Ltd. are parties to the Third Amended Credit Agreement as lenders. The Third Amended Credit Agreement amends and restates in its entirety

our previously outstanding Second Amended and Restated Credit Agreement and all amendments thereto (the "Second Amended Credit Agreement"). The Third 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 Third Amended Credit Agreement. Our breach of any covenant in the Third 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 Third 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, joint lead arrangers, joint bookrunners and lenders under the Third 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 Third Amended Credit Agreement provides for potential borrowings of up to $750 million. Such increased borrowing limits may make it more difficult for us to comply with leverage ratios and other restrictive covenants in the Third 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.

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 2019, 2018 and 2017, the exchange rate between all applicable foreign currencies and the U.S. Dollar resulted in a decrease in net sales of approximately $13.5 million, an increase of approximately $5.2 million and an increase of approximately $0.6 million, respectively.

For the year ended December 31, 2019, approximately $320.8 million, or 32.2%, of our net sales were denominated in foreign currencies, with our CNY- and Euro-denominated sales representing our largest currency risks. 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 will be required to expend significant resources for research, development, testing and regulatory approval or clearance of our products under development, and these products may not be developed successfully or approved for commercial use.

Most of our products under development will require significant additional research, development, engineering and, in some cases, preclinical and clinical testing, as well as regulatory approval or clearance and a commitment of significant additional resources prior to their commercialization. It is possible that our products may not:

- be developed successfully;
- be proven safe or effective in clinical trials;
- offer therapeutic or other improvements over current treatments and products;
- meet applicable regulatory standards or receive regulatory approvals or clearances;
- be capable of production in commercial quantities at acceptable costs and in compliance with regulatory requirements;

- be successfully marketed; or
- be covered by private or public insurers.

We are currently conducting 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-corruption 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-corruption laws presents greater challenges to our operations. If our employees or agents violate the provisions of the FCPA or other anti-corruption laws, we may incur fines or penalties, which could have a material adverse effect on our operating results or financial condition.

We are dependent upon key personnel.

Our success is dependent on key management personnel, including Fred P. Lampropoulos, our Chairman of the Board, President and Chief Executive Officer. Mr. Lampropoulos is not subject to any agreement prohibiting his departure, and we do not maintain key man life insurance on his life. The loss of Mr. Lampropoulos, or of certain other key management personnel, could have a materially adverse effect on our business and operations. Our success also depends on, among other factors, the successful recruitment and retention of key operating, manufacturing, sales and other personnel.

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.

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 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 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.

We may be a party to litigation in the course of our business or otherwise, which could affect our financial condition and results of operations.

We may become party to or otherwise involved in legal proceedings, claims or other legal matters, arising in the course of our business. In particular, our company, our Chief Executive Officer and our Chief Financial Officer have been named in a complaint filed in the Central District of California, which alleges violations of certain federal securities laws. Legal proceedings can be complex and take many months, or even years, to reach resolution, with the final outcome depending on a number of variables, some of which are not within our control. Litigation is subject to significant uncertainty and may be expensive, time-consuming, and disruptive to our operations. Although it is our intention to vigorously defend ourselves in such legal proceedings, their ultimate resolution and potential financial and other impacts on us are uncertain. If a legal proceeding is resolved against us, it could result in significant compensatory damages or injunctive relief that could materially adversely affect our financial condition, results of operations and cash flows.

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.

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.

The exit of the UK from the European Union, and current uncertainty about whether such exit could harm our business and results of operations in Europe and elsewhere.

On June 23, 2016, the UK held a referendum in which voters approved an exit from the European Union, commonly referred to as "Brexit." On January 31, 2020 Article 50 of the European Union's Lisbon Treaty process by which a member state leaves the European Union expired and the UK has now entered a transition process ending on December 31, 2020 (the "Transitional Period") with an option to request an extension of the deadline to be made by June, 2020. During the Transitional Period, the government will engage in negotiations on the future relationship between the UK and the European Union. There is therefore a substantial risk that at the end of the Transitional Period, there could be a Brexit without agreement between the UK and the EU. As a result of the disruption in the relationship between the UK 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 UK and the EU countries and increased regulatory complexities, which could affect our ability to sell products in certain EU countries and in the UK. Currently, all of our European production is in EU countries outside of the UK. However, during the fiscal year ended December 31, 2019, approximately 1.9% of our world-wide revenues arose from sales into the UK. Disruptions arising from the exit of the UK from the EU, or from stalled or failed negotiations between the UK and the EU, could result in various trade barriers limiting or prohibiting our ability to export or sell our products into the UK.

In the fiscal year ended in December 31, 2019, approximately 11.9% of our world-wide revenue arose from sales into EU countries, other than the UK. 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 UK 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 to address the potential impact of Brexit on our ability to market, sell and distribute our products in the UK. 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.

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

Certain of the interest rates applicable to our Third Amended Credit Agreement, and applicable to hedging instruments we have purchased to offset interest rate risk under our Third 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 UK 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 Third 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 Third Amended Credit Agreement and other instruments, which could harm our operations.

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.

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.

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 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.

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 are subject to work stoppage, transportation, severe weather, natural disasters, outbreak of disease 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.

Additionally, outbreaks of contagious diseases, such as the COVID-19 outbreak, and related quarantines may cause significantly reduced demand for our products in those regions, disrupt manufacturing and other business activities or could prevent our products from being delivered to the affected areas or to other locations indirectly impacted by such an outbreak, which could have a material adverse effect on our business and results of 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 and taxation of foreign earnings, among others, that will generally be effective for taxable years beginning after December 31, 2017. U.S. federal and state regulatory and standard-setting bodies continue to issue guidance and regulations related to the TCJA that could have a material financial statement impact on our effective tax rate in future periods. 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.

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 years ended December 31, 2019 and 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 9.4% and 10.8% of our net sales, respectively. 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.

Actions of activist shareholders, including a proxy contest, could be disruptive and potentially costly and the possibility that activist shareholders may contest, or seek changes that conflict with, our strategic direction could cause uncertainty about the strategic direction of our business.

On January 27, 2020, we received notice from Starboard Value and Opportunity Master Fund Ltd ("Starboard") that it intends to nominate up to seven individuals to stand for election as directors at our 2020 Annual Meeting of Shareholders. Members of our Board of Directors and our management team have had initial discussions with representatives of Starboard regarding their interest in the Company. Other than the director nominations, Starboard has not informed us of any particular changes they wish for us to make or specific plans they want us to adopt. While our Board of Directors and management team strive to maintain constructive, ongoing communications with all of our shareholders, including Starboard, and we welcome constructive input from all shareholders toward the shared goal of enhancing stakeholder value, activist campaigns that contest, or seek to change, our strategic direction could have an adverse effect on us because: (i) responding to actions by activist shareholders could disrupt our operations, be costly and time consuming, and divert the attention of our Board of Directors and senior management from the pursuit of business strategies, which could adversely affect our results of operations and financial condition; (ii) perceived uncertainties as to our future direction may lead to the perception of a change in the direction of the business, instability or lack of continuity which may be exploited by our competitors, cause concern to our current or potential customers, may result in the loss of potential business opportunities and make it more difficult to attract and retain qualified personnel and business partners; and (iii) these types of actions could cause significant fluctuations in our stock price based on temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

Our business is subject to complex and evolving U.S., state 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. Individual states have also begun to enact data privacy laws. For example, California's Consumer Protection Act went into effect on January 1, 2020, giving consumers the right to demand certain information and actions from companies who collect personal information. 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, possibly resulting in fines or orders requiring that we change our data practices, which could have an adverse effect on our business and 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.

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).

Our failure to comply with applicable environmental, health and safety 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 a limited amount of 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. Certain environmental laws and regulations may impose "strict 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, rendering us liable without regard to our negligence or fault. Because of these laws, any accidental release may have an adverse effect on our business, operations or financial condition.

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.

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.

The market price of our common stock has recently 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 and our principal office for Asian distribution located in Beijing, China. 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 India, Hong Kong, Italy, Dubai, Australia, Russia, Canada, Brazil, Malaysia, South Korea, Japan, South Africa, Great Britain, Vietnam, Taiwan, New Zealand, Indonesia, and France, as well as in Massachusetts and Texas. Our principal manufacturing and packaging facilities are located in Virginia, Texas, Utah, Pennsylvania, Ireland, Brazil, Australia, France, Singapore, Mexico, and The Netherlands. Our research and development activities are conducted principally at facilities located in California, Texas, Pennsylvania, Utah, Ireland, France, and Singapore.

Our total manufacturing, commercial, distribution, and research space is approximately 2.0 million square feet, of which approximately 1.0 million square feet is owned, and 1.0 million square feet is leased.

The following is a summary of the approximate square footage of our key facilities as of December 31, 2019:

Location	Main Purpose	Area (sq. ft.)
Utah	HQ, Manufacturing, Distribution, Research	724,170
Mexico	Manufacturing	196,690
Virginia	Manufacturing, Distribution	187,659
Ireland	Manufacturing, Research	139,680
The Netherlands	Distribution	136,501
Texas	Manufacturing, Research	94,000
Singapore	Manufacturing, Research	68,000
China	Distribution	37,100

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 Utah and Texas.

In February 2020, we completed construction of a manufacturing and research and development facility, which we own, near our South Jordan, Utah, headquarters, totaling approximately 90,000 square feet.

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. For example, in December 2019 our company, our Chief Executive Officer and our Chief Financial Officer were named in a complaint filed in the Central District of California, which alleges violations of certain federal securities laws. 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 have responded to the subpoena, as well as additional related requests. We have incurred, and anticipate that we will continue to incur, substantial costs in connection with the matter. The investigation is ongoing and at this stage we are unable to predict its scope, duration or outcome. Investigations such as this may result in the imposition of, among other things, significant damages, injunctions, fines or civil or criminal claims or penalties against our company or individuals.

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.

PART II

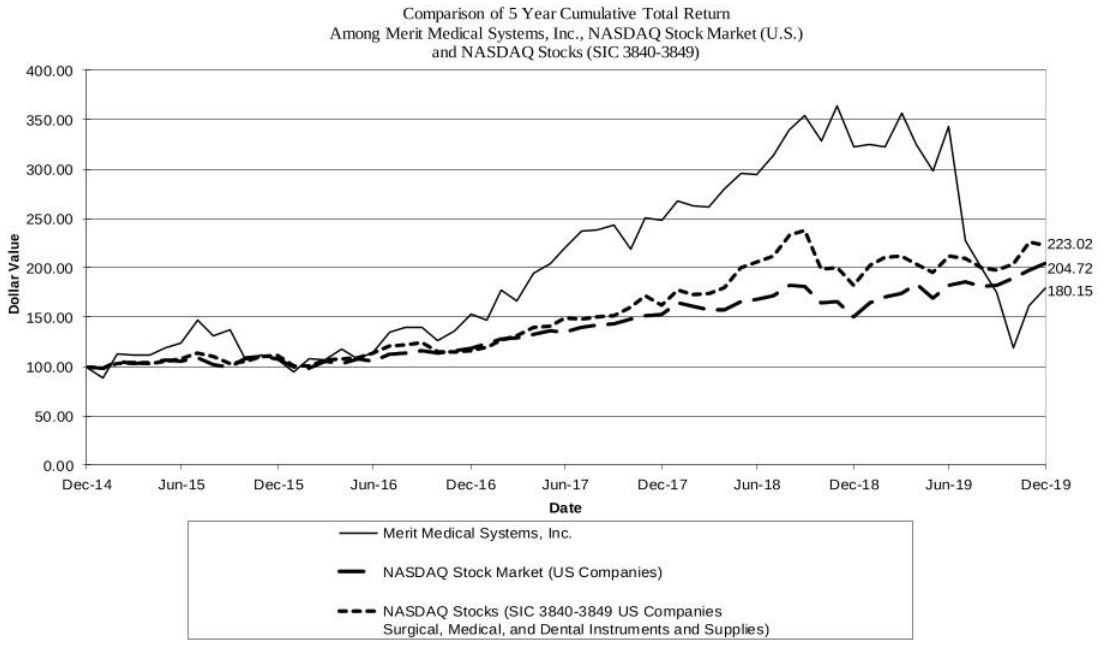
Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Price for the Common Stock

Our common stock is traded on the NASDAQ Global Select Market under the symbol "MMSI." As of February 27, 2020, the number of shares of our common stock outstanding was 55,216,906 held by approximately 104 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, 2014 to December 31, 2019.



	12/2014	12/2015	12/2016	12/2017	12/2018	12/2019
Merit Medical Systems, Inc.	$ 100.00	$ 107.27	$ 152.91	$ 249.28	$ 322.04	$ 180.15
NASDAQ Stock Market (U.S. Companies)	100.00	107.71	118.26	152.92	150.42	204.72
NASDAQ Stocks (SIC 3840-3849 U.S. Companies)	100.00	111.44	115.68	162.19	182.93	223.02

The stock performance graph assumes for comparison that the value of our common stock and of each index was $100 on December 31, 2014 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 2020. Used with permission. All rights reserved.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table contains information regarding our equity compensation plans as of December 31, 2019 (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	4,319 (1),(3)	$ 34.10	1,784 (2),(3)

(1) Consists of 2,933,734 shares of common stock subject to the options granted under the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan and 1,385,677 shares of common stock subject to the options granted under the Merit Medical Systems, Inc. 2018 Long-Term Incentive Plan.

(2) Consists of 69,877 shares available to be issued under the 1996 Merit Medical Systems, Inc. Non-Qualified Employee Stock Purchase Plan and 1,714,323 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.

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

	2019	2018	2017	2016	2015
Operating Data:					
Net Sales	$ 994,852	$ 882,753	$ 727,852	$ 603,838	$ 542,149
Gross Profit	432,366	394,770	326,253	265,025	235,781
Income from Operations	15,434	58,617	33,069	34,876	37,543
Income Before Income Taxes	2,193	49,519	35,881	25,386	31,200
Net Income	5,451	42,017	27,523	20,121	23,802
Diluted Earnings Per Common Share:	$ 0.10	$ 0.78	$ 0.55	$ 0.45	$ 0.53
Balance Sheet Data:					
Working capital	$ 272,882	$ 254,491	$ 200,501	$ 155,092	$ 116,093
Total assets	1,757,321	1,620,012	1,111,811	942,803	778,728
Long-term debt, less current portion	431,984	373,152	259,013	314,373	197,593
Stockholders' equity	949,944	932,775	676,334	498,189	466,103
Cash Flow Data:					
Net cash provided by operating activities	$ 77,813	$ 86,533	$ 62,727	$ 53,599	$ 69,458

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 set forth 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, breast cancer localization and guidance, biopsy, 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, 2019, we reported sales of approximately $994.9 million, up approximately $112.1 million or 12.7%, over 2018 sales of approximately $882.8 million.

Gross profit as a percentage of sales decreased to 43.5% for the year ended December 31, 2019 as compared to 44.7% for the year ended December 31, 2018.

Net income for the year ended December 31, 2019 was approximately $5.5 million, or $0.10 per share, as compared to $42.0 million, or $0.78 per share, for the year ended December 31, 2018.

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 and lengthened our average collection period as certain geographic markets have customary payment terms which are, on average, longer than payment terms in the United States; however, we believe over time this expansion will help improve our profitability. Our international sales growth was strong for the year ended December 31, 2019. In 2019, international sales were approximately $419.1 million, or 42.1% of our net sales, up 8.5% from international sales of $386.3 million in 2018.

We believe our forecasted growth will be facilitated by recently obtained regulatory approvals, such as:

- Clearance from the China National Medical Products Association (NMPA) to market the SwiftNinja® Steerable Microcatheter and the InQwire® Amplatz Guide Wire in China.
- Authorization of the CE mark for the Cianna Scout® Surgical Guidance System.
- Notice from BlueGrass Vascular Technologies that the FDA has granted De Novo classification for its Surfacer® Inside-Out® Access Catheter System. Merit owns approximately 19.5% of the common equity of BlueGrass Vascular and has been the worldwide exclusive distributor of the system for the last three years. Merit has the option to acquire the remaining equity of Bluegrass Vascular during the first part of 2020.

We continue to consolidate facilities, strategically reduce operating expenses and incentivize our sales force to focus on products that will improve our financial performance. We currently plan to move production of 14 products to our facilities in Mexico or Texas, and anticipate consolidating four facilities from 2020-2021. We presently estimate these consolidations to result in cost savings of approximately $6 million to $10 million annually.

As we have significant sales and distribution in China and Southeast Asia, we recognize the potential impact the coronavirus epidemic may have on our business. We currently expect the adverse impact on our net sales during the first quarter of 2020 to be in the range of $14 million to $19 million.

Results of Operations

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

	2019	2018	2017
Net sales	100 %	100 %	100 %
Gross profit	43.5	44.7	44.8
Selling, general and administrative expenses	32.9	31.3	31.5
Research and development expenses	6.6	6.7	7.1
Impairment and other charges	2.4	0.1	0.1
Contingent consideration expense (benefit)	(0.0)	(0.1)	—
Acquired in-process research and development expenses	0.1	0.1	1.7
Income from operations	1.6	6.6	4.5
Income before income taxes	0.2	5.6	4.9
Net income	0.5	4.8	3.8

Listed below are the sales by product category within each operating segment for the years ended December 31, 2019, 2018 and 2017 (in thousands):

	% Change	2019	% Change	2018	% Change	2017
Cardiovascular						
Stand-alone devices	11.0 %	$ 401,466	31.3 %	$ 361,613	44.1 %	$ 275,456
Cianna Medical	n/a	49,536	n/a	6,292	— %	—
Custom kits and procedure trays	0.8 %	135,856	6.9 %	134,756	5.7 %	126,089
Inflation devices	(1.9)%	90,681	15.7 %	92,419	8.1 %	79,875
Catheters	14.4 %	177,876	21.7 %	155,525	12.7 %	127,747
Embolization devices	4.1 %	52,072	1.0 %	50,038	7.6 %	49,532
CRM/EP	9.5 %	53,494	16.5 %	48,834	15.0 %	41,914
Total	13.1 %	960,981	21.2 %	849,477	20.8 %	700,613
Endoscopy						
Endoscopy devices	1.8 %	33,871	22.2 %	33,276	15.0 %	27,239
Total	12.7 %	$ 994,852	21.3 %	$ 882,753	20.5 %	$ 727,852

Cardiovascular Sales. Our cardiovascular sales for the year ended December 31, 2019 were approximately $961.0 million, up 13.1%, when compared to the corresponding period for 2018 of approximately $849.5 million. Sales for the year ended December 31, 2019 were favorably affected by increased sales of (a) our stand-alone devices (particularly our Map™ Merit Angioplasty Packs, Merit Laureate® Hydrophilic Guide Wire products, Dual Cap® Disinfection & Protection System, as well as sales from our acquisitions of the BD product lines and the assets of Vascular Insights, among others) of approximately $39.9 million, up 11.0%; (b) full year sales of Cianna Medical products of $49.5 million; and (c) catheters (particularly our Prelude® Radial Introducer Sheath product line, our Merit Maestro® Microcatheters and our new Prelude IDeal™) of approximately $22.4 million, up 14.4%.

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 BD and the 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%.

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 decreased sales 1.3% for the year ended December 31, 2019 compared to sales calculated using the applicable average foreign exchange rates for 2018 and increased sales 0.6% for the year ended December 31, 2018 compared to sales calculated using the applicable foreign exchange rates for 2017.

Endoscopy Sales. Our endoscopy sales for the year ended December 31, 2019 were approximately $33.9 million, up 1.8%, when compared to sales in 2018 of approximately $33.3 million. Sales for the year ended December 31, 2019 were favorably affected by increased sales of our EndoMAXX™ fully covered esophageal stent, our Elation® balloon dilator, and our AEROmini® fully covered esophageal stent, partially offset by decreased sales of other stents. 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 and our acquisition of BD, as well as 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, 2019 were approximately $419.1 million, or 42.1% of net sales, up 8.5% from 2018. International sales for the year ended December 31, 2018 were approximately $386.3 million, or 43.8% of net sales, up 25.8% from 2017. The increase in our international sales during 2019 was primarily related to a year-over-year sales increase in China of approximately $20.6 million, or 22.2%, in Southeast Asia of approximately $4.1 million, or 24.9%, and in Russia of approximately $2.6 million, or 30.0%. 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).

Gross Profit. Our gross profit as a percentage of sales was 43.5%, 44.7%, and 44.8% for the years ended December 31, 2019, 2018 and 2017, respectively. The decrease in gross profit as a percentage of sales for 2019, as compared to 2018, was primarily related to increased amortization expense associated with current and prior year acquisitions ($49.7 million in 2019 compared to $31.8 million in 2018), increased costs associated with new distribution sites, and adverse impacts from tariffs and foreign currency fluctuations, which were partially offset by improvements associated with changes in product mix. 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 acquisitions and unfavorable manufacturing variances associated with our operations in Australia, which was partially offset by improvements associated with changes in product mix.

Selling, General and Administrative Expenses. Our selling, general and administrative expenses increased approximately $51.3 million, or 18.6%, for the year ended December 31, 2019 compared to 2018 and $46.9 million, or 20.5%, for the year ended December 31, 2018 compared to 2017. Selling, general and administrative expenses as a percentage of sales were 32.9%, 31.3% and 31.5% for the years ended December 31, 2019, 2018 and 2017, respectively.

The increase in selling, general, and administrative expenses for the year ended December 31, 2019 compared to the year ended December 31, 2018 was primarily related to higher compensation expenses associated with an increase in headcount to support recent acquisitions and the growth in operations, higher commission expense associated with increased sales, higher severance costs ($5.0 million compared to $0.9 million in 2018) related to restructuring, and legal costs associated with the investigation by the U.S. Department of Justice ($6.5 million in 2019 compared to $5.6 million in 2018), partially offset by decreased acquisition and integration-related costs ($3.5 million in 2019 compared to $7.6 million in 2018).

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).

Research and Development Expenses. Research and development ("R&D") expenses increased by $6.1 million or 10.2% to approximately $65.6 million for the year ended December 31, 2019, compared to approximately $59.5 million in 2018. The increase in R&D expenses for the year ended December 31, 2019 was largely due to hiring additional research and development personnel to support various new core and acquired product developments, as well as higher clinical and regulatory costs. Research and development expenses increased by approximately $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. Our research and development expenses as a percentage of sales were 6.6%, 6.7% and 7.1% for 2019, 2018, and 2017, 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.

Impairment and Other Charges. For the year ended December 31, 2019 we recorded impairment charges of $23.8 million, primarily due to our write-off of our NinePoint note receivable and purchase option of $20.5 million due to our assessment of the collectability of the note receivable and management's decision not to exercise our option to purchase the business. We also recorded impairment of certain intangible assets of $3.3 million, $0.7 million and $0.8 million for the years ended December 31, 2019, 2018 and 2017, respectively, based on changes in revenue expectations associated with these product lines and restructuring.

Contingent Consideration (Benefit). In fiscal 2019, 2018 and 2017, we recorded ($0.2) million, ($0.7) million and ($0.3) million, respectively, of net contingent consideration (benefit) from changes in the estimated fair value of our contingent consideration obligations stemming from our previously disclosed business acquisitions. Expense (benefit) in each fiscal year relates to changes in the probability and timing of achieving certain revenue and operational milestones, as well as expense for the passage of time.

Acquired In-process Research and Development. During the years ended December 31, 2019, 2018 and 2017, we incurred in-process research and development charges of approximately $0.5 million, $0.6 million and $12.1 million, respectively. Higher in-process research and development charges in the year ended December 31, 2017 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 to our consolidated financial statements set forth in Item 8 of this report.

Our operating profits by business segment for the years ended December 31, 2019, 2018 and 2017 were as follows (in thousands):

	2019	2018	2017
Operating Income (Loss)			
Cardiovascular	$ 25,780	$ 49,289	$ 24,819
Endoscopy	(10,346)	9,328	8,250
Total operating income	$ 15,434	$ 58,617	$ 33,069

Cardiovascular Operating Income. Our cardiovascular operating income for the year ended December 31, 2019 was approximately $25.8 million, compared to cardiovascular operating income of approximately $49.3 million for the year ended December 31, 2018. This decrease in cardiovascular operating income was primarily related to decreased gross margin percentage, higher compensation expenses, higher severance costs ($5.0 million compared to $0.9 million in 2018), and legal costs associated with the investigation by the U.S. Department of Justice ($6.5 million in 2019 compared to $5.6 million in 2018), partially offset by decreased acquisition and integration-related costs ($3.5 million in 2019 compared to $7.6 million in 2018) and increased sales. Our cardiovascular operating income for the year ended December 31, 2018 was approximately $49.3 million, compared to 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.

Endoscopy Operating Income (Loss). Our endoscopy operating income for the year ended December 31, 2019 was a loss of approximately ($10.3) million, compared to operating income of approximately $9.3 million for the year ended December 31, 2018. This decrease was primarily the result of the impairment of a note receivable and a purchase option for NinePoint of approximately $20.5 million. 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 and the acquisition of BD).

Effective Tax Rate. Our effective income tax rate for the years ended December 31, 2019, 2018 and 2017 was (148.6%), 15.2%, and 23.3%, respectively. The decrease in the effective income tax rate for 2019 compared to 2018 was primarily the result of book to tax differences related to stock options and deferred compensation as well as uncertain tax positions lapsing that generated a greater benefit due to lower pre-tax book income. 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.

Other Income (Expense). Our other income (expense) for the years ended December 31, 2019, 2018 and 2017 was approximately ($13.2) million, ($9.1) million, and $2.8 million, respectively. The change in other income (expense) for 2019 over 2018 was principally the result of increased interest expense due to higher average debt balances during 2019, the write-off of $1.6 million of accrued interest related to the NinePoint note receivable, and increased expense related to foreign currency remeasurement. 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 the gain on bargain purchase related to the 2017 acquisition of the Argon critical care division of approximately $11.0 million.

Net Income. Our net income for the years ended December 31, 2019, 2018 and 2017 was approximately $5.5 million, $42.0 million, and $27.5 million, respectively. The decrease in net income for 2019, when compared to 2018, was primarily due to total charges of $22.1 million related to NinePoint (including the entire carrying value of the purchase option and note receivable, along with $1.6 million of accrued interest), increased selling, general, and administrative expenses as a percentage of sales, lower gross profit as a percentage of sales, and increased interest expense compared to 2018.

The increase in net income for the year ended December 31, 2018, when compared to 2017, was 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 tax reform), partially offset by slightly lower gross margins and increased interest expense due to higher average debt balances in 2018.

Total Assets. Total assets utilized in our cardiovascular segment were approximately $1.7 billion as of December 31, 2019, compared to approximately $1.6 billion as of December 31, 2018 and approximately $1.1 billion as of December 31, 2017. Total assets utilized in our endoscopy segment were approximately $12.3 million as of December 31, 2019, compared to approximately $31.0 million as of December 31, 2018 and approximately $8.0 million as of December 31, 2017. The decrease in endoscopy segment total assets from December 31, 2018 to December 31, 2019 was primarily related to the impairment of the purchase option and note receivable with NinePoint.

Off-Balance Sheet Arrangements. We have committed to provide loans of up to an additional €2 million at the discretion of Selio Medical Limited at a rate of 5% per annum. The current note receivable balance from Selio is $250,000. If exercised these loans would be securitized by all the present and future assets and property of the borrower. Aside from this arrangement, 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, 2019, 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	$ 440,000	$ 7,500	$ 15,938	$ 416,562	$ —
Interest on long-term debt [(1)]	58,769	12,910	25,464	20,395	—
Operating leases	106,359	13,949	23,306	15,603	53,501
Royalty obligations	4,194	738	1,438	1,435	583
Total contractual cash	$ 609,322	$ 35,097	$ 66,146	$ 453,995	$ 54,084

(1) Interest payments on our variable long-term debt were forecasted using the LIBOR forward curves plus a base of 1.50% based on the terms of our Third Amended Credit Agreement. Interest payments on a portion of our long-term debt were forecasted using a fixed rate of 2.62% through July 2021, and a fixed rate of 3.21% from July 2021 through July 2024, as a result of our interest rate swaps (see Note 9 to our consolidated financial statements set forth in Item 8 of this report).

As of December 31, 2019, we had approximately $76.7 million of contingent consideration liabilities, $2.2 million of unrecognized tax positions, and $14.9 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 and operating leases, is contained in Notes 8, 10, and 18 to our consolidated financial statements set forth in Item 8 of this report.

Cash Flows

At December 31, 2019 and 2018, we had cash and cash equivalents of approximately $44.3 million and $67.4 million respectively, of which approximately $31.7 million and $57.3 million, respectively, were held by foreign subsidiaries. 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 evaluation of the permanent reinvestment assertion, we are no longer permanently reinvested with respect to our historic unremitted foreign earnings as of December 31, 2018. 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, 2019 and 2018, we had cash and cash equivalents of approximately $11.3 million and $18.6 million, respectively, held by our subsidiary in China.

Cash flows provided by operating activities. We generated cash from operating activities of approximately $77.8 million, $86.5 million and $62.7 million during the years ended December 31, 2019, 2018 and 2017, respectively. Net cash provided by operating activities decreased $8.7 million for the year ended December 31, 2019 compared to the year ended December 31, 2018. Significant changes in operating assets and liabilities affecting cash flows during these years included:

- Cash (used for) accounts receivable was approximately $(17.9) million and $(27.5) million for the years ended December 31, 2019 and 2018, respectively, due primarily to increases in sales volume, and

- Cash (used for) provided by accounts payable was ($2.3) million and $15.7 million for the years ended December 31, 2019 and 2018, respectively, due primarily to growth in operations and timing of payments.

The $23.8 million increase in net cash provided by operating activities for the year ended December 31, 2018 compared to the year ended December 31, 2017 was driven by an increase in net income of approximately $14.5 million and an increase of approximately $21.1 million in non-cash items, partially offset by a decrease in the net change from operating assets and liabilities of approximately $11.7 million. Significant changes in operating assets and liabilities affecting cash flows during these years included:

- Cash (used for) accounts receivable was approximately $(27.5) million and $(12.8) million for the years ended December 31, 2018 and 2017, respectively, due primarily to increases in product sales volume;

- Cash (used for) inventory was approximately ($28.2) million and ($17.8) million for the years ended December 31, 2018 and 2017, respectively. 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; and

- Cash provided by accounts payable was approximately $15.7 million and $0.4 million for the years ended December 31, 2018 and 2017, respectively, due primarily to growth in operations and timing of payments.

Cash flows used in investing activities. We used cash in investing activities of approximately $134.5 million, $378.8 million, and $146.8 million for the years ended December 31, 2019, 2018 and 2017, respectively. We invested in capital expenditures for property and equipment of approximately $78.2 million, $63.3 million, and $38.6 million for the years ended December 31, 2019, 2018 and 2017, respectively. Capital expenditures in each fiscal year were primarily related to investment in buildings, property and equipment to support development and production of new and expanded product lines and to facilitate growth in our distribution markets. These investments include construction of a new manufacturing and research and development facility in South Jordan, Utah completed in early 2020 and expansion of our manufacturing facility in Tijuana, Mexico to incorporate production of our biopsy and drainage products acquired from BD and other products. 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 $50 to $55 million in 2020 for buildings, property and equipment.

Cash outflows invested in acquisitions for the year ended December 31, 2019 were approximately $53.9 million and were primarily related to our acquisition of Brightwater and STD Pharmaceutical. Cash outflows for acquisitions in 2018 were approximately $301.8 million and primarily related to our acquisition of BD product lines and Cianna Medical. Cash outflows for acquisitions in 2017 were $105.6 million and primarily related to our acquisition of the assets of Laurane Medical, the assets of Osseon LLC, Vascular Access Technologies, the critical care division of Argon and a custom procedure pack business from ITL Healthcare Pty Ltd. (“ITL”). Each year also included additional less significant acquisitions; for further discussion, refer to Note 3 to our consolidated financial statements set forth in Item 8 of this report.

Cash flows provided by financing activities. Cash provided by financing activities for the years ended December 31, 2019, 2018 and 2017 was approximately $33.5 million, $328.3 million and $96.5 million, respectively. In 2019 we increased our net borrowings by approximately $44.5 million to partially finance our current period acquisitions and pay contingent consideration of $15.7 million, which is classified as a financing activity, principally related to our Cianna Medical acquisition. In 2018, our primary financing activities included a 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) and additional net borrowings under our credit agreement of approximately $116.5 million to fund our acquisition activity. This was partially offset by approximately $2.6 million used to purchase common stock to pay employee taxes resulting from the exercise of stock options. Our primary financing activities in 2017 included a public equity offering of 5,175,000 shares of common stock from which we received proceeds of approximately $136.6 million, which is net of approximately $8.8 million in underwriting discounts. This was partially offset by net paydowns on our outstanding debt of approximately $46.0 million.

As of December 31, 2019, we had outstanding borrowings of $440 million under the Third Amended Credit Agreement, with available borrowings of approximately $133.8 million, based on the leverage ratio required pursuant to

the Third Amended Credit Agreement. Our interest rate as of December 31, 2019 was a fixed rate of 2.62% on $175 million as a result of an interest rate swap (see Note 9 to our consolidated financial statements set forth in Item 8 of this report) and a variable floating rate of 3.30% on $265 million. Our interest rate as of December 31, 2018 was a fixed rate of 2.12% on $175 million as a result of an interest rate swap and a variable floating rate of 3.52% on $213.5 million. As of December 31, 2018 we also had a variable rate of 3.39% on $7 million related to our collateralized debt facility with HSBC in China. See Note 8 to our consolidated financial statements set forth in Item 8 of this report for additional details regarding the Third Amended Credit Agreement and our long-term debt.

We currently believe that our existing cash balances, anticipated future cash flows from operations and borrowings under the Third 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.

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:

Valuation of Goodwill and Intangible Assets. 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 base the fair value of identifiable intangible assets acquired in a business combination on valuations that use information and assumptions that a market participant would use, including assumptions for estimated revenue projections, growth rates, cash flows, discount rates, useful life, and other relevant assumptions.

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 using a quantitative assessment, which uses a combination of a guideline public company market-based approach and a discounted cash flow income-based approach. The quantitative assessment considers whether the carrying amount of a reporting unit exceeds its fair value, in which case an impairment charge is recorded to the extent the reporting unit's carrying value exceeds its fair value. This analysis requires significant judgment, including estimation of future cash flows and the length of time they will occur, which is based on internal forecasts, and a determination of a discount rate based on our weighted average cost of capital. During our annual test of goodwill balances in 2019, which was completed during the third quarter of 2019, 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, 2019, we compared the carrying value of the amortizing intangible assets acquired in our July 2015 acquisition of certain assets from Distal Access, LLC ("Distal Access"), our June 2017 acquisition of certain assets from Lazarus Medical Technologies, LLC ("Lazarus"), and our July 2017 acquisition of certain assets from Pleuratech APS ("Pleuratech"), all of which pertained to our cardiovascular segment, to the undiscounted cash flows expected to result from the asset groups and determined that the carrying amounts were not

recoverable. We then determined the fair value of the amortizing assets related to the Distal Access, Lazarus, and Pleuratech acquisitions based on estimated future cash flows discounted back to their present value using discount rates that reflect 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 acquired products and uncertainty about future product development and commercialization associated with the acquired technologies. The excess of the carrying values compared to the fair values was recognized as an intangible asset impairment charge. We recorded impairment charges relating to intangible assets acquired from Distal Access, Lazarus, and Pleuratech of approximately $869,000, $548,000 and $1.8 million, respectively.

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.

Contingent Consideration. 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 operational milestones. In connection with a business combination, any contingent consideration is recorded at fair value on the acquisition date based upon the consideration expected to be transferred in the future. We base the fair value of contingent consideration obligations acquired in a business combination on valuations that use information and assumptions that a market participant would use, including assumptions for estimated revenue growth rates, discount rates, probabilities of achieving regulatory, performance, or revenue-based milestones and other relevant factors.

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.

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):

- Chinese Yuan Renminbi (CNY),
- Euro (EUR), and

We also have a limited market risk relating to the following currencies (among others):

- British Pound (GBP)
- 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, 2019, a portion of our net sales (approximately $320.8 million, representing approximately 32.2% 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 CNY- and Euro-denominated revenues represent our largest currency risks. 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. Our Euro-denominated expenses associated with our European operations (manufacturing sites, a distribution facility and sales representatives) provide a natural hedge for Euro-denominated revenues. 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. 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 CNY and EUR, before the effect of any hedging activities:

	USD Relative to Other Currency	
	10% Strengthening	10% Weakening
Impact to Operating Income:		
CNY	$ (8,314)	$ 8,314
EUR	$ 5,610	$ (5,610)

During the year ended December 31, 2019, 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 percentages):

	Year Ended December 31, 2019 Currency Impact to Reported Amounts	
	Increase/(Decrease)	Percent Increase/(Decrease)
Net Sales	(13,521)	(1.3)%
Cost of Sales	(4,944)	(0.9)%
Gross Profit [1]	(8,577)	(1.9)%

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

The impact to sales for the year ended December 31, 2019 was primarily a result of unfavorable impacts due to sales denominated in EUR, CNY, BRL and GBP. The impact to cost of sales was primarily a result of favorable impacts from EUR fluctuations related to manufacturing costs from our facilities in Europe denominated in EUR and MXN fluctuations on our manufacturing costs from our facility in Tijuana, Mexico denominated in MXN.

We forecast our net exposure related to sales and expenses denominated in foreign currencies. As of December 31, 2019, 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	8,540
Brazilian Real	BRL	10,315
Canadian Dollar	CAD	8,025
Swiss Franc	CHF	3,660
Chinese Renminbi	CNY	591,000
Danish Krone	DKK	33,575
Euro	EUR	37,750
British Pound	GBP	8,380
Japanese Yen	JPY	1,145,000
Korean Won	KRW	8,950,000
Mexican Peso	MXN	527,000
Norwegian Krone	NOK	15,475
Swedish Krona	SEK	54,170

We also 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, 2019, 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	14,282
Brazilian Real	BRL	19,500
Canadian Dollar	CAD	1,706
Swiss Franc	CHF	306
Chinese Renminbi	CNY	52,598
Danish Krone	DKK	5,987
Euro	EUR	752
British Pound	GBP	7,594
Hong Kong Dollar	HKD	11,000
Japanese Yen	JPY	1,530,000
Korean Won	KRW	4,868,000
Mexican Peso	MXN	35,000
Norwegian Krone	NOK	3,767
New Zealand Dollar	NZD	1,542
Swedish Krona	SEK	13,577
Singapore Dollar	SGD	1,790
South African Rand	ZAR	50,843

See Note 9 to our consolidated financial statements set forth in Item 8 of this report 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, 2019, we had outstanding borrowings of approximately $440 million under the Third 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, 2019 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. On December 23, 2019, we entered into a pay-fixed, receive-variable interest rate swap with Wells Fargo, with a notional amount of $75 million, to fix the one-month LIBOR rate at 1.71% for the period from July 6, 2021 to July 31, 2024. These instruments are intended to reduce our exposure to interest rate fluctuations and were not entered into for

speculative purposes. Excluding the amount that is subject to a fixed rate under the interest rate swaps 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 $2.7 million annually for each one percentage point change in the average interest rate under these borrowings.

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

Item 8. Financial Statements and Supplementary Data.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors 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, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States 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, 2019, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 2, 2020, expressed an unqualified opinion on the Company's internal control over financial reporting.

Change in Accounting Principle

As discussed in Note 1 to the financial statements, effective January 1, 2019, the Company adopted FASB ASC Topic 842, *Leases*, using the modified retrospective approach.

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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Acquisitions –Brightwater Medical Acquisition – Refer to Note 3 to the financial statements

Critical Audit Matter Description

On June 14, 2019, the Company completed the acquisition of Brightwater Medical, Inc. ("Brightwater"). The Company accounted for this acquisition under the acquisition method of accounting for business combinations. Accordingly, the purchase price was allocated to the assets acquired and liabilities assumed based on their respective fair values, including developed technology intangible assets of $32.0 million. The determination of the fair value of the developed technology intangible assets required management to make significant estimates and assumptions related to future cash flows and the discount rate.

We identified the valuation of the acquired developed technology intangible assets from Brightwater as a critical audit matter because of the significant estimates and assumptions management made to determine the fair value of these assets. This required a high degree of auditor judgment and an increased extent of effort, including the involvement of our fair value specialists, when performing audit procedures to evaluate the reasonableness of management's forecasts of future cash flows and the discount rate.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the forecasts of future cash flows and discount rate for the acquired Brightwater developed technology intangible assets included the following, among others:

- We tested the effectiveness of internal controls over the valuation of the developed technology intangible assets, including those over forecasts of future cash flows and the selection of the discount rate.
- We assessed the reasonableness of management's forecasted cash flows by inquiring of management regarding its processes for developing projected financial information and comparing the projections to historical results achieved by the acquired entity, historical results of the Company and other acquisitions completed in recent years, and comparable peer companies.
- We performed sensitivity analyses of the significant assumptions used in the valuation model to evaluate the change in fair value resulting from changes in the significant assumptions.
- With the assistance of our fair value specialists, we (1) evaluated the reasonableness of the valuation methodology; (2) evaluated the reasonableness of the discount rate through comparing the data underlying the determination of the discount rate to independent sources and developing a range of independent estimates and comparing those to the discount rates selected by management; and (3) tested the mathematical accuracy of the discounted cash flow calculation.

/s/ DELOITTE & TOUCHE LLP

Salt Lake City, Utah
March 2, 2020
We have served as the Company's auditor since 1988.

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2019 AND 2018
(In thousands)

	December 31, 2019	December 31, 2018
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 44,320	$ 67,359
Trade receivables — net of allowance for uncollectible accounts — 2019 — $3,108 and 2018 — $2,355	155,365	137,174
Other receivables	10,016	11,879
Inventories	225,698	197,536
Prepaid expenses and other current assets	12,497	11,326
Prepaid income taxes	3,491	3,627
Income tax refund receivables	3,151	933
Total current assets	454,538	429,834
PROPERTY AND EQUIPMENT:		
Land and land improvements	27,554	26,801
Buildings	153,863	151,251
Manufacturing equipment	244,368	221,029
Furniture and fixtures	57,623	54,765
Leasehold improvements	43,311	33,678
Construction-in-progress	83,685	53,491
Total property and equipment	610,404	541,015
Less accumulated depreciation	(231,619)	(209,563)
Property and equipment — net	378,785	331,452
OTHER ASSETS:		
Intangible assets:		
Developed technology — net of accumulated amortization —2019 — $149,947 and 2018 — $102,357	379,529	383,147
Other — net of accumulated amortization — 2019 — $65,607 and 2018 — $49,136	65,783	79,566
Goodwill	353,193	335,433
Deferred income tax assets	3,788	3,001
Right-of-use operating lease assets	80,244	—
Other assets	41,461	57,579
Total other assets	923,998	858,726
TOTAL ASSETS	$ 1,757,321	$ 1,620,012

See notes to consolidated financial statements.

(continued)

	December 31, 2019	December 31, 2018
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 54,623	$ 54,024
Accrued expenses	105,184	96,173
Current portion of long-term debt	7,500	22,000
Short-term operating lease liabilities	11,550	—
Income taxes payable	2,799	3,146
Total current liabilities	181,656	175,343
LONG-TERM DEBT	431,984	373,152
DEFERRED INCOME TAX LIABILITIES	45,236	56,363
LONG-TERM INCOME TAXES PAYABLE	347	392
LIABILITIES RELATED TO UNRECOGNIZED TAX BENEFITS	1,990	3,013
DEFERRED COMPENSATION PAYABLE	14,855	11,219
DEFERRED CREDITS	2,122	2,261
LONG-TERM OPERATING LEASE LIABILITIES	72,714	—
OTHER LONG-TERM OBLIGATIONS	56,473	65,494
Total liabilities	807,377	687,237
COMMITMENTS AND CONTINGENCIES (Notes 3, 8, 9, 10 and 18)		
STOCKHOLDERS' EQUITY:		
Preferred stock — 5,000 shares authorized as of December 31, 2019 and December 31, 2018; no shares issued	—	—
Common stock, no par value; shares authorized — 2019 and 2018 - 100,000; issued and outstanding as of December 31, 2019 - 55,213 and December 31, 2018 - 54,893	587,017	571,383
Retained earnings	368,221	363,425
Accumulated other comprehensive loss	(5,294)	(2,033)
Total stockholders' equity	949,944	932,775
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 1,757,321	$ 1,620,012

See notes to consolidated financial statements. (concluded)

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF INCOME
YEARS ENDED DECEMBER 31, 2019, 2018 AND 2017
(In thousands, except per share amounts)

	2019	2018	2017
NET SALES	$ 994,852	$ 882,753	$ 727,852
COST OF SALES	562,486	487,983	401,599
GROSS PROFIT	432,366	394,770	326,253
OPERATING EXPENSES:			
Selling, general and administrative	327,274	276,018	229,134
Research and development	65,615	59,532	51,403
Impairment and other charges	23,750	657	809
Contingent consideration (benefit)	(232)	(698)	(298)
Acquired in-process research and development	525	644	12,136
Total operating expenses	416,932	336,153	293,184
INCOME FROM OPERATIONS	15,434	58,617	33,069
OTHER INCOME (EXPENSE):			
Interest income	(291)	1,199	381
Interest expense	(12,413)	(10,360)	(7,736)
Gain on bargain purchase	—	—	11,039
Other income (expense) - net	(537)	63	(872)
Total other income (expense) — net	(13,241)	(9,098)	2,812
INCOME BEFORE INCOME TAXES	2,193	49,519	35,881
INCOME TAX EXPENSE (BENEFIT)	(3,258)	7,502	8,358
NET INCOME	$ 5,451	$ 42,017	$ 27,523
EARNINGS PER COMMON SHARE:			
Basic	$ 0.10	$ 0.80	$ 0.56
Diluted	$ 0.10	$ 0.78	$ 0.55
AVERAGE COMMON SHARES:			
Basic	55,075	52,268	48,805
Diluted	56,235	53,931	50,101

See notes to consolidated financial statements.

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
YEARS ENDED DECEMBER 31, 2019, 2018 AND 2017
(In thousands)

	2019	2018	2017
Net income	$ 5,451	$ 42,017	$ 27,523
Other comprehensive income (loss):			
Cash flow hedges	(5,456)	64	901
Income tax benefit (expense)	1,404	(16)	(350)
Foreign currency translation adjustment	(18)	(3,606)	3,117
Income tax benefit (expense)	61	(9)	(252)
Total other comprehensive income (loss)	(4,009)	(3,567)	3,416
Total comprehensive income	$ 1,442	$ 38,450	$ 30,939

See notes to consolidated financial statements.

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED DECEMBER 31, 2019, 2018 AND 2017
(In thousands)

	Total	Common Stock Shares	Common Stock Amount	Retained Earnings	Accumulated Other Comprehensive Income (Loss)
BALANCE — January 1, 2017	$ 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)
Net income	5,451			5,451	
Reclassify deferred gain on sale-leaseback upon adoption of ASC 842	93			93	
Reclassify stranded tax effects upon adoption of ASU 2018-02				(748)	748
Other comprehensive loss	(4,009)				(4,009)
Stock-based compensation expense	9,382		9,382		
Options exercised	4,930	288	4,930		
Issuance of common stock under Employee Stock Purchase Plans	1,415	35	1,415		
Shares surrendered in exchange for exercise of stock options	(93)	(3)	(93)		
BALANCE — December 31, 2019	$ 949,944	55,213	$ 587,017	$ 368,221	$ (5,294)

See notes to consolidated financial statements.

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2019, 2018 AND 2017
(In thousands)

	2019	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	$ 5,451	$ 42,017	$ 27,523
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	92,100	69,546	53,582
Gain on bargain purchase	—	—	(11,039)
Loss on sales and/or abandonment of property and equipment	115	625	427
Write-off of certain intangible assets and other long-term assets	25,563	814	988
Acquired in-process research and development	525	644	12,136
Amortization of right-of-use operating lease assets	12,256	—	—
Amortization of deferred credits	(139)	(142)	(147)
Amortization of long-term debt issuance costs	721	804	685
Deferred income taxes	(12,436)	2,052	(1,304)
Stock-based compensation expense	9,382	6,117	4,075
Changes in operating assets and liabilities, net of effects from acquisitions:			
Trade receivables	(17,900)	(27,522)	(12,844)
Other receivables	1,859	(2,754)	(3,557)
Inventories	(27,044)	(28,172)	(17,834)
Prepaid expenses and other current assets	(1,239)	(2,000)	(1,236)
Prepaid income taxes	128	(444)	(611)
Income tax refund receivables	(2,247)	232	(588)
Other assets	(5,141)	315	(3,735)
Trade payables	(2,295)	15,726	417
Accrued expenses	9,580	12,706	6,461
Income taxes payable	(351)	918	21
Long-term income taxes payable	(45)	(4,454)	4,846
Liabilities related to unrecognized tax benefits	(794)	267	(19)
Deferred compensation payable	3,635	39	1,970
Operating lease liabilities	(11,970)	—	—
Other long-term obligations	(1,901)	(801)	2,510
Total adjustments	72,362	44,516	35,204
Net cash provided by operating activities	77,813	86,533	62,727
CASH FLOWS FROM INVESTING ACTIVITIES:			
Capital expenditures for:			
Property and equipment	(78,173)	(63,324)	(38,623)
Intangible assets	(3,324)	(3,012)	(2,577)
Proceeds from the sale of property and equipment	920	55	21
Issuance of note receivable	—	(10,750)	—
Cash paid in acquisitions, net of cash acquired	(53,904)	(301,789)	(105,582)
Net cash used in investing activities	(134,481)	(378,820)	(146,761)

See notes to consolidated financial statements.

(continued)

	2019	2018	2017
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock	$ 6,252	$ 214,993	$ 143,810
Offering costs	—	(366)	(816)
Proceeds from issuance of long-term debt	246,659	639,108	197,214
Payments on long-term debt	(202,159)	(522,608)	(243,214)
Long-term debt issuance costs	(1,479)	—	(416)
Contingent payments related to acquisitions	(15,740)	(231)	(61)
Payment of taxes related to an exchange of common stock	—	(2,616)	—
Net cash provided by financing activities	33,533	328,280	96,517
EFFECT OF EXCHANGE RATES ON CASH	96	(970)	682
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(23,039)	35,023	13,165
CASH AND CASH EQUIVALENTS:			
Beginning of period	67,359	32,336	19,171
End of period	$ 44,320	$ 67,359	$ 32,336
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION			
Cash paid during the period for:			
Interest (net of capitalized interest of $1,290, $647 and $513, respectively)	$ 12,434	$ 10,324	$ 7,707
Income taxes	$ 12,069	$ 8,692	$ 6,049
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES			
Property and equipment purchases in accounts payable	$ 7,952	$ 4,989	$ 1,992
Receivable for issuance of common stock associated with option exercises	$ —	$ —	$ 137
Acquisition purchases in accrued expenses and other long-term obligations	$ 10,541	$ 72,209	$ 10,488
Merit common stock surrendered (3, 43, and 0 shares, respectively) in exchange for exercise of stock options	$ 93	$ 2,261	$ —
Right-of-use operating lease assets obtained in exchange for operating lease liabilities	$ 10,637	$ —	$ —

See notes to consolidated financial statements. (concluded)

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2019, 2018 AND 2017

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 using a quantitative assessment, which uses a combination of a guideline public company market-based approach and a discounted cash flow income-based approach. The quantitative assessment considers whether the carrying amount of a reporting unit

exceeds its fair value, in which case an impairment charge is recorded to the extent the reporting unit's carrying value exceeds its fair value.

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.

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, 2019, 2018 and 2017 was approximately $31.4 million, $28.3 million, and $26.8 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 $15.1 million and $11.7 million at December 31, 2019 and 2018, respectively, which is included in other assets in our consolidated balance sheets. We have recorded a deferred compensation payable of approximately $14.9 million and $11.2 million at December 31, 2019 and 2018, respectively, to reflect the liability to our employees under this plan.

Other Assets. Other assets as of December 31, 2019 and 2018 consisted of the following (in thousands):

	2019	2018
Deferred compensation plan assets	$ 15,053	$ 11,716
Investments in privately held companies	17,129	22,530
Long-term notes receivable	2,722	13,504
Other	6,557	9,829
Total	$ 41,461	$ 57,579

We analyze our investments in privately held companies 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 at cost minus impairment, if applicable, plus or minus changes in valuation resulting from observable transactions for identical or similar investments.

On April 6, 2018, we entered into long-term agreements with NinePoint, pursuant to which we (a) became the exclusive worldwide distributor for the NvisionVLE® Imaging System and (b) acquired an option to purchase up to 100% of the outstanding equity in NinePoint, both in exchange for total consideration of $10 million. In addition, we made a loan to NinePoint for $10.5 million bearing interest at a rate of 9.0% and collateralized by NinePoint's rights, interest and title to the NvisionVLE® Imaging System. In 2019, we determined our investments in NinePoint were impaired and recorded total impairment charges of $20.5 million for our investments in NinePoint. We also wrote off $1.6 million of accrued interest related to the note receivable from NinePoint. In January 2020, our option to purchase the outstanding equity of NinePoint expired.

Other Long-term Obligations. Other long-term obligations as of December 31, 2019 and 2018 consisted of the following (in thousands):

	2019	2018
Contingent consideration liabilities	$ 48,088	$ 58,486
Other long-term obligations	8,385	7,008
Total	$ 56,473	$ 65,494

In connection with a business combination, any contingent consideration is recorded at fair value on the acquisition date based upon the consideration expected to be transferred in the future. We re-measure the estimated liability each quarter based upon changes in the timing and amount of revenue estimates, as well as changes in the discount rate or periods. Changes in the estimated fair value are recorded through operating expense in our consolidated statements of income.

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 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, except in limited cases which are not material.

Determine the transaction price. Payment by the customer is due under customary fixed payment terms, and we evaluate if collectability is reasonably assured. Our contracts do not typically contain a 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, 2019, 2018 and 2017. 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 as calculated using the treasury stock method.

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

Level 1: Quoted market prices in active markets for identical assets or liabilities.
Level 2: Observable market-based inputs or inputs that are corroborated by market data.
Level 3: Unobservable inputs that are not corroborated by market data.

Stock-Based Compensation. We recognize the fair value compensation cost relating to stock-based payment transactions in accordance with Accounting Standards Codification (“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, 2019, 2018 and 2017 was approximately $9.4 million, $6.1 million and $4.1 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 2% of net sales for the years ended December 31, 2019, 2018 and 2017, respectively.

Foreign Currency. The financial statements of our foreign subsidiaries are measured using local currencies as the functional currency, with the exception of our manufacturing 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 Third 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).

New Financial Accounting Standards

Recently Adopted

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842)* ("ASC 842"), which requires lessees to recognize right-of-use ("ROU") assets and related lease liabilities on the balance sheet for all leases greater than one year in duration. We adopted ASC 842 on January 1, 2019 using 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 did not require any transition accounting for leases that expired before the earliest comparative period presented. The adoption of this standard resulted in the recording of ROU assets and lease liabilities for all of our lease agreements with original terms of greater than one year. The adoption of ASC 842 did not have a significant impact on our consolidated statements of income or cash flows. See Note 18 for the required disclosures relating to our lease agreements.

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which simplifies the accounting for nonemployee share-based payment transactions by expanding the scope of ASC Topic 718, *Compensation - Stock Compensation*, to include share-based payment transactions for acquiring goods and services from nonemployees. Under the new standard, most of the guidance on stock compensation payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. This standard became effective for us on January 1, 2019. The adoption of this standard did not have a material impact on our consolidated financial statements.

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 (AOCI) to retained earnings for stranded tax effects

resulting from U.S. federal tax legislation commonly referred to as the Tax Cuts and Jobs Act, which was enacted in December 2017 (the "2017 Tax Act"). ASU 2018-02 became effective for us on January 1, 2019 and resulted in a decrease of approximately $748,000 to retained earnings due to the reclassification from AOCI of the effect of the corporate income tax rate change on our cash flow hedges. The adoption of this standard did not 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 became effective for us on January 1, 2019. The adoption of this standard did not have a material impact on our consolidated financial statements.

Not Yet Adopted

In August 2018, the FASB issued ASU 2018-15, *Intangibles – Goodwill and Other – Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). ASU 2018-15 is effective for annual periods beginning after December 15, 2019, including interim periods within those annual periods. Early adoption is permitted. We adopted ASU 2018-15 on January 1, 2020 on a prospective basis, and do not expect the adoption will result in a material impact for future periods.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which removes, modifies and adds various disclosure requirements related to fair value disclosures. Disclosures related to transfers between fair value hierarchy levels will be removed and further detail around changes in unrealized gains and losses for the period and unobservable inputs used in determining level 3 fair value measurements will be added, among other changes. ASU 2018-13 is effective for interim and annual reporting periods beginning after December 15, 2019, and early adoption is permitted. We will modify our disclosures beginning in the first quarter of 2020 to conform to this guidance. We do not expect the adoption of this standard and the associated changes to our disclosures to have a material impact to our consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which replaces the current incurred loss impairment methodology for financial assets with a methodology that reflects expected credit losses. The new credit losses model must be applied to loans, accounts receivable, and other financial assets. ASU 2016-13 is effective for annual periods beginning after December 15, 2019, including interim periods within those annual periods. We plan to adopt the new standard in the first quarter of 2020 using a modified retrospective approach with a cumulative-effect adjustment to retained earnings as of the beginning of the year of adoption. We do not believe this guidance will have a material impact on our statements of operations or cash flows.

We currently believe that 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, 2019, 2018 and 2017.

	Year Ended December 31, 2019			Year Ended December 31, 2018			Year Ended December 31, 2017		
	United States	International	Total	United States	International	Total	United States	International	Total
Cardiovascular									
Stand-alone devices	$ 222,263	$ 179,203	$ 401,466	$ 202,129	$ 159,484	$ 361,613	$ 148,620	$ 126,836	$ 275,456
Cianna Medical	49,324	212	49,536	6,292	—	6,292	—	—	—
Custom kits and procedure trays	92,038	43,818	135,856	92,975	41,781	134,756	92,474	33,615	126,089
Inflation devices	32,795	57,886	90,681	31,717	60,702	92,419	31,848	48,027	79,875
Catheters	81,183	96,693	177,876	68,708	86,817	155,525	62,284	65,463	127,747
Embolization devices	21,222	30,850	52,072	20,433	29,605	50,038	22,374	27,158	49,532
CRM/EP	44,291	9,203	53,494	41,970	6,864	48,834	36,746	5,168	41,914
Total	543,116	417,865	960,981	464,224	385,253	849,477	394,346	306,267	700,613
Endoscopy									
Endoscopy devices	32,595	1,276	33,871	32,189	1,087	33,276	26,357	882	27,239
Total	$ 575,711	$ 419,141	$ 994,852	$ 496,413	$ 386,340	$ 882,753	$ 420,703	$ 307,149	$ 727,852

3. ACQUISITIONS

On October 11, 2019, we entered into a subscription and shareholders' agreement to acquire 3,900 ordinary shares and 1,365 C ordinary shares of Selio Medical Limited ("Selio"), an option to purchase all ordinary shares in Selio throughout a 45 day period commencing from the date Selio receives FDA Section 510(k) approval of a medical device it is currently developing, and an option to purchase all remaining shares on the third anniversary date of the agreement if we elect to purchase all ordinary shares. The shares of stock we acquired, which represent an ownership interest of approximately 19.5%, have been recorded as an equity investment accounted for at cost because we are not able to exercise significant influence over the operations of Selio. The investment and purchase option of approximately $2.6 million are reflected within other assets in the accompanying consolidated balance sheets. In addition, we have a loan to Selio of $250,000, reflected within other assets, and have committed to provide a loan up to an additional €2 million at the discretion of the borrower. Amounts outstanding under the loan accrue interest at a rate of 5% per annum payable monthly. All amounts outstanding under the loan agreement become due and payable at the first anniversary of the expiration of our option to purchase all ordinary shares.

On August 1, 2019, we entered into a share purchase agreement to acquire Fibrovein Holdings Limited, which is the owner of 100% of the capital stock of STD Pharmaceutical Products Limited, a UK private company engaged in the manufacture, distribution and sale of pharmaceutical sclerotherapy products ("STD Pharmaceutical"). The purchase consideration consisted of an upfront payment of approximately $13.7 million, net of cash acquired. We also recorded a contingent consideration liability of $934,000 related to royalties potentially payable pursuant to the terms of the share purchase agreement. We accounted for this acquisition as a business combination. 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 STD Pharmaceutical acquisition, which were included in selling, general and administrative expenses, were not material. During the fourth quarter, certain immaterial measurement period adjustments have been made to the preliminary purchase price allocation which was first presented in our Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2019. The purchase price was preliminarily allocated as follows (in thousands):

Assets Acquired	
Trade receivables	$ 277
Inventories	843
Prepaid expenses and other assets	49
Intangibles	
Developed technology	10,428
Goodwill	4,975
Total assets acquired	16,572
Liabilities Assumed	
Trade payables	(53)
Accrued expenses	(29)
Deferred income tax liabilities	(1,890)
Total liabilities assumed	(1,972)
Total net assets acquired	**$ 14,600**

We are amortizing the developed technology intangible asset acquired from STD Pharmaceutical over 12 years. The goodwill consists largely of the synergies we hope to achieve from combining operations and is not expected to be deductible for income tax purposes.

On June 14, 2019, we consummated an acquisition transaction contemplated by a merger agreement to acquire Brightwater Medical, Inc. ("Brightwater"). The purchase consideration consisted of an upfront payment of $35 million plus a final working capital adjustment of approximately $39,000, net of cash acquired, with potential earn-out payments of up to an additional $5 million for achievement of CE certification with respect to the Brightwater ConvertX®, a single-use device used to replace a series of devices and procedures used to treat severe obstructions of the ureter, and up to an additional $10 million for the achievement of sales milestones specified in the merger agreement. The ConvertX device is designed to be implanted once and converted from a nephroureteral catheter to a nephroureteral stent without requiring sedation or local anesthesia. Brightwater recently received FDA clearance for the ConvertX biliary stent device. We accounted for this acquisition as a business combination. 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 Brightwater acquisition, which were included in selling, general and administrative expenses, were not material. During the fourth quarter of 2019, certain immaterial measurement period adjustments have been made to the

preliminary purchase price allocation primarily related to the deferred tax liabilities associated with the fair value of the acquired net assets which was offset to goodwill. The purchase price was preliminarily allocated as follows (in thousands):

Assets Acquired	
Trade receivables	$ 55
Inventories	349
Property and equipment	409
Other long-term assets	30
Intangibles	
Developed technology	31,960
Customer lists	83
Trademarks	250
Goodwill	17,492
Total assets acquired	50,628
Liabilities Assumed	
Trade payables	(58)
Accrued expenses	(261)
Other long-term obligations	(1,522)
Deferred income tax liabilities	(4,148)
Total liabilities assumed	(5,989)
Total net assets acquired	**$ 44,639**

We are amortizing the developed technology intangible asset acquired from Brightwater over 13 years, the related trademarks over five years and the customer list on an accelerated basis over one year. The total weighted-average amortization period for these acquired intangible assets is approximately 12.9 years. The goodwill consists largely of the synergies and economies of scale we hope to achieve from combining the acquired assets and operations with our historical operations and is not expected to be deductible for income tax purposes.

On March 28, 2019, we paid $2 million to acquire convertible participating preferred shares of Fluidx Medical Technology, LLC ("Fluidx"), owner of certain technology proposed to be used in the development of embolic and adhesive agents for use in arterial, venous, vascular graft and cardiovascular applications inside and outside the heart and related appendages. Our investment in Fluidx has been recorded as an equity investment accounted for at cost and reflected within other assets in our accompanying consolidated balance sheet because we are not able to exercise significant influence over the operations of Fluidx. Our total current investment in Fluidx represents an ownership of approximately 11.6% of the outstanding equity interests of Fluidx.

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 Insights' 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 a targeted treatment area. We accounted for this acquisition as a business combination. The purchase consideration included an upfront payment of $40 million, and a final working capital adjustment of approximately $15,000 paid by Vascular Insights in the third quarter of 2019. We are also 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. During the year ended December 31, 2019 net sales of products acquired from Vascular Insights were approximately $7.5 million. It is not practical to separately report earnings related to the products acquired from Vascular Insights, as we cannot split out sales costs related solely to the products we acquired from Vascular Insights, principally because our sales representatives sell multiple products (including the products we acquired from Vascular Insights) in our cardiovascular business segment. Acquisition-related costs associated with the Vascular Insights acquisition, which were included in selling, general and administrative expenses during the year ended December 31,

2018, were not material. The following table summarizes the purchase price allocated to the net assets acquired as follows (in thousands):

Inventories	$	1,353
Intangibles		
Developed technology		32,750
Customer list		840
Trademarks		1,410
Goodwill		21,832
Total net assets acquired	**$**	**58,185**

We are amortizing the developed technology intangible asset acquired from Vascular Insights 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. The goodwill arising principally from synergies anticipated upon consolidation of operations is expected the be deductible for income tax purposes.

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 a final working capital adjustment of approximately $1.2 million in cash, with earn-out payments of $15 million for achievement of supply chain and scalability metrics paid in the third quarter of 2019 and potential payments up to an additional $50 million for the achievement of sales milestones specified in the merger agreement. 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 years ended December 31, 2019 and 2018, net sales of Cianna Medical products were approximately $49.5 million and $6.3 million, respectively. 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 segment. Acquisition-related costs associated with the Cianna Medical acquisition, which were included in selling, general and administrative expenses during the year ended December 31, 2018, were approximately $3.5 million. During the measurement period, which ended in November 2019, adjustments were made to finalize the allocation of purchase price related to deferred

income tax liabilities and goodwill. The following table summarizes the 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 current 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	61,379
Total assets acquired	219,629
Liabilities Assumed	
Trade payables	(1,497)
Accrued expenses	(2,384)
Other long-term liabilities	(1,527)
Deferred income tax liabilities	(25,940)
Total liabilities assumed	(31,348)
Total net assets acquired	**$ 188,281**

We are amortizing the developed technology intangible assets of Cianna Medical 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. The goodwill consists largely of the synergies and economies of scale we hope to achieve from combining the acquired assets and operations with our historical operations and is not expected to be deductible for income tax purposes.

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 of Cagent 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 during the year ended December 31, 2018, were not material. The purchase price was allocated as follows (in thousands):

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

We are amortizing the developed technology intangible asset of DirectACCESS 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. The goodwill arising principally from synergies anticipated upon consolidation of operations is expected to be deductible for income tax purposes.

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, 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. 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. The results of operations related to NinePoint have been included in our endoscopy segment since the acquisition date. During the years ended December 31, 2019 and 2018 our net sales of NinePoint products were approximately $2.9 million and $3.0 million, respectively. Our exposure to loss related to our transaction with NinePoint was the carrying value of the amounts paid to and due from NinePoint. In 2019, we determined our investments in NinePoint were impaired, and we recorded impairment charges of $20.5 million for the NinePoint note receivable and purchase option and $1.6 million related to interest accrued on the note receivable. In January 2020, our option to purchase the outstanding equity of NinePoint expired.

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 and TruCut® Biopsy Needles as well as the Aspira® Pleural Effusion Drainage Kits, and the Aspira® Peritoneal Drainage System. We accounted for this acquisition as a business combination. During the years ended December 31, 2019 and 2018, net sales of BD products were approximately $46.8 million and $42.1 million, respectively. 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 were included in selling, general and administrative expenses during the year ended December 31, 2018, were approximately $1.8 million. 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):

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 net assets acquired	**$**	**101,880**

We are amortizing the developed technology intangible assets acquired from BD 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 eight years. The goodwill arising principally from synergies anticipated upon consolidation of operations is expected to be deductible for income tax purposes.

On October 2, 2017 we acquired a custom procedure pack business located in Melbourne, Australia from 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. The goodwill consists largely of the synergies and economies of scale we hope to achieve from combining the acquired assets and operations with our historical operations and is not expected to be deductible for income tax purposes. 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, 2019, 2018 and 2017, our net sales of ITL products were approximately $7.7 million, $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 in-process research and development expense for the year ended December 31, 2017, because 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 goodwill arising principally from synergies anticipated upon consolidation of operations is expected the be deductible for income tax purposes. 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, 2019, 2018 and 2017, our net sales of Osseon products were approximately $1.7 million, $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. The goodwill arising principally from synergies anticipated upon consolidation of operations is expected the be deductible for income tax purposes.

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. We paid $2.0 million in connection with this agreement. We recorded the amount paid upon closing as a license agreement intangible asset, which we were amortizing over 15 years. During 2019, we recorded an impairment of this asset of approximately $1.8 million.

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, 2019, we had paid $620,000 in connection with this 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. During 2019, we cancelled this agreement with Lazarus Medical, impaired the license agreement, and are no longer required to complete future obligations under the terms of this contract.

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 goodwill arising principally from synergies anticipated upon consolidation of operations is not expected the be deductible for income tax purposes. 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, 2019, 2018 and 2017, our net sales of the Argon critical care products were approximately $46.8 million, $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):

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)
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 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, 2019, 2018 and 2017, our net sales of the products acquired from Catheter Connections were approximately $15.9 million, $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):

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. The goodwill arising principally from synergies anticipated upon consolidation of operations is expected the be deductible for income tax purposes.

The following table summarizes our consolidated results of operations for the years ended December 31, 2018 and 2017, as well as unaudited pro forma consolidated results of operations as though 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	
	As Reported	Pro Forma	As Reported	Pro Forma
Net sales	$ 882,753	$ 928,336	$ 727,852	$ 768,571
Net income	42,017	20,699	27,523	(13,720)
Earnings per common share:				
Basic	$ 0.80	$ 0.40	$ 0.56	$ (0.28)
Diluted	$ 0.78	$ 0.38	$ 0.55	$ (0.27)

Note: The pro forma results for the year ended December 31, 2019 are not included in the table above because the operating results of the Argon critical care division, Cianna Medical, and Vascular Insights acquisitions were included in our consolidated statements of income for these periods

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 or the acquisition of the Argon critical care division had occurred on January 1, 2016, 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 STD Pharmaceutical, Brightwater, DirectACCESS, ITL, Laurane, Osseon, VAT, or Catheter Connections acquisitions as we do not deem the pro forma effect of these transactions to be material.

4. INVENTORIES

Inventories at December 31, 2019 and 2018, consisted of the following (in thousands):

	2019	2018
Finished goods	$ 134,467	$ 117,703
Work-in-process	17,602	14,380
Raw materials	73,629	65,453
Total inventories	$ 225,698	$ 197,536

5. GOODWILL AND INTANGIBLE ASSETS

The changes in the carrying amount of goodwill for the years ended December 31, 2019 and 2018, are as follows (in thousands):

	2019	2018
Goodwill balance at January 1	$ 335,433	$ 238,147
Effect of foreign exchange	(199)	(1,304)
Additions and adjustments as the result of acquisitions	17,959	98,590
Goodwill balance at December 31	$ 353,193	$ 335,433

Total accumulated goodwill impairment losses aggregated to $8.3 million as of December 31, 2019 and 2018. We did not have any goodwill impairments for the years ended December 31, 2019, 2018 and 2017. The total goodwill balance as of December 31, 2019 and 2018, is related to our cardiovascular segment.

Other intangible assets at December 31, 2019 and 2018, consisted of the following (in thousands):

	December 31, 2019		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patents	$ 22,703	$ (6,863)	$ 15,840
Distribution agreements	8,012	(6,794)	1,218
License agreements	26,987	(12,746)	14,241
Trademarks	30,240	(9,477)	20,763
Covenants not to compete	964	(964)	—
Customer lists	39,984	(28,763)	11,221
In-process technology	2,500	—	2,500
Total	$ 131,390	$ (65,607)	$ 65,783

	December 31, 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

Aggregate amortization expense for the years ended December 31, 2019, 2018 and 2017 was approximately $60.7 million, $41.2 million and $26.8 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. We identified indicators of impairment associated with certain acquired intangible assets based on our qualitative assessment, which required us to complete an interim quantitative impairment assessment. The primary indicator of impairment was slower than anticipated sales growth in the acquired products and uncertainty about future product development and commercialization associated with the acquired technologies.

During the year ended December 31, 2019, we recorded impairment charges related to our amortizing intangible assets of approximately $869,000 from our July 2015 acquisition of certain assets from Distal Access, LLC, $548,000 from our June 2017 acquisition of certain assets from Lazarus Medical Technologies, LLC, and $1.8 million from our July 2017 acquisition of certain assets from Pleuratech ApS for a total of approximately $3.3 million. 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. The impairment charges recorded in 2019, 2018, and 2017 all pertained to our cardiovascular segment.

Estimated amortization expense for the developed technology and other intangible assets for the next five years consists of the following as of December 31, 2019 (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2020	$ 59,386
2021	52,032
2022	50,682
2023	49,485
2024	46,506

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.

As of December 31, 2018, we 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 $1.9 million and $347,000 during the years ended December 31, 2019 and 2018, respectively.

As of December 31, 2018, we had 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, we recorded tax expense of approximately $638,000 and $5.6 million for foreign withholding taxes on unremitted foreign earnings during the years ended December 31, 2019 and 2018, respectively.

For the years ended December 31, 2019, 2018 and 2017, income before income taxes is broken out between U.S. and foreign-sourced operations and consisted of the following (in thousands):

	2019	2018	2017
Domestic	$ (37,277)	$ 21,084	$ 14,531
Foreign	39,470	28,435	21,350
Total	$ 2,193	$ 49,519	$ 35,881

The components of the provision for income taxes for the years ended December 31, 2019, 2018 and 2017, consisted of the following (in thousands):

	2019	2018	2017
Current expense (benefit):			
Federal	$ 479	$ (1,132)	$ 3,849
State	662	582	645
Foreign	8,037	6,000	5,168
Total current expense	9,178	5,450	9,662
Deferred expense (benefit):			
Federal	(8,111)	4,400	(314)
State	(3,523)	(667)	(216)
Foreign	(802)	(1,681)	(774)
Total deferred (benefit) expense	(12,436)	2,052	(1,304)
Total income tax expense (benefit)	$ (3,258)	$ 7,502	$ 8,358

The difference between the income tax expense reported and amounts computed by applying the statutory federal rate of 21.0% to pretax income for years ended December 31, 2019 and 2018, and 35% for the year ended December 31, 2017, consisted of the following (in thousands):

	2019	2018	2017
Computed federal income tax expense at applicable statutory rate	$ 461	$ 10,399	$ 12,559
State income taxes	(2,241)	(59)	279
Tax credits	(1,567)	(1,734)	(1,377)
Foreign tax rate differential	(1,536)	(1,361)	(3,329)
Uncertain tax positions	(794)	267	(19)
Deferred compensation insurance assets	(503)	186	(479)
Transaction-related expenses	154	223	90
U.S. transition tax	—	(3,271)	10,612
TCJA remeasurement of deferred taxes	—	(71)	(8,383)
Stock-based payments	(1,654)	(4,278)	(2,264)
Bargain purchase gain	—	—	(1,570)
In-process research and development	—	—	1,486
Net GILTI	1,861	347	—
Foreign withholding tax	638	5,590	—
Other — including the effect of graduated rates	1,923	1,264	753
Total income tax expense (benefit)	$ (3,258)	$ 7,502	$ 8,358

Deferred income tax assets and liabilities at December 31, 2019 and 2018, consisted of the following temporary differences and carry-forward items (in thousands):

	2019	2018
Deferred income tax assets:		
Allowance for uncollectible accounts receivable	$ 693	$ 606
Accrued compensation expense	9,244	7,414
Inventory differences	2,207	1,269
Net operating loss carryforwards	21,187	20,226
Deferred revenue	552	46
Stock-based compensation expense	4,672	2,833
Operating lease assets	16,838	—
Federal R&D Tax Credits	1,376	—
Other	6,189	9,243
Total deferred income tax assets	62,958	41,637
Deferred income tax liabilities:		
Prepaid expenses	(1,128)	(1,142)
Property and equipment	(21,242)	(20,045)
Intangible assets	(53,933)	(58,883)
Foreign withholding tax	(5,240)	(5,590)
Operating lease liabilities	(15,847)	—
Other	(2,372)	(4,350)
Total deferred income tax liabilities	(99,762)	(90,010)
Valuation allowance	(4,644)	(4,989)
Net deferred income tax liabilities	$ (41,448)	$ (53,362)
Reported as:		
Deferred income tax assets	$ 3,788	$ 3,001
Deferred income tax liabilities	(45,236)	(56,363)
Net deferred income tax liabilities	$ (41,448)	$ (53,362)

The deferred income tax balances are not netted as they represent deferred amounts applicable to different taxing jurisdictions. Deferred income tax balances reflect the temporary differences between the carrying amounts of assets and liabilities and their tax basis and are stated at enacted tax rates expected to be in effect when taxes are actually paid or recovered. The valuation allowance is primarily related to state credit carryforwards, non-US net operating loss carryforwards, and capital loss carryforwards for which we believe it is more likely than not that the deferred tax assets will not be realized. The valuation allowance decreased by approximately $345,000 during the year ended December 31, 2019 and increased by approximately $567,000 and $636,000 during the years ended December 31, 2018 and 2017, respectively.

As of December 31, 2019 and 2018, we had U.S federal net operating loss carryforwards of approximately $93.3 million and $86.3 million, respectively, which were generated by Cianna Medical, VAT, DFINE, Biosphere Medical, Inc., and Brightwater Medical, Inc. prior to our acquisition of these companies. Brightwater Medical, Inc. was acquired on June 14, 2019. These net operating loss carryforwards are subject to annual limitations under Internal Revenue Code Section 382. We anticipate that we will utilize the net operating loss carryforwards over the next 23 years. We utilized a total of approximately $20.6 million and $11.9 million in U.S. federal net operating loss carryforwards during the years ended December 31, 2019 and 2018, respectively.

As of December 31, 2019, we had approximately $3.4 million of non-U.S. net operating loss carryforwards, of which approximately $2.4 million have no expiration date and approximately $1.0 million expire at various dates through 2028. As of December 31, 2018, we had $5.9 million of non-U.S. net operating loss carryforwards, of which approximately $5.2 million had no expiration date and approximately $761,000 expire at various dates through 2027. Non-U.S. net operating loss carryforwards utilized during the years ended December 31, 2019 and 2018 were not material.

We are subject to income taxes in the U.S. and numerous foreign jurisdictions. Significant judgment is required in determining our worldwide provision for income taxes and recording the related assets and liabilities. In the ordinary course of our business, there are many transactions and calculations where the ultimate tax determination is uncertain. In our opinion, we have made adequate provisions for income taxes for all years subject to audit. We are no longer subject to U.S. federal, state, and local income tax examinations by tax authorities for years before 2016. In foreign jurisdictions, we are no longer subject to income tax examinations for years before 2013.

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

The total liability for unrecognized tax benefits at December 31, 2019, including interest and penalties, was approximately $2.5 million, of which approximately $2.2 would favorably impact our effective tax rate if recognized. Approximately $230,000 of the total liability at December 31, 2019 was presented as a reduction to non-current deferred income tax assets on our consolidated balance sheet. The total liability for unrecognized tax benefits at December 31, 2018, including interest and penalties, was approximately $3.3 million, of which approximately $3.0 million would favorably impact our effective tax rate if recognized. None of the total liability at December 31, 2018 was presented as a reduction to non-current deferred income tax assets on our consolidated balance sheet. As of December 31, 2019 and 2018, the total liability for uncertain tax benefits, as presented on our consolidated balance sheets, has been reduced by approximately $307,000 related to certain liabilities for unrecognized tax benefits, which, if realized, would reduce the transition tax under the TCJA by approximately $307,000. As of December 31, 2019 and 2018, we had accrued approximately $366,000 and $373,000 respectively, in total interest and penalties related to unrecognized tax benefits. We account for interest and penalties for unrecognized tax benefits as part of our income tax provision. During the years ended December 31, 2019, 2018 and 2017, our liability for unrecognized tax benefit was increased (decreased) for interest and penalties by approximately ($7,000), $69,000 and $88,000, respectively. It is reasonably possible that within the next 12 months the total liability for unrecognized tax benefits may change, net of potential decreases due to the expiration of statutes of limitation, up to $650,000.

A reconciliation of the beginning and ending amount of liabilities associated with uncertain tax benefits for the years ended December 31, 2019, 2018 and 2017, consisted of the following (in thousands):

	2019	2018	2017
Unrecognized tax benefits, opening balance	$ 2,947	$ 2,749	$ 2,549
Gross increases (decreases) in tax positions taken in a prior year	(244)	35	80
Gross increases in tax positions taken in the current year	229	586	403
Lapse of applicable statute of limitations	(771)	(423)	(283)
Unrecognized tax benefits, ending balance	$ 2,161	$ 2,947	$ 2,749

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

7. ACCRUED EXPENSES

Accrued expenses at December 31, 2019 and 2018, consisted of the following (in thousands):

	2019	2018
Payroll and related liabilities	$ 39,781	$ 37,396
Current portion of contingent liabilities	28,621	23,760
Advances from employees	286	540
Accrued rebates payable	9,202	6,789
Other accrued expenses	27,294	27,688
Total	$ 105,184	$ 96,173

Note: Accrued rebates payable is presented in 2019 as it has increased relative to total current liabilities from the prior year. Accrued expenses have been reclassified for all periods presented for comparability

8. REVOLVING CREDIT FACILITY AND LONG-TERM DEBT

Principal balances outstanding under our long-term debt obligations as of December 31, 2019 and 2018, consisted of the following (in thousands):

	2019	2018
Term loans	$ 148,125	$ 72,500
Revolving credit loans	291,875	316,000
Collateralized debt facility (paid in full)	—	7,000
Less unamortized debt issuance costs	(516)	(348)
Total long-term debt	439,484	395,152
Less current portion	7,500	22,000
Long-term portion	$ 431,984	$ 373,152

Third Amended and Restated Credit Agreement

On July 31, 2019, we entered into a Third Amended and Restated Credit Agreement (the "Third Amended Credit Agreement"). The Third Amended Credit Agreement is a syndicated loan agreement with Wells Fargo Bank, National Association and other parties. The Third Amended Credit Agreement amends and restates in its entirety our previously outstanding Second Amended and Restated Credit Agreement and all amendments thereto. The Third Amended Credit Agreement provides for a term loan of $150 million and a revolving credit commitment up to an aggregate amount of $600 million, inclusive of sub-facilities for multicurrency borrowings, standby letters of credit and swingline loans. On

July 31, 2024, all principal, interest and other amounts outstanding under the Third Amended Credit Agreement are payable in full. At any time prior to the maturity date, we may repay any amounts owing under all term loans and revolving credit loans in whole or in part, without premium or penalty, other than breakage fees (as defined in the Third Amended Credit Agreement).

Revolving credit loans denominated in dollars and term loans made under the Third Amended Credit Agreement bear interest, at our election, at either the Base Rate or the Eurocurrency Rate (as such terms are defined in the Third Amended Credit Agreement) plus the Applicable Margin (as defined in the Third Amended Credit Agreement). Revolving credit loans denominated in an Alternative Currency (as defined in the Third 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 (as defined in the Third Amended Credit Agreement). Interest on each loan featuring the Base Rate is due and payable on the last business day of each calendar quarter commencing December 31, 2019; interest on each loan featuring the Eurocurrency Rate is due and payable on the last day of each interest period applicable thereto, and if such interest period extends over three months, at the end of each three-month interval during such interest period.

The Third Amended Credit Agreement is collateralized by substantially all of our assets. The Third Amended Credit Agreement contains affirmative and negative covenants, representations and warranties, events of default and other terms customary for loans of this nature. In particular, the Third Amended Credit Agreement requires that we maintain certain financial covenants, as follows:

	Covenant Requirement
Consolidated Total Leverage Ratio [1]	4.0 to 1.0
Consolidated Interest Coverage Ratio [2]	3.0 to 1.0
Facility Capital Expenditures [3]	$50 million

(1) Maximum Consolidated Total Net Leverage Ratio (as defined in the Third Amended Credit Agreement) as of any fiscal quarter end.
(2) Minimum ratio of Consolidated EBITDA (as defined in the Third Amended Credit Agreement and adjusted for certain expenditures) to Consolidated interest expense (as defined in the Third Amended Credit Agreement) for any period of four consecutive fiscal quarters.
(3) Maximum level of the aggregate amount of all Facility Capital Expenditures (as defined in the Third Amended Credit Agreement) in any fiscal year.

As of December 31, 2019, we believe we were in compliance with all covenants set forth in the Third Amended Credit Agreement.

As of December 31, 2019, we had outstanding borrowings of $440 million under the Third Amended Credit Agreement, with additional available borrowings of approximately $133.8 million, based on the leverage ratio required pursuant to the Third Amended Credit Agreement. Our interest rate as of December 31, 2019 was a fixed rate of 2.62% on $175 million as a result of an interest rate swap (see Note 9) and a variable floating rate of 3.30% on $265 million. Our interest rate as of December 31, 2018 was a fixed rate of 2.12% on $175 million as a result of an interest rate swap and a variable floating rate of 3.52% on $213.5 million.

Future Payments

Future minimum principal payments on our long-term debt as of December 31, 2019, are as follows (in thousands):

Years Ending December 31,	Future Minimum Principal Payments
2020	$ 7,500
2021	7,500
2022	8,438
2023	11,250
2024	405,312
Total future minimum principal payments	$ 440,000

9. DERIVATIVES

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

We formally document, designate and assess the effectiveness of transactions that receive hedge accounting initially and on an ongoing basis. For qualifying hedges, the change in fair value is deferred in accumulated other comprehensive income, a component of stockholders' equity in the accompanying consolidated balance sheets, and recognized in earnings at the same time the hedged item affects earnings. Changes in the fair value of derivatives not designated as hedging instruments are recorded in earnings throughout the term of the derivative.

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

Derivatives Designated as Cash Flow Hedges

On August 5, 2016, we entered into a pay-fixed, receive-variable interest rate swap with a current notional amount of $175 million with Wells Fargo to fix the one-month LIBOR rate at 1.12%. The variable portion of the interest rate swap is tied to the one-month LIBOR rate (the benchmark interest rate). On a monthly basis, the interest rates under both the interest rate swap and the underlying debt reset, the swap is settled with the counterparty, and interest is paid. The interest rate swap is scheduled to expire on July 6, 2021.

On December 23, 2019, we entered into a pay-fixed, receive-variable interest rate swap with a notional amount of $75 million with Wells Fargo to fix the one-month LIBOR rate at 1.71% for the period from July 6, 2021 to July 31, 2024. The variable portion of the interest rate swap is tied to the one-month LIBOR rate (the benchmark interest rate). On a monthly basis, the interest rates under both the interest rate swap and the underlying debt will reset, the swap will be settled with the counterparty, and interest will be paid.

At December 31, 2019 and 2018, our interest rate swaps qualified as cash flow hedges. The fair value of our interest rate swaps at December 31, 2019 was an asset of approximately $1.2 million (partially offset by approximately $307,000 in deferred taxes), and a liability of ($290,000), partially offset by approximately ($75,000) in deferred taxes. The fair value of our interest rate swap at December 31, 2018 was an asset of approximately $5.8 million, which was offset by approximately $1.5 million in deferred taxes.

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

Derivatives Designated as Cash Flow Hedges

For derivative instruments that are designated and qualify as cash flow hedges, the gain or loss on the derivative instrument is temporarily reported as a component of other comprehensive income (loss) and then reclassified into earnings in the same line item associated with the forecasted transaction and in the same period or periods during which the hedged transaction affects earnings. We entered into forward contracts on various foreign currencies to manage the risk associated with forecasted exchange rates which impact revenues, cost of sales, and operating expenses in various international markets. The objective of the hedges is to reduce the variability of cash flows associated with the forecasted purchase or sale of the associated foreign currencies.

We enter into approximately 150 cash flow foreign currency hedges every month. As of December 31, 2019, 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	8,540
Brazilian Real	BRL	10,315
Canadian Dollar	CAD	8,025
Swiss Franc	CHF	3,660
Chinese Renminbi	CNY	591,000
Danish Krone	DKK	33,575
Euro	EUR	37,750
British Pound	GBP	8,380
Japanese Yen	JPY	1,145,000
Korean Won	KRW	8,950,000
Mexican Peso	MXN	527,000
Norwegian Krone	NOK	15,475
Swedish Krona	SEK	54,170

Derivatives Not Designated as Cash Flow Hedges

We forecast our net exposure in various receivables and payables to fluctuations in the value of various currencies, and we enter into foreign currency forward contracts to mitigate that exposure. We enter into approximately 20 foreign

currency fair value hedges every month. As of December 31, 2019, we had entered into foreign currency forward contracts related to those balance sheet accounts with the following notional amounts (in thousands and in local currencies):

Currency	Symbol	Forward Notional Amount
Australian Dollar	AUD	14,282
Brazilian Real	BRL	19,500
Canadian Dollar	CAD	1,706
Swiss Franc	CHF	306
Chinese Renminbi	CNY	52,598
Danish Krone	DKK	5,987
Euro	EUR	752
British Pound	GBP	7,594
Hong Kong Dollar	HKD	11,000
Japanese Yen	JPY	1,530,000
Korean Won	KRW	4,868,000
Mexican Peso	MXN	35,000
Norwegian Krone	NOK	3,767
New Zealand Dollar	NZD	1,542
Swedish Krona	SEK	13,577
Singapore Dollar	SGD	1,790
South African Rand	ZAR	50,843

Balance Sheet Presentation of Derivatives. As of December 31, 2019 and 2018, all derivatives, both those designated as hedging instruments and those that were not designated as hedging instruments, were recorded gross at fair value on our consolidated balance sheets. We are not subject to any master netting agreements.

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

		Fair Value	
	Balance Sheet Location	December 31, 2019	December 31, 2018
Derivative instruments designated as hedging instruments			
Assets			
Interest rate swaps	Other assets (long-term)	$ 1,192	$ 5,772
Foreign currency forward contracts	Prepaid expenses and other assets	1,663	613
Foreign currency forward contracts	Other assets (long-term)	466	151
(Liabilities)			
Interest rate swaps	Other long-term obligations	(290)	—
Foreign currency forward contracts	Accrued expenses	(1,813)	(711)
Foreign currency forward contracts	Other long-term obligations	(764)	(101)
Derivative instruments not designated as hedging instruments			
Assets			
Foreign currency forward contracts	Prepaid expenses and other assets	$ 318	$ 814
(Liabilities)			
Foreign currency forward contracts	Accrued expenses	(1,678)	(796)

Income Statement Presentation of Derivatives

Derivatives Designated as Cash Flow Hedges

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

	Amount of Gain/(Loss) recognized in OCI Year Ended December 31,				Amount of Gain/(Loss) reclassified from AOCI Year ended December 31,		
	2019	2018	2017		2019	2018	2017
Derivative instrument				**Location in statements of income**			
Interest rate swaps	$ (2,830)	$ 1,559	$ 853	*Interest expense*	$ 2,040	$ 1,537	$ 95
Foreign currency forward contracts	(587)	539	491	*Revenue*	577	136	(277)
				Cost of sales	(578)	361	625

All other amounts included in earnings related to designated cash flow hedges are immaterial.

As of December 31, 2019, approximately $315,000, or $234,000 after taxes, was expected to be reclassified from accumulated other comprehensive income to earnings in revenue and cost of sales over the succeeding twelve months. As of December 31, 2019, approximately $877,000, or $651,000 after taxes, was expected to be reclassified from accumulated other comprehensive income to earnings in interest expense over the succeeding twelve months.

Derivatives Not Designated as Hedging Instruments

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

		Year ended December 31,		
Derivative Instrument	**Location in statements of income**	**2019**	**2018**	**2017**
Foreign currency forward contracts	Other income (expense)	$ (307)	$ 4,147	$ (4,746)

See Note 16 for more information about our derivatives.

10. COMMITMENTS AND CONTINGENCIES

We are obligated under non-terminable operating leases for manufacturing facilities, finished good distribution centers, office space, equipment, vehicles, and land. See Note 18 for disclosures regarding these operating leases.

Loan Commitment. We have committed to provide loans of up to an additional €2 million at the discretion of Selio at a rate of 5% per annum. The current note receivable balance from Selio is $250,000. If exercised these loans would be securitized by all the present and future assets and property of the borrower.

Royalties. As of December 31, 2019, we had entered into a number of agreements to license or acquire rights to certain intellectual property which require us to make royalty payments during the term of the agreements generally based on a percentage of sales. Total royalty expense during the years ended December 31, 2019, 2018 and 2017, approximated $6.7 million, $5.3 million and $4.4 million, respectively. Minimum contractual commitments under royalty agreements to be paid within twelve months of December 31, 2019 were not significant. See Note 3 for discussion of future royalty commitments related to acquisitions.

Litigation. In the ordinary course of business, we are involved in various claims and litigation matters. These claims and litigation matters may include actions involving product liability, intellectual property, contract disputes, and employment or other matters that are significant to our business. For example, in December 2019 our company, our Chief Executive Officer and our Chief Financial Officer were named in a complaint filed in the Central District of California,

which alleges violations of certain federal securities laws. 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 have responded to the subpoena, as well as additional related requests. We have incurred, and anticipate that we will continue to incur, substantial costs in connection with the matter. The investigation is ongoing and at this stage we are unable to predict its scope, duration or outcome. Investigations such as this may result in the imposition of, among other things, significant damages, injunctions, fines, or civil or criminal claims or penalties against our company or individuals.

In the event of unexpected further developments, it is possible that the ultimate resolution of any of the foregoing matters, or other similar matters, if resolved in a manner unfavorable to us, may be materially adverse to our business, financial condition, results of operations or liquidity. Legal costs for these matters, such as outside counsel fees and expenses, are charged to expense in the period incurred.

11. EARNINGS PER COMMON SHARE (EPS)

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

	2019	2018	2017
Net income	$ 5,451	$ 42,017	$ 27,523
Average common shares outstanding	55,075	52,268	48,805
Basic EPS	$ 0.10	$ 0.80	$ 0.56
Average common shares outstanding	55,075	52,268	48,805
Effect of dilutive stock options	1,160	1,663	1,296
Total potential shares outstanding	56,235	53,931	50,101
Diluted EPS	$ 0.10	$ 0.78	$ 0.55
Stock options excluded as the impact was anti-dilutive	1,750	396	381

12. EMPLOYEE STOCK PURCHASE PLAN, STOCK OPTIONS AND WARRANTS.

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

2018 Long-Term Incentive Plan. In June 2018, our Board of Directors adopted and our shareholders approved, the Merit Medical Systems, Inc. 2018 Long-Term Incentive Plan, which was subsequently amended effective December 14, 2018 (the “2018 Incentive Plan”) to supplement the Merit Medical Systems, Inc. 2006 Long-Term Incentive plan (the "2006 Incentive Plan"). The 2018 Incentive Plan provides for the granting of stock options, stock appreciation rights, restricted stock, stock units (including restricted stock units) and performance awards. Options may be granted to directors, officers, outside consultants and key employees and may be granted upon such terms and such conditions as the Compensation Committee of our Board of Directors determines. Options will typically vest on an annual basis over a three to five-year life with a contractual life of 7 years. As of December 31, 2019, a total of 1,714,323 shares remained available to be issued under the 2018 Incentive Plan.

2006 Long-Term Incentive Plan. In May 2006, our Board of Directors adopted, and our shareholders approved, the 2006 Incentive Plan. As of December 31, 2019, the 2006 Incentive Plan was no longer being used for the granting of equity awards. However, as of December 31, 2019, options granted under this plan were still outstanding, vesting, and being exercised and will continue to be outstanding until the vesting periods end and the terms of the equity awards expire.

Employee Stock Purchase Plan. We have a non-qualified Employee Stock Purchase Plan ("ESPP"), which has an expiration date of June 30, 2026. As of December 31, 2019, the total number of shares of common stock that remained available to be issued under our non-qualified plan was 69,877 shares. ESPP participants purchase shares on a quarterly basis at a price equal to 95% of the market price of the common stock at the end of the applicable offering period.

Stock-Based Compensation Expense. The stock-based compensation expense before income tax expense for the years ended December 31, 2019, 2018 and 2017, consisted of the following (in thousands):

	2019	2018	2017
Cost of sales	$ 1,289	$ 870	$ 632
Research and development	961	553	376
Selling, general and administrative	7,132	4,694	3,067
Stock-based compensation expense before taxes	$ 9,382	$ 6,117	$ 4,075

We recognize stock-based compensation expense (net of a forfeiture rate) for those awards which are expected to vest on a straight-line basis over the requisite service period. We estimate the forfeiture rate based on our historical experience and expectations about future forfeitures. As of December 31, 2019, the total remaining unrecognized compensation cost related to non-vested stock options, net of expected forfeitures, was approximately $28.6 million and is expected to be recognized over a weighted average period of 3.00 years.

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

	2019	2018	2017
Risk-free interest rate	1.38% - 2.56%	2.63% - 2.77%	1.77% - 1.83%
Expected option term	3.0 - 5.0 years	5.0 years	5.0 years
Expected dividend yield	—	—	—
Expected price volatility	28.66% - 39.38%	34.06% - 34.32%	33.81% - 34.07%

The average risk-free interest rate is determined using the U.S. Treasury rate in effect as of the date of grant, based on the expected term of the stock option. We determine the expected term of the stock options using the historical exercise behavior of employees. The expected price volatility was determined using a weighted average of daily historical volatility of our stock price over the corresponding expected option life and implied volatility based on recent trends of the daily historical volatility. For options with a vesting period, compensation expense is recognized on a straight-line basis over the service period, which corresponds to the vesting period. During the years ended December 31, 2019, 2018 and 2017, approximately 1.2 million, 692,000 and 1.3 million stock-based compensation grants were made, respectively, for a total fair value of approximately $20.9 million, $11.1 million and $12.4 million, net of estimated forfeitures, respectively.

The table below presents information related to stock option activity for the years ended December 31, 2019, 2018 and 2017 (in thousands):

	2019	2018	2017
Total intrinsic value of stock options exercised	$ 9,910	$ 25,692	$ 9,264
Cash received from stock option exercises	4,837	8,510	5,552
Excess tax benefit from the exercise of stock options	1,654	4,278	2,264

Changes in stock options for the year ended December 31, 2019, consisted of the following (shares and intrinsic value in thousands):

	Number of Shares	Weighted Average Exercise Price	Remaining Contractual Term (in years)	Intrinsic Value
Beginning balance	3,507	$ 26.30		
Granted	1,244	52.45		
Exercised	(288)	16.48		
Forfeited/expired	(144)	37.86		
Outstanding at December 31	4,319	34.10	4.40	$ 23,512
Exercisable	1,532	21.98	3.07	16,403
Ending vested and expected to vest	4,186	33.77	4.36	23,344

The weighted average grant-date fair value of options granted during the years ended December 31, 2019, 2018 and 2017 was $16.78, $16.05 and $9.57, respectively.

The following table summarizes information about stock options outstanding at December 31, 2019 (shares in thousands):

	Options Outstanding			Options Exercisable	
Range of Exercise	Number Outstanding	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$9.95 - $17.27	1,052	2.27	$ 15.04	795	$ 14.62
$18.80 - $25.89	335	3.32	$ 20.36	200	$ 20.25
$28.20	914	4.26	$ 28.20	335	$ 28.20
$28.93 - $50.50	957	5.29	$ 42.02	202	$ 42.36
$51.31 - $57.26	1,061	6.18	$ 55.28	—	$ —
$9.95 - $57.26	4,319			1,532	

13. SEGMENT REPORTING AND FOREIGN OPERATIONS

We report our operations in two operating segments: cardiovascular and endoscopy. Our cardiovascular segment consists of cardiology and radiology medical device products which assist in diagnosing and treating coronary artery disease, peripheral vascular disease and other non-vascular diseases and includes embolotherapeutic, cardiac rhythm management ("CRM"), electrophysiology ("EP"), critical care, Cianna Medical, interventional oncology and spine devices, and breast cancer localization and guidance. Our endoscopy segment consists of gastroenterology and pulmonology medical device products which assist in the palliative treatment of expanding esophageal, tracheobronchial and biliary strictures caused by malignant tumors. We evaluate the performance of our operating segments based on operating income (loss). See Note 2 for a detailed breakout of our sales by operating segment and product group, disaggregated between domestic and international sales.

During the years ended December 31, 2019, 2018 and 2017, we had international sales of approximately $419.1 million, $386.3 million and $307.1 million, respectively, or approximately 42%, 44% and 42%, respectively, of net sales, primarily in China, Japan, Germany, France, the United Kingdom, Australia, and Russia. China represents our most significant international sales market with sales of approximately $113.3 million, $92.7 million, and $73.4 million for the years ended December 31, 2019, 2018 and 2017, respectively. International sales are attributed based on location of the customer receiving the product.

Our long-lived assets (which are comprised of our net property, plant and equipment) by geographic area at December 31, 2019, 2018 and 2017, consisted of the following (in thousands):

	2019	2018	2017
United States	$ 273,816	$ 231,864	$ 202,504
Ireland	44,912	45,283	45,671
Other foreign countries	60,057	54,305	44,645
Total	$ 378,785	$ 331,452	$ 292,820

Financial information relating to our reportable operating segments and reconciliations to the consolidated totals for the years ended December 31, 2019, 2018 and 2017, are as follows (in thousands):

	2019	2018	2017
Net Sales			
Cardiovascular	$ 960,981	$ 849,477	$ 700,613
Endoscopy	33,871	33,276	27,239
Total net sales	994,852	882,753	727,852
Operating Expenses			
Cardiovascular	382,313	321,461	281,095
Endoscopy	34,619	14,692	12,089
Total operating expenses	416,932	336,153	293,184
Operating Income			
Cardiovascular	25,780	49,289	24,819
Endoscopy	(10,346)	9,328	8,250
Total operating income	15,434	58,617	33,069
Total other income (expense) - net	(13,241)	(9,098)	2,812
Income tax expense (benefit)	(3,258)	7,502	8,358
Net income	$ 5,451	$ 42,017	$ 27,523

Total assets by business segment at December 31, 2019, 2018 and 2017, consisted of the following (in thousands):

	2019	2018	2017
Cardiovascular	$ 1,745,057	$ 1,588,970	$ 1,103,806
Endoscopy	12,264	31,042	8,005
Total	$ 1,757,321	$ 1,620,012	$ 1,111,811

Total depreciation and amortization by business segment for the years ended December 31, 2019, 2018 and 2017 consisted of the following (in thousands):

	2019	2018	2017
Cardiovascular	$ 91,151	$ 68,722	$ 52,700
Endoscopy	949	824	882
Total	$ 92,100	$ 69,546	$ 53,582

Total capital expenditures for property and equipment by business segment for the years ended December 31, 2019, 2018 and 2017 consisted of the following (in thousands):

	2019	2018	2017
Cardiovascular	$ 77,631	$ 63,032	$ 38,437
Endoscopy	542	292	186
Total	$ 78,173	$ 63,324	$ 38,623

14. EMPLOYEE BENEFIT PLANS

We have a contributory 401(k) savings and profit sharing plan (the "Plan") covering all U.S. full-time employees who are at least 18 years of age. The Plan has a 90-day minimum service requirement. We may contribute, at our discretion, matching contributions based on the employees' compensation. Contributions we made to the Plan for the years ended December 31, 2019, 2018 and 2017, totaled approximately $3.1 million, $3.5 million and $2.4 million, respectively.

We also have defined contribution plans covering some of our foreign employees. We contribute between 2% and 32% of the employee's compensation for certain foreign non-management employees, and between 2% and 32% of the employee's compensation for certain foreign management employees. Contributions made to these plans for the years ended December 31, 2019, 2018 and 2017, totaled approximately $3.5 million, $3.0 million and $2.3 million, respectively.

15. QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)

Quarterly data for the years ended December 31, 2019 and 2018 consisted of the following (in thousands, except per share amounts):

	Quarter Ended			
	March 31	June 30	September 30	December 31
2019				
Net sales	$ 238,349	$ 255,532	$ 243,049	$ 257,922
Gross profit	104,636	111,964	104,136	111,630
Income (loss) from operations	9,523	12,201	(2,881)	(3,409)
Income tax expense (benefit)	651	2,140	(2,292)	(3,757)
Net income (loss)	6,195	6,859	(3,398)	(4,205)
Basic earnings (loss) per common share	0.11	0.12	(0.06)	(0.08)
Diluted earnings (loss) per common share	0.11	0.12	(0.06)	(0.08)
2018				
Net sales	$ 203,035	$ 224,810	$ 221,659	$ 233,249
Gross profit	88,056	100,009	102,039	104,666
Income from operations	8,781	15,114	21,061	13,661
Income tax expense	1,090	624	2,766	3,022
Net income	5,269	10,941	16,619	9,188
Basic earnings per common share	0.10	0.22	0.31	0.17
Diluted earnings per common share	0.10	0.21	0.30	0.16

As discussed in Note 1, an impairment charge of $20.5 was recorded in the three months ended December 31, 2019 due to our write-off of our NinePoint note receivable and purchase option, along with $1.6 million of accrued interest. Basic and diluted earnings per share are computed independently for each of the quarters presented. Therefore, the sum of the quarterly amounts may not equal the total computed for the year.

16. FAIR VALUE MEASUREMENTS

Assets (Liabilities) Measured at Fair Value on a Recurring Basis

Our financial assets and (liabilities) carried at fair value measured on a recurring basis as of December 31, 2019 and 2018, consisted of the following (in thousands):

			Fair Value Measurements Using		
	Total Fair Value at December 31, 2019	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Interest rate contract [1]	$ 1,192	$ —	$ 1,192	$ —
Interest rate contract [1]	$ (290)	—	$ (290)	$ —
Foreign currency contract assets, current and long-term [2]	$ 2,447	$ —	$ 2,447	$ —
Foreign currency contract liabilities, current and long-term [3]	$ (4,255)	$ —	$ (4,255)	$ —
Contingent consideration liabilities	$ (76,709)	$ —	$ —	$ (76,709)

			Fair Value Measurements Using	
	Total Fair Value at December 31, 2018	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Interest rate contract [1]	$ 5,772	$ —	$ 5,772	$ —
Foreign currency contract assets, current and long-term [2]	$ 1,578	$ —	$ 1,578	$ —
Foreign currency contract liabilities, current and long-term [3]	$ (1,608)	$ —	$ (1,608)	$ —
Contingent receivable asset	$ 607	$ —	$ —	$ 607
Contingent consideration liabilities	$ (82,236)	$ —	$ —	$ (82,236)

(1) The fair value of the interest rate contracts is determined using Level 2 fair value inputs and is recorded as other long-term assets or other long-term obligations in the consolidated balance sheets.

(2) The fair value of the foreign currency contract assets (including those designated as hedging instruments and those not designated as hedging instruments) is determined using Level 2 fair value inputs and is recorded as prepaid and other assets or other long-term assets in the consolidated balance sheets.

(3) The fair value of the foreign currency contract liabilities (including those designated as hedging instruments and those not designated as hedging instruments) is determined using Level 2 fair value inputs and is recorded as accrued expenses or other long-term obligations in the consolidated balance sheets.

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

contingent consideration liability during the years ended December 31, 2019 and 2018, consisted of the following (in thousands):

	2019	2018
Beginning balance	$ 82,236	$ 10,956
Contingent consideration liability recorded as the result of acquisitions (see Note 3)	10,517	72,209
Fair value adjustments recorded to income	(304)	(698)
Contingent payments made	(15,740)	(231)
Ending balance	$ 76,709	$ 82,236

As of December 31, 2019, approximately $48.1 million was included in other long-term obligations and approximately $28.6 million was included in accrued expenses in our consolidated balance sheet. As of December 31, 2018, approximately $58.5 million was included in other long-term obligations and $23.8 was included in accrued expenses in our consolidated balance sheet. The cash paid to settle the contingent consideration liability recognized at fair value as of the acquisition date (including measurement-period adjustments) has been reflected as a cash outflow from financing activities in the accompanying consolidated statements of cash flows.

During the year ended December 31, 2016, we sold an equity investment for cash and for the right to receive additional payments based on various contingent milestones. We determined the fair value of the contingent payments using Level 3 inputs defined under authoritative guidance for fair value measurements, and we recorded a contingent receivable asset, which as of December 31, 2018 had a value of approximately $607,000. We recorded all changes in fair value to operating expenses as part of our cardiovascular segment in our consolidated statements of income. For the year ended December 31, 2019, there were no significant changes to the fair value of the contingent receivable which impacted net income and we collected payments of approximately $535,000. As of December 31, 2019, the receivable was settled in full and there was no balance remaining to collect. During the year ended December 31, 2018, there were no significant changes to the fair value of the contingent receivable which impacted net income and we collected payments of approximately $153,000. As of December 31, 2018, approximately $607,000 was included in other receivables as a current asset in our consolidated balance sheet.

The recurring Level 3 measurement of our contingent consideration liability and contingent receivable includes the following significant unobservable inputs at December 31, 2019 and 2018 (amounts in thousands):

Contingent consideration asset or liability	Fair value at December 31, 2019	Valuation technique	Unobservable inputs	Range
Revenue-based royalty payments contingent liability	$ 7,710	Discounted cash flow	Discount rate	13% - 24%
			Projected year of payments	2020-2034
Revenue milestones contingent liability	$ 66,114	Monte Carlo simulation	Discount rate	9% - 13.5%
			Projected year of payments	2020-2023
Regulatory approval contingent liability	$ 2,885	Scenario-based method	Discount rate	2.4%
			Probability of milestone payment	65%
			Projected year of payment	2022

Contingent consideration asset or liability	Fair value at December 31, 2018	Valuation technique	Unobservable inputs	Range
Revenue-based royalty payments contingent liability	$ 10,661	Discounted cash flow	Discount rate	9.9% - 25%
			Projected year of payments	2018-2037
Supply chain milestone contingent liability	$ 13,593	Discounted cash flow	Discount rate	5.3%
			Probability of milestone payment	95%
			Projected year of payments	2019
Revenue milestones contingent liability	$ 57,982	Discounted cash flow	Discount rate	3.3% - 13%
			Projected year of payments	2019-2023
Contingent receivable asset	$ 607	Discounted cash flow	Discount rate	10%
			Probability of milestone payment	67%
			Projected year of payments	2019

The contingent consideration liability and contingent receivable are re-measured to fair value each reporting period using projected revenues, discount rates, probabilities of payment, and projected payment dates. Projected contingent payment amounts are discounted back to the current period using a discounted cash flow model. Projected revenues are based on our most recent internal operational budgets and long-range strategic plans. An increase (decrease) in either the discount rate or the time to payment, in isolation, may result in a significantly lower (higher) fair value measurement. A decrease in the probability of any milestone payment may result in lower fair value measurements. Our determination of the fair value of the contingent consideration liability and contingent receivable could change in future periods based upon our ongoing evaluation of these significant unobservable inputs. We intend to record any such change in fair value to operating expenses in our consolidated statements of income.

Fair Value of Other Financial Instruments

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

We recognize or disclose the fair value of certain assets, such as non-financial assets, primarily property and equipment, intangible assets and goodwill in connection with impairment evaluations. All of our nonrecurring valuations use significant unobservable inputs and therefore fall under Level 3 of the fair value hierarchy. During the years ended December 31, 2019, 2018 and 2017, we had losses of approximately $3.3 million, $657,000 and $809,000, respectively, related to certain acquired intangible assets (see Note 5). In addition, we had losses of approximately $837,000 and $157,000 for the years ended December 31, 2019 and 2018, respectively, related to the measurement of other non-financial assets, property and equipment and patents, at fair value on a nonrecurring basis subsequent to their initial recognition.

Our equity investments in privately held companies, including options to acquire these companies, were $17.1 million and $22.5 million at December 31, 2019 and 2018, respectively. Our outstanding long-term notes receivable, including accrued interest, were approximately $2.7 million and $13.5 million, as of December 31, 2019 and 2018, respectively. We assess the credit support available and the value of any underlying collateral to determine if there are any other-than temporary impairments. Credit losses represent the difference between the present value of cash flows expected to be collected on these notes receivable and the amortized cost basis. For the year ended December 31, 2019 we recorded impairment charges of $20.5 million due to our write-off of our NinePoint note receivable and purchase option due to our assessment of the collectability of the note receivable and management’s decision not to exercise our option to purchase

this business. We also wrote off $1.6 million of accrued interest related to the note receivable. These valuations use significant unobservable inputs and therefore fall under Level 3 of the fair value hierarchy.

17. COMMON STOCK AND ACCUMULATED OTHER COMPREHENSIVE INCOME

On July 30, 2018, we closed a public offering of 4,025,000 shares of common stock and received proceeds of approximately $205.0 million, which is net of approximately $12.0 million in underwriting discounts and commissions and approximately $366,000 in other direct cost incurred in connection with this equity offering. The net proceeds from the offering were used primarily to repay outstanding borrowings (principally revolving credit loans) under our Second Amended Credit Agreement.

On March 28, 2017, we closed a public offering of 5,175,000 shares of common stock and received 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 in connection with this equity offering. The net proceeds from the offering were used primarily to repay outstanding borrowings (including our term loan and revolving credit loans) under our Second Amended Credit Agreement.

The changes in each component of Accumulated Other Comprehensive Income (Loss) for the years ended December 31, 2019 and 2018 were as follows:

	Cash Flow Hedges	Foreign Currency Translation	Total
December 31, 2016	**$ 2,923**	**$ (4,805)**	**$ (1,882)**
OCI (loss)	1,344	3,117	4,461
Income taxes	(350)	(252)	(602)
Reclassifications to:			
Revenue	277		277
Cost of Sales	(625)		(625)
Interest Expense	(95)		(95)
Net OCI (loss)	551	2,865	3,416
December 31, 2017	**3,474**	**(1,940)**	**1,534**
OCI (loss)	2,098	(3,606)	(1,508)
Income taxes	(16)	(9)	(25)
Reclassifications to:			
Revenue	(136)		(136)
Cost of Sales	(361)		(361)
Interest Expense	(1,537)		(1,537)
Net OCI (loss)	48	(3,615)	(3,567)
December 31, 2018	**3,522**	**(5,555)**	**(2,033)**
OCI (loss)	(3,417)	(18)	(3,435)
Income taxes	1,404	61	1,465
Reclassifications to:			
Revenue	(577)		(577)
Cost of Sales	578		578
Interest Expense	(2,040)		(2,040)
Net OCI (loss)	(4,052)	43	(4,009)
Reclassification of stranded tax effects [1]	748		748
December 31, 2019	**$ 218**	**$ (5,512)**	**$ (5,294)**

(1) Amounts reclassified to retained earnings as a result of the adoption of ASU 2018-02.

18. LEASES

We adopted ASC 842 using the modified retrospective approach, electing the practical expedient that allows us not to restate our comparative periods prior to the adoption of the standard on January 1, 2019. As such, the disclosures required under ASC 842 are not presented for periods before the date of adoption. For the comparative periods prior to adoption, we present the disclosures which were required under ASC 840.

We have operating leases for facilities used for manufacturing, research and development, sales and distribution, and office space, as well as leases for manufacturing and office equipment, vehicles, and land. Our leases have remaining terms of less than one year to approximately 30 years. A number of our lease agreements contain options to renew at our discretion for periods of up to 15 years and options to terminate the leases within one year. The lease term used to calculate ROU assets and lease liabilities includes renewal and termination options that are deemed reasonably certain to be exercised. Lease agreements with lease and non-lease components are generally accounted for as a single lease component. We do not have any bargain purchase options in our leases. For leases with an initial term of one year or less, we do not record a ROU asset or lease liability on our consolidated balance sheet. Substantially all of the ROU assets and lease liabilities as of December 31, 2019 recorded on our consolidated balance sheet are related to our cardiovascular segment.

From time to time we enter into agreements to sublease a portion of our facilities to third-parties. Such sublease income is not material. We also lease certain hardware consoles to customers and record rental revenue as a component of net sales. Rental revenue under such console leasing arrangements for the years ended December 31, 2019 and 2018 was not significant.

The following was included in our consolidated balance sheet as of December 31, 2019 (in thousands):

	As of December 31, 2019
Assets	
ROU operating lease assets	$ 80,244
Liabilities	
Short-term operating lease liabilities	$ 11,550
Long-term operating lease liabilities	72,714
Total operating lease liabilities	$ 84,264

During the year ended December 31, 2015, we entered into sale and leaseback transactions to finance certain production equipment for approximately $2.0 million. At that time, we deferred the gain from the sale and leaseback transaction, of which approximately $93,000 remained as of December 31, 2018. As part of the adoption of ASC 842, we wrote-off the deferred gain as an adjustment to equity through retained earnings as of January 1, 2019.

We recognize lease expense on a straight-line basis over the term of the lease. Net lease cost for the years ended December 31, 2019, 2018, and 2017 was approximately $16.5 million, $14.5 million, and $13.6 million, respectively. The components of lease costs for the year ended December 31, 2019 were as follows, in thousands:

Lease Cost	Classification	Year Ended December 31, 2019
Operating lease cost (a)	Selling, general and administrative expenses	$ 16,828
Sublease (income) (b)	Selling, general and administrative expenses	(361)
Net lease cost		$ 16,467

(a) Includes expense related to short-term leases and variable payments, which were not significant.
(b) Does not include rental revenue from leases of hardware consoles to customers, which was not significant.

Supplemental cash flow information for the year ended December 31, 2019 was as follows:

	Year Ended December 31, 2019
Cash paid for amounts included in the measurement of lease liabilities	$ 14,646
Right-of-use assets obtained in exchange for lease obligations	$ 10,637

Generally, our lease agreements do not specify an implicit rate. Therefore, we estimate our incremental borrowing rate, which is defined as the interest rate we would pay to borrow on a collateralized basis, considering such factors as length of lease term and the risks of the economic environment in which the leased asset operates. As of December 31, 2019, the following disclosures for remaining lease term and discount rates were applicable:

	December 31, 2019
Weighted average remaining lease term	12.3 years
Weighted average discount rate	3.2%

As of December 31, 2019, maturities of operating lease liabilities were as follows, in thousands:

Year ended December 31,	Amounts due under Operating Leases
2020	$ 13,949
2021	12,938
2022	10,368
2023	8,273
2024	7,330
Thereafter	53,501
Total lease payments	106,359
Less: Imputed interest	(22,095)
Total	$ 84,264

As previously disclosed in our 2018 Form 10-K under the prior guidance of ASC 840, minimum payments under operating lease agreements as of December 31, 2018 were as follows, in thousands:

Year ended December 31,	Operating Leases
2019	$ 13,421
2020	11,319
2021	9,995
2022	8,053
2023	6,953
Thereafter	52,754
Total minimum lease payments	$ 102,495

As of December 31, 2019, we had additional operating leases for office space that had not yet commenced. These leases will commence during 2019 and are not deemed material.

Supplementary Financial Data

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

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

None.

Item 9A. Controls and Procedures.

EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934 ("Exchange Act"), as of December 31, 2019. Based on this evaluation, our principal executive officer and principal financial officer concluded that as of December 31, 2019, our disclosure controls and procedures were effective, at a reasonable assurance level, to ensure that information we are required to disclose in the reports we file or submit under the Exchange Act is (a) recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and is (b) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2019. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in *Internal Control-Integrated Framework (2013)*. Based on the criteria discussed above and our management's assessment, our management concluded that, as of December 31, 2019, our internal control over financial reporting was effective.

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

During the quarter ended December 31, 2019, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934).

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Merit Medical Systems, Inc. and subsidiaries (the "Company") as of December 31, 2019, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control — Integrated Framework (2013) issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2019, of the Company and our report dated March 2, 2020, expressed an unqualified opinion on those financial statements and included an explanatory paragraph regarding the Company's adoption of the FASB's new standard related to leases.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

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

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ DELOITTE & TOUCHE LLP
Salt Lake City, Utah
March 2, 2020

Item 9B. Other Information.

None.

PART III

Items 10, 11, 12, 13 and 14.

The information required by these items is incorporated by reference to our definitive proxy statement relating to our 2020 Annual Meeting of Shareholders. We currently anticipate that our definitive proxy statement will be filed with the SEC not later than 120 days after December 31, 2019, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) Documents filed as part of this Report:

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

(2) Financial Statement Schedule.

— Schedule II - Valuation and qualifying accounts

Years Ended December 31, 2019, 2018 and 2017

(In thousands)

Description	Balance at Beginning of Year	Additions Charged to Costs and Expenses (a)	Deduction (b)	Balance at End of Year
ALLOWANCE FOR UNCOLLECTIBLE ACCOUNTS:				
2017	(1,587)	(1,012)	830	(1,769)
2018	(1,769)	(1,055)	469	(2,355)
2019	(2,355)	(1,163)	410	(3,108)

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

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

Years Ended December 31, 2019, 2018 and 2017
(In thousands)

Description	Balance at Beginning of Year	Additions Charged to Costs and Expenses (c)	Deduction	Balance at End of Year
TAX VALUATION ALLOWANCE:				
2017	(3,786)	(636)	—	(4,422)
2018	(4,422)	(567)	—	(4,989)
2019	(4,989)	—	345	(4,644)

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

(b) Exhibits:

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

Exhibit No.	Index to Exhibits
1.1	Underwriting Agreement, dated March 22, 2017, by and among Merit Medical Systems, Inc., Merrill Lynch, Pierce, Fenner & Smith Incorporated, and Piper Jaffray & Co.*
1.2	Underwriting Agreement, dated July 25, 2018, by and among Merit Medical Systems, Inc., Wells Fargo Securities, LLC and Piper Jaffray & Co.*
2.1	Asset Purchase Agreement by and between Merit Medical Systems, Inc. and Becton, Dickinson and Company dated November 15, 2017*
2.2	Agreement and Plan of Merger, dated October 1, 2018, by and among Merit Medical Systems, Inc., CMI Transaction Co., Cianna Medical, Inc. and Fortis Advisors LLC, as the Securityholder's Representative *

2.3	Asset Purchase Agreement, dated December 14, 2018, by and among Merit Medical Systems, Inc., Vascular Insights, LLC and VI Management, Inc.*
3.1	Amended and Restated Articles of Incorporation dated May 31, 2018*
3.2	Third Amended and Restated Bylaws dated May 31, 2018*
4.1	Specimen Certificate of the Common Stock*
4.2	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934
10.1	Merit Medical Systems, Inc. Long Term Incentive Plan (as amended and restated) dated March 25, 1996*†
10.2	Lease Agreement dated as of June 8, 1993 for office and manufacturing facility*
10.3	Amended and Restated Deferred Compensation Plan*†
10.4	Seventh Amendment to the First Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan*†
10.5	Merit Medical Systems, Inc. Amended and Restated Deferred Compensation Plan, effective January 1, 2008*†
10.6	Second Amendment to the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan*†
10.7	Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan*†
10.8	First Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, effective September 19, 2010*†
10.9	Second Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated November 29, 2010 *†
10.10	Third Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, effective October 1, 2010*†
10.11	Fourth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated December 31, 2011*†
10.12	Fifth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated December 28, 2012*†
10.13	Sixth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated December 31, 2013.*†
10.14	Seventh Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated June 10, 2014*†
10.15	Eighth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated December 29, 2014*†
10.16	Second Amended and Restated Credit Agreement dated as of July 6, 2016 by and among Merit Medical Systems, Inc., Wells Fargo Bank, National Association, Well Fargo Securities, LLC and the lenders named therein*

10.17	Form of Indemnification Agreement, dated June 13, 2016, between the Company and each of the following individuals: Fred P. Lampropoulos, Kent W. Stanger, Nolan E. Karras, A. Scott Anderson, Franklin J. Miller, M.D., Michael E. Stillabower, M.D., F. Ann Millner, Ed. D., Ronald A. Frost, Joseph C. Wright, Justin J. Lampropoulos, and Brian G. Lloyd*†
10.18	Form of Employment Agreement, dated May 26, 2016 between the Company and each of the following individuals: Ronald A. Frost, Joseph C. Wright, Justin J. Lampropoulos, and Brian G. Lloyd*†
10.19	Employment Agreement, dated May 26, 2016 between the Company and Fred P. Lampropoulos*†
10.20	Third Amendment to the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan dated February 13, 2015*†
10.21	Merit Medical Systems, Inc., Restatement of the 1996 Employee Stock Purchase Plan dated July 1, 2000*†
10.22	First Amendment to the Merit Medical Systems, Inc., 1996 Employee Stock Purchase Plan dated April 1, 2001*†
10.23	Second Amendment to the Merit Medical Systems, Inc., 1996 Employee Stock Purchase Plan dated January 1, 2006*†
10.24	Third Amendment to the Merit Medical Systems, Inc., 1996 Employee Stock Purchase Plan dated April 7, 2006*†
10.25	Fourth Amendment to the Merit Medical Systems, Inc., 1996 Employee Stock Purchase Plan dated February 13, 2015*†
10.26	Indemnification Agreement, dated July 23, 2016, between the Company and David M. Liu*†
10.27	First Amendment to Second Amended and Restated Credit Agreement, dated September 28, 2016*
10.28	Second Amendment to Second Amended and Restated Credit Agreement, dated March 20, 2017, entered into by and among Merit Medical Systems, Wells Fargo Bank, National Association and the lenders and subsidiary guarantors named therein*
10.29	Indemnification Agreement with Thomas J. Gunderson*†
10.30	Third Amendment to Second Amended and Restated Credit Agreement and Incremental Increase Agreement, dated December 13, 2017, entered into by and among Merit Medical Systems, Inc., Wells Fargo Bank National Association and the lenders and subsidiary guarantors named therein*
10.31	First Amendment to Employment Agreement made and entered into by and between Merit Medical Systems, Inc. and Fred P. Lampropoulos as of the 11th day of December, 2017*†
10.32	Form of First Amendment to Employment Agreement for each of Ronald A. Frost, Justin J. Lampropoulos, Joseph C. Wright, and Brian G. Lloyd*†
10.33	First Amendment to Lease Agreement dated May 22, 2017 for office and manufacturing facility*
10.34	Asset Purchase Agreement by and between Merit Medical Systems, Inc. and Becton, Dickinson and Company dated November 15, 2017*

10.35	Fourth Amendment to Second Amended and Restated Credit Agreement, dated March 28, 2018, entered into by and among Merit Medical Systems, Inc., Wells Fargo Bank National Association and the lenders and subsidiary guarantors named therein*
10.36	Merit Medical Systems, Inc. 2018 Long-Term Incentive Plan effective May 24, 2018*†
10.37	Indemnification Agreement dated made and entered into by and between Merit Medical Systems, Inc. and Raul Parra as of the 1st day of August, 2018.*†
10.38	Employment Agreement made and entered into by and between Merit Medical Systems, Inc. and Raul Parra as of the 1st day of August, 2018.*†
10.39	First Amendment to the Merit Medical Systems, Inc. 2018 Long-Term Incentive Plan effective December 14, 2018*†
10.40	Form of Indemnification Agreement, dated December 14, 2018 between the Company and Jill Anderson*†
10.41	Merit Medical Systems, Inc. 2019 Executive Bonus Plan, dated January 1, 2019*†
10.42	Ninth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated August 1, 2016*†
10.43	Tenth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated January 1, 2017*†
10.44	Eleventh Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated January 1, 2019*†
10.45	Twelfth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, effective June 1, 2018*†
10.46	Third Amended and Restated Credit Agreement entered into by and among Merit Medical Systems, Inc., Wells Fargo Bank National Association and the lenders and subsidiary guarantors named therein, dated July 9, 2019*
10.47	Indemnification Agreement with Lynne N. Ward dated August 13, 2019*†
10.48	Thirteenth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, effective January 1, 2019†
21	Subsidiaries of Merit Medical Systems, Inc.
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer
31.2	Certification of Chief Financial Officer
32.1	Certification of Chief Executive Officer
32.2	Certification of Chief Financial Officer

101	The following materials from the Merit Medical Systems, Inc. Annual Report on Form 10-K for the fiscal year ended December 31, 2019, formatted in iXBRL (Inline eXtensible Business Reporting Language): (i) Consolidated Statements of Earnings, (ii) Consolidated Statements of Comprehensive Income, (iii) Consolidated Balance Sheets, (iv) Consolidated Statements of Cash Flows, (v) Consolidated Statements of Equity, and (vi) Notes to Consolidated Financial Statements
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document).

* These exhibits are incorporated herein by reference.

† Indicates management contract or compensatory plan or arrangement.

(c) Schedules:

None

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, on March 2, 2020.

MERIT MEDICAL SYSTEMS, INC.

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

ADDITIONAL SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on form 10-K has been signed below by the following persons in the capacities indicated on March 2, 2020.

Signature	Capacity in Which Signed
/s/: FRED P. LAMPROPOULOS Fred P. Lampropoulos	President, Chief Executive Officer and Director (Principal executive officer)
/s/: RAUL PARRA Raul Parra	Chief Financial Officer and Treasurer (Principal financial and accounting officer)
/s/: A. SCOTT ANDERSON A. Scott Anderson	Director
/s/: JILL D. ANDERSON Jill D. Anderson	Director
/s/: THOMAS J. GUNDERSON Thomas J. Gunderson	Director
/s/: NOLAN E. KARRAS Nolan E. Karras	Director
/s/: DAVID M. LIU David M. Liu	Director
/s/: FRANKLIN J. MILLER Franklin J. Miller	Director
/s/: F. ANN MILLNER F. Ann Millner	Director
/s/: KENT W. STANGER Kent W. Stanger	Director
/s/: LYNNE N. WARD Lynne N. Ward	Director

EXHIBIT 4.2

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

Merit Medical Systems, Inc. ("Merit" "we" "us" or "our") has one class of securities, our common stock, registered under Section 12 of the Securities Exchange Act of 1934, as amended.

The general terms and provisions of our common stock are summarized below. The below summary does not purport to be complete, and is subject to and qualified in its entirety by reference to our Amended and Restated Articles of Incorporation, as amended, referred to herein as our "Articles," and our Second Amended and Restated Bylaws, referred to herein as our "Bylaws," each of which have been filed as exhibits to our most recent Annual Report on Form 10-K, of which this exhibit is a part, and the applicable provisions of the Utah Code. We encourage you to review complete copies of our Articles and Bylaws and the applicable provisions of the Utah Code for additional information.

Authorized Capital Stock

We are authorized to issue 100,000,000 shares of common stock, no par value per share. We are also authorized to issue 5,000,000 shares of preferred stock, no par value per share. As of February 27, 2020, approximately 55,216,906 shares of common stock, and no shares of preferred stock, were issued and outstanding.

Description of Common Stock

Voting Rights. Holders of outstanding shares of common stock are entitled to one vote for each share held of record on all matters submitted to a vote of our shareholders. Our common stock does not have cumulative voting rights.

Dividend Rights. Subject to preferences that may be applicable to any outstanding shares of preferred stock, holders of common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by our Board of Directors out of funds legally available for dividend payments. We have never issued a cash dividend on our common stock and do not anticipate doing so in the foreseeable future.

Liquidation Rights. In the event of any liquidation, dissolution or winding-up of our affairs, holders of outstanding common stock at such time will be entitled to share ratably in our assets that are legally available for such purpose after payment or provision for payment of all of our debts and obligations, and after liquidation payments to holders of outstanding shares of preferred stock, if any.

Other Rights and Preferences. The holders of common stock have no preferences or rights of conversion, exchange, pre-emption or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock.

Listing

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

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is ZB, National Association, dba Zions Bank.

Description of Preferred Stock

We are authorized to issue 5,000,000 shares of preferred stock, in one or more series, from time to time, with such rights and preferences as determined by our Board of Directors with respect to such series.

Anti-Takeover Effects of Provisions of Utah Law and Our Charter Documents

Director Liability. Our Articles limit the personal liability of our directors to our company and our shareholders to the fullest extent permitted by applicable law. The inclusion of this provision in our Articles may reduce the likelihood of derivative litigation against our directors and may discourage or deter shareholders or management from bringing a lawsuit against our directors for breach of their duty of care.

Shareholder Action and Meetings of Shareholders. Our Bylaws provide that shareholders wishing to propose business to be brought before a meeting of shareholders will be required to comply with various advance notice requirements. The inclusion of this provision in our Bylaws may deter our shareholders from submitting proposals for consideration at a meeting of shareholders.

Classified Board of Directors. Our Articles provide for our Board of Directors to be divided into three classes of directors, with each class as nearly equal in number as possible, serving staggered three-year terms. As a result, approximately one-third of the Board of Directors will be elected each year. We believe the classified board provision will help to assure the continuity and stability of our Board of Directors and the business strategies and policies of our company as determined by the Board of Directors. The classified board provision could also have the effect of discouraging a third party from making a tender offer or attempting to obtain control of our company. In addition, the classified board provision could delay shareholders who do not agree with the policies of the Board of Directors from removing a majority of the directors for two years.

Authorized but Unissued Shares. Our authorized capital stock consists of 100,000,000 shares of common stock and 5,000,000 shares of preferred stock. As of February 27, 2020, we had approximately 55,216,906 shares of common stock outstanding and no shares of preferred stock outstanding. Accordingly, our Articles would permit us to issue up to 38,708,233 additional shares of common stock (after taking into account 6,074,861 shares reserved for issuance under existing employee benefit plans or pursuant to exercise of existing options), and up to 5,000,000 shares of preferred stock. However, such issuances would be subject to the rules of the NASDAQ Global Select Market, which in some cases may require shareholder approval or impose other limitations. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions, and employee benefit plans. The existence of authorized but unissued shares of common stock and preferred stock could make it more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Utah Control Shares Acquisitions Act. We are subject to the Control Shares Acquisitions Act, or Control Shares Act, as set forth in Section 61-6-1 to 61-6-12 of the Utah Code.

The Control Shares Act provides that any person or entity that acquires control shares of an issuing public corporation in a control share acquisition is denied voting rights with respect to the acquired shares, unless a majority of the disinterested shareholders of the issuing public corporation elects to restore such voting rights.

For purposes of the Control Shares Act:

- person or entity acquires "control shares" whenever it acquires shares that, not considering application of the Control Shares Act, would bring its voting power after the acquisition within any of the following ranges of voting power of the issuing public corporation: (i) 1/5 to (but less than) 1/3 of all voting power, (ii) 1/3 to (but less than) a majority of all voting power; or (iii) a majority or more of all voting power;

- an "issuing public corporation" is any Utah corporation, other than a depository institution, that has (a) 100 or more shareholders, (b) a principal place of business, principal office or substantial assets within Utah, and (c) more than 10% of its shareholders resident in Utah, more than 10% of its shares owned by Utah residents or 10,000 shareholders resident in Utah; and

- "control share acquisition" is generally defined as the direct or indirect acquisition (including through a series of acquisitions) of either ownership or voting power associated with issued and outstanding control shares (excluding voting power pursuant to a revocable proxy solicited by the issuing public corporation or its board of directors in connection with meetings of its shareholders).

Under the Control Shares Act, any person or entity that acquires control shares pursuant to a control share acquisition acquires voting rights with respect to those shares only to the extent consent is granted by a majority of the disinterested shareholders of each class of capital stock outstanding prior to the acquisition. To obtain such consent, the acquiring person may file an "acquiring person statement" with the issuing public corporation setting forth the number of shares acquired and certain other specified information. Upon delivering the statement, an acquiring person or entity may request a special meeting of shareholders if it undertakes to pay the issuing public corporation's expenses of a special shareholders' meeting. Following receipt of such a request and undertaking, the directors of an issuing public corporation must call a special meeting (generally within 50 days) to consider the voting rights to be given to the shares acquired or to be acquired in the control shares acquisition. If no request for a special meeting is made, the voting rights to be accorded the control shares are to be presented at the issuing public corporation's next special or annual meeting of shareholders.

If either (i) the acquiring person does not file an acquiring person statement with the issuing public corporation or (ii) the shareholders do not vote to restore voting rights to the control shares, the issuing public corporation may, if its articles of incorporation or bylaws so provide, redeem the control shares from the acquiring person at fair market value. Our Articles and Bylaws do not currently provide for such a redemption right.

Unless otherwise provided in the articles of incorporation or bylaws of an issuing public corporation, all shareholders are entitled to dissenters' rights if the control shares are accorded full voting rights and the acquiring person has obtained control shares with at least a majority of voting power. Notice of such dissenter's rights must be sent to shareholders as soon as practicable thereafter. Our Articles and Bylaws do not currently deny such dissenters' rights.

The directors or shareholders of a corporation may elect to exempt the stock of the corporation from the provisions of the Control Shares Act through adoption of a provision to that effect in the corporation's articles of

incorporation or bylaws. To be effective, such an exemption must be adopted prior to the control shares acquisition. Neither our directors nor our shareholders have taken any such action.

We expect the Control Shares Act to have an anti-takeover effect with respect to transactions not approve in advance by our Board of Directors. The Control Shares Act may also discourage takeover attempts that might result in a premium over the market price for the shares of common stock held by our shareholders.

Business Combinations. Under Sections 16-10a-1801 to 16-10a-1804 of the Utah Code and certain amendments to Section 16-10a-840 of the Utah Code, all of which took effect on May 9, 2017, we are prohibited from entering into a business combination, such as a merger, consolidation, recapitalization, asset sale, or disposition of stock, with any person that meets the definition of "interested shareholder" (discussed further below), including any entity that is, or after the business combination would be, an affiliate or associate of an interested shareholder, for a period of five years after the date such person became an interested shareholder, unless one of the of the following conditions is met:

- the business combination, or the acquisition of stock that resulted in the person becoming an interested shareholder, was approved by our Board of Directors prior to the person becoming an interested shareholder;

- the business combination is approved by a majority of our non-interested shareholders at a meeting called no earlier than five years after the date the person first became an interested shareholder; or

- the cash and other consideration to be delivered to the holder of each share of our common stock meets certain minimum value criteria.

For purposes of the business combination provisions, an "interested shareholder" includes any person who owns (or, in the case of affiliates and associates, did own within the last five years) 20% or more of that corporation's voting stock.

These amendments may have an anti-takeover effect with respect to such business combinations.

Thirteenth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan

Merit Medical Systems, Inc. (the "Employer") hereby adopts this Thirteenth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan (the "Plan") on the date noted below.

WHEREAS, the Employer previously adopted the Plan; and

WHEREAS, the Employer desires to make a Discretionary matching contribution for the 2019 plan year pursuant to Adoption Agreement section 28.A.b. in the amount of 60% on every dollar deferred up to 5% compensation for the period January 1, 2019 to September 30, 2019; and

WHEREAS, the Employer reserves the right to amend said Plan from time to time; and

WHEREAS, the Employer desires to amend the Plan to modify Employer matching contributions with regards to the Period of determination.

NOW, THEREFORE, effective January 1, 2019, the Plan is amended by replacing the Adoption Agreement section(s) as noted below with the following language:

28. EMPLOYER MATCHING CONTRIBUTIONS (Plan Section 12.1(a)(2)) (skip if matching contributions are NOT selected at Question 12.d.)

C. **Period of determination.** The matching contribution formula will be applied on the following basis (and Elective Deferrals and any Compensation or dollar limitation used in determining the matching contribution will be based on the applicable period):

i. [ ] the Plan Year
j. [ ] each payroll period
k. [ ] each month
l. [ ] each Plan Year quarter
m. [ ] each payroll unit (e.g., hour)
n. [X] N/A (Plan only provides for discretionary matching contributions; i.e., a.1. or b. is selected above)

NOTE: For any discretionary match, the Employer will determine the calculation methodology at the time the matching contribution is determined.

G. **True-up contributions.** Under Period of determination above, if j. - m. is selected, does the Employer have the discretion to true-up the Employer matching contribution (i.e., apply the Employer matching contribution on a Plan Year basis)? (leave blank if not applicable).

z. [ ] Yes (may not be elected if the "ADP and/or ACP test safe harbor" provisions are being used).

Except as amended hereinabove, the Plan shall remain unchanged, and as amended herein, shall continue in full force and effect.

IN WITNESS WHEREOF, the Employer has executed this Amendment this 18th day of December, 2019.

MERIT MEDICAL SYSTEMS, INC.

By: /s/ Fred Lampropoulos

Title: Chairman and Chief Executive Officer

SUBSIDIARIES OF MERIT MEDICAL SYSTEMS, INC.
as of December 31, 2019

Subsidiary Name	**Jurisdiction of Incorporation/Organization**
Merit Medical Australia Pty Ltd.	Australia
IntelliMedical Technologies Pty Ltd.	Australia
ITL Healthcare Pty Ltd.	Australia
Merit Medical Austria GmbH	Austria
Merit Medical Belgium Sprl	Belgium
Merit Medical Comercialização, Distribuição, Importação e Exportação de Produtos Hospitalares LTDA.	Brazil
Merit Medical Canada Ltd.	Canada
Merit Medical Beijing Co. Ltd.	China
BioSphere Medical Japan, Inc.	Delaware
BioSphere Medical, Inc.	Delaware
Brightwater Medical, Inc.	Delaware
BSMD Ventures, Inc.	Delaware
Cianna Medical, Inc.	Delaware
DFINE, Inc.	Delaware
Vascular Access Technologies, Inc.	Delaware
Merit Medical Denmark A/S	Denmark
Merit Medical Egypt LLC	Egypt
Merit Medical Finland Ltd.	Finland
BioSphere Medical SA	France
Merit Medical France SAS	France
Dfine Europe GmbH	Germany
Merit Medical GmbH	Germany
Merit Medical Asia Company Limited	Hong Kong
Merit Medical Systems India Private Limited	India
Merit Medical (NRI) Ireland Limited	Ireland
Merit Medical Ireland, Ltd.	Ireland
Merit Medical System’s NRI Limited	Ireland
STD Pharmaceutical (Ireland) Limited	Ireland
Merit Medical Italy S.R.L.	Italy
Merit Medical Japan KK	Japan
Merit Medical Malaysia Sdn. Bhd	Malaysia
Merit Maquiladora México, S. DE R.L. DE C.V.	Mexico
Merit Mexico Sales, S. de R.L. de C.V.	Mexico
Merit Medical Coatings B.V.	Netherlands
Merit Medical Nederland B.V.	Netherlands
Argon Medical Devices Netherlands BV	Netherlands
Merit Medical New Zealand Limited	New Zealand
Merit Medical Norway AS	Norway
Thomas Medical Products, Inc.	Pennsylvania
Merit Medical Portugal, S.A.	Portugal
LLC Merit Technologies	Russia
Merit Medical Singapore Holdings Pte. Ltd	Singapore
Merit Medical Singapore Pte. Ltd.	Singapore

Merit Medical Korea Co., Ltd.	South Korea
Merit Medical South Africa (Pty) LTD	South Africa
Merit Medical Africa (Pty) LTD	South Africa
Merit Medical Spain S.L.Unipersonal	Spain
Merit Medical Systems AB	Sweden
Merit Medical Switzerland AG	Switzerland
Merit Medical Turkey Tıbbi Ürünler Ticaret Anonim Şirketi	Turkey
Merit Medical ME FZ-LLC	United Arab Emirates
Merit Medical UK Limited	United Kingdom
Fibrovein Holdings Limited	United Kingdom
STD Pharmaceutical Products Limited	United Kingdom
Merit Holdings, Inc.	Utah
Merit Sensor Systems, Inc.	Utah

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-226320 on Form S-3ASR, Registration Statement No. 333-193059 on Form S-3/A, and Registration Statement Nos. 333-225426, 333-206297, 333-206296, 333-163104, 333-135614, 333-129267, 333-58112 and 333-58162 on Form S-8 of our reports dated February 28, 2020, relating to the financial statements of Merit Medical Systems, Inc. and the effectiveness of Merit Medical Systems, Inc.'s internal control over financial reporting appearing in this Annual Report on Form 10-K for the year ended December 31, 2019.

/s/ DELOITTE & TOUCHE LLP

Salt Lake City, Utah
March 2, 2020

EXHIBIT 31.1

CERTIFICATION

I, Fred P. Lampropoulos, certify that:

1. I have reviewed this Annual Report on Form 10-K (the "Report") of Merit Medical Systems, Inc. (the "Registrant");

2. Based on my knowledge, this Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Report;

3. Based on my knowledge, the financial statements, and other financial information included in this Report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this Report;

4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with general accepted accounting principles;

c) evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Report based on such evaluation; and

d) disclosed in this Report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: March 2, 2020

/s/ Fred P. Lampropoulos
Fred P. Lampropoulos
President and Chief Executive Officer
(principal executive officer)

EXHIBIT 31.2

CERTIFICATION

I, Raul Parra, certify that:

1. I have reviewed this Annual Report on Form 10-K (the "Report") of Merit Medical Systems, Inc. (the "Registrant");

2. Based on my knowledge, this Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Report;

3. Based on my knowledge, the financial statements, and other financial information included in this Report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this Report;

4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal controls over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with general accepted accounting principles;

c) evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Report based on such evaluation; and

d) disclosed in this Report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: March 2, 2020

/s/ Raul Parra
Raul Parra
Chief Financial Officer
(principal financial officer)

EXHIBIT 32.1

Certification of Principal Executive Officer
Pursuant to 18 U.S.C. Section 1350, as Adopted
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report on Form 10-K of Merit Medical Systems, Inc. (the "Company") for the year ended December 31, 2019, as filed with the Securities and Exchange Commission (the "Report"), I, Fred P. Lampropoulos, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15 (d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 2, 2020

/s/ Fred P. Lampropoulos
Fred P. Lampropoulos
President and Chief Executive Officer
(principal executive officer)

This certification accompanies the foregoing Report pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. A signed original of this certification has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

EXHIBIT 32.2

Certification of Chief Financial Officer
Pursuant to 18 U.S.C. Section 1350, as Adopted
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report on Form 10-K of Merit Medical Systems, Inc. (the "Company") for the year ended December 31, 2019, as filed with the Securities and Exchange Commission (the "Report"), I, Raul Parra, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 2, 2020

/s/ Raul Parra
Raul Parra
Chief Financial Officer
(principal financial officer)

This certification accompanies the foregoing Report pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. A signed original of this certification has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.