
# FOUNDATIONS FOR GROWTH

2020 ANNUAL REPORT

# A MESSAGE FROM THE CHAIRMAN & CEO

## /// DEAR SHAREHOLDERS,

2020 represented a year of challenges, opportunities, and accomplishments. We entered the year with substantial momentum toward our publicly-stated goals of plant consolidation, movement of product lines to our Mexico facility, and reduction of unprofitable operations.

Then the global pandemic hit late in the first quarter. The health and safety of our employees was our number one priority. We were able to put into place protocols and processes which allowed our company, as an essential service provider, to maintain production throughout the entire year. Work at home capabilities, as well as previously employed virtual communication programs, allowed us to provide uninterrupted service and supply to our customers. Our on-site medical clinic, as well as our physician-led support programs, allowed us to implement recommended employee safety programs worldwide. Revenues, however, were initially reduced as healthcare facilities responded to the influx of COVID-19 patients.

Through Merit's agility and response to government requests, we were able to produce critical care and testing products which helped maintain our workforce and provide needed supplies to our customers.

As the year progressed and medical procedures were reinstated in many healthcare facilities, Merit once again responded. All in all, an approximate 3% reduction of revenue compared to 2019 was a remarkable accomplishment. At the same time, our discipline and cost controls contributed to improved profitability and increased operating cash flow.

We maintained our research and development initiatives and received approval for our Wrapsody™ endoprosthesis product line in Europe, while finalizing the process for our U.S. trial of the Wrapsody, which kicked off in the first quarter of 2021.

In November we announced our financial initiatives for the next three years as part of our Foundations for Growth program. This plan sets a clear course of operating and financial objectives which affect all of Merit's facilities and has involved over 500 Merit employees engaged in the planning and implementation process.

Today your company is focused, prepared and enthused about the future. The addition of three new directors, as well as previously elected directors, has provided experience, guidance and support for the initiatives we have discussed.

A stronger, more capable, and more confident company exited 2020 with a commitment and resolve for continued growth and further accomplishments in 2021.

Sincerely,

FRED P. LAMPROPOULOS | CHAIRMAN & CEO

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

# FORM 10-K

**(Mark One)**

☒ **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
**for the fiscal year ended December 31, 2020**
**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 (§ 232.405 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant on June 30, 2020, based upon the closing price of the common stock as reported by the NASDAQ Global Select Market on such date, was approximately $2.5 billion. As of February 24, 2021, the registrant had 55,690,669 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 2021 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. 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. Investors are cautioned not to unduly rely on any such forward-looking statements.

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. 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. 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.

Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties. Please see Item 1A "Risk Factors" for a discussion of these risks and uncertainties.

### 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 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. We maintain an internet website at www.merit.com.

***COVID-19 Pandemic***

During the last year, the COVID-19 pandemic has had a pervasive impact on our business, suppliers, customers, employees, families and communities. Because of the global nature of the pandemic, authorities have implemented numerous measures designed to contain the virus, including travel bans and restrictions, border closures, quarantines, shelter-in-place orders, business limitations and shutdowns. Notwithstanding the challenges we faced during the past year, we responded to adjust to changes in demand for various products. We also responded to the needs of governmental and other entities to obtain swabs used in COVID-19 testing kits. In addition, we quickly implemented stringent safety protocols to promote the safety of our employees in the workplace while producing essential medical products. In March 2020, we put into place temperature screening stations, work-at-home policies for non-operations employees, restrictions to permit only "business critical" visitors in our facilities, social-distancing standards, face mask requirements and restrictions on business travel.

The COVID-19 response by hospitals and healthcare professionals has placed a severe strain on healthcare systems around the world. Many of our hospital customers have been prioritizing their efforts on their COVID-19 response and have diverted focus and resources away from their normal operations and restricted access to their sites in efforts to contain the spread of the virus. The prioritization of COVID-19 treatment and containment has presented us with unique operational challenges, including delays in purchasing decisions by customers, obstacles to our ability to market, deliver and service our products, and disruptions and delays in our logistics and supply chain. We refer you to "Management's Discussion and Analysis of Financial Position and Results of Operations" for a more detailed discussion of the potential impact of the COVID-19 pandemic and associated economic disruptions, and the actual operational and financial impacts that we have experienced to date.

***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: radiology; 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.

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

We conduct our business through two operating segments: cardiovascular (which includes peripheral intervention, cardiac intervention, custom procedural solutions, and original equipment manufacturer ("OEM")) and endoscopy. For information relating to our operating segments and product categories, see Note 13 to our consolidated financial statements set forth in Item 8 of this report and Management's Discussion and Analysis set forth in Item 7 of this report. We revised these product categories during 2020 and reported historical revenue under these revised product categories for the years ended December 31, 2019, 2018, and 2017 in a Current Report on Form 8-K, filed with the SEC on April 3, 2020.

The following sections describe our principal product offerings by reporting segment and product category.

***Cardiovascular***

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. Our cardiovascular segment includes the following product categories: peripheral intervention, cardiac intervention, custom procedural solutions, and OEM.

**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. Products in our peripheral intervention product category are organized into the following product groups: peripheral intervention, spine, and oncology.

*Merit Vascular - Peripheral*

Our peripheral intervention products include product offerings in the following product portfolios: access (peripheral), angiography, biopsy, drainage, delivery systems, embolotherapy, and intervention (peripheral). The principal product offerings in our access (peripheral) portfolio 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, sold through our distribution agreement with Bluegrass Vascular Technologies, Inc. ("Bluegrass Vascular").

The products in our angiography portfolio are used to identify blockages and other disease states in the blood vessel. The principal product offerings in our angiography portfolio include our:

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

We offer an extensive line of soft tissue biopsy products and accessories. The principal product offerings in our biopsy portfolio include our soft tissue core needle 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.

We offer a broad line of drainage products. The principal product offerings in our drainage portfolio include our:

- Aspira® Pleural Effusion Drainage and Aspira® Peritoneal Drainage Systems, a compassionate treatment option for end-stage cancer, allowing patients to spend more time at home by reducing the need for frequent hospital visits to treat their drainage needs;
- Family of ReSolve® Drainage Catheters, including our ReSolve ConvertX® Stent System and ReSolve Mini™ Locking Drainage Catheter, and our related tubing sets and drainage bag;
- 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 percutaneous catheters.

The principal product offerings in our delivery systems portfolio 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, small microcatheters designed for pushability and trackability through small and tortuous vessels; and
- True Form™ Reshapable Guide Wire, designed to be shaped and reshaped multiple times, reducing the need for multiple guide wires.

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 product offerings in our embolotherapy portfolio include our:

- Embosphere® Microspheres, a highly studied, round embolic for consistent and predictable results; and
- Quadrasphere® Microspheres, soft embolics with a consistent cross-sectional diameter for predictable, flow-directed targeting.

The products in our intervention (peripheral) 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 product offerings in our intervention (peripheral) portfolio include our:

- ClariVein® Specialty Infusion Catheter 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 that treat 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; and
- EN Snare® and One Snare® Endovascular Snare Systems, a complete line of snares designed to manipulate, capture and retrieve foreign material in the body.

*Merit Spine*

Our spine products are used in the treatment of vertebral compression fractures and metastatic spinal tumors and in musculoskeletal biopsy procedures. Our spine product line includes the following product portfolios: vertebral augmentation, radiofrequency ablation, and bone biopsy systems. Our primary product offerings in the vertebral augmentation and radiofrequency ablation portfolios 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.

The bone biopsy systems portfolio contains a full offering of manual bone biopsy products, including our Madison™, Huntington™, Kensington™, Preston™ and Westbrook™ biopsy products.

*Merit Oncology*

Our oncology products are dedicated to the accurate diagnosis and localization of breast and soft tissue tumors and the innovative treatment of early-stage breast cancer. Our primary product offerings in our oncology portfolio include our:

- SCOUT® Radar Localization System, a nonradioactive, wire-free tumor localization system that facilitates successful surgical removal of marked lesions and lymph nodes, improving workflow and the patient experience;
- CorVocet® Biopsy System, one of our innovative soft tissue core needle biopsy and accessory products, designed to cut a full core of tissue and provide large specimens for pathological examination;
- Achieve®, Temno® and Tru-Cut® Soft Tissue Biopsy Devices; and
- SAVI® Brachytherapy, a precise, targeted approach to accelerated partial breast irradiation with lower toxicities and reduced treatment duration.

**Cardiac Intervention**

We manufacture and sell a variety of products designed to treat various heart conditions. Products in our cardiac intervention product category are organized into the following product portfolios: access (cardiac), angiography, electrophysiology and CRM, fluid management, hemodynamic monitoring, hemostasis, and intervention (cardiac).

*Merit Vascular - Cardiac*

The principal product offerings in our access portfolio (cardiac) include our 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.

The principal product offerings in our angiography portfolio include our InQwire® Guide Wires and Performa® Diagnostic and Ultimate™ catheters for femoral and radial procedures.

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 product offerings in our electrophysiology and CRM portfolio 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 and Fixed Curve Sheath Introducer, featuring a neutral position indicator and tactile click to help physicians identify curve orientation with an expanded product line that includes fixed curve shapes.

The product offerings in our fluid management portfolio include manifolds, control syringes and tubing.

The principal product offerings in our hemostasis portfolio include our Prelude SYNC EVO™ and PreludeSYNC Distal™ Radial Compression devices, designed to reduce and stop blood flow after radial access procedures, and the SafeGuard® Pressure Assisted Device which provides hemostasis after femoral procedures.

The principal product offerings in our intervention (cardiac) portfolio include a full line of inflation devices and hemostasis valves, including the BasixCompak™, basixTOUCH™, basixALPHA™ (added in late 2020), Blue Diamond™ and DiamondTouch™ inflation devices and the PhD™ Hemostasis Valve, the latest addition to our hemostasis valve portfolio.

**Custom Procedural Solutions**

Our custom procedural solutions product category 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. The principal product offerings in this product category include:

- Critical care products;
- Dual Cap® Disinfection Protection System and Medallion ® syringes;
- Cultura™ swab and collection system (including vials with viral transport media), introduced May 2020 in response to the COVID-19 pandemic;
- Manifold Kits; and
- Trays and Packs.

**OEM**

We provide coating services for medical tubes and wires under 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 sensor components for microelectromechanical systems. These components consist 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.

***Endoscopy***

The products in our endoscopy operating segment, Merit Endotek™, are organized in two product portfolios: gastroenterology and pulmonary.

Our gastroenterology products include a complete range of innovative, gastrointestinal solutions. Our primary product offerings in our gastroenterology portfolio include our:

- Alimaxx-ES™ and EndoMAXX® Fully Covered Esophageal Stents, for maintaining esophageal luminal patency in certain esophageal strictures;
- 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; and
- Elation® Fixed Wire, Wire Guided and new 5-stage Balloon Dilators, intended for use in the alimentary tract.

Our pulmonary products consist of laser-cut tracheobronchial stents, advanced over-the-wire and direct visualization delivery systems and dilation balloons to endoscopically dilate strictures. Our primary product offerings in our pulmonary portfolio include our:

- AERO®, AEROmini® and AERO DV® Fully Covered Tracheobronchial Stents, for the treatment of tracheobronchial strictures produced by malignant neoplasms; and
- Elation Pulmonary Balloon Dilator, for the dilation of strictures of the trachea and bronchi.

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

***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 statistics published by the National Center for Health 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.** Traditionally, 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. Due to the various restrictions imposed in response to the COVID-19 pandemic, during 2020 most medical conventions in which we have participated transitioned to virtual meetings. Additionally, 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 product research and development.

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 develop 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. S**ales of our products in the U.S. accounted for approximately 57%, 58% and 56% of our net sales for the years ended December 31, 2020, 2019 and 2018, respectively. In the U.S., we have a dedicated, direct sales organization primarily focused on selling to end-user physicians, hospitals and alternate site facilities (e.g., office-based labs), 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 2020, our international sales declined approximately 1.3% below our 2019 international sales and accounted for approximately 43% of our net sales.

Our largest non-U.S. market is China, which represented approximately 12% of our net sales in 2020 and reported net sales of approximately $113.2 million, $113.3 million, and $92.7 million for the years ended December 31, 2020, 2019 and 2018, respectively. 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 our products, primarily to hospitals. We use 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.

In 2020, we experienced a significant disruption of our busines throughout the world as a result of the COVID-19 pandemic, and many medical procedures that use our products were delayed or canceled. While the full impact of the COVID-19 pandemic is still unknown at this time, if the reduction in medical procedures continues or declines, we will continue to see a material adverse impact on our global operations, as well as our overall financial condition. For further discussion of risks and uncertainties associated with the COVID-19 pandemic, please refer to disclosure under the heading "*The COVID-19 pandemic has negatively impacted our business and operations around the world and may continue to materially and adversely impact our business, operations and financial results*." set forth in Item 1A "Risk Factors".

In Europe, the Middle East and Africa ("EMEA), we have both direct and modified direct sales operations. Such sales operations are active throughout the region, including the largest markets in Western, Southern, Central and Eastern Europe and the emerging markets within EMEA.

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, wire-free tumor localization 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 alternate site-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.

***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 recent years, 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, 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, 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 to a range of enterprises 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 Texas, Virginia, Utah, Mexico, Brazil, Ireland, France, The Netherlands, and Singapore. See Item 2. "Properties."

We have distribution centers located in Virginia, Utah, Canada, Brazil, The Netherlands, United Kingdom ("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 radiology; 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 BD, Teleflex, Medtronic, Abbott Laboratories, Terumo Corporation, Edwards Lifesciences Corporation, Cook Medical, and Boston Scientific. Our primary competitors in our spine market are Medtronic, Stryker Corporation, and Johnson & Johnson. Our primary competitors in our oncology market are BD, Hologic, Inc., Argon Medical Devices, Inc. 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, 2020, we owned approximately 1,700 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, 2020, 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***

**DOJ Settlement and Corporate Integrity Agreement**. On October 13, 2020, we entered into a Settlement Agreement with the United States Department of Justice ("DOJ") to fully resolve the DOJ's investigation into past marketing transactions and practices. The DOJ asserted that we provided benefits, allegedly in the form of patient referrals advertising assistance, practice development, practice support, and educational grants to induce healthcare providers to purchase and use our products in medical procedures performed on federal healthcare program beneficiaries, in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b(b), and caused the submission of false claims under the False Claims Act, 31 U.S.C. §3729 (as further described in the Settlement Agreement, the "Covered Conduct"). We denied the allegations but determined that a settlement was in the best interests of our company moving forward.

Under the Settlement Agreement and related agreements, we agreed to make settlement payments in the aggregate amount of $18.0 million plus interest. In total, we paid approximately $18.7 million in settlement payments, interest and additional expenses associated with the Settlement Agreement, including fees paid to settle claims of the relator's counsel. In exchange, the DOJ, the Office of the Inspector General of the U.S. Department of Health and Human Services ('OIG"), the Defense Health Agency ("DHA"), on behalf of the TRICARE Program, and the relator named therein agreed to release us from liability arising from the Covered Conduct.

The settlement was also conditioned upon our entering into a Corporate Integrity Agreement ("CIA") with the OIG. Under the CIA, the OIG will not exclude us from participating in federal health care programs if we comply with the obligations set forth therein. The CIA imposes compliance, monitoring, reporting, certification, oversight and training obligations on the Company, certain of which have previously been implemented. The CIA requires, among other matters, that we (i) maintain a Compliance Officer, a Compliance Committee, board review and oversight of certain federal healthcare compliance matters, compliance programs, and disclosure programs; (ii) establish robust compliance policies and procedures to meet the requirements of all federal health care programs and the U.S. Food and Drug Administration ("FDA"); (iii) provide management certifications and compliance training and education; (iv) engage an independent review organization to conduct a thorough review of our systems, policies, processes and procedures related to promotional materials, product evaluations, consulting agreements, trainings provided to healthcare professionals, sponsorships, grants and charitable contributions; (v) implement a risk assessment and internal review process; (vi) establish a disclosure program for whistleblowers; (vii) increase oversight of the interactions between our sales personnel and healthcare providers; and (viii) report or disclose certain events and physician payments.

Our failure to comply with our obligations under the CIA could result in monetary penalties and the Company being excluded from participating in federal health care programs.

The foregoing descriptions of the Settlement Agreement and the CIA are qualified in their entirety by the full terms of the Settlement Agreement and the Corporate Integrity Agreement, which are attached as Exhibit 10.47 and Exhibit 10.48 hereto, respectively, and incorporated herein by reference.

**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, as amended ("MDD"). In May 2017, the EU adopted Regulation (EU) 2017/745 ("MDR"), which will repeal and replace the MDD with effect from May 26, 2021. Under transitional provisions, medical devices with notified body certificates issued under the MDD prior to May 26, 2021 may continue to be placed on the market for the remaining validity of the certificate, until May 26, 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. While we are preparing to comply with these new regulations, there may be some products that we will discontinue or postpone introduction in the EU or which may not be fully compliant at the time the transitional period expires because of a number of factors, including changing business strategies, cost of obtaining MDR certification, availability of necessary data and the capacity of Notified Bodies. 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 May 2020, we received the CE mark for the Merit Wrapsody™ Endovascular Stent Graft System, and we are pursuing regulatory approval in the U.S. and elsewhere. We are conducting a large, multinational pivotal human clinical trial of the Wrapsody™ Stent Graft which is required to obtain approval from the FDA and some international regulatory agencies. 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 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.

**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 MDD and MDR, 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 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 are increasing 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.

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 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.

**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, comparative effectiveness research, and enhancements to fraud and abuse requirements and enforcement. However, the long-term viability of the Affordable Care Act, and its impact on our business and results of operations, remains uncertain. Any legislative and executive initiatives may significantly change the scope and impact of the Affordable Care Act and, in turn, the medical device industry.

**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"). Many state laws also regulate the use and disclosure of health information and require notification in the event of breach of such information.

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 applies 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 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.

After the recent Brexit deal between the UK and the EU, the GDPR no longer directly applies in the UK. However, the UK Data Protection Act 2018 will remain in force, which incorporates the GDPR into UK legislation with some minor amendments to take account of the UK's departure from the EU. Thus, we have to continue to comply with the GDPR (including as it applies in the UK). Further, there is a four-month transition period beginning January 1, 2021 with regard to data transfers from the European Economic Area to the UK, which will be automatically extended by two months if neither the UK nor the EU objects. After this period, if the European Commission does not adapt an adequacy decision in respect of the UK, it will be necessary to implement appropriate safeguards such as standard contractual clauses or binding corporate rules in order to enable data transfers to the UK.

**CARES Act.** On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was signed into law. The $2.2 trillion economic stimulus bill contains numerous tax law changes. The CARES Act established a program with provisions to allow U.S. companies to defer the employer's portion of social security taxes between March 27, 2020 and December 31, 2020 and pay such taxes in two installments in 2021 and 2022. As permitted by the CARES Act, we have deferred payment of the employer's portion of social security payroll tax payments.

***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.

***Sustainability***

We take our responsibility to conduct our business in a sustainable manner seriously and have identified both risks and opportunities related to our sustainability program, as we strive for continued growth and profitability.

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, repeated sterilization to address such risks is not possible because it may adversely affect the quality of the plastic used in many of our products and 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 opportunities to deliver sustainable, long-term growth of our business. 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.

By assessing our sustainability opportunities, we have developed areas of focus where we are positioned to make a positive impact. These include programs designed to reduce waste, improve efficiency, and protect the environment including our:

- ISO 14001 certification – we have achieved this certification at many of our facilities with a continued goal of achieving this certification at all our manufacturing facilities in 2021 (ISO 14001 is the international standard that specifies requirements for an effective environmental management system);
- ISO 45001 certification – our goal is to achieve this certification at all our manufacturing facilities within the next 12 to 18 months (ISO 45001 is the international standard that specifies requirements for an effective safety management system);
- ISO 50001 certification – we have achieved this certification at our Galway facility, and our goal is to achieve ISO 50001 certification at all our manufacturing facilities within the next 12 to 18 months (ISO 50001 is the international standard that specifies requirements for an effective energy 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;
- 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; and
- environmental tracking system at our world-wide facilities to facilitate monthly reporting and accountability for energy, water, waste, recycling, and other scope 1, 2, and 3 emissions metrics.

In 2020 we provided in-kind donations of our medical devices to support two medical or humanitarian missions, and we worked closely with a local Utah university to donate product for use in their educational and instructional programs. The COVID-19 pandemic caused disruptions to our operations and the operations of the non-profit organizations to which we typically donate, which hindered our ability to provide this type of support at the same levels we have in the past, but we plan on continuing and expanding this practice in 2021. To learn more about our sustainability programs and accomplishments, please visit www.merit.com/about/corporate-sustainability/.

***Human Capital Management***

As of December 31, 2020, we had 5,989 employees located in approximately 39 different countries in a variety of different roles. In the highly competitive medical device industry, we consider attracting, developing, and retaining talented people in technical, operational, marketing, sales, research, management, and other positions to be critical to our overall long-term growth strategy. Our ability to recruit and retain such talent depends on several factors, including compensation and benefits, talent development, career opportunities, and work environment. We invest in our people and cultivate a company culture committed to supporting a diverse and inclusive workforce.

**Diversity and Inclusion.** Our goal is to create a diverse and inclusive global culture that reflects the diversity of the customers we serve and encourages an environment where employees feel welcomed, respected, and valued. With this goal in mind, in late 2020 the Company hired its first Chief Human Resources Officer who, in part, has been charged with working with our leadership team to strengthen and enhance our diversity and inclusion efforts company wide. We are committed to providing equal opportunity in all aspects of employment. In the U.S., we are an equal opportunity/affirmative action employer committed to making employment decisions without regard to race, religion, ethnicity or national origin, gender, sexual orientation, gender identity or expression, age, disability, protected veteran status or any other characteristics protected by law. As a result, over 50% of our U.S. population identifies as non-white.

**Employee Engagement.** The engagement of our workforce is critical to delivering on our competitive strategy, and we place high importance on informed and engaged employees. We communicate frequently and transparently with our employees through a variety of communication methods, including video and written communications, town hall meetings, and our company intranet, and we acknowledge individual contributions to Merit by celebrating milestones of service in

five-year increments. As a result of the COVID-19 pandemic, we also further strengthened our communication platforms. Our employee communications during the pandemic have kept our employees informed on critical priorities, important actions being taken by management in response to the pandemic, and continued efforts to protect employee health, safety and well-being.

**COVID-19 Response; Health and Safety.** During the COVID-19 pandemic, the majority of our operations employees have continued to work from our facilities, where we have adopted health screening, implemented social distancing and personal protective equipment requirements, enhanced cleaning and sanitation procedures, and modified workspaces to reduce the potential for disease transmission. Most employees who do not require access to our facility to perform their work have been working from home during the pandemic, without a significant impact to productivity.

***Information Security***

We maintain strong cybersecurity systems to guard against unauthorized access, malicious software, corruption of data, disruption of our networks and systems and unauthorized release of confidential information. We employ an experienced and dedicated information security team, follow industry best practices, and work with our employees globally to create awareness and mitigate cyber risk. On an ongoing basis, we assess risks and implement procedures and practices designed to improve the security, confidentiality, integrity and availability of our systems. We voluntarily engage third-party security auditors to test our systems and controls at least annually against the most widely recognized security standards and regulations. We have developed and continue to implement a continuing cyber awareness training program which is designed to increase awareness of cybersecurity threats throughout our company and reduce the risk of human error. As part of that training, we conduct phishing testing on all our employees with e-mail access and emphasize information security through events held each year during our Cyber Awareness Month.

We have established controls and procedures to escalate enterprise level issues, including cybersecurity matters, to the appropriate management levels within our organization and our Board of Directors, or members or committees thereof, as appropriate. Our Board of Directors has delegated to its Audit Committee specific oversight responsibility for enterprise risk management, including our approach to managing cybersecurity risk. The Audit Committee regularly reviews information security risks and receives reports from our Chief Technology Officer and other members of the Company's management regarding those risks. Under our framework, cybersecurity issues are analyzed by subject matter experts for potential financial, operational, and reputational risks, based on, among other factors, the nature of the matter and breadth of impact. Matters determined to present potential material impacts to the Company's financial results, operations, and/or reputation are immediately reported by management to our Board of Directors or the Audit Committee, as appropriate, in accordance with our escalation framework. In addition, we have established procedures to ensure that management responsible for overseeing the effectiveness of disclosure controls is informed in a timely manner of known cybersecurity risks and incidents that may materially impact our operations and that timely public disclosure is made as appropriate. We maintain insurance coverage that may, subject to policy terms and conditions, cover certain aspects of cybersecurity risks; however, such insurance coverage may be unavailable or insufficient to cover all losses or all types of claims that may arise in the continually evolving area of cyber risk.

***Recent Developments***

None.

***Available Information***

We file annual, quarterly and current reports and other information with the SEC. The SEC 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, corporate initiatives, 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:

### COVID-19 Pandemic Risks

***The COVID-19 pandemic has negatively impacted our business and operations around the world and may continue to materially and adversely impact our business, operations and financial results.***

The COVID-19 pandemic has created significant disruption and uncertainty in the global economy, has negatively impacted our business, results of operations and financial condition, and we anticipate that it may continue to negatively impact our business, results of operations and financial condition for the foreseeable future.

Numerous national, international, state and local jurisdictions have imposed, and others in the future may impose, a variety of government orders and restrictions for their residents to control the spread of COVID-19. Such orders or restrictions may cause significant alteration of our operations, work stoppages, slowdowns and delays, travel restrictions and event cancellations, among other effects, thereby significantly and negatively impacting our operations. Other disruptions or potential disruptions include (i) restrictions on our personnel and personnel of business partners to travel and access customers for training and case support; (ii) reductions in spending by our customers; (iii) delays in approvals by regulatory bodies; (iv) diversion of or limitations on employee resources that would otherwise be focused on the operations of our business, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; (v) reductions in our sales team, including through layoffs, furloughs or other losses of sales representatives; (vi) additional government requirements or other incremental mitigation efforts that may further impact our or our suppliers' capacity to manufacture our products; (vii) disruption of our research and development activities; and (viii) delays in ongoing studies and pre-clinical trials.

In addition, elective procedures that use our products significantly decreased in number during 2020 as health care organizations around the world prioritized the treatment of patients with COVID-19 and reduced spending in other areas. For example, in the United States, governmental authorities have recommended, and in certain cases required, that elective, deferrable, specialty and other procedures and appointments, be suspended or canceled to avoid non-essential patient exposure to medical environments and potential infection with COVID-19 and to focus limited resources and personnel capacity toward the treatment of COVID-19 patients. Specifically, many of these procedures that use our products have been suspended or postponed. While certain of these procedures have resumed in certain locations, it is unclear when or if all procedures in all locations will resume.

While we have seen increases in demand for certain product lines during the pandemic, including our Cultura™ nasopharyngeal swab and test kit, this increased demand has not been, and may not be, sufficient to offset the revenue declines in other areas. We also expect continued pressure on our margins due to decreased demand for products with gross margins that are higher than the company average.

In addition, most of the hospitals and clinics that purchase our products have instituted strict procedures at their facilities in an effort to prevent the spread of COVID-19, including restrictions on sales representatives entering these facilities. This has been, and currently remains, a major impediment to our sales efforts, as supporting existing customers and acquiring new customers is much more difficult in this environment. These restrictions have had a significant adverse effect on our sales and, until they are lifted, our business, operations and financial results will continue to be adversely impacted.

Further, once the pandemic subsides, we anticipate there will be substantial backlog of patients seeking appointments with physicians and surgeries to be performed at hospitals and ambulatory surgery centers relating to a variety of medical conditions, and as a result, patients seeking procedures that use our products will have to navigate limited provider capacity. On the other hand, we do not know if demand for these postponed, elective procedures will return to the levels we experienced prior to the pandemic. We believe this limited provider, hospital and ambulatory surgery center capacity,

and a decline in demand for the procedures that use our products, could have a significant adverse effect on our business, operations and financial results following the end of the pandemic.

These challenges and restrictions will likely continue for the duration of the pandemic, which is uncertain, and may even continue beyond the pandemic. Many areas are relaxing restrictions and resuming business operations, but a resurgence in infections or mutations of the coronavirus that causes COVID-19 could cause authorities to reinstate such restrictions or impose additional restrictions. All of these factors also may cause or contribute to disruptions and delays in our logistics and supply chain. The extent to which the COVID-19 pandemic impacts our business, operations and financial results will depend on future developments that are uncertain and cannot be predicted, including new information that may emerge concerning the severity and spread of the virus and the actions by government entities, our customers and other parties to contain the virus or treat its impact, among others. To the extent the COVID-19 pandemic adversely affects our business, operations and financial results, it may also have the effect of heightening other risks described herein, such as those relating to general economic conditions, demand for our products, relationships with suppliers and sales efforts.

**Business, Economic, Industry and Operational Risks**

***Changes in general economic conditions, geopolitical conditions, domestic and foreign 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 replacement of the North American Free Trade Agreement ("NAFTA") with the United States Mexico Canada Agreement ("USMCA") which became effective on July 1, 2020. At this time, it is unknown whether the current administration will attempt to renegotiate the terms of the USMCA or implement its own policies and regulations to replace those established by the Trump Administration. In addition, with changes in the balance of power between the parties in the U.S. Congress, new legislation could be passed into law. It is unclear what the effect of any such action would have, either positively or negatively, on our industry or our Company. If any new legislation and/or regulations are implemented, or if existing trade agreements are renegotiated, it may be inefficient and expensive for us to alter our business operations in order to adapt to or comply with such changes.

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. Furthermore, regulations and trade policies implemented by foreign governments to reduce the costs of healthcare or promote business in their countries could also cause our sales to decline in such countries. For example, China has implemented a volume-based procurement process designed to decrease prices for medical devices and other products. These events could result in increased costs, lower margins and lower sales than we would otherwise expect, which could have a material adverse effect on our business, financial condition, results of operations, or cash flows. Our customers and suppliers may also be affected by these events, so even if we are not directly impacted, we may still experience lower demand for our products and increases in our manufacturing costs because of the effects these events may have on our customers and suppliers.

The United Kingdom's ("UK") departure from the European Union ("EU") (commonly known as "Brexit") has created uncertainties affecting business operations in the UK, the EU and a number of other countries, including with respect to compliance with the regulatory regimes regarding the labeling and registration of the products we sell in these markets. While we have taken proactive steps to mitigate possible disruption to our operations, we could face increased costs, volatility in exchange rates, market instability and other risks, depending on the effects of existing and future agreements between the UK and EU regarding Brexit and the future EU/UK trading relationship.

The above factors, including a number of other economic and geopolitical factors both in the U.S. and abroad, could ultimately have material adverse effects on our business, financial condition, results of operations or cash flows, including the following :

- 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 enacted by countries, such as China, in response to changes in U.S. trade policies and tariffs;
- 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.

***Consolidation in the healthcare industry, group purchasing organizations and public procurement policies have lead to demands for price concessions, which reduces our revenues and 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 has lead to lower revenues and required 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.

***Termination or interruption of, or a failure to monitor, our supply relationships and increases in labor costs and 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. If any of these sterilizers goes out of business or fails to comply with quality or regulatory requirements, we may be unable to find a suitable supplier to replace them. This could significantly delay or stop production and cause sales of such products to materially decline. 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, climate change (including new and existing laws and regulations to address climate change), competition, import duties, tariffs, currency exchange rates and political uncertainty around the world. Our suppliers often 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 are often passed on to us. Our costs may also be impacted by laws to increase minimum wages, including the potential increase to the federal minimum wage in the United States that has been recently proposed by the current administration.

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.

***Any damage or interruption to our facilities, infrastructure, manufacturing processes or information technology systems, or those of our suppliers, could result in lost revenues and our business could be seriously harmed.***

Damage or interruption to our facilities or systems relating to manufacturing, distribution, research and development, or information technology because of fire, extreme weather conditions, natural disaster, power loss, communications failure, geopolitical disruption, labor strikes, riots, cyber-attack, health epidemics and pandemics, unauthorized entry or other events could significantly disrupt our operations, the operations of suppliers and critical infrastructure. These events may also delay or prevent product manufacturing and shipment during the time required to repair, rebuild or replace the damaged facilities or systems. We have recently closed certain facilities, and the resulting consolidation may further exacerbate the effects of these events or make it more difficult for us to respond to the effects of these events. Climate change may increase both the frequency and severity of natural disasters and, consequently, risks to our operations and growth. Although we maintain property damage and business interruption insurance coverage on our facilities, our insurance might not cover all losses under such circumstances, and we may not be able to renew or obtain such insurance in the future on acceptable terms with adequate coverage or at reasonable costs.

***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.

**Strategic, Business Development and Employee Attraction and Retention Risks**

***We may be unable to successfully manage growth and maintain operational efficiencies.***

Successful implementation and execution of our business strategy will require that we effectively manage our growth. As the Company grows, we are often faced with decisions to (i) expand certain product lines and discontinue others, (ii) open or expand new facilities and close others, (iii) allocate resources between new and established markets, or (iv) allocate resources between the expansion of organic business and the acquisition of new product lines. The outcome of each choice in these decisions is uncertain, and even with the exercise of excellent business judgment, results may not align with expectations because of the many factors listed in this section. In addition, 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. We may not have the resources available to implement certain necessary changes, and as a result, growth may be delayed or we may not be able to take advantage of certain business opportunities. 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. Any failure to manage growth effectively could have a material adverse effect on our business, operations or financial condition.

***Substantial costs are incurred when identifying, evaluating, negotiating and closing acquisitions, and failure to integrate acquired businesses may adversely impact our business and financial results.***

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. We have incurred, and will likely continue to incur, significant expenses in connection with negotiating and consummating various acquisition and other strategic transactions. 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.

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. Further, as a result of certain acquisitions, 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.

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 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 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, effects of the COVID-19 pandemic 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.

***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.

***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 May 26, 2020, we entered into an agreement with Starboard Value and Opportunity Master Fund Ltd ("Starboard"). Starboard is a significant shareholder and had previously informed us that it intended to nominate up to seven individuals to stand for election as directors at our 2020 Annual Meeting of Shareholders. Pursuant to the agreement, Starboard agreed to withdraw its slate of directors and we agreed to nominate three new directors. These three directors were elected to our Board of Directors at the 2020 Annual Meeting of Shareholders. Additional terms of the agreement with Starboard can be found in our Current Report on Form 8-K, filed with the SEC on May 27, 2020.

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, cause concern in the minds of our employees and lead to the departure of critical employees, 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.

***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.

**Intellectual Property**

***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.

***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 (i) stop selling our products, (ii) redesign our products, (iii) discontinue the use of related trademarks, technologies or designs, (iv) pay damages or indemnification obligations, or (v) enter into royalty or licensing arrangements. 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.

**Regulatory, Litigation, Tax and Legal Compliance Risks**

***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.

In particular, we are currently conducting a large, multinational pivotal human clinical trial of the Wrapsody™ Stent Graft. A successful outcome of this trial is required to obtain approval from the FDA and some international regulatory agencies. However, there is no assurance that we will be able to obtain the necessary regulatory clearances or approvals for the Wrapsody™ Stent Graft or any other products 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 MDD, 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 the MDR, which will repeal and replace the MDD with effect from May 26, 2021. Under transitional provisions, medical devices with notified body certificates issued under the MDD prior to May 26, 2021 may continue to be placed on the market for the remaining validity of the certificate, until May 26, 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 plan to be fully compliant with the MDR ahead of expiry dates, however for multiple reasons, including but not limited to changing business strategies, costs of obtaining MDR certification, availability of necessary data and Notified Body capacity, there may be some products that we will discontinue in the EU or which may not be fully compliant at the time of expiry.

China and some of its provinces have also implemented policies and regulations to reduce prices for medical devices, such as a volume-based procurement process. China-based companies may also have certain competitive advantages because of these policies and regulations.

Complying with and obtaining regulatory approval in foreign countries, including compliance with the MDR when effective, 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 and we are currently operating under a Corporate Integrity Agreement. If governmental authorities determine that we have violated laws, regulations or our Corporate Integrity Agreement, 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, DOJ, the OIG 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.

In October 2020, we entered into a Settlement Agreement with the DOJ to resolve their investigation into our past marketing transactions and practices. Under the Settlement Agreement and related agreements, we paid approximately $18.7 million (which includes interest and certain fees) in exchange for a release from liability for the alleged conduct. The settlement was also conditioned upon our entering into a CIA with the OIG, see "Regulation – DOJ Settlement and Corporate Integrity Agreement" in Item 1 of this report. Even if we fully comply with the CIA, we have incurred, and anticipate that we will continue to incur, substantial costs in connection with the settlement and compliance with the CIA. It is unclear what impact the settlement has had and may have on our reputation. This matter has consumed a significant amount of our resources and management's attention.

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. If we fail to comply with applicable regulatory requirements and the terms of the CIA, 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, which in turn may have a negative impact our business, results of operations, financial condition and ability to obtain financing on reasonable terms.

***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. Allegations of such violations could lead to expensive and time-consuming investigations by government authorities and result in conviction

of these violations or settlement costs and additional restrictions, like a CIA, as was the outcome of our DOJ investigation discussed above.

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.

***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 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 (including HIPAA, the HITECH Act and the rules issued thereunder), 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 applicable 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 (in particular taking into account the recent decision of the European Court of Justice in Case C-311/18 (Schrems II)). 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. Moreover, climate change and sustainability efforts and potential climate change regulations could lead to business interruption, significantly increased costs and other adverse consequences to our business. 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 significant expenditures.

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.

***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.

***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.

***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.

**Information Technology and Cybersecurity Risks**

***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 (i) lose customers, (ii) be subject to fraud, (iii) breach our agreements with or duties toward customers, physicians, other health care professionals and employees, (iv) be subject to regulatory sanctions or penalties, (v) incur expenses or lose revenues, (vi) sustain damage to our reputation, or (vii) 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.

**Market, Liquidity and Credit Risks**

***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.

***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 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, DOJ, OIG, FDA, or another regulatory authority; significant litigation or a decline, or rise, of stock prices in capital markets generally.

***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 2020, 2019 and 2018, the exchange rate between all applicable foreign currencies and the U.S. Dollar resulted in a decrease in net sales of

approximately $1.3 million, a decrease of approximately $13.5 million and an increase of approximately $5.2 million, respectively.

For the year ended December 31, 2020, approximately $323.8 million, or 33.6%, of our net sales were denominated in foreign currencies, with our CNY- and Euro-denominated sales representing our largest currency risks to net sales. 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.

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

We are subject to taxation in numerous countries, states and other jurisdictions. Our effective tax rate is derived from a combination of applicable tax rates in the various countries, states and other jurisdictions in which we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of these jurisdictions. Our effective tax rate may, however, differ from the estimated amount due to numerous factors, including a change in the mix of our profitability from country to country and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations, which could have an adverse effect on our business, financial condition or results of operation.

***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.

## 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, Singapore, Great Britain, Vietnam, Taiwan, New Zealand, Indonesia, and France, as well as in Massachusetts, California and Texas. Our principal manufacturing and packaging facilities are located in Utah, Virginia, Texas, Ireland, Brazil, France, Singapore, Mexico, and The Netherlands. Our research and development activities are conducted principally at facilities located in Utah, California, Texas, 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, 2020:

| 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 cardiovascular segment 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.**

See Note 10 “Commitments and Contingencies” to our consolidated financial statements set forth in Item 8 of this report and incorporated herein by reference.

**Item 4. Mine Safety Disclosures.**

The disclosure required by this item is not applicable.

## PART II

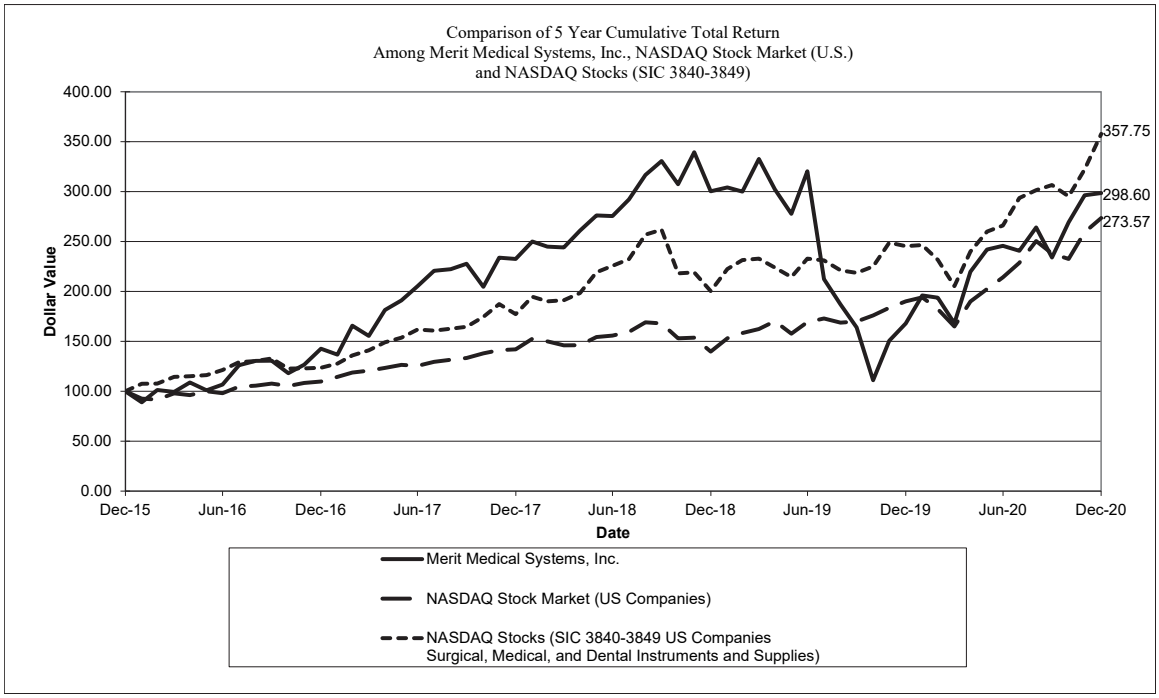
**Item 5.** **Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.**

***Market Price for the Common Stock***

Our common stock is traded on the NASDAQ Global Select Market under the symbol "MMSI." As of February 24, 2021, the number of shares of our common stock outstanding was 55,690,669 held by approximately 101 shareholders of record, not including shareholders whose shares are held in securities position listings. We did not repurchase any shares during the years ended December 31, 2020, 2019, or 2018.

***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, 2015 to December 31, 2020.




| | 12/2015 | 12/2016 | 12/2017 | 12/2018 | 12/2019 | 12/2020 |
|---|---|---|---|---|---|---|
| Merit Medical Systems, Inc. | $ 100.00 | $ 142.55 | $ 232.38 | $ 300.22 | $ 167.94 | $ 298.60 |
| NASDAQ Stock Market (U.S. Companies) | 100.00 | 109.80 | 141.97 | 139.65 | 190.06 | 273.57 |
| NASDAQ Stocks (SIC 3840-3849 U.S. Companies) | 100.00 | 123.58 | 177.27 | 200.31 | 245.40 | 357.75 |

The stock performance graph assumes for comparison that the value of our common stock and of each index was $100 on December 31, 2015 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 2021. Used with permission. All rights reserved.

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

| | 2020 | 2019 | 2018 | 2017 | 2016 |
|---|---|---|---|---|---|
| **Operating Data:** | | | | | |
| Net sales | $ 963,875 | $ 994,852 | $ 882,753 | $ 727,852 | $ 603,838 |
| Gross profit | 401,177 | 432,366 | 394,770 | 326,253 | 265,025 |
| Income (loss) from operations | (1,562) | 15,434 | 58,617 | 33,069 | 34,876 |
| Income (loss) before income taxes | (13,231) | 2,193 | 49,519 | 35,881 | 25,386 |
| Net income (loss) | (9,843) | 5,451 | 42,017 | 27,523 | 20,121 |
| Diluted earnings (loss) per common share | $ (0.18) | $ 0.10 | $ 0.78 | $ 0.55 | $ 0.45 |
| **Balance Sheet Data:** | | | | | |
| Working capital | $ 244,703 | $ 272,882 | $ 254,491 | $ 200,501 | $ 155,092 |
| Total assets | 1,664,396 | 1,757,321 | 1,620,012 | 1,111,811 | 942,803 |
| Long-term debt, less current portion | 343,722 | 431,984 | 373,152 | 259,013 | 314,373 |
| Stockholders' equity | 958,575 | 949,944 | 932,775 | 676,334 | 498,189 |
| **Cash Flow Data:** | | | | | |
| Net cash provided by operating activities | $ 165,270 | $ 77,813 | $ 86,533 | $ 62,727 | $ 53,599 |
| Capital expenditures for property and equipment | (45,988) | (78,173) | (63,324) | (38,623) | (32,837) |

**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 five core product categories: peripheral intervention, cardiac intervention, custom procedural solutions, OEM and endoscopy.

For the year ended December 31, 2020, we reported sales of approximately $963.9 million, down approximately ($31.0) million or (3.1)%, compared to 2019 sales of approximately $994.9 million.

Gross profit as a percentage of sales was 41.6% for the year ended December 31, 2020 as compared to 43.5% for the year ended December 31, 2019.

Net loss for the year ended December 31, 2020 was approximately ($9.8) million, or ($0.18) per share, as compared to net income of approximately $5.5 million, or $0.10 per share, for the year ended December 31, 2019.

During the year ended December 31, 2020, the global COVID-19 pandemic impacted our business in various ways. The most significant impact to sales occurred in the second quarter, with sales for the three-month period ended June 30, 2020 down approximately (14.5)% over the comparative quarter of 2019. In the second half of the year, total sales were approximately equal to the prior year comparative period; however, sales fluctuated by product category due, in part, to

the extent various products are used in deferrable procedures. In response to the COVID-19 pandemic, we implemented certain cost reduction and operating efficiency initiatives, including decreasing discretionary spending, delaying product launches, deferring or rationalizing capital spending and reducing the number of research and development projects, among other initiatives. In April 2020, due to the significant impact of the COVID-19 pandemic on our business, results of operations and financial condition, and uncertainty regarding the scope and duration of that impact, we reduced headcount, implemented targeted furloughs and temporarily reduced salaries for a number of groups, including all executive positions. These temporary salary reductions were eliminated by December 31, 2020.

We continue to focus our efforts to expand our presence in foreign markets, particularly Europe, Middle East and Africa ("EMEA"), China, Southeast Asia, Japan, Australia and Brazil, with the objective of capitalizing on additional market opportunities. These efforts have increased certain of 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. Due in part to restrictions regarding deferrable and elective procedures, our international sales declined for the year ended December 31, 2020. In 2020, international sales were approximately $413.8 million, or 42.9% of our net sales, down (1.3)% from international sales of $419.1 million in 2019.

On November 10, 2020, we introduced a corporate transformation initiative known as "Foundations for Growth" with multi-year financial targets for growth and improved profitability. As part of this initiative, we continue review the need to consolidate facilities, strategically reduce operating expenses and incentivize our sales force to focus on products that will improve our financial performance. During 2020, we moved production of 23 products to our facilities in Mexico or Texas, and we closed manufacturing operations in Temecula, California; Malvern, Pennsylvania; West Jordan, Utah; and Melbourne, Australia.

***Results of Operations***

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

| | 2020 | 2019 | 2018 |
|---|---|---|---|
| Net sales | 100 % | 100 % | 100 % |
| Gross profit | 41.6 | 43.5 | 44.7 |
| Selling, general and administrative expenses | 30.9 | 32.9 | 31.3 |
| Research and development expenses | 6.0 | 6.6 | 6.7 |
| Legal settlement | 1.9 | — | — |
| Impairment charges | 3.8 | 2.4 | 0.1 |
| Contingent consideration (benefit) | (0.8) | (0.0) | (0.1) |
| Acquired in-process research and development expense | 0.0 | 0.1 | 0.1 |
| Income (loss) from operations | (0.2) | 1.6 | 6.6 |
| Income (loss) before income taxes | (1.4) | 0.2 | 5.6 |
| Net income (loss) | (1.0) | 0.5 | 4.8 |

**Sales**

Listed below are the sales by product category within each operating segment for the years ended December 31, 2020, 2019 and 2018 (in thousands):

| | % Change | 2020 | % Change | 2019 | % Change | 2018 |
|---|---|---|---|---|---|---|
| **Cardiovascular** | | | | | | |
| Peripheral Intervention | (2.7)% | $ 341,568 | 27.1 % | $ 350,936 | 35.4 % | $ 276,113 |
| Cardiac Intervention | (8.2)% | 279,671 | 9.4 % | 304,797 | 18.5 % | 278,496 |
| Custom Procedural Solutions | 8.5 % | 203,196 | 3.9 % | 187,359 | 8.3 % | 180,332 |
| OEM | (6.9)% | 109,767 | 2.9 % | 117,889 | 20.4 % | 114,536 |
| Total | (2.8)% | 934,202 | 13.1 % | 960,981 | 21.2 % | 849,477 |
| | | | | | | |
| **Endoscopy** | | | | | | |
| Endoscopy devices | (12.4)% | 29,673 | 1.8 % | 33,871 | 22.2 % | 33,276 |
| | | | | | | |
| Total | (3.1)% | $ 963,875 | 12.7 % | $ 994,852 | 21.3 % | $ 882,753 |

*Cardiovascular Sales.* Our cardiovascular sales for the year ended December 31, 2020 were approximately $934.2 million, down (2.8)%, when compared to the year ended December 31, 2019 of approximately $961.0 million. Sales for the year ended December 31, 2020 were unfavorably affected by decreased sales of (a) our cardiac intervention products (particularly our intervention, angiography and access products) of $279.7 million, down (8.2%); (b) our OEM products (particularly our cardiac rhythm management/electrophysiology ("CRM/EP") products and coatings) of $109.8 million, down (6.9%); and (c) our peripheral intervention products (particularly our radar localization, vertebral compression fracture, biopsy, angiography and intervention products, offset partially by increased sales of drainage products) of $341.6 million, down (2.7%). These decreases were partially offset by increased sales of our custom procedural solutions products (particularly our critical care products, which saw increased demand due to the COVID-19 pandemic, including $19.1 million in sales of our new Cultura nasopharyngeal swab and test kits used to collect and transport samples for COVID-19 testing, partially offset by decreased sales of kits) of $203.2 million, up 8.5%.

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 primarily affected by increased sales of (a) our peripheral intervention products (particularly our radar localization, intervention, and drainage products) of approximately $350.9 million, up 27.1%, including a full year of sales of Cianna Medical, Inc. ("Cianna Medical") products and product lines acquired from BD; (b) our cardiac intervention products (particularly our intervention, angiography and CRM/EP products) of approximately $304.8 million, up 9.4%; (c) our custom procedural solutions product (particularly our kits and critical care products, offset partially by trays) of approximately $187.4 million, up 3.9%.

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 (0.1)% for the year ended December 31, 2020 compared to sales calculated using the applicable average foreign exchange rates for 2019 and decreased sales (1.3)% for the year ended December 31, 2019 compared to sales calculated using the applicable foreign exchange rates for 2018.

*Endoscopy Sales.* Our endoscopy sales for the year ended December 31, 2020 were approximately $29.7 million, down (12.4)%, when compared to sales for the year ended December 31, 2019 of approximately $33.9 million. Sales for the year ended December 31, 2020 were unfavorably affected by decreased sales of the NvisionVLE® Imaging System as a result of the suspension of our distribution agreement with NinePoint Medical, Inc. ("NinePoint"), as well as decreased sales of probes and certain stents. Our endoscopy sales for the year ended December 31, 2019 were approximately $33.9 million, up 1.8%, when compared to sales for the same period 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.

*International Sales*. International sales for the year ended December 31, 2020 were approximately $413.8 million, or 42.9% of net sales, down (1.3)% from the same period of 2019. International sales for the year ended December 31, 2019 were approximately $419.1 million, or 42.1% of net sales, up 8.5% from the year ended December 31, 2018. The decrease in our international sales during 2020 was primarily a result of lower sales in EMEA, which decreased approximately (1.6%) or $(2.9) million and lower rest of world sales which decreased approximately (8.7%) or $(2.6) million, compared to the same period of 2019. Our sales in APAC were essentially flat year over year. The increase in our international sales during 2019 was primarily related to year-over-year increased sales in APAC (particularly China and Southeast Asia), which increased $28.6 million or 16.5% compared to the same period of 2018.

**Gross Profit**

Our gross profit as a percentage of sales was 41.6%, 43.5%, and 44.7% for the years ended December 31, 2020, 2019 and 2018, respectively. The decrease in gross profit as a percentage of sales for 2020, as compared to 2019, was primarily due to changes in product mix and increased obsolescence expense associated with lower forecasted demand for certain of our products as a result of the COVID-19 pandemic, partially offset by improvements in manufacturing variances from operational efficiencies, among other factors. 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 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.

**Operating Expenses**

*Selling, General and Administrative Expenses*. Our selling, general and administrative ("SG&A") expenses decreased approximately ($29.5) million, or (9.0)%, for the year ended December 31, 2020 compared to 2019 and increased $51.3 million, or 18.6%, for the year ended December 31, 2019 compared to 2018. SG&A expenses as a percentage of sales were 30.9%, 32.9% and 31.3% for the years ended December 31, 2020, 2019 and 2018, respectively.

The decrease in SG&A expenses for the year ended December 31, 2020 compared to the year ended December 31, 2019 was primarily related to lower compensation expenses associated with headcount reductions and temporary salary reductions as a result of our expense reduction initiatives, lower commission expense associated with decreased sales, lower travel, entertainment and promotional expenses due to travel restrictions during the COVID-19 pandemic, and decreased acquisition and integration-related costs ($1.3 million in 2020 compared to $3.5 million in 2019), partially offset by increased idle capacity costs related to lower demand for certain products due to the COVID-19 pandemic and increased bad debt expense.

The increase in SG&A 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 during 2019 to support acquisitions and the growth in operations in that period, 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).

*Research and Development Expenses*. Research and development ("R&D") expenses decreased by ($8.1) million or (12.3)% to approximately $57.5 million for the year ended December 31, 2020, compared to approximately $65.6 million in 2019. The decrease in R&D expenses for the year ended December 31, 2020 was largely due to lower discretionary expenses (such as travel) and lower compensation expenses associated with headcount reductions and temporary salary reductions as a result of our expense reduction initiatives, as well as lower expenses as a result of a reduced number of research and development projects.

Research and development expenses increased by approximately $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 core and acquired product developments, as well as higher clinical and regulatory costs.

Our research and development expenses as a percentage of sales were 6.0%, 6.6% and 6.7% for 2020, 2019, and 2018, 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.

*Legal Settlement*. We recorded $18.7 million of expense during the year ended December 31, 2020 in connection with a settlement agreement with the DOJ to fully resolve the DOJ's investigation of certain marketing and promotional practices.

*Impairment Charges*. For the year ended December 31, 2020 we recorded impairment charges of $36.5 million, which included approximately $1.8 million related to certain right-of-use operating lease assets and property and equipment, $6.0 million related to equity investments and purchase options, and $28.7 million related to certain acquired intangible assets, which included a partial impairment charge of $8.2 million of intangible assets from our acquisition of STD Pharmaceutical Products Limited ("STD Pharmaceutical"), a partial impairment charge of $8.0 million of intangible assets from our acquisition of certain assets from Laurane Medical S.A.S, a partial impairment charge of $4.8 million related to our license agreements with ArraVasc Limited, and other intangible asset impairments charges of $7.7 million related to intangible assets from our acquisition of certain assets from DirectACCESS Medical, LLC, in-process technology intangible assets of Sontina Medical LLC acquired in connection with our acquisition of certain divested assets from BD, and a customer list intangible asset from our acquisition of ITL Healthcare Pty Ltd ("ITL").

For the year ended December 31, 2019 we recorded impairment charges of $23.8 million, including a $20.5 million 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 the business, and $3.3 million of impairment charges of certain intangible assets based on changes in revenue expectations and restructuring. For the year ended December 31, 2018 we recorded impairment charges of certain intangible assets of $0.7 million.

*Contingent Consideration (Benefit)*. For the years ended December 31, 2020, 2019 and 2018, we recorded ($8.0) million, ($0.2) million and ($0.7) 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. The (benefit) in each fiscal year relates to changes in revenue estimates, changes in the probability of achieving relevant milestones and changes in the discount rate or expected period of payment, partially offset by expense for the passage of time.

*Acquired In-process Research and Development*. During the years ended December 31, 2020, 2019 and 2018, we incurred in-process research and development charges of approximately $0.3 million, $0.5 million and $0.6 million, respectively associated with various asset acquisitions.

**Operating Income (Loss)**

Our operating profit by operating segment for the years ended December 31, 2020, 2019 and 2018 was as follows (in thousands):

| **Operating Income (Loss)** | **2020** | **2019** | **2018** |
|---|---|---|---|
| Cardiovascular | $ (7,042) | $ 25,780 | $ 49,289 |
| Endoscopy | 5,480 | (10,346) | 9,328 |
| Total operating income (loss) | $ (1,562) | $ 15,434 | $ 58,617 |

*Cardiovascular Operating Income (Loss).* Our cardiovascular operating loss for the year ended December 31, 2020 was approximately ($7.0) million, compared to cardiovascular operating income of approximately $25.8 million for the year ended December 31, 2019. This decrease in cardiovascular operating income was primarily related to lower sales and decreased gross margin percentage during the COVID-19 pandemic, expenses of $18.7 million associated with our settlement with the DOJ, impairment charges within our cardiovascular operating segment ($36.5 million in 2020 compared to $3.3 million in 2019), partially offset by lower compensation and discretionary expenses resulting from cost cutting initiatives and our response to the COVID-19 pandemic and an increase in contingent consideration benefit from changes in the estimated fair value of contingent consideration liabilities associated with prior acquisitions.

Our cardiovascular operating income for the year ended December 31, 2019 was approximately $25.8 million, compared to 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 DOJ ($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.

*Endoscopy Operating Income (Loss).* Our endoscopy operating income for the year ended December 31, 2020 was approximately $5.5 million, compared to an operating loss of approximately ($10.3) million for the year ended December 31, 2019. This increase in endoscopy operating income relative to 2019 was primarily due to lower impairment expense in our endoscopy operating segment (none in 2020 compared to $20.5 million in 2019) and lower compensation and discretionary expenses related to cost-cutting initiatives from our response to the COVID-19 pandemic, offset partially by lower sales and lower gross margins, due in part to changes in product demand during the COVID-19 pandemic.

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.

**Other Income (Expense)**

Our other expense for the years ended December 31, 2020, 2019 and 2018 was approximately ($11.7) million, ($13.2) million, and ($9.1) million, respectively. The decrease in other expense for 2020 compared to 2019 was principally the result of decreased interest expense due to lower average debt balances and a lower average interest rate during 2020, a gain on the sale of our Hypotube product line in 2020, and increased interest income from notes receivable, partially offset by increased expense related to foreign currency remeasurement.

The change in other 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.

**Effective Tax Rate**

Our provision for income taxes for the years ended December 31, 2020, 2019 and 2018 was a tax expense (benefit) of $(3.4) million, $(3.3) million and $7.5 million, respectively, which resulted in an effective income tax rate of 25.6%, (148.6%), and 15.2%, respectively. The increase in the effective income tax rate for 2020 compared to 2019 was primarily the result of a pre-tax loss during the 2020 period, as well as a change in the jurisdictional mix of earnings. 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.

**Net Income (Loss)**

Our net income (loss) for the years ended December 31, 2020, 2019 and 2018 was approximately ($9.8) million, $5.5 million, and $42.0 million, respectively. The decrease in net income for 2020, when compared to 2019, was primarily related to lower sales and decreased gross margin percentage during the COVID-19 pandemic, expenses of $18.7 million associated with our settlement with the DOJ, impairment charges ($36.5 million in 2020 compared to $23.8 million in 2019), partially offset by lower compensation and discretionary expenses resulting from cost cutting initiatives and our response to the COVID-19 pandemic and an increase in the benefit from changes in contingent consideration liabilities associated with prior acquisitions.

The decrease in net income for the year ended December 31, 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.

***Total Assets***

Total assets utilized in our cardiovascular operating segment were approximately $1.7 billion as of December 31, 2020, compared to approximately $1.7 billion as of December 31, 2019 and approximately $1.6 billion as of December 31, 2018. Total assets utilized in our endoscopy operating segment were approximately $9.5 million as of December 31, 2020, compared to approximately $12.3 million as of December 31, 2019 and approximately $31.0 million as of December 31, 2018.

The decrease in endoscopy total assets from December 31, 2019 to December 31, 2020 was primarily related to lower inventory levels and lower intangible asset balances (due to amortization). 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 until one year and 45 days have passed from the date Selio receives FDA Section 510(k) approval of a medical device it is currently developing. 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, 2020, 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 | $ 351,625 | $ 7,500 | $ 19,688 | $ 324,437 | $ — |
| Interest on long-term debt [(1)] | 23,331 | 6,392 | 12,708 | 4,231 | — |
| Operating leases | 102,140 | 14,947 | 21,493 | 15,792 | 49,908 |
| Royalty obligations | 4,958 | 931 | 1,935 | 1,771 | 321 |
| Total contractual cash | $ 482,054 | $ 29,770 | $ 55,824 | $ 346,231 | $ 50,229 |

(1) Interest payments on our variable long-term debt were forecasted using the LIBOR forward curves plus a base of 1.25% 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 2.37% through July 2021 and a fixed rate of 2.96% 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, 2020, we had approximately $55.7 million of contingent consideration liabilities, $1.7 million of unrecognized tax positions, and $16.8 million of deferred compensation payable that have been recognized as liabilities that have not been included in the contractual obligations table due to uncertainty as to when such amounts may be settled.

Additional information regarding our capital commitments and contractual obligations, including royalty payments 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, 2020 and 2019, we had cash and cash equivalents of approximately $56.9 million and $44.3 million respectively, of which approximately $42.3 million and $31.7 million, respectively, were held by foreign subsidiaries. We do not consider our foreign earnings to be permanently reinvested. 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, 2020 and 2019, we had cash and cash equivalents of approximately $15.5 million and $11.3 million, respectively, held by our subsidiary in China.

*Cash flows provided by operating activities.* We generated cash from operating activities of approximately $165.3 million, $77.8 million and $86.5 million during the years ended December 31, 2020, 2019 and 2018, respectively. Net cash provided by operating activities increased approximately $87.5 million for the year ended December 31, 2020 compared to the year ended December 31, 2019. Significant changes in operating assets and liabilities affecting cash flows during these years included:

- Cash provided by (used for) accounts receivable was approximately $10.4 million and $(17.9) million for the years ended December 31, 2020 and 2019, respectively, due primarily to decreases in sales volume and increased allowance due to economic uncertainty, and

- Cash provided by (used for) inventories was $29.4 million and $(27.0) million for the years ended December 31, 2020 and 2019, respectively, due primarily to reduced production during the economic downturns related to the pandemic and efforts to manage inventory levels.

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.

*Cash flows used in investing activities.* We used cash in investing activities of approximately $58.6 million, $134.5 million, and $378.8 million for the years ended December 31, 2020, 2019 and 2018, respectively. We invested in capital expenditures for property and equipment of approximately $46.0 million, $78.2 million, and $63.3 million for the years ended December 31, 2020, 2019 and 2018, 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 $45 to $50 million in 2021 for buildings, property and equipment.

Cash outflows invested in acquisitions for the year ended December 31, 2020 were approximately $11.0 million and were primarily related to our acquisition of KA Medical. Cash outflows for acquisitions in 2019 were approximately $53.9 million and were primarily related to our acquisition of Brightwater Medical, Inc. (“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. For further discussion, refer to Note 3 to our consolidated financial statements set forth in Item 8 of this report.

*Cash flows provided by (used in) financing activities.* Cash provided by (used in) financing activities for the years ended December 31, 2020, 2019 and 2018 was approximately ($95.7) million, $33.5 million, and $328.3 million, respectively. In 2020 we decreased our net borrowings by approximately $88.4 million and paid contingent consideration of approximately $13.1 million, which is classified as a financing activity, principally related to our Cianna Medical acquisition. 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, 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.

As of December 31, 2020, we had outstanding borrowings of approximately $351.6 million under the Third Amended Credit Agreement, with additional available borrowings of approximately $389 million, based on the leverage ratio required pursuant to the Third Amended Credit Agreement. Our interest rate as of December 31, 2020 was a fixed rate of 2.37% on $175 million as a result of an interest rate swap (see Note 9) and a variable floating rate of 1.40% on approximately $176.6 million. 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 and a variable floating rate of 3.30% on $265 million. The foregoing fixed rates are exclusive of changes in the notional amount and fixed rate associated with our interest rate swaps beginning July 6, 2021 and potential future changes in the applicable margin. See Note 8 and Note 9 to our consolidated financial statements set forth in Item 8 of this report for additional details regarding the Third Amended Credit Agreement, our long-term debt and our interest rate swaps.

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***

Our significant accounting policies are summarized in Note 1 to our consolidated financial statements set forth in Item 8 of this report. While all of these significant accounting policies affect the reporting of our financial condition and results of operations, 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 annually as of July 1, or whenever impairment indicators arise. When impairment indicators are identified, we may elect to perform an optional qualitative assessment to determine whether it is more likely than not that the fair value of our reporting units has fallen below their carrying value. This assessment involves significant judgment, especially in the current environment due to uncertainties about the duration and impact of

the COVID-19 pandemic. During our annual impairment test performed as of July 1 we utilized four 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 the amount, timing and duration of future cash flows, 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 2020, which was completed during the third quarter of 2020, 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 years ended December 31, 2020, 2019 and 2018, we compared the carrying value of the amortizing intangible assets acquired in acquisitions of certain assets to the undiscounted cash flows expected to result from these asset groups and determined that the carrying amounts were not recoverable. We then determined the fair value of the amortizing assets based on estimated future cash flows discounted back to their present value using discount rates that reflect the risk profile of the underlying activities. During the years ended December 31, 2020, 2019 and 2018 we recorded total impairment charges associated with intangible assets in our cardiovascular segment of approximately $28.7 million, $3.3 million, and $0.7 million, respectively. These expenses are reflected within impairment charges in our consolidated statements of income (loss). The primary factors driving impairment of certain intangible assets were slower-than-anticipated sales growth in the acquired products, planned closure and restructuring activities, uncertainty about future product development and commercialization associated with the acquired technologies, and in 2020 economic uncertainties associated with the COVID-19 pandemic. See Note 5 to our consolidated financial statements set forth in Item 8 of this report for additional details regarding impairments of intangible assets.

*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 other relevant 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 approval, performance, or revenue-based milestones and other relevant factors. These assumptions are impacted by our best estimates of the timing and duration of the current COVID-19 pandemic.

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 and developments related to the COVID-19 pandemic 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. Our revenue milestone contingent liability associated with the November 2018 acquisition of Cianna Medical includes a sales growth multiplier, and our revenue milestones for the acquisition of Brightwater and Vascular Insights, LLC include payment thresholds. These and other similar contract features of our contingent consideration liabilities create sensitivity regarding the occurrence, timing, and amount of future payments.

For the years ended December 31, 2020, 2019 and 2018, we recognized contingent consideration benefit of approximately $8.0 million, $0.2 million and $0.7 million, respectively, from changes in the estimated fair value of our contingent consideration obligations stemming from our previously disclosed business acquisitions. Changes in the fair value of our contingent consideration liabilities were primarily attributable to slower-than-anticipated sales growth in the

acquired products, the anticipated timing of milestone payments, and in 2020 economic uncertainties associated with the COVID-19 pandemic. See Note 16 to our consolidated financial statements set forth in Item 8 of this report for additional details regarding our contingent liabilities.

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

***Currency Exchange Rate Risk***

Our consolidated financial statements are denominated in, and our principal currency is, the U.S. Dollar. For the year ended December 31, 2020, a portion of our net sales (approximately $323.8 million, representing approximately 33.6% 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 principal market risk relates to changes in the value of the Chinese Yuan Renminbi (CNY) and Euro (EUR) relative U.S. Dollar (USD), with limited market risk relating to various other currencies. 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, a strengthening of the U.S. Dollar against the Euro will generally have a positive effect on our operating income.

We forecast our net exposure related to sales and expenses denominated in foreign currencies. As of December 31, 2020 and 2019, we had entered into foreign currency forward contracts, which qualified as cash flow hedges, with aggregate notional amounts of approximately $168.2 million and $212.5 million, respectively. 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, 2020 and 2019, we had entered into foreign currency forward contracts, which were not designated as hedging instruments, related to those balance sheet accounts with aggregate notional amounts of approximately $74.8 million and $65.0 million, respectively.

A sensitivity analysis of changes in the fair value of all currency exchange rate derivative contracts at December 31, 2020 and 2019 indicates that, if the U.S. Dollar strengthened or weakened by 10 percent against all currencies, it would have the following impact on the fair value of these contracts (in thousands):

| | 2020 | 2019 |
|---|---|---|
| 10% Strengthening | $ 2,768 | $ 1,517 |
| 10% Weakening | $ (2,768) | $ (1,517) |

Gains or losses on the fair value of derivative contracts would generally be offset by gains and losses on the underlying hedged transaction or net exposure. These offsetting gains and losses are not reflected above. See Note 9 to our consolidated financial statements set forth in Item 8 of this report for additional discussion of our foreign currency forward contracts.

***Interest Rate Risk***

As discussed in Note 8 to our consolidated financial statements set forth in Item 8 of this report, as of December 31, 2020, we had outstanding borrowings of approximately $351.6 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 Bank, which as of December 31, 2020 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 Bank, 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 $2.3 million annually for each one percentage point change in the average interest rate under these borrowings.

## 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, 2020 and 2019, the related consolidated statements of income (loss), comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, 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, 2020, 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 1, 2021, 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, the Company changed its method of accounting for leases in 2019 due to the adoption of Accounting Standards Update No. 2016-02, *Leases (Topic 842)*, 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 Matters**

The critical audit matters communicated below are matters arising from the current-period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

***Intangible Assets – Impairment Charges – Refer to Notes 1 and 5 to the financial statements***

*Critical Audit Matter Description*

The Company has recorded finite-lived intangible assets with carrying values of $367.9 million at December 31, 2020. The Company evaluates amortizing intangible assets for impairment whenever events or changes in circumstances indicate that their carrying amounts may not be recoverable and compares the carrying value of the amortizing intangible assets to the undiscounted cash flows expected to result from the asset group and determines whether the carrying amount is recoverable. If the carrying amount is not recoverable, an impairment charge is recorded based on the difference between the carrying amount and the fair value. The Company estimates the fair value of intangible assets using a discounted cash flow model which includes estimates of future projections of revenues and cash flows. During the year ended December 31, 2020, the Company recorded total impairment charges related to intangible assets of approximately $28.7 million.

We identified the intangible asset impairment charges as a critical audit matter because of the significant estimates and assumptions management makes to determine the fair value of intangible assets to record the impairment charge. This required a high degree of auditor judgment and an increased extent of effort when performing audit procedures to evaluate the reasonableness of management's estimates of future projections of revenues and cash flows.

*How the Critical Audit Matter Was Addressed in the Audit*

Our audit procedures related to management's estimates of future projections of revenues and cash flows used for the intangible asset impairment tests included the following, among others:

- We tested the effectiveness of controls over the impairment tests of intangible assets, including management's controls over estimates of future projections of revenues and cash flows.
- We assessed the reasonableness of management's estimates of future projections of revenues and cash flows through comparison to historical results and the Company's strategic plans and initiatives.
- We evaluated whether the estimates of future projections of revenues and cash flows were consistent with evidence obtained in other areas of the audit.

***Other Long-term Obligations - Contingent Consideration Liability – Refer to Notes 1, 3, and 16 to the financial statements***

*Critical Audit Matter Description*

Certain of the Company's past business combinations involve the potential for payment of future contingent consideration, generally based on a percentage of future product revenues or upon attaining specified future revenue milestones. As of December 31, 2020, the Company has recorded $55.7 million of contingent consideration liabilities of which $46.3 million are based on revenue milestones. Contingent consideration liabilities are 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 (loss). During the year ended December 31, 2020, the Company recorded a benefit of $8.0 million for the estimated change in fair value of contingent consideration liabilities. Included within contingent consideration liabilities is a liability for the estimated earn-out payment based on a revenue growth multiplier specified in the agreement from the November 2018 acquisition of Cianna Medical, Inc. The fair value of this revenue milestone contingent consideration liability was estimated using a Monte Carlo simulation model, which is a complex valuation methodology with inputs that include revenue projections and a discount rate.

We identified the Cianna Medical, Inc. revenue milestone contingent consideration liability as a critical audit matter because of management's estimates of revenue projections and the complex valuation methodology and discount rate used to determine the fair value of the contingent consideration liability. 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 estimates of revenue projections and to evaluate the appropriateness of the valuation methodology and discount rate.

*How the Critical Audit Matter Was Addressed in the Audit*

Our audit procedures related to management's estimates of revenue projections and the valuation methodology and discount rate used to determine the fair value of the Cianna Medical, Inc. revenue milestone contingent consideration liability included the following, among others:

- We tested the effectiveness of controls over management's valuation of contingent consideration liabilities, including those related to estimates of revenue projections and the valuation methodology and discount rate.
- We evaluated management's ability to accurately estimate revenue projections and the reasonableness of revenue projections by comparing management's historical revenue estimates to subsequent results, taking into account changes in market conditions.
- With the assistance of our fair value specialists, we evaluated the reasonableness of the valuation methodology and the discount rate by:
    - Evaluating whether the valuation methodology is appropriate in accordance with generally accepted valuation principles in the circumstances and whether the methodology used for determining fair value is applied consistently with the preceding periods.
    - Testing the source information underlying the determination of the discount rate and testing the mathematical accuracy of the calculation
    - Developing a range of independent estimates for the discount rate and comparing those to the discount rate selected by management.
- We evaluated whether the estimates of revenue projections were consistent with evidence obtained in other areas of the audit.

/s/ DELOITTE & TOUCHE LLP

Salt Lake City, Utah
March 1, 2021
We have served as the Company's auditor since 1988.

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**
**CONSOLIDATED BALANCE SHEETS**
**DECEMBER 31, 2020 AND 2019**
**(In thousands)**

| ASSETS | December 31, 2020 | December 31, 2019 |
|---|---|---|
| CURRENT ASSETS: | | |
| Cash and cash equivalents | $ 56,916 | $ 44,320 |
| Trade receivables — net of allowance for credit losses — 2020 — $5,313 and 2019 — $3,108 | 146,641 | 155,365 |
| Other receivables | 7,774 | 10,016 |
| Inventories | 198,019 | 225,698 |
| Prepaid expenses and other current assets | 13,120 | 12,497 |
| Prepaid income taxes | 3,688 | 3,491 |
| Income tax refund receivables | 3,549 | 3,151 |
| Total current assets | 429,707 | 454,538 |
| PROPERTY AND EQUIPMENT: | | |
| Land and land improvements | 28,400 | 27,554 |
| Buildings | 188,878 | 153,863 |
| Manufacturing equipment | 268,894 | 244,368 |
| Furniture and fixtures | 61,586 | 57,623 |
| Leasehold improvements | 48,800 | 43,311 |
| Construction-in-progress | 46,889 | 83,685 |
| Total property and equipment | 643,447 | 610,404 |
| Less accumulated depreciation | (260,719) | (231,619) |
| Property and equipment — net | 382,728 | 378,785 |
| OTHER ASSETS: | | |
| Intangible assets: | | |
| Developed technology — net of accumulated amortization —2020 — $193,164 and 2019 — $149,947 | 318,059 | 379,529 |
| Other — net of accumulated amortization — 2020 — $56,943 and 2019 — $65,607 | 49,856 | 65,783 |
| Goodwill | 363,533 | 353,193 |
| Deferred income tax assets | 4,597 | 3,788 |
| Right-of-use operating lease assets | 78,240 | 80,244 |
| Other assets | 37,676 | 41,461 |
| Total other assets | 851,961 | 923,998 |
| TOTAL ASSETS | $ 1,664,396 | $ 1,757,321 |

See notes to consolidated financial statements.

(continued)

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**
**CONSOLIDATED BALANCE SHEETS**
**DECEMBER 31, 2020 AND 2019**
**(In thousands)**

| LIABILITIES AND STOCKHOLDERS' EQUITY | December 31, 2020 | December 31, 2019 |
|---|---|---|
| CURRENT LIABILITIES: | | |
| Trade payables | $ 49,837 | $ 54,623 |
| Accrued expenses | 111,944 | 105,184 |
| Current portion of long-term debt | 7,500 | 7,500 |
| Short-term operating lease liabilities | 12,903 | 11,550 |
| Income taxes payable | 2,820 | 2,799 |
| Total current liabilities | 185,004 | 181,656 |
| Long-term debt | 343,722 | 431,984 |
| Deferred income tax liabilities | 33,312 | 45,236 |
| Long-term income taxes payable | 347 | 347 |
| Liabilities related to unrecognized tax benefits | 1,016 | 1,990 |
| Deferred compensation payable | 16,808 | 14,855 |
| Deferred credits | 1,923 | 2,122 |
| Long-term operating lease liabilities | 70,941 | 72,714 |
| Other long-term obligations | 52,748 | 56,473 |
| Total liabilities | 705,821 | 807,377 |
| Commitments and contingencies | | |
| STOCKHOLDERS' EQUITY: | | |
| Preferred stock — 5,000 shares authorized as of December 31, 2020 and December 31, 2019; no shares issued | — | — |
| Common stock, no par value; shares authorized — 2020 and 2019 - 100,000; issued and outstanding as of December 31, 2020 - 55,623 and December 31, 2019 - 55,213 | 606,224 | 587,017 |
| Retained earnings | 357,803 | 368,221 |
| Accumulated other comprehensive loss | (5,452) | (5,294) |
| Total stockholders' equity | 958,575 | 949,944 |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | $ 1,664,396 | $ 1,757,321 |

See notes to consolidated financial statements. (concluded)

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF INCOME (LOSS)**
**YEARS ENDED DECEMBER 31, 2020, 2019 AND 2018**
**(In thousands, except per share amounts)**

| | 2020 | 2019 | 2018 |
|---|---|---|---|
| NET SALES | $ 963,875 | $ 994,852 | $ 882,753 |
| COST OF SALES | 562,698 | 562,486 | 487,983 |
| GROSS PROFIT | 401,177 | 432,366 | 394,770 |
| OPERATING EXPENSES: | | | |
| Selling, general and administrative | 297,724 | 327,274 | 276,018 |
| Research and development | 57,537 | 65,615 | 59,532 |
| Legal settlement | 18,684 | — | — |
| Impairment charges | 36,504 | 23,750 | 657 |
| Contingent consideration (benefit) | (7,960) | (232) | (698) |
| Acquired in-process research and development | 250 | 525 | 644 |
| Total operating expenses | 402,739 | 416,932 | 336,153 |
| INCOME (LOSS) FROM OPERATIONS | (1,562) | 15,434 | 58,617 |
| OTHER INCOME (EXPENSE): | | | |
| Interest income | 604 | (291) | 1,199 |
| Interest expense | (9,994) | (12,413) | (10,360) |
| Other income (expense) - net | (2,279) | (537) | 63 |
| Total other expense — net | (11,669) | (13,241) | (9,098) |
| INCOME (LOSS) BEFORE INCOME TAXES | (13,231) | 2,193 | 49,519 |
| INCOME TAX (BENEFIT) EXPENSE | (3,388) | (3,258) | 7,502 |
| NET INCOME (LOSS) | $ (9,843) | $ 5,451 | $ 42,017 |
| EARNINGS (LOSS) PER COMMON SHARE: | | | |
| Basic | $ (0.18) | $ 0.10 | $ 0.80 |
| Diluted | $ (0.18) | $ 0.10 | $ 0.78 |
| WEIGHTED AVERAGE SHARES OUTSTANDING: | | | |
| Basic | 55,434 | 55,075 | 52,268 |
| Diluted | 55,434 | 56,235 | 53,931 |

See notes to consolidated financial statements.

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**
**YEARS ENDED DECEMBER 31, 2020, 2019 AND 2018**
**(In thousands)**

| | 2020 | 2019 | 2018 |
|---|---|---|---|
| Net income (loss) | $ (9,843) | $ 5,451 | $ 42,017 |
| Other comprehensive income (loss): | | | |
| Cash flow hedges | (9,523) | (5,456) | 64 |
| Income tax benefit (expense) | 2,365 | 1,404 | (16) |
| Foreign currency translation adjustment | 7,786 | (18) | (3,606) |
| Income tax benefit (expense) | (786) | 61 | (9) |
| Total other comprehensive loss | (158) | (4,009) | (3,567) |
| Total comprehensive income (loss) | $ (10,001) | $ 1,442 | $ 38,450 |

See notes to consolidated financial statements.

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**
**YEARS ENDED DECEMBER 31, 2020, 2019 AND 2018**
**(In thousands)**

| | | Common Stock | | Retained | Accumulated Other |
|---|---|---|---|---|---|
| | Total | Shares | Amount | Earnings | Comprehensive Income (Loss) |
| BALANCE — January 1, 2018 | $ 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) |
| Net loss | (9,843) | | | (9,843) | |
| Cumulative effect adjustment upon adoption of ASU 2016-13, *Credit Losses* | (575) | | | (575) | |
| Other comprehensive loss | (158) | | | | (158) |
| Stock-based compensation expense | 13,433 | | 13,433 | | |
| Options exercised | 6,948 | 442 | 6,948 | | |
| Issuance of common stock under Employee Stock Purchase Plans | 1,159 | 30 | 1,159 | | |
| Shares surrendered in exchange for payment of payroll tax liabilities | (866) | (23) | (866) | | |
| Shares surrendered in exchange for exercise of stock options | (1,467) | (39) | (1,467) | | |
| BALANCE — December 31, 2020 | $ 958,575 | 55,623 | $ 606,224 | $ 357,803 | $ (5,452) |

See notes to consolidated financial statements.

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**
**YEARS ENDED DECEMBER 31, 2020, 2019 AND 2018**
**(In thousands)**

| | 2020 | 2019 | 2018 |
|---|---|---|---|
| CASH FLOWS FROM OPERATING ACTIVITIES: | | | |
| Net income (loss) | $ (9,843) | $ 5,451 | $ 42,017 |
| Adjustments to reconcile net income (loss) to net cash provided by operating activities: | | | |
| Depreciation and amortization | 94,070 | 92,100 | 69,546 |
| Gain on sale of business | (517) | — | — |
| Loss on sales and/or abandonment of property and equipment | 2,159 | 115 | 625 |
| Write-off of certain intangible assets and other long-term assets | 36,609 | 25,563 | 814 |
| Acquired in-process research and development | 250 | 525 | 644 |
| Amortization of right-of-use operating lease assets | 12,746 | 12,256 | — |
| Fair value adjustments to contingent consideration | (7,960) | (232) | (698) |
| Amortization of deferred credits | (130) | (139) | (142) |
| Amortization of long-term debt issuance costs | 604 | 721 | 804 |
| Deferred income taxes | (11,295) | (12,436) | 2,052 |
| Stock-based compensation expense | 14,339 | 9,382 | 6,117 |
| Changes in operating assets and liabilities, net of acquisitions and divestitures: | | | |
| Trade receivables | 10,425 | (17,900) | (27,522) |
| Other receivables | 1,668 | 1,787 | (2,588) |
| Inventories | 29,429 | (27,044) | (28,172) |
| Prepaid expenses and other current assets | (446) | (1,239) | (2,000) |
| Prepaid income taxes | (162) | 128 | (444) |
| Income tax refund receivables | (339) | (2,247) | 232 |
| Other assets | (3,511) | (5,141) | 149 |
| Trade payables | 333 | (2,295) | 15,726 |
| Accrued expenses | 4,603 | 4,719 | 12,623 |
| Income taxes payable | (86) | (351) | 918 |
| Long-term income taxes payable | — | (45) | (4,454) |
| Liabilities related to unrecognized tax benefits | (576) | (794) | 267 |
| Deferred compensation payable | 1,953 | 3,635 | 39 |
| Operating lease liabilities | (12,659) | (11,970) | — |
| Other long-term obligations | 3,606 | 3,264 | (20) |
| Total adjustments | 175,113 | 72,362 | 44,516 |
| Net cash provided by operating activities | 165,270 | 77,813 | 86,533 |
| | | | |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | | |
| Capital expenditures for: | | | |
| Property and equipment | (45,988) | (78,173) | (63,324) |
| Intangible assets | (3,288) | (3,324) | (3,012) |
| Proceeds from the sale of property and equipment | 42 | 920 | 55 |
| Proceeds from sale of business | 1,285 | — | — |
| Cash received for settlement of current note receivable | 250 | — | — |
| Issuance of note receivable | — | — | (10,750) |
| Cash paid in acquisitions, net of cash acquired | (10,953) | (53,904) | (301,789) |
| Net cash used in investing activities | $ (58,652) | $ (134,481) | $ (378,820) |

See notes to consolidated financial statements.

(continued)

**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**
**YEARS ENDED DECEMBER 31, 2020, 2019 AND 2018**
**(In thousands)**

| | 2020 | 2019 | 2018 |
|---|---|---|---|
| CASH FLOWS FROM FINANCING ACTIVITIES: | | | |
| Proceeds from issuance of common stock | $ 6,635 | $ 6,252 | $ 214,993 |
| Offering costs | — | — | (366) |
| Proceeds from issuance of long-term debt | 68,625 | 246,659 | 639,108 |
| Payments on long-term debt | (157,000) | (202,159) | (522,608) |
| Long-term debt issuance costs | — | (1,479) | — |
| Contingent payments related to acquisitions | (13,100) | (15,740) | (231) |
| Payment of taxes related to an exchange of common stock | (866) | — | (2,616) |
| Net cash provided by (used in) financing activities | (95,706) | 33,533 | 328,280 |
| EFFECT OF EXCHANGE RATES ON CASH | 1,684 | 96 | (970) |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS | 12,596 | (23,039) | 35,023 |
| CASH AND CASH EQUIVALENTS: | | | |
| Beginning of period | 44,320 | 67,359 | 32,336 |
| End of period | $ 56,916 | $ 44,320 | $ 67,359 |
| SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION | | | |
| Cash paid during the period for: | | | |
| Interest (net of capitalized interest of $813, $1,290 and $647, respectively) | $ 10,077 | $ 12,434 | $ 10,324 |
| Income taxes | $ 8,918 | $ 12,069 | $ 8,692 |
| SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES | | | |
| Property and equipment purchases in accounts payable | $ 2,180 | $ 7,952 | $ 4,989 |
| Current note receivable converted to equity investment | $ 899 | $ — | $ — |
| Proceeds from sale of business in other receivables | $ 321 | $ — | $ — |
| Acquisition purchases in accrued expenses and other long-term obligations | $ 4,358 | $ 10,541 | $ 72,209 |
| Merit common stock surrendered (39, 3 and 43 shares, respectively) in exchange for exercise of stock options | $ 1,467 | $ 93 | $ 2,261 |
| Right-of-use operating lease assets obtained in exchange for operating lease liabilities | $ 10,938 | $ 10,637 | $ — |

See notes to consolidated financial statements. (concluded)

## 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 five product categories: peripheral intervention, cardiac intervention, custom procedural solutions, original equipment manufacturer ("OEM") and endoscopy.

We manufacture our products in plants located in the U.S., Mexico, The Netherlands, Ireland, France, Brazil 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.

**Reclassifications.** Certain reclassifications have been made to the 2019 and 2018 periods to conform to the 2020 presentation. In the consolidated statements of cash flows for the year ended December 31, 2020, the fair value adjustment to contingent consideration is presented as a reconciling item between net income (loss) and cash flows from operating activities. A corresponding reclassification for the years ended December 31, 2019 and 2018 of approximately $0.2 million and $0.7 million, respectively, has been made for comparability, along with corresponding reclassifications to the change in certain operating assets and liabilities.

**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 credit losses on trade receivables is recorded based on our expectation of credit losses and is based upon our historical bad debt experience, current economic conditions, expectations of future economic conditions and 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 credit losses.

**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. When impairment indicators are identified, we may elect to perform an optional qualitative assessment to determine whether it is more likely than not that the fair value of our reporting units has fallen below their carrying value. During our annual impairment test we utilize four 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 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.

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, 2020, 2019 and 2018 was approximately $35.4 million, $31.4 million, and $28.3 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 $17.1 million and $15.1 million at December 31, 2020 and 2019, respectively, which is included in other assets in our consolidated balance sheets. We

have recorded a deferred compensation payable of approximately $16.8 million and $14.9 million at December 31, 2020 and 2019, respectively, to reflect the liability to our employees under this plan.

**Other Assets**. Other assets as of December 31, 2020 and 2019 consisted of the following (in thousands):

| | 2020 | 2019 |
|---|---|---|
| Deferred compensation plan assets | $ 17,074 | $ 15,053 |
| Investments in privately held companies | 12,043 | 17,129 |
| Long-term notes receivable | 2,196 | 2,722 |
| Other | 6,363 | 6,557 |
| Total | $ 37,676 | $ 41,461 |

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 (loss). 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.

**Other Long-term Obligations.** Other long-term obligations as of December 31, 2020 and 2019 consisted of the following (in thousands):

| | 2020 | 2019 |
|---|---|---|
| Contingent consideration liabilities | $ 36,917 | $ 48,088 |
| Other long-term obligations | 15,831 | 8,385 |
| Total | $ 52,748 | $ 56,473 |

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 revenue estimates, changes in the probability of achieving relevant milestones and changes in the discount rate or expected period of payment. Changes in the estimated fair value are recorded through operating expense in our consolidated statements of income (loss).

**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. W*e 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. Contract assets are recognized for the future right to invoice customers, and contract liabilities are recognized for unearned revenue if payment is received prior to our fulfillment of performance obligations. We do not have material contract assets or contract liabilities.

Reserves are recorded as a reduction in net sales and are not considered material to our consolidated statements of income (loss) for the years ended December 31, 2020, 2019 and 2018. 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**. When billed to our customers, shipping and handling charges 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, including new product development, clinical trials, and regulatory compliance, 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 (loss) per common share is computed by both the basic method, which uses the weighted average number of our common shares outstanding, and the diluted method, which includes the dilutive common shares from stock options and restricted stock units as calculated using the treasury stock method. Performance stock units are considered contingently issuable awards and are excluded from the weighted average basic share calculation. These awards are included in the weighted average dilutive share calculation, to the extent they are dilutive, based on the number of shares, if any, that would be issuable as of the end of the reporting period assuming the end of the reporting period is also the end of the performance period.

**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. The fair value of our performance stock units linked to total shareholder return is estimated using Monte-Carlo simulations. Compensation expense is adjusted each period based on the grant-date fair value and the number of shares that are probable of being awarded based on the performance conditions of the awards. Restricted stock units are valued based on the closing stock price on the date of grant. Cash-settled share-based awards, or liability awards, are remeasured at fair value each reporting period until the awards are settled. Stock-based compensation expense for the years ended December 31, 2020, 2019 and 2018 was approximately $14.3 million, $9.4 million and $6.1 million, respectively (see Note 12).

**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. Due to the diversified nature and number of our customers, concentrations of credit risk with respect to accounts receivable are limited.

**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. Transactional exchange gains or losses are included in other income (expense) in determining net income (loss) 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 August 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("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 became effective for us on January 1, 2020. The adoption of this standard did not have a material impact on our consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820)*, which removes, modifies and adds various disclosure requirements related to fair value disclosures. ASU 2018-13 became effective for us beginning on January 1, 2020. We have modified our disclosures to conform with this guidance (see Note 16).

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which replaced the incurred loss impairment methodology for financial assets with a methodology that reflects expected credit losses. The new credit loss model must be applied to loans, accounts receivable, and other financial assets. ASU 2016-13 became effective for us beginning on January 1, 2020. We adopted this standard using a modified retrospective approach with a cumulative-effect adjustment to retained earnings of $575,000 as of the beginning of 2020. See Note 16 for additional disclosures related to our allowance for current expected credit losses. The adoption of this guidance did not have a material impact on our statements of income (loss) or cash flows.

***Not Yet Adopted***

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting,* which provides temporary optional expedients and exceptions in accounting for modifications of contracts that reference the London interbank offered rate ("LIBOR") or another reference rate expected to be discontinued as a result of reference rate reform. In January 2021 the FASB issued ASU 2021-01, *Reference Rate Reform (Topic 848): Scope,* which amends the scope of ASU 2020-04. ASU 2020-04 and ASU 2021-01 are effective as of March 12, 2020 and may be applied prospectively to transactions through December 31, 2022. We are currently assessing the anticipated impact of these standards on our consolidated financial statements.

We currently believe that all other issued and not yet effective accounting standards are not relevant to our financial statements.

## 2. REVENUES

**Disaggregation of Revenue.** Our revenue is disaggregated based on reporting segment, product category and geographical region. Beginning in the first quarter of 2020, we revised our product categories to more clearly reflect how we sell our products to our customers. We presented historical information under the new revised product categories in a Current Report on Form 8-K, filed with the SEC on April 3, 2020.

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 four product categories: peripheral intervention, cardiac intervention, custom procedural solutions, and OEM. Within these product categories, we sell a variety of products, including cardiology and radiology devices (which assist in diagnosing and treating coronary arterial disease, peripheral vascular disease and other non-vascular diseases), as well as embolotherapeutic, cardiac rhythm management, electrophysiology, critical care, breast cancer localization and guidance, biopsy, 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.

The following table presents sales by operating segment disaggregated based on product category and geographic region for the years ended December 31, 2020, 2019 and 2018 (in thousands).

| | Year Ended December 31, 2020 | | | Year Ended December 31, 2019 | | | Year Ended December 31, 2018 | | |
|---|---|---|---|---|---|---|---|---|---|
| | United States | International | Total | United States | International | Total | United States | International | Total |
| **Cardiovascular** | | | | | | | | | |
| Peripheral Intervention | $211,999 | $ 129,569 | $341,568 | $226,788 | $ 124,148 | $350,936 | $171,277 | $ 104,836 | $276,113 |
| Cardiac Intervention | 108,109 | 171,562 | 279,671 | 115,604 | 189,193 | 304,797 | 104,263 | 174,233 | 278,496 |
| Custom Procedural Solutions | 110,269 | 92,927 | 203,196 | 99,659 | 87,700 | 187,359 | 96,730 | 83,602 | 180,332 |
| OEM | 91,826 | 17,941 | 109,767 | 101,065 | 16,824 | 117,889 | 91,954 | 22,582 | 114,536 |
| Total | 522,203 | 411,999 | 934,202 | 543,116 | 417,865 | 960,981 | 464,224 | 385,253 | 849,477 |
| | | | | | | | | | |
| **Endoscopy** | | | | | | | | | |
| Endoscopy devices | 27,858 | 1,815 | 29,673 | 32,595 | 1,276 | 33,871 | 32,189 | 1,087 | 33,276 |
| | | | | | | | | | |
| Total | $550,061 | $ 413,814 | $963,875 | $575,711 | $ 419,141 | $994,852 | $496,413 | $ 386,340 | $882,753 |

## 3. ACQUISITIONS AND OTHER STRATEGIC TRANSACTIONS

### 2020 Acquisitions

On November 6, 2020, we entered into a unit purchase agreement to acquire KA Medical, LLC ("KA Medical"). Subject to the terms and conditions of the unit purchase agreement, we paid $10.4 million in cash at closing, net of cash acquired, subject to adjustments for working capital and other matters, with an additional $4 million payable no later than 12 months following the agreement. KA Medical developed the Micro Plug Set, a self-expanding nitinol vascular occlusion device, which is FDA-cleared and CE marked. 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 KA Medical acquisition, which were included in selling, general and administrative expenses, were not material.

The purchase price was preliminarily allocated as follows (in thousands):

| | | |
|---|---|---|
| **Assets Acquired** | | |
| Trade receivables | $ | 24 |
| Other receivables | | 13 |
| Inventories | | 216 |
| Property and equipment | | 298 |
| Other long-term assets | | 147 |
| Intangible assets | | |
| Developed technology | | 6,000 |
| Goodwill | | 8,283 |
| Total assets acquired | | 14,981 |
| | | |
| **Liabilities Assumed** | | |
| Trade payables | | (31) |
| Accrued expenses | | (507) |
| Total liabilities assumed | | (538) |
| | | |
| **Total net assets acquired** | **$** | **14,443** |

We are amortizing the developed technology intangible asset acquired from KA Medical over 17 years. The goodwill consists largely of the synergies expected from combining operations and is expected to be deductible for income tax purposes.

**2019 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. 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.

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 an immaterial working capital adjustment, 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 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.

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.

The following table summarizes the purchase price allocation and other disclosures for acquisitions accounted for as business combinations during the year ended December 31, 2019 (in thousands). During the year ended December 31, 2020, certain non-significant measurement period adjustments were recorded to our purchase price allocation for the assets acquired from Brightwater, including reassessment of tax assets and liabilities.

| | STD Pharmaceutical | Brightwater |
|---|---|---|
| **Assets Acquired** | | |
| Trade receivables | $ 277 | $ 55 |
| Inventories | 843 | 349 |
| Prepaid expenses and other current assets | 49 | — |
| Property and equipment | — | 409 |
| Other long-term assets | — | 30 |
| Intangible assets | | |
| Developed technology | 10,428 | 31,960 |
| Customer lists | — | 83 |
| Trademarks | — | 250 |
| Goodwill | 4,975 | 17,607 |
| Total assets acquired | 16,572 | 50,743 |
| | | |
| **Liabilities Assumed** | | |
| Trade payables | (53) | (58) |
| Accrued expenses | (29) | (261) |
| Other long-term obligations | — | (1,522) |
| Deferred income tax liabilities | (1,890) | (4,263) |
| Total liabilities assumed | (1,972) | (6,104) |
| | | |
| **Total net assets acquired** | **$ 14,600** | **$ 44,639** |
| | | |
| **Amortization Period of Intangible Assets** | | |
| Developed technology | 12 years | 13 years |
| Customer lists (on an accelerated basis) | — | 1 year |
| Trademarks | — | 5 years |
| **Weighted Average** | **12 years** | **12.9 years** |

The sales and results of operations related to the STD Pharmaceutical and Brightwater acquisitions have been included in our cardiovascular segment and were not material. It is not practical to separately report earnings related to these acquisitions, as we cannot split out sales costs related solely to the products acquired, principally because our sales representatives sell multiple products within our cardiovascular business segment. Acquisition costs related to the STD Pharmaceutical and Brightwater acquisitions, which were included in selling, general and administrative expenses, were not material. Goodwill related to these acquisitions arises principally from synergies and economies of scale anticipated upon consolidation of operations and is not expected to be deductible for income tax purposes.

**2018 Acquisitions**

On December 14, 2018, we consummated an acquisition transaction contemplated by an asset purchase agreement with Vascular Insights, LLC and VI Management, Inc. (combined "Vascular Insights") and acquired Vascular 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 an immaterial working capital adjustment. We are also obligated to pay up to an additional $20 million based on achieving certain revenue milestones specified in the asset purchase agreement.

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 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.

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.

The following table summarizes the purchase price allocation and other required disclosures for acquisitions accounted for as business combinations during the year ended December 31, 2018 (in thousands).

| | Vascular Insights | Cianna Medical | DirectACCESS | BD |
|---|---|---|---|---|
| **Assets Acquired** | | | | |
| Trade receivables | $ — | $ 6,151 | $ — | $ — |
| Inventories | 1,353 | 5,803 | 971 | 5,804 |
| Prepaid expenses and other current assets | — | 315 | — | — |
| Property and equipment | — | 1,047 | — | 748 |
| Other long-term assets | — | 14 | — | — |
| Intangibles | | | | |
| Developed technology | 32,750 | 134,510 | 4,840 | 74,000 |
| Customer list | 840 | 3,330 | 120 | 4,200 |
| Trademarks | 1,410 | 7,080 | 400 | 4,900 |
| In-process technology | — | — | — | 2,500 |
| Goodwill | 21,832 | 61,379 | 938 | 9,728 |
| Total assets acquired | 58,185 | 219,629 | 7,269 | 101,880 |
| | | | | |
| **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** | **$ 58,185** | **$ 188,281** | **$ 7,269** | **$ 101,880** |
| | | | | |
| **Amortization Period of Intangible Assets** | | | | |
| Developed technology | 12 years | 11 years | 10 years | 8 years |
| Customer lists (on an accelerated basis) | 8 years | 8 years | 5 years | 7 years |
| Trademarks | 9 years | 10 years | 10 years | 9 years |
| Weighted Average | 11.8 years | 10.7 years | 9.9 years | 8.0 years |
| | | | | |
| Sales for the years ended | | | | |
| December 31, 2020 | $5.5 million | $45.3 million | Not Material | $42.6 million |
| December 31, 2019 | $7.5 million | $49.5 million | Not Material | $46.8 million |
| December 31, 2018 | Not Material | $6.3 million | Not Material | $42.1 million |

The sales and results of operations related to these acquisitions have been included in our cardiovascular segment. It is not practical to separately report earnings related to these acquisitions, as we cannot split out sales costs related solely to the products acquired, principally because our sales representatives sell multiple products within our cardiovascular business segment. Acquisition costs related to these acquisitions were included in selling, general and administrative expenses. Acquisition costs related to the Vascular Insights and DirectAccess acquisitions were not material, and acquisition costs related to the Cianna Medical and BD acquisitions were $3.5 million and $1.8 million, respectively. Goodwill related to these acquisitions arises principally from synergies and economies of scale anticipated upon consolidation of operations. Goodwill related to the Cianna Medical acquisition is not expected to be deductible for income tax purposes, while

goodwill related to the Vascular Insights, DirectAccess, and BD acquisitions is expected to be deductible for income tax purposes.

**Pro Forma**

The following table summarizes our consolidated results of operations for the year ended December 31, 2018, as well as unaudited pro forma consolidated results of operations as though the 2018 acquisitions of Cianna Medical and Vascular Insights had occurred on January 1, 2017 (in thousands, except per common share amounts):

| | 2018 | |
|---|---|---|
| | As Reported | Pro Forma |
| Net sales | $ 882,753 | $ 928,336 |
| Net income | 42,017 | 20,699 |
| Earnings per common share: | | |
| Basic | $ 0.80 | $ 0.40 |
| Diluted | $ 0.78 | $ 0.38 |

Note: The pro forma results for the years ended December 31, 2020 and 2019 are not included in the table above because the operating results of the Cianna Medical, and Vascular Insights acquisitions were included in our consolidated statements of income (loss) 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, and interest expense on long-term debt. The pro forma information should not be considered indicative of actual results that would have been achieved if the acquisition of Cianna Medical and Vascular Insights had occurred on January 1, 2017, or results that may be obtained in any future period. The pro forma consolidated results of operations do not include the 2018 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. We do not deem the pro forma effects to our consolidated results of operations of the KA Medical, STD Pharmaceutical, Brightwater and DirectACCESS acquisitions to be material.

## 4. INVENTORIES

Inventories at December 31, 2020 and 2019, consisted of the following (in thousands):

| | 2020 | 2019 |
|---|---|---|
| Finished goods | $ 110,933 | $ 134,467 |
| Work-in-process | 19,308 | 17,602 |
| Raw materials | 67,778 | 73,629 |
| Total inventories | $ 198,019 | $ 225,698 |

## 5. GOODWILL AND INTANGIBLE ASSETS

The changes in the carrying amount of goodwill for the years ended December 31, 2020 and 2019, are as follows (in thousands):

| | 2020 | 2019 |
|---|---|---|
| Goodwill balance at January 1 | $ 353,193 | $ 335,433 |
| Effect of foreign exchange | 1,941 | (199) |
| Additions and adjustments as the result of acquisitions | 8,399 | 17,959 |
| Goodwill balance at December 31 | $ 363,533 | $ 353,193 |

Total accumulated goodwill impairment losses aggregated to $8.3 million as of December 31, 2020 and 2019. We did not have any goodwill impairments for the years ended December 31, 2020, 2019 and 2018. The total goodwill balance as of December 31, 2020 and 2019 is related to our cardiovascular segment.

Other intangible assets at December 31, 2020 and 2019, consisted of the following (in thousands):

| | December 31, 2020 | | |
|---|---|---|---|
| | Gross Carrying Amount | Accumulated Amortization | Net Carrying Amount |
| Patents | $ 23,669 | $ (6,460) | $ 17,209 |
| Distribution agreements | 3,250 | (2,319) | 931 |
| License agreements | 14,453 | (6,647) | 7,806 |
| Trademarks | 30,273 | (12,414) | 17,859 |
| Customer lists | 35,154 | (29,103) | 6,051 |
| Total | $ 106,799 | $ (56,943) | $ 49,856 |

| | 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 |

Aggregate amortization expense for the years ended December 31, 2020, 2019 and 2018 was approximately $58.6 million, $60.7 million and $41.2 million, respectively.

Estimated amortization expense for the developed technology and other intangible assets for the next five years consists of the following as of December 31, 2020 (in thousands):

| Year Ending December 31, | Estimated Amortization Expense |
|---|---|
| 2021 | $ 49,701 |
| 2022 | 48,496 |
| 2023 | 47,323 |
| 2024 | 44,313 |
| 2025 | 42,503 |

During the years ended December 31, 2020, 2019, and 2018, we identified indicators of impairment associated with certain acquired intangible assets based on our qualitative assessment, which required us to then complete a quantitative impairment assessment. The primary indicators of impairment were slower-than-anticipated sales growth in the acquired products, planned closure and restructuring activities, uncertainty about future product development and commercialization associated with certain acquired technologies, and in 2020 economic uncertainties associated with the COVID-19 pandemic.

During the year ended December 31, 2020, we recorded total impairment charges related to our intangible assets of approximately $28.7 million which included a partial impairment charge of $8.2 million of intangible assets from our acquisition of STD Pharmaceutical, a partial impairment charge of $8.0 million of intangible assets from our acquisition of certain assets from Laurane Medical S.A.S, a partial impairment charge of $4.8 million related to our license agreements with ArraVasc Limited, and other intangible asset impairments charges of $7.7 million related to intangible assets from our acquisition of certain assets from DirectACCESS Medical, LLC, in-process technology intangible assets of Sontina Medical LLC acquired in connection with our acquisition of certain divested assets from Becton, Dickinson and Company,

and a customer list intangible asset from our acquisition of ITL Healthcare Pty Ltd ("ITL"). During the year ended December 31, 2019, we recorded impairment charges related to our amortizing intangible assets from our acquisitions of certain assets from Distal Access, LLC, Lazarus Medical Technologies, LLC, and Pleuratech ApS for a total of approximately $3.3 million. During the year ended December 31, 2018, we recorded impairment charges of $657,000 related to our acquisition of certain assets from Quellent, LLC. The impairment charges recorded in 2020, 2019, and 2018 all pertained to our cardiovascular segment and are reflected within impairment charges in our consolidated statements of income (loss).

## 6. INCOME TAXES

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was signed into law. The $2.2 trillion economic stimulus bill contains numerous tax law changes. We evaluated the tax changes to determine what provisions would apply to us. As permitted by the CARES Act we have deferred payment of the employer's portion of social security payroll tax payments.

For the years ended December 31, 2020, 2019 and 2018, income (loss) before income taxes is broken out between U.S. and foreign-sourced operations and consisted of the following (in thousands):

| | 2020 | 2019 | 2018 |
|---|---|---|---|
| Domestic | $ (32,216) | $ (37,277) | $ 21,084 |
| Foreign | 18,985 | 39,470 | 28,435 |
| Total | $ (13,231) | $ 2,193 | $ 49,519 |

The components of the provision for income taxes for the years ended December 31, 2020, 2019 and 2018, consisted of the following (in thousands):

| | 2020 | 2019 | 2018 |
|---|---|---|---|
| Current expense (benefit): | | | |
| Federal | $ (937) | $ 479 | $ (1,132) |
| State | 437 | 662 | 582 |
| Foreign | 8,407 | 8,037 | 6,000 |
| Total current expense (benefit) | 7,907 | 9,178 | 5,450 |
| | | | |
| Deferred expense (benefit): | | | |
| Federal | (2,688) | (8,111) | 4,400 |
| State | (4,524) | (3,523) | (667) |
| Foreign | (4,083) | (802) | (1,681) |
| Total deferred expense (benefit) | (11,295) | (12,436) | 2,052 |
| | | | |
| Total income tax expense (benefit) | $ (3,388) | $ (3,258) | $ 7,502 |

The difference between the income tax expense (benefit) reported and amounts computed by applying the statutory federal rate of 21.0% to pretax income (loss) for the years ended December 31, 2020, 2019 and 2018, consisted of the following (in thousands):

| | 2020 | 2019 | 2018 |
|---|---|---|---|
| Computed federal income tax expense (benefit) at applicable statutory rate of 21% | $ (2,778) | $ 461 | $ 10,399 |
| State income tax expense (benefit) | (1,448) | (2,241) | (59) |
| Tax credits | (2,098) | (1,567) | (1,734) |
| Foreign tax rate differential | (1,230) | (1,536) | (1,361) |
| Uncertain tax positions | (576) | (794) | 267 |
| Deferred compensation insurance assets | (299) | (503) | 186 |
| Transaction-related expenses | — | 154 | 223 |
| U.S. transition tax | — | — | (3,271) |
| TCJA remeasurement of deferred taxes | — | — | (71) |
| Stock-based payments | (1,815) | (1,654) | (4,278) |
| Net GILTI | 3,960 | 1,861 | 347 |
| Foreign withholding tax | 228 | 638 | 5,590 |
| Foreign permanent differences [(1)] | 1,728 | 937 | 96 |
| Valuation allowance [(1)] | 1,879 | 131 | 21 |
| DOJ settlement | 1,890 | — | — |
| Remeasurement of state deferred taxes | (1,765) | — | — |
| Other — including the effect of graduated rates [(1)] | (1,064) | 855 | 1,147 |
| Total income tax expense (benefit) | $ (3,388) | $ (3,258) | $ 7,502 |

(1) Amounts for the years ended December 31, 2019 and 2018 in the table above have been updated for presentation and comparative purposes.

Deferred income tax assets and liabilities at December 31, 2020 and 2019, consisted of the following temporary differences and carry-forward items (in thousands):

| | 2020 | 2019 |
|---|---|---|
| Deferred income tax assets: | | |
| Allowance for credit losses on trade receivables | $ 1,198 | $ 693 |
| Accrued compensation expense | 9,694 | 9,244 |
| Inventory differences | 3,161 | 2,207 |
| Net operating loss carryforwards | 18,622 | 21,187 |
| Deferred revenue | 617 | 552 |
| Stock-based compensation expense | 7,360 | 4,672 |
| Operating lease assets | 15,182 | 16,838 |
| Federal R&D tax credit | 3,607 | 1,376 |
| Other | 13,993 | 6,189 |
| Total deferred income tax assets | 73,434 | 62,958 |
| | | |
| Deferred income tax liabilities: | | |
| Prepaid expenses | (1,078) | (1,128) |
| Property and equipment | (20,671) | (21,242) |
| Intangible assets | (47,178) | (53,933) |
| Foreign withholding tax | (5,358) | (5,240) |
| Operating lease liabilities | (13,855) | (15,847) |
| Other | (3,796) | (2,372) |
| Total deferred income tax liabilities | (91,936) | (99,762) |
| Valuation allowance | (10,213) | (4,644) |
| Net deferred income tax liabilities | $ (28,715) | $ (41,448) |
| | | |
| Reported as: | | |
| Deferred income tax assets | $ 4,597 | $ 3,788 |
| Deferred income tax liabilities | (33,312) | (45,236) |
| Net deferred income tax liabilities | $ (28,715) | $ (41,448) |

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 increased by approximately $5.6 million during the year ended December 31, 2020, decreased by approximately $345,000 during the year ended December 31, 2019, and increased by approximately $567,000 during the year ended December 31, 2018.

As of December 31, 2020, we had U.S federal net operating loss carryforwards of approximately $66.9 million, which were generated by Cianna Medical, Vascular Access Technologies, Inc., DFINE Inc., Biosphere Medical, Inc., and Brightwater prior to our acquisition of these companies. These net operating loss carryforwards are subject to annual limitations under Internal Revenue Code Section 382. If unused, $41.7 million of the NOLs will expire between 2025 and 2037. Approximately $25.2 million of the NOLs incurred after December 31, 2017 can be carried forward indefinitely. We anticipate that we will utilize all current net operating loss carryforwards prior to their expiration dates over the next 15 years. We utilized a total of approximately $23.7 million in U.S. federal net operating loss carryforwards during the year ended December 31, 2020.

As of December 31, 2020, we had approximately $27 million of non-U.S. net operating loss carryforwards, of which approximately $25.8 million have no expiration date and approximately $1.2 million expire at various dates through 2030. Non-U.S. net operating loss carryforwards utilized during the year ended December 31, 2020 were not material.

We do not consider our foreign earnings to be permanently reinvested. Consequently, we have recorded tax expense of approximately $228,000, $638,000 and $5.6 million for foreign withholding taxes on unremitted foreign earnings during the years ended December 31, 2020, 2019 and 2018, respectively.

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 2017. In foreign jurisdictions, we are no longer subject to income tax examinations for years before 2014.

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, 2020, including interest and penalties, was approximately $2 million, of which approximately $1.6 million would favorably impact our effective tax rate if recognized. Approximately $627,000 of the total liability at December 31, 2020 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, 2019, including interest and penalties, was approximately $2.5 million, of which approximately $2.2 million 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. As of December 31, 2020 and 2019, 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, 2020 and 2019, we had accrued approximately $276,000 and $366,000 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, 2020, 2019 and 2018, our liability for unrecognized tax benefit was increased (decreased) for interest and penalties by approximately ($90,000), ($7,000) and $69,000, 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 $250,000.

A reconciliation of the beginning and ending amount of liabilities associated with uncertain tax benefits for the years ended December 31, 2020, 2019 and 2018, consisted of the following (in thousands):

| | 2020 | 2019 | 2018 |
|---|---|---|---|
| Unrecognized tax benefits, opening balance | $ 2,161 | $ 2,947 | $ 2,749 |
| Gross increases (decreases) in tax positions taken in a prior year | 115 | (244) | 35 |
| Gross increases in tax positions taken in the current year | 283 | 229 | 586 |
| Lapse of applicable statute of limitations | (885) | (771) | (423) |
| Unrecognized tax benefits, ending balance | $ 1,674 | $ 2,161 | $ 2,947 |

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, 2020 and 2019, consisted of the following (in thousands):

| | 2020 | 2019 |
|---|---|---|
| Payroll and related liabilities | $ 41,023 | $ 39,781 |
| Current portion of contingent liabilities | 18,833 | 28,621 |
| Advances from employees | 259 | 286 |
| Accrued rebates payable | 9,532 | 9,202 |
| Other accrued expenses | 42,297 | 27,294 |
| Total | $ 111,944 | $ 105,184 |

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

Principal balances outstanding under our long-term debt obligations as of December 31, 2020 and 2019, consisted of the following (in thousands):

| | 2020 | 2019 |
|---|---|---|
| Term loans | $ 140,625 | $ 148,125 |
| Revolving credit loans | 211,000 | 291,875 |
| Less unamortized debt issuance costs | (403) | (516) |
| Total long-term debt | 351,222 | 439,484 |
| Less current portion | 7,500 | 7,500 |
| Long-term portion | $ 343,722 | $ 431,984 |

*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; 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, 2020, we believe we were in compliance with all covenants set forth in the Third Amended Credit Agreement.

As of December 31, 2020, we had outstanding borrowings of approximately $351.6 million under the Third Amended Credit Agreement, with additional available borrowings of approximately $389 million, based on the leverage ratio required pursuant to the Third Amended Credit Agreement. Our interest rate as of December 31, 2020 was a fixed rate of 2.37% on $175 million as a result of an interest rate swap (see Note 9) and a variable floating rate of 1.40% on approximately $176.6 million. 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 and a variable floating rate of 3.30% on $265 million. The foregoing fixed rates are exclusive of changes in the notional amount and fixed rate associated with our interest rate swaps beginning July 6, 2021 as described in Note 9 and potential future changes in the applicable margin.

*Future Payments*

Future minimum principal payments on our long-term debt as of December 31, 2020, are as follows (in thousands):

| Years Ending December 31, | Future Minimum Principal Payments |
|---|---|
| 2021 | $ 7,500 |
| 2022 | 8,438 |
| 2023 | 11,250 |
| 2024 | 324,437 |
| Total future minimum principal payments | $ 351,625 |

## 9. DERIVATIVES

**General. O**ur 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 (loss) (“AOCI”), 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 Bank 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 Bank 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, 2020 and 2019, our interest rate swaps qualified as cash flow hedges. The fair value of our interest rate swaps at December 31, 2020 was a liability of ($4.4) million, partially offset by approximately ($1.1) million in deferred taxes. The fair value of our interest rate swap 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.

**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, 2020 and 2019, we had entered into foreign currency forward contracts, which qualified as cash flow hedges, with aggregate notional amounts of approximately $168.2 million and $212.5 million, respectively.

*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, 2020 and 2019, we had entered into foreign currency forward contracts related to those balance sheet accounts with aggregate notional amounts of approximately $74.8 million and $65.0 million, respectively.

**Balance Sheet Presentation of Derivatives.** As of December 31, 2020 and 2019, 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 of Derivative Instruments Designated as Hedging Instruments*** | **Balance Sheet Location** | **December 31, 2020** | **December 31, 2019** |
|---|---|---|---|
| *Assets* | | | |
| Interest rate swaps | Other assets (long-term) | $ — | $ 1,192 |
| Foreign currency forward contracts | Prepaid expenses and other assets | 1,777 | 1,663 |
| Foreign currency forward contracts | Other assets (long-term) | 424 | 466 |
| | | | |
| *(Liabilities)* | | | |
| Interest rate swaps | Accrued expenses | (896) | — |
| Interest rate swaps | Other long-term obligations | (3,462) | (290) |
| Foreign currency forward contracts | Accrued expenses | (5,281) | (1,813) |
| Foreign currency forward contracts | Other long-term obligations | (866) | (764) |

| ***Fair Value of Derivative Instruments Not Designated as Hedging Instruments*** | **Balance Sheet Location** | **December 31, 2020** | **December 31, 2019** |
|---|---|---|---|
| *Assets* | | | |
| Foreign currency forward contracts | Prepaid expenses and other assets | $ 877 | $ 318 |
| | | | |
| *(Liabilities)* | | | |
| Foreign currency forward contracts | Accrued expenses | (2,120) | (1,678) |

**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") in our consolidated statements of comprehensive income (loss) and consolidated balance sheets (in thousands):

| | **Amount of Gain/(Loss) Recognized in OCI Year Ended December 31,** | | |
|---|---|---|---|
| **Derivative instrument** | **2020** | **2019** | **2018** |
| *Interest rate swaps* | $ (6,131) | $ (2,830) | $ 1,559 |
| *Foreign currency forward contracts* | (5,516) | (587) | 539 |

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

| | Consolidated Statements of Income (Loss) Year Ended December 31, | | | Amount of Gain/(Loss) reclassified from AOCI Year ended December 31, | | |
|---|---|---|---|---|---|---|
| Location in statements of income | 2020 | 2019 | 2018 | 2020 | 2019 | 2018 |
| *Interest expense* | $ (9,994) | $ (12,413) | $ (10,360) | $ (872) | $ 2,040 | $ 1,537 |
| *Revenue* | 963,875 | 994,852 | 882,753 | 36 | 577 | 136 |
| *Cost of sales* | (562,698) | (562,486) | (487,983) | (1,288) | (578) | 361 |

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

As of December 31, 2020, approximately ($4.3) million or ($3.2) million after taxes, was expected to be reclassified from AOCI to earnings in revenue and cost of sales over the succeeding twelve months. As of December 31, 2020, approximately $(1.5) million, or $(1.1) million after taxes, was expected to be reclassified from AOCI 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 (loss) for the years presented (in thousands):

| | | Year ended December 31, | | |
|---|---|---|---|---|
| Derivative Instrument | Location in statements of income (loss) | 2020 | 2019 | 2018 |
| *Foreign currency forward contracts* | Other income (expense) | $ (2,190) | $ (307) | $ 4,147 |

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 until one year and 45 days have passed from the date Selio receives FDA Section 510(k) approval of a medical device it is currently developing. 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, 2020, 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. During the years ended December 31, 2020, 2019 and 2018, total royalty expense approximated $7.1 million, $6.7 million and $5.3 million, respectively. Minimum contractual commitments under royalty agreements to be paid within twelve months of December 31, 2020 were not significant. See Note 16 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. We have filed a Motion to Dismiss and are awaiting the Court's ruling on the motion.

In addition to the foregoing matters, on October 13, 2020, we entered into a Settlement Agreement with the United States Department of Justice ("DOJ") to fully resolve the DOJ's investigation into past marketing and promotional transactions practices of the Company. Under the Settlement Agreement, we agreed to pay settlement payments in the aggregate of $18 million plus interest and enter into a Corporate Integrity Agreement with the U.S. Office of Inspector General. In total, we paid approximately $18.7 million in settlement payments, interest and additional expenses associated with the Settlement Agreement, including fees paid to settle claims of the relator's counsel. Our failure to comply with the obligations of the Settlement Agreement or Corporate Integrity Agreement could result in monetary penalties and our exclusion from federal health care programs. In the event of unexpected further developments, it is possible that the ultimate outcome 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 (loss) per common share for the following periods consisted of the following (in thousands, except per share amounts):

| | 2020 | 2019 | 2018 |
|---|---|---|---|
| Net income (loss) | $ (9,843) | $ 5,451 | $ 42,017 |
| Average common shares outstanding | 55,434 | 55,075 | 52,268 |
| Basic EPS | $ (0.18) | $ 0.10 | $ 0.80 |
| | | | |
| Average common shares outstanding | 55,434 | 55,075 | 52,268 |
| Effect of dilutive stock options | — | 1,160 | 1,663 |
| Total potential shares outstanding | 55,434 | 56,235 | 53,931 |
| Diluted EPS | $ (0.18) | $ 0.10 | $ 0.78 |
| | | | |
| Equity awards excluded as the impact was anti-dilutive [1] | 4,216 | 1,750 | 396 |

[1] Does not reflect the impact of incremental repurchases under the treasury stock method.

## 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 (including performance stock units). 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 seven years. As of December 31, 2020, a total of 1,297,062 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, 2020, the 2006 Incentive Plan was no longer being used for the granting of equity awards. However, as of December 31, 2020, 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, 2020, the total number of shares of common stock that remained available to be issued under our non-qualified plan was 40,073 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, 2020, 2019 and 2018, consisted of the following (in thousands):

| | 2020 | 2019 | 2018 |
|---|---|---|---|
| Cost of sales | | | |
| Nonqualified stock options | $ 1,357 | $ 1,289 | $ 870 |
| Research and development | | | |
| Nonqualified stock options | 1,157 | 961 | 553 |
| Selling, general and administrative | | | |
| Nonqualified stock options | 7,332 | 7,132 | 4,694 |
| Performance-based restricted stock units | 2,829 | — | — |
| Restricted stock units | 758 | — | — |
| Cash-settled share-based awards | 906 | — | — |
| Total selling, general and administrative | 11,825 | 7,132 | 4,694 |
| | | | |
| Stock-based compensation expense before taxes | $ 14,339 | $ 9,382 | $ 6,117 |

*Nonqualified Stock Options*

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, 2020, the total remaining unrecognized compensation cost related to non-vested stock options, net of expected forfeitures, was approximately $25.4 million and is expected to be recognized over a weighted average period of 2.5 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 years ended December 31, 2020, 2019 and 2018:

| | 2020 | 2019 | 2018 |
|---|---|---|---|
| Risk-free interest rate | 0.29% - 1.67% | 1.38% - 2.56% | 2.63% - 2.77% |
| Expected option term | 4.0 - 5.0 years | 3.0 - 5.0 years | 5.0 years |
| Expected dividend yield | — | — | — |
| Expected price volatility | 38.65% - 45.12% | 28.66% - 39.38% | 34.06% - 34.32% |

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 based upon historical volatility for our stock and other factors. 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, 2020, 2019 and 2018, approximately 329,000, 1.2 million and 692,000 nonqualified stock option grants were made, respectively, for a total fair value of approximately $4.5 million, $20.9 million and $11.1 million, net of estimated forfeitures, respectively.

The table below presents information related to stock option activity for the years ended December 31, 2020, 2019 and 2018 (in thousands):

| | 2020 | 2019 | 2018 |
|---|---|---|---|
| Total intrinsic value of stock options exercised | $ 11,733 | $ 9,910 | $ 25,692 |
| Cash received from stock option exercises | 5,481 | 4,837 | 8,510 |
| Excess tax benefit from the exercise of stock options | 1,815 | 1,654 | 4,278 |

Changes in stock options for the year ended December 31, 2020, 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 | 4,319 | $ 34.10 | | |
| Granted | 329 | 39.21 | | |
| Exercised | (442) | 16.17 | | |
| Forfeited/expired | (264) | 42.37 | | |
| Outstanding at December 31 | 3,942 | 35.98 | 3.97 | $ 77,350 |
| Exercisable | 1,936 | 29.38 | 2.95 | 50,678 |
| Ending vested and expected to vest | 3,860 | 35.79 | 3.94 | 76,482 |

The weighted average grant-date fair value of options granted during the years ended December 31, 2020, 2019 and 2018 was $13.70, $16.78 and $16.05, respectively.

*Stock-Settled Performance-Based Restricted Stock Units ("PSUs") and Time-Vested Restricted Stock Units ("RSUs")*

We grant PSUs to certain of our executive officers. Conversion of PSUs occurs at the end of one, two and three-year performance periods, or one year after the agreement date, whichever is later. The conversion ratio is based upon attaining targeted levels of free cash flow ("FCF") and relative shareholder return as compared to the Russell 2000 Index ("rTSR"), as defined in the award agreements. After reviewing the anticipated impact of the COVID-19 pandemic on our ongoing and forecasted operations and financial performance, during the three-month period ended June 30, 2020, our Board of Directors amended the PSUs with a one-year performance period in an effort to more closely align our executive management compensation with the interests of our shareholders. This amendment reduced the targeted levels of FCF and reduced the maximum FCF multiplier to 100% for the one-year awards, which lowered the potential shares of our common stock to be granted pursuant to the one-year awards by 25,415 shares. We have accounted for this amendment in accordance with ASC 718 as a "Type I" modification. The two and three-year PSUs were not amended.

The payout for each PSU is equal to one share of common stock multiplied by a FCF multiplier (between 0% and 100% in the case of the one-year awards, as amended, or 0% and 200% in the case of the two and three-year awards) and a rTSR multiplier (between 75% and 125%). PSUs convey no shareholder rights unless and until shares are issued in settlement of the award. We use Monte-Carlo simulations to estimate the grant-date fair value of the PSUs linked to total shareholder return. Compensation expense is recognized using the grant-date fair value for the number of shares that are probable of being awarded based on the performance conditions. Each reporting period, this probability assessment is updated, and cumulative catchups are recorded based on the level of FCF that is expected to be achieved. At the end of the performance period, cumulative expense is calculated based on the actual level of FCF achieved.

We grant RSUs to our non-employee directors, which are subject to continued service through the vesting date, which is one year from the date of grant. The expense recognized for RSUs is equal to the closing stock price on the date of grant, which is recognized over the vesting period.

Changes in PSUs and RSUs for the year ended December 31, 2020, consisted of the following:

| | PSUs | | RSUs | |
|---|---|---|---|---|
| | Stock Units (In Thousands) | Weighted Average Grant Date Fair Value | Stock Units (In Thousands) | Weighted Average Grant Date Fair Value |
| Beginning nonvested balance | — | $ — | — | $ — |
| Granted | 122 | 43.60 | 34 | 42.98 |
| Vested | — | — | — | — |
| Impact of amendments | (20) | 43.43 | — | — |
| Nonvested balance at December 31 | 102 | 43.63 | 34 | 42.98 |
| Expected to vest at December 31, 2020 | 102 [1] | 43.63 | 34 | 42.98 |

[1] Based on the maximum target payout of 100% for one-year awards, as amended, and 200% for two and three-year awards. Each unit will convert to between .75 and 1.25 shares of common stock based upon the rTSR performance of our common stock.

The weighted average grant-date fair value of PSUs and RSUs for the year December 31, 2020 was $43.60 and $42.98, respectively. There were no PSUs or RSUs granted for the years ended December 31, 2019 and 2018, and there were no PSUs or RSUs that vested in the years ended December 31, 2020, 2019 and 2018.

The fair value of each PSU was estimated as of the grant date using the following assumptions for awards granted in the year ended December 31, 2020:

| | 2020 |
|---|---|
| Risk-free interest rate | 1.1% - 1.3% |
| Performance period | 0.8 - 2.8 years |
| Expected dividend yield | — |
| Expected price volatility | 40.2% - 56.1% |

The risk-free interest rate of return was determined using the U.S. Treasury rate at the time of grant with a remaining term equal to the expected term of the award. The expected volatility was based on a weighted average volatility of our stock price and the average volatility of our compensation peer group's volatilities. The expected dividend yield was assumed to be zero because, at the time of the grant, we had no plans to declare a dividend.

As of December 31, 2020, the total remaining unrecognized compensation cost related to stock-settled performance stock units and restricted stock units was approximately $2.5 million and $0.7 million, respectively, which is expected to be recognized over a weighted average period of 1.4 years and 0.5 years, respectively.

*Cash-Settled Performance-Based Share-Based Awards ("Liability Awards")*

During the year ended December 31, 2020, we granted liability awards to our Chief Executive Officer. These awards entitle him to a cash payment equal to a total target cash incentive of $1.0 million multiplied by rTSR and FCF multipliers, as defined in the award agreements. During the three-month period ended June 30, 2020, after reviewing the anticipated impact of the COVID-19 pandemic on our ongoing and forecasted operations and financial performance, our Board of Directors amended the liability awards with a one-year performance period in an effort to more closely align our Chief Executive Officer's compensation with the interests of our shareholders. The two and three-year liability awards were not amended. As amended, the potential maximum payout of these awards is 125% of the target cash incentive for one-year awards, and 250% of the target cash incentive for two and three-year awards, for a total maximum potential payment of approximately $2.1 million. Settlement generally occurs at the end of one, two and three-year performance periods based upon the same performance metrics and vesting period as our performance stock units. These awards are classified as liabilities and reported in accrued expenses and other long-term liabilities within our consolidated balance sheet. The fair value of these awards is remeasured at each reporting period until the awards are settled. As of December 31, 2020, the total remaining unrecognized compensation cost related to cash-settled performance-based share-based awards was

approximately $1.0 million, which is expected to be recognized over a weighted average period of 1.5 years. There were no liability awards vested or forfeited in the years ended December 31, 2020, 2019 and 2018.

## 13. SEGMENT REPORTING AND FOREIGN OPERATIONS

We report our operations in two operating segments: cardiovascular and endoscopy. Our cardiovascular segment consists of four product categories: peripheral intervention, cardiac intervention, custom procedural solutions, and OEM. Within these product categories, we sell a variety of products, including cardiology and radiology devices (which assist in diagnosing and treating coronary arterial disease, peripheral vascular disease and other non-vascular diseases), as well as embolotherapeutic, cardiac rhythm management, electrophysiology, critical care, breast cancer localization and guidance, biopsy, and interventional oncology and spine devices. Our endoscopy segment consists of gastroenterology and pulmonology devices which assist in the palliative treatment of expanding esophageal, tracheobronchial and biliary strictures caused by malignant tumors. We evaluate the performance of our operating segments based on net sales and operating income (loss). See Note 2 for a detailed breakout of our sales by operating segment and product category, disaggregated between domestic and international sales.

During the years ended December 31, 2020, 2019 and 2018, we had international sales of approximately $413.8 million, $419.1 million and $386.3 million, respectively, or approximately 43%, 42% and 44%, 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 $113.2 million, $113.3 million, and $92.7 million for the years ended December 31, 2020, 2019 and 2018, 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 and equipment) by geographic area at December 31, 2020, 2019 and 2018, consisted of the following (in thousands):

| | 2020 | 2019 | 2018 |
|---|---|---|---|
| United States | $ 277,643 | $ 273,816 | $ 231,864 |
| Ireland | 42,951 | 44,912 | 45,283 |
| Other foreign countries | 62,134 | 60,057 | 54,305 |
| Total | $ 382,728 | $ 378,785 | $ 331,452 |

Financial information relating to our reportable operating segments and reconciliations to the consolidated totals for the years ended December 31, 2020, 2019 and 2018, are as follows (in thousands):

| | 2020 | 2019 | 2018 |
|---|---|---|---|
| **Net Sales** | | | |
| Cardiovascular | $ 934,202 | $ 960,981 | $ 849,477 |
| Endoscopy | 29,673 | 33,871 | 33,276 |
| Total net sales | 963,875 | 994,852 | 882,753 |
| | | | |
| **Operating Income (Loss)** | | | |
| Cardiovascular | (7,042) | 25,780 | 49,289 |
| Endoscopy | 5,480 | (10,346) | 9,328 |
| Total operating income (loss) | (1,562) | 15,434 | 58,617 |
| | | | |
| Total other expense - net | (11,669) | (13,241) | (9,098) |
| Income tax (benefit) expense | (3,388) | (3,258) | 7,502 |
| | | | |
| Net income (loss) | $ (9,843) | $ 5,451 | $ 42,017 |

Total assets by operating segment at December 31, 2020, 2019 and 2018, consisted of the following (in thousands):

| | 2020 | 2019 | 2018 |
|---|---|---|---|
| Cardiovascular | $ 1,654,866 | $ 1,745,057 | $ 1,588,970 |
| Endoscopy | 9,530 | 12,264 | 31,042 |
| Total | $ 1,664,396 | $ 1,757,321 | $ 1,620,012 |

Total depreciation and amortization by operating segment for the years ended December 31, 2020, 2019 and 2018, consisted of the following (in thousands):

| | 2020 | 2019 | 2018 |
|---|---|---|---|
| Cardiovascular | $ 93,160 | $ 91,151 | $ 68,722 |
| Endoscopy | 910 | 949 | 824 |
| Total | $ 94,070 | $ 92,100 | $ 69,546 |

Total capital expenditures for property and equipment by operating segment for the years ended December 31, 2020, 2019 and 2018, consisted of the following (in thousands):

| | 2020 | 2019 | 2018 |
|---|---|---|---|
| Cardiovascular | $ 45,803 | $ 77,631 | $ 63,032 |
| Endoscopy | 185 | 542 | 292 |
| Total | $ 45,988 | $ 78,173 | $ 63,324 |

## 14. EMPLOYEE BENEFIT PLANS

We have defined contribution plans covering all U.S. full-time adult employees and certain of our foreign employees. Our contributions to these plans are discretionary in certain countries, including the U.S. Beginning in September 2019, we ceased discretionary contributions to certain of our defined contribution plans. Total expense for contributions made to these plans for the years ended December 31, 2020, 2019 and 2018 was approximately $3.9 million, $6.6 million and $6.5 million, respectively.

## 15. QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)

Quarterly data for the years ended December 31, 2020 and 2019 consisted of the following (in thousands, except per share amounts):

| | Quarter Ended | | | |
|---|---|---|---|---|
| | March 31 | June 30 | September 30 | December 31 |
| **2020** | | | | |
| Net sales | $ 243,525 | $ 218,371 | $ 243,975 | $ 258,004 |
| Gross profit | 103,784 | 84,216 | 102,014 | 111,163 |
| Income (loss) from operations | 1,362 | (18,995) | 64 | 16,007 |
| Income tax expense (benefit) | 1,162 | (3,242) | 825 | (2,133) |
| Net income (loss) | (3,154) | (19,058) | (3,009) | 15,378 |
| Earnings (loss) per common share - basic | (0.06) | (0.34) | (0.05) | 0.28 |
| Earnings (loss) per common share - diluted | (0.06) | (0.34) | (0.05) | 0.27 |
| | | | | |
| **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) |
| Earnings (loss) per common share - basic | 0.11 | 0.12 | (0.06) | (0.08) |
| Earnings (loss) per common share - diluted | 0.11 | 0.12 | (0.06) | (0.08) |

During the three months ended December 31, 2020, we recorded a partial impairment charge of $8.2 million of intangible assets from our August 2019 acquisition of STD Pharmaceutical (see Note 5). During the three months 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, along with a write-off of $1.6 million of accrued interest (see Note 16). Basic and diluted earnings (loss) 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, 2020 and 2019, consisted of the following (in thousands):

| | | | Fair Value Measurements Using | | |
|---|---|---|---|---|---|
| | Total Fair Value at December 31, 2020 | | Quoted prices in active markets (Level 1) | Significant other observable inputs (Level 2) | Significant unobservable inputs (Level 3) |
| Interest rate contract liabilities, current and long-term [1] | $ | (4,358) | $ — | $ (4,358) | $ — |
| Foreign currency contract assets, current and long-term [2] | $ | 3,078 | $ — | $ 3,078 | $ — |
| Foreign currency contract liabilities, current and long-term [3] | $ | (8,267) | $ — | $ (8,267) | $ — |
| Contingent consideration liabilities | $ | (55,750) | $ — | $ — | $ (55,750) |

| | | | 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 asset, long-term [1] | $ | 1,192 | $ — | $ 1,192 | $ — |
| Interest rate contract liability, long-term [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) |

[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, accrued expenses 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 or other milestones. See Note 3 for further information regarding these acquisitions. Contingent consideration liabilities are re-measured to fair value at each reporting period, with the change in fair value recognized within operating expenses in the accompanying consolidated statements of income (loss). 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 liabilities during the years ended December 31, 2020 and 2019, consisted of the following (in thousands):

| | 2020 | 2019 |
|---|---|---|
| Beginning balance | $ 76,709 | $ 82,236 |
| Contingent consideration liability recorded as the result of acquisitions | — | 10,517 |
| Contingent consideration (benefit) | (7,960) | (304) |
| Contingent payments made | (13,100) | (15,740) |
| Effect of foreign exchange | 101 | — |
| Ending balance | $ 55,750 | $ 76,709 |

As of December 31, 2020, approximately $36.9 million was included in other long-term obligations and approximately $18.8 million was included in accrued expenses in our consolidated balance sheet related to contingent liabilities. As of December 31, 2019, approximately $48.1 million was included in other long-term obligations and $28.6 was included in accrued expenses in our consolidated balance sheet related to contingent liabilities. Cash paid to settle contingent consideration liabilities 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. During the year ended December 31, 2019, we collected payments of approximately $535,000 to settle the receivable in full.

The recurring Level 3 measurement of our contingent consideration liabilities includes the following significant unobservable inputs at December 31, 2020 and 2019 (amounts in thousands):

| Contingent consideration liability | Fair value at December 31, 2020 | Valuation technique | Unobservable inputs | Range | Weighted Average[1] |
|---|---|---|---|---|---|
| Revenue-based royalty payments contingent liability | $ 4,545 | Discounted cash flow | Discount rate | 12% - 15% | 13.5% |
| | | | Projected year of payments | 2021-2034 | 2026 |
| Revenue milestones contingent liability | $ 46,305 | Monte Carlo simulation | Discount rate | 7.5% - 12% | 9.0% |
| | | | Projected year of payments | 2021-2030 | 2022 |
| Regulatory approval contingent liability | $ 4,900 | Scenario-based method | Discount rate | 1% | |
| | | | Probability of milestone payment | 100% | |
| | | | Projected year of payment | 2021-2024 | 2022 |

(1) Unobservable inputs were weighted by the relative fair value of the instruments. No weighted average is reported for contingent consideration liabilities without a range of unobservable inputs.

| Contingent consideration 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 |

The contingent consideration liabilities 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 contingent consideration liabilities 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 (loss).

*Contingent Payments to Related Parties.* During the years ended December 31, 2020 and 2019, we made contingent payments of approximately $800,000 and $1.0 million to a current director of Merit and former shareholder of Cianna Medical which we acquired in 2018. The terms of the acquisition, including contingent consideration payments, were determined prior to the appointment of the former Cianna Medical shareholder as a director of Merit. As a former shareholder of Cianna Medical, the Merit director may be eligible for additional payments for the achievement of sales milestones specified in our merger agreement with Cianna Medical.

**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. Our long-term debt re-prices frequently due to variable rates and entails no significant changes in credit risk and, as a result, we believe the fair value of long-term debt approximates carrying value. 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.

**Impairment Charges**

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.

*Intangible Assets.* During the years ended December 31, 2020, 2019 and 2018, we had losses of approximately $28.7 million, $3.3 million and $657,000, respectively, related to certain acquired intangible assets (see Note 5).

*Right of Use Operating Lease Assets.* During the year ended December 31, 2020, we identified changes in events and circumstances relating to a certain right-of-use ("ROU") operating lease asset. We compared the anticipated undiscounted cash flows generated by a sublease to the carrying value of the ROU operating lease and related long-lived assets and determined that the carrying value was not recoverable. Consequently, we recorded an impairment loss of approximately

$1.5 million, which is equal to the excess of the carrying value of the assets over their estimated fair value. The impairment loss was driven by site consolidation decisions and changes in our projected cash flows for the ROU operating lease asset and related long-lived assets, due to changes in the real estate market as a result of the COVID-19 pandemic. These changes include an increase in the anticipated time to identify a lessee, an increase in anticipated lease concessions, and a decrease in the expected lease rates for the property.

*Property and Equipment.* During the year ended December 31, 2020, we had losses of approximately $359,000 related to the measurement of certain property and equipment measured at fair value based on restructuring activities associated with the suspension of our distribution agreement with NinePoint.

*Equity Investments, Purchase Options, and Notes Receivable.* During the year ended December 31, 2020, we recognized $2.5 million of impairment expense related to our equity method investment in the 19.5 percent ownership in preferred shares of Fusion Medical, Inc. ("Fusion") due to uncertainty about future product development and commercialization associated with the technologies and a charge of $3.5 million related to Bluegrass Vascular due to our decision not to exercise our option to purchase the company. Our equity investments in privately held companies, including options to acquire these companies, were $12.0 million and $17.1 million at December 31, 2020 and 2019, respectively, which are included within other long-term assets in our consolidated balance sheets. 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. 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.

Prior to the adoption of ASU 2016-13 on January 1, 2020, we assessed the credit support available for notes receivable and the value of any underlying collateral to determine if there were 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 reported in interest income in the consolidated statements of income (loss) for the year ended December 31, 2019. These valuations used significant unobservable inputs and therefore fall under Level 3 of the fair value hierarchy.

**Current Expected Credit Loss**

Our outstanding long-term notes receivable, including accrued interest and our allowance for current expected credit losses, were approximately $2.2 million and $2.7 million, as of December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an allowance for current expected credit losses of $730,000 associated with these notes receivable and our contractual obligation to extend credit to Selio. We assess the allowance for current expected credit losses on an individual security basis, due to the limited number of securities, using a probability of default model, which is based on relevant information about past events, including historical experience, current conditions and reasonable and supportable forecasts that affect the expected collectability of securities. During the year ended December 31, 2020, we adjusted the probability of default for all notes receivable for certain periods during the loan term due to changes in macroeconomic conditions and our expectations of collectability as a result of the COVID-19 pandemic. The table below presents a rollforward of the allowance for current expected credit losses on our notes receivable for the year ended December 31, 2020 (in thousands):

| | 2020 |
|---|---|
| Beginning balance | $ — |
| Cumulative effect adjustment upon adoption of ASU 2016-13, *Credit Losses* | 575 |
| Provision for credit loss expense | 155 |
| Ending balance | $ 730 |

## 17. COMMON STOCK AND ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)

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.

The changes in each component of Accumulated Other Comprehensive Income (Loss) for the years ended December 31, 2020, 2019 and 2018 were as follows (in thousands):

| | Cash Flow Hedges | Foreign Currency Translation | Total |
|---|---|---|---|
| **December 31, 2017** | **$ 3,474** | **$ (1,940)** | **$ 1,534** |
| Other comprehensive income (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 other comprehensive income (loss) | 48 | (3,615) | (3,567) |
| **December 31, 2018** | **3,522** | **(5,555)** | **(2,033)** |
| Other comprehensive income (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 other comprehensive income (loss) | (4,052) | 43 | (4,009) |
| Reclassification of stranded tax effects [1] | 748 | | 748 |
| **December 31, 2019** | **218** | **(5,512)** | **(5,294)** |
| Other comprehensive income (loss) | (11,647) | 7,786 | (3,861) |
| Income taxes | 2,365 | (786) | 1,579 |
| Reclassifications to: | | | |
| Revenue | (36) | | (36) |
| Cost of sales | 1,288 | | 1,288 |
| Interest expense | 872 | | 872 |
| Net other comprehensive income (loss) | (7,158) | 7,000 | (158) |
| **December 31, 2020** | **$ (6,940)** | **$ 1,488** | **$ (5,452)** |

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

## 18. LEASES

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 29 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, 2020 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, 2020 and 2019 was not significant.

The following was included in our consolidated balance sheet as of December 31, 2020 and 2019 (in thousands):

| | 2020 | 2019 |
|---|---|---|
| *Assets* | | |
| ROU operating lease assets | $ 78,240 | $ 80,244 |
| | | |
| *Liabilities* | | |
| Short-term operating lease liabilities | $ 12,903 | $ 11,550 |
| Long-term operating lease liabilities | 70,941 | 72,714 |
| Total operating lease liabilities | $ 83,844 | $ 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 for operating leases on a straight-line basis over the term of the lease. Net lease cost for the years ended December 31, 2020, 2019 and 2018 was approximately $16.7 million, $16.5 million, and $14.5 million, respectively. The components of lease costs for the years ended December 31, 2020 and 2019 were as follows, in thousands:

| Lease Cost | Classification | 2020 | 2019 |
|---|---|---|---|
| Operating lease cost (a) | Selling, general and administrative expenses | $ 16,735 | $ 16,828 |
| Sublease (income) (b) | Selling, general and administrative expenses | (15) | (361) |
| Net lease cost | | $ 16,720 | $ 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 years ended December 31, 2020 and 2019 was as follows, in thousands:

| | Year Ended 2020 | Year Ended 2019 |
|---|---|---|
| Cash paid for amounts included in the measurement of lease liabilities | $ 15,059 | 14,646 |
| Right-of-use assets obtained in exchange for lease obligations | $ 10,938 | 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, 2020 and 2019, the following disclosures for remaining lease term and discount rates were applicable:

| | 2020 | 2019 |
|---|---|---|
| Weighted average remaining lease term | 11.5 years | 12.3 years |
| Weighted average discount rate | 3.3% | 3.2% |

As of December 31, 2020, maturities of operating lease liabilities were as follows, in thousands:

| Year ended December 31, | Amounts due under operating leases |
|---|---|
| 2021 | $ 14,947 |
| 2022 | 12,198 |
| 2023 | 9,295 |
| 2024 | 8,669 |
| 2025 | 7,123 |
| Thereafter | 49,908 |
| Total lease payments | 102,140 |
| Less: Imputed interest | (18,296) |
| Total | $ 83,844 |

As of December 31, 2020, we had additional operating leases for office space that had not yet commenced. These leases will commence during 2021 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, 2020. Based on this evaluation, our principal executive officer and principal financial officer concluded that as of December 31, 2020, 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, 2020. 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, 2020, our internal control over financial reporting was effective.

**CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING**

During the quarter ended December 31, 2020, 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, 2020, 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, 2020, 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, 2020, of the Company and our report dated March 1, 2021, expressed an unqualified opinion on those financial statements and included an explanatory paragraph regarding the Company's adoption of the FASB ASC Topic 842, *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 1, 2021

**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 2021 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, 2020, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended.

## PART IV

**Item 15. Exhibits and Financial Statement Schedules.**

(a) Documents filed as part of this Report:

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

Report of Independent Registered Public Accounting Firm — Internal Control

Report of Independent Registered Public Accounting Firm — Financial Statements

Consolidated Balance Sheets as of December 31, 2020 and 2019

Consolidated Statements of Income (Loss) for the Years Ended December 31, 2020, 2019 and 2018

Consolidated Statements of Comprehensive Income (Loss) for the Years Ended December 31, 2020, 2019 and 2018

Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2020, 2019 and 2018

Consolidated Statements of Cash Flows for the Years Ended December 31, 2020, 2019 and 2018

Notes to Consolidated Financial Statements

(2) Financial Statement Schedules.

— Schedule II - Valuation and qualifying accounts

**Years Ended December 31, 2020, 2019 and 2018**
**(In thousands)**

| Allowance for Uncollectible Accounts: | Balance at Beginning of Year | Additions Charged to Costs and Expenses (a) | Deduction (b) | Balance at End of Year |
|---|---|---|---|---|
| **2018** | $ (1,769) | $ (1,055) | $ 469 | $ (2,355) |
| **2019** | $ (2,355) | $ (1,163) | $ 410 | $ (3,108) |
| **2020(c)** | $ (3,108) | $ (3,115) | $ 910 | $ (5,313) |

(a) We record a bad debt provision based upon historical bad debt experience, current economic conditions, expectations of future economic conditions, and management's evaluation of our ability to collect individual outstanding balances.

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

(c) Beginning in 2020, the "Allowance for Uncollectible Accounts" is referred to as "Trade Receivables - Allowance for Credit Losses" in our consolidated balances sheet.

**Years Ended December 31, 2020, 2019 and 2018**
**(In thousands)**

| Tax Valuation Allowance: | Balance at Beginning of Year | Additions Charged to Costs and Expenses (a) | Deduction | Balance at End of Year |
|---|---|---|---|---|
| **2018** | $ (4,422) | $ (567) | $ - | $ (4,989) |
| **2019** | $ (4,989) | $ - | $ 345 | $ (4,644) |
| **2020** | $ (4,644) | $ (5,569) | $ - | $ (10,213) |

(a) 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 July 25, 2018, by and among Merit Medical Systems, Inc., Wells Fargo Securities, LLC and Piper Jaffray & Co.* |
| 2.1 | 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 * |
| 2.2 | 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, dated January 1, 2004*† |
| 10.4 | Merit Medical Systems, Inc. Amended and Restated Deferred Compensation Plan, effective January 1, 2008*† |
| 10.5 | Second Amendment to the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan*† |
| 10.6 | Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan*† |
| 10.7 | First Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, effective September 19, 2010*† |

| | |
|---|---|
| 10.8 | Second Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated November 29, 2010 *† |
| 10.9 | Third Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, effective October 1, 2010*† |
| 10.10 | Fourth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated December 31, 2011*† |
| 10.11 | Fifth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated December 28, 2012*† |
| 10.12 | Sixth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated December 31, 2013.*† |
| 10.13 | Seventh Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated June 10, 2014*† |
| 10.14 | Eighth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated December 29, 2014*† |
| 10.15 | 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* |
| 10.16 | 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*† |
| 10.17 | Employment Agreement, dated May 26, 2016 between the Company and Fred P. Lampropoulos*† |
| 10.18 | Third Amendment to the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan dated February 13, 2015*† |
| 10.19 | Merit Medical Systems, Inc., Restatement of the 1996 Employee Stock Purchase Plan dated July 1, 2000*† |
| 10.20 | First Amendment to the Merit Medical Systems, Inc., 1996 Employee Stock Purchase Plan dated April 1, 2001*† |
| 10.21 | Second Amendment to the Merit Medical Systems, Inc., 1996 Employee Stock Purchase Plan dated January 1, 2006*† |
| 10.22 | Third Amendment to the Merit Medical Systems, Inc., 1996 Employee Stock Purchase Plan dated April 7, 2006*† |
| 10.23 | Fourth Amendment to the Merit Medical Systems, Inc., 1996 Employee Stock Purchase Plan dated February 13, 2015*† |
| 10.24 | 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*† |
| 10.25 | Form of First Amendment to Employment Agreement for each of Ronald A. Frost, Justin J. Lampropoulos, Joseph C. Wright, and Brian G. Lloyd*† |
| 10.26 | First Amendment to Lease Agreement dated May 22, 2017 for office and manufacturing facility* |

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| 10.27 | Merit Medical Systems, Inc. 2018 Long-Term Incentive Plan effective May 24, 2018*† |
| 10.28 | Employment Agreement made and entered into by and between Merit Medical Systems, Inc. and Raul Parra as of the 1st day of August, 2018.*† |
| 10.29 | First Amendment to the Merit Medical Systems, Inc. 2018 Long-Term Incentive Plan effective December 14, 2018*† |
| 10.30 | Merit Medical Systems, Inc. 2019 Executive Bonus Plan, dated January 1, 2019*† |
| 10.31 | Ninth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated August 1, 2016*† |
| 10.32 | Tenth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated January 1, 2017*† |
| 10.33 | Eleventh Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated January 1, 2019*† |
| 10.34 | Twelfth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated June 1, 2018*† |
| 10.35 | 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* |
| 10.36 | Thirteenth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, effective January 1, 2019*† |
| 10.37 | Performance Stock Unit Award Agreement (One Year Performance Period), dated February 26, 2020, by and between Merit Medical Systems, Inc. and Fred Lampropoulos. *† |
| 10.38 | Performance Stock Unit Award Agreement (Two Year Performance Period), dated February 26, 2020, by and between Merit Medical Systems, Inc. and Fred Lampropoulos. * † |
| 10.39 | Performance Stock Unit Award Agreement (Three Year Performance Period), dated February 26, 2020, by and between Merit Medical Systems, Inc. and Fred Lampropoulos.*† |
| 10.40 | Form of Performance Stock Unit Award Agreement (One Year Performance Period), dated February 26, 2020, by and between Merit Medical Systems, Inc. and each of the following individuals: Raul Parra, Ronald A. Frost, Joseph C. Wright, Justin J. Lampropoulos, and Brian G. Lloyd. *† |
| 10.41 | Form of Performance Stock Unit Award Agreement (Two Year Performance Period), dated February 26, 2020, by and between Merit Medical Systems, Inc. and each of the following individuals: Raul Parra, Ronald A. Frost, Joseph C. Wright, Justin J. Lampropoulos, and Brian G. Lloyd. *† |
| 10.42 | Form of Performance Stock Unit Award Agreement (Three Year Performance Period), dated February 26, 2020, by and between Merit Medical Systems, Inc. and each of the following individuals: Raul Parra, Ronald A. Frost, Joseph C. Wright, Justin J. Lampropoulos, and Brian G. Lloyd. *† |
| 10.43 | Agreement by and among Merit, Starboard Value LP and certain of its affiliates, dated May 26, 2020* |

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|---|---|
| 10.44 | Amendment to Performance Stock Unit Award Agreement, dated June 22, 2020, by and between Merit Medical Systems, Inc. and Fred Lampropoulos *† |
| 10.45 | Form of Amendment to Performance Stock Unit Award Agreement, dated June 22, 2020, by and between Merit Medical Systems, Inc. and each of the following individuals: Raul Parra, Ronald A. Frost, Joseph C. Wright, Justin J. Lampropoulos and Brian G. Lloyd *† |
| 10.46 | First Amendment to the Merit Medical Systems, Inc. 2019 Executive Bonus Plan, effective June 22, 2020 *† |
| 10.47 | Settlement Agreement, dated October 13, 2020, by and among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS"), and the Defense Health Agency ("DHA"), acting on behalf of the TRICARE Program (collectively, the "United States"); the Company; and Charles J. Wolf, M.D. ("Relator"), through their authorized representatives.* |
| 10.48 | Corporate Integrity Agreement, dated October 13, 2020, by and between the OIG-HHS and the Company.* |
| 10.49 | Form of Indemnification Agreement, dated October 24, 2020, between the Company and each of the following individuals: A. Scott Anderson, F. Ann Millner, Ed. D., Lynne N. Ward, and Thomas J. Gunderson † |
| 10.50 | Form of Indemnification Agreement, dated October 24, 2020, between the Company and each of the following individuals: Lonny J. Carpenter, David K. Floyd, and James T. Hogan † |
| 10.51 | Form of Indemnification Agreement, dated October 24, 2020, between the Company and each of the following individuals: Fred Lampropoulos, Raul Parra, Brian G. Lloyd, Joseph Wright, Ron Frost, Justin J. Lampropoulos, Brent Bowen, John Knorpp, and Michel J. Voigt (dated January 1, 2021)† |
| 10.52 | Employment Agreement between the Company and Justin J. Lampropoulos, dated November 19, 2020† |
| 10.53 | Employment Agreement between the Company and Michel J. Voigt, dated December 11, 2020† |
| 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, 2020, formatted in iXBRL (Inline eXtensible Business Reporting Language): (i) Consolidated Statements of Earnings (Loss), (ii) Consolidated Statements of Comprehensive Income (Loss), (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 1, 2021.

MERIT MEDICAL SYSTEMS, INC.

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

## ADDITIONAL SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on form 10-K has been signed below by the following persons in the capacities indicated on March 1, 2021.

| Signature | Capacity in Which Signed |
|---|---|
| /s/: FRED P. LAMPROPOULOS<br>Fred P. Lampropoulos | President, Chief Executive Officer and Director<br>(Principal executive officer) |
| /s/: RAUL PARRA<br>Raul Parra | Chief Financial Officer and Treasurer<br>(Principal financial and accounting officer) |
| /s/: A. SCOTT ANDERSON<br>A. Scott Anderson | Director |
| /s/: JILL D. ANDERSON<br>Jill D. Anderson | Director |
| /s/: LONNY J. CARPENTER<br>Lonny J. Carpenter | Director |
| /s/: DAVID K. FLOYD<br>David K. Floyd | Director |
| /s/: THOMAS J. GUNDERSON<br>Thomas J. Gunderson | Director |
| /s/: JAMES T. HOGAN<br>James T. Hogan | Director |
| /s/: F. ANN MILLNER<br>F. Ann Millner | Director |
| /s/: LYNNE N. WARD<br>Lynne N. Ward | Director |

# CORPORATE INFORMATION

## EXECUTIVE OFFICERS

Fred P. Lampropoulos
Chairman, Chief Executive Officer

Raul Parra
Chief Financial Officer, Treasurer

Ronald A. Frost
Chief Operating Officer

Brian G. Lloyd
Chief Legal Officer, Corporate Secretary

Robert Fredericks
Chief Strategy & Innovation Officer

Michel J. Voigt
Chief Human Resources Officer

Joseph C. Wright
President, International

Justin J. Lampropoulos
President, EMEA

## BOARD OF DIRECTORS

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

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

Jill D. Anderson
Co-Founder and Former Chief Executive Officer
Cianna Medical, Inc.

Lonny J. Carpenter
Former President, Global Quality and
Business Operations, Stryker Corporation

David K. Floyd
Former Group President
Stryker Corporation

Thomas J. Gunderson
Chairman at Minneapolis
Heart Institute Foundation, Inc.

James T. Hogan
Former President of Latin America,
Medtronic plc (formerly Medtronic Inc.)

F. Ann Millner, Ed. D.
Regents Professor and Professor
of Health Administrative Services
Weber State University

Lynne N. Ward
Former Executive Director of My529
(formerly Utah Educational Savings Plan)

## FORM 10-K

Merit Medical Systems, Inc. filed an Annual Report on Form 10-K with the U.S. Securities and Exchange Commission for the fiscal year ended December 31, 2020. A copy may be obtained by written request from Brian G. Lloyd, Corporate Secretary, at Merit's corporate office in South Jordan, Utah.

## ANNUAL MEETING

All shareholders are invited to attend Merit's Annual Meeting of Shareholders to be held virtually via live webcast at on Thursday, June 17, 2021, at 2:00 p.m. Mountain Time.

## STOCK TRANSFER AGENT/REGISTRAR

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

## MARKET INFORMATION

Merit's common stock is traded on the NASDAQ Global Select Market System under the symbol "MMSI." As of February 24, 2021, the number of shares of common stock outstanding was 55,690,669, held by approximately 101 shareholders of record, not including shareholders whose shares are held in securities position listings.

## PR/MEDIA INQUIRIES:

Teresa Johnson
Merit Medical Systems, Inc.
(801) 208-4295

## INVESTOR INQUIRIES:

Mike Piccinino, CFA, IRC
Westwicke - ICR
(443) 213-0509

## FOR MORE INFORMATION, CONTACT

Brian G. Lloyd
Corporate Secretary
Merit Medical Systems, Inc.
(801) 253-1600

## CORPORATE OFFICES

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

## INDEPENDENT ACCOUNTANTS

Deloitte & Touche LLP

## LEGAL COUNSEL

Parr Brown Gee & Loveless
Corporate and Securities Counsel

Stoel Rives LLP
Intellectual Property Counsel

Workman Nydegger
Intellectual Property Counsel

Understand. Innovate. Deliver.™

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