MERIT MEDICAL®

2022 ANNUAL REPORT

A MESSAGE FROM THE CHAIRMAN & CEO

DEAR SHAREHOLDERS,

In 2022, Merit completed the second year of a three-year Foundations for Growth (FFG) program. The FFG program has helped us strengthen the foundational capabilities of our business. This includes expanding our ability to scale, improving profitability, delivering top-line growth, and innovating in the marketplace.

Despite the macroeconomic headwinds facing our industry, we delivered record-setting revenue, and experienced operating margin and free cash flow levels that yielded shareholder returns at the upper end of the medical device industry.

The foundation for our success stems from innovation. We launched multiple products, including the PreludeSYNC EZ™ Radial Compression Device, TEMNO Elite® Biopsy System, Prelude Roadster® Guide Sheath, SafeGuard Focus Cool™ Compression Device, Resolve® Thoracostomy Tray, and the smallest and shortest configuration of the Elation® Pulmonary Balloon Dilator.

In addition, we were granted FDA clearance for the SCOUT Bx™ Delivery System, and we received FDA "Breakthrough Device Designation" for Embosphere® Microspheres for use in genicular artery embolization for symptomatic knee osteoarthritis.

Our innovation continued with several patient studies. The WRAPSODY™ Registry (WRAP) Study is being conducted to evaluate the clinical benefits associated with the WRAPSODY Cell-Impermeable Endoprosthesis in hemodialysis patients with vessel stenosis or occlusion. We enrolled the first patient in a multicenter observational study to evaluate the use of EmboCube® Embolization Gelatin to control bleeding or hemorrhage. In Canada, we enrolled the first patient in the Streamlined Localization (STREAMLoc) registry study that assessed clinical utility of using the SCOUT® Radar Localization System at biopsy.

We remain focused on creating a more sustainable future. Merit was named one of "America's Most Responsible Companies" by *Newsweek*. In addition, during 2022 our facilities in Salt Lake City, Galway, Paris, Richmond, and Venlo received one or more new ISO certifications for safety, environment, and/or energy.

At Merit, taking care of our people and the community is a core value. This year, we launched our first-ever global employee engagement survey and put into place more than 500 specific action plans based on employee feedback. We continued to make additional investments in employee development, compensation, and benefits. Through partnering with several non-profit organizations, we also donated lifesaving medical devices to those in need through missions across the globe.

We believe the continued execution of FFG initiatives will further position Merit for long-term success and perpetuate its mission to be the most customer-focused company in healthcare. We also believe this focus will, in turn, enable us to continue to deliver increased shareholder value well into the future.

Sincerely,

FRED P. LAMPROPOULOS | CHAIRMAN & CEO

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

☒ **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the fiscal year ended December 31, 2022

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. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2022, based upon the closing price of the common stock as reported by the NASDAQ Global Select Market on such date, was approximately $3.0 billion. As of February 22, 2023, the registrant had 57,318,032 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 its 2023 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 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

During the last three years, COVID-19 has had an unsteady but significant impact on our business, suppliers, customers, employees, families and communities. Measures designed to contain the virus, including travel bans and restrictions, border closures, quarantines, shelter-in-place orders, business limitations and shutdowns continued during portions of the year ended December 31, 2022.

In efforts to contain the spread of the virus, many of our hospital customers prioritized their efforts on their COVID-19 response, diverting their focus and resources away from their normal operations and restricting access to their sites. In 2022, these restrictions were generally reduced, and we were able to achieve the highest annual revenue in the history of the Company. However, lingering effects continue, including unpredictable freight and other logistical expenses and obstacles, and the responses of government authorities and our customers vary from region to region. Please refer to the discussion of the risks and uncertainties associated with COVID-19 under the heading "*The COVID-19 pandemic and related ongoing implications have 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 below in Item 1A "Risk Factors."

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; orthopedic spine surgery; interventional oncology; pain management; breast cancer surgery, 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.

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® Introducer Sheaths 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, 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
- Merit Wrapsody ™ Endoprosthesis, a cell-impermeable endoprosthesis which is designed to maintain long-term vessel patency in patients with obstructions in the dialysis outflow circuit (this device is not currently available for use in the United States).

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;
- Our newest offering of Merit SplashWire® hydrophilic Steerable Guide Wires, combining optimum lubricity, exceptional torque response and enhanced visibility;
- 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 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 SB-Kawasumi Laboratories, Inc.;
- 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 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
- HepaSphere® 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;
- Dynamis AV™ PTA Dilatation Catheter, a line of balloon catheters that facilitates the opening of blockages located in the arteriovenous system of dialysis patients;
- 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 inflation 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. We also offer an extensive line of soft tissue biopsy products and accessories. 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™, 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;
- 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 Medical 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 COVID-19, during 2020 and 2021 most medical conventions in which we participated were virtual meetings; however, many of the groups hosting those conventions resumed in-person meetings during 2022. Additionally, we are building out digital and direct-to-customer programs to increase awareness of our products, and 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 work closely with 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, develop 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 rapidly conceive, design, develop and introduce new products that meet customer needs.

U.S. and International Sales. Sales of our products in the U.S. accounted for 57% of our net sales for each of the years ended December 31, 2022, 2021 and 2020, respectively. In the U.S., we have dedicated, direct sales organizations 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 2022, our international sales grew 7.4% over our 2021 international sales and accounted for 43% of our net sales. Our largest non-U.S. market is China, which represented 13% of our net sales in 2022 and reported net sales of $149.3 million, $138.2 million, and $113.2 million for the years ended December 31, 2022, 2021 and 2020, respectively. We maintain a distribution center and administrative office in Beijing. 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.

Beginning in 2020, we experienced a significant disruption of our business throughout the world as a result of COVID-19, and this disruption continued through 2021 and 2022. We are unable to calculate the full impact of COVID-19 on our business, and we are unable to predict whether we will continue to be affected by it, but we experienced a material adverse impact on our global operations and financial condition during 2020. In 2021, we saw growth in global sales compared to 2020 as the demand for our products increased when many of the medical procedures delayed from 2020 were performed and the restrictions put in place in response to the pandemic were generally reduced. That trend continued during 2022, and we were able to achieve the highest annual revenue in the history of the Company. For further discussion of the risks and uncertainties associated with COVID-19, please refer to disclosure under the heading "*The COVID-19 pandemic and related ongoing implications have 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, electrophysiology, endoscopy, dialysis and embolism.

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. In 2022, our Chief Executive Officer and our Executive Vice President of Global Research & Development worked closely

with our sales and marketing teams to incorporate feedback from physicians and clinicians in the field, which contributed to innovative new products and improvements to our existing products.

In 2022, we completed projects that resulted in the newest additions to our product lineup: Prelude Roadster®, Sync EZ™, Safeguard Focus Cool™, and Scout BX™.

Currently, we have research and development facilities in California, Texas, Utah, Ireland, France, and Singapore.

Manufacturing

We manufacture many of our products using 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 have also received various International Standards Organization ("ISO") certifications for many of our facilities; for further details, please refer to Item 1. "Business - Sustainability" below. Merit Sensor Systems, Inc. ("Merit Sensors") develops and markets silicon pressure sensors to a range of enterprises and presently supplies the sensors we use 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 use 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 ship our products through distribution centers located in Virginia, Utah, Canada, Brazil, The Netherlands, United Kingdom ("UK"), South Africa, 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, product features, customer service, breadth of line, and customer relationships. We believe our products are attractive to customers due to their innovative design, the quality of materials and workmanship, clinical performance, and our strong focus on customer needs, and our prompt attention to customer requests. Some of our primary competitive strengths are our relative stability in the marketplace; comprehensive, broad line of ancillary products; manufacturing integration to secure our supply chain; and strong cadence of new products and product line extensions that enhance our portfolio.

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, radar localization, waste-disposal systems, embolic beads, 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 has not historically had a material adverse effect on our financial results; however, fluctuations and uncertainties in supply chain, transportation logistics, and freight expenses that we have experienced during the past several years have challenged our operating capabilities and could result in disruptions in our operations and materially impact our financial results. For further discussion of the risks and uncertainties associated with recent disruptions in supply chain and logistics, please refer to disclosure under the heading "*Termination or interruption of our supply relationships and increases in labor costs and the prices of our component parts, finished products, third-party services and raw materials, particularly petroleum-based products, is negatively impacting our business and could have a further adverse effect on our business, operations or financial condition.*" set forth in Item 1A "Risk Factors."

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, 2022, we owned approximately 1,600 U.S. and international patents and patent applications.

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

The Merit® name and logo are trademarks in the U.S. and other countries. In addition to the Merit name and logo, we have used, registered or applied for registration of other specific trademarks and service marks to help distinguish our products, technologies and services from those of our competitors in the U.S. and foreign countries. See Item 1. "Business - 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, 2022, we owned approximately 650 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

Corporate Integrity Agreement. In October 2020, we entered into a Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG"), a five-year agreement that was a condition of our settlement with the United States Department of Justice ("DOJ"). The CIA subjects us to certain compliance, monitoring, reporting, certification, oversight and training obligations. 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 and compliance and disclosure programs; (ii) establish 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. We recently completed our second reporting period under the CIA and continue to implement compliance program enhancements.

Our failure to comply with our obligations under the CIA could result in monetary penalties and our exclusion from participation in federal health care programs.

The foregoing description of the CIA is qualified in its entirety by the full terms of the CIA, which is attached as Exhibit 10.44 hereto and incorporated herein by reference.

Regulatory Approvals. Our products and operations are global and are subject to regulations by the 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, distribution, and post-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, in May 2017, the EU adopted Regulation (EU) 2017/745 ("MDR"), which replaced Council Directive 93/92/EEC ("MDD") as of May 26, 2021. Under transitional provisions, medical devices with notified body certificates issued under MDD prior to May 26, 2021 may continue to be placed on the market for the remaining validity of the certificate or until May 26, 2024, whichever is first. After the expiry of any applicable transitional period, only devices that have been CE marked under MDR may be placed on the market in the EU. On January 6, 2023, the EU Commission proposed a draft amendment to the MDR which would extend the transitional period, thus allowing for additional time to transition to the new requirements of the MDR. At time of publication, the amendment had not been through the entire legislative process, leaving some uncertainty as to whether or not it would be approved.

We are preparing to comply with these new regulations under the MDR before the transitional period expires. However, there will be products that we will instead choose to discontinue or postpone introduction in the EU. This decision will depend on a number of factors, including changing business strategies, timing and cost of obtaining MDR certification, availability of necessary data and the capacity of notified bodies. MDR includes increasingly stringent requirements in multiple areas, such as pre-market clinical evidence, review of high-risk devices, labeling and post-market surveillance. Under 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 receiving 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 Cell-Impermeable Endoprosthesis, 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 Endoprosthesis, which is required for us 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 could 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. With the U.S. and other countries exploring export sanctions in response to military exercises and escalating tensions in certain parts of the world, any such export restrictions may affect the company's business in certain regions of the world.

Additional Post-Market Requirements. As a medical device manufacturer, we are subject to other post-market requirements in multiple jurisdictions, including (i) product listing, (ii) establishment registration, (iii) Unique Device Identification ("UDI"), and (iv) reports of corrections and removals. We are also subject to regulations that 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. The FDA also regularly inspects companies to determine compliance with the QSRs and other post-market requirements. Please refer to our discussion of the risks and uncertainties associated with these post-market requirements under the heading "*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.*" set forth in Item 1A "Risk Factors."

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 in which the device is used only when the payer determines that healthcare outcomes are supported by medical evidence and the device and 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, for uses outside of the U.S., a similar foreign regulatory agency, there is no certainty that third-party payers will cover and reimburse for the cost of the device and/or related procedures involving the use of the device. 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 and/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. Our international operations are subject to the Foreign Corrupt Practices Act (the "FCPA"), the U.K. Bribery Act and other foreign anti-corruption laws. 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. In certain countries, the individuals and entities that we regularly interact with may meet the definition of a foreign government official for purposes of the FCPA. As part of our compliance program, we train our U.S. and international employees, and we also train and monitor foreign third parties with whom we contract (e.g., distributors), to comply with the FCPA and other 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 international operations, we continue to increase the scope of our compliance programs to match the risks relating to the potential for violations of the FCPA and other anti-corruption laws. Our compliance program includes (i) policies addressing not only the FCPA, but also the provisions of a variety of anti-corruption laws in multiple foreign jurisdictions, (ii) provisions relating to books and records that apply to us as a public company, and (iii) effective training for our personnel and relevant third parties.

Transparency Laws. The U.S. Physician Payment Sunshine Act, and similar state laws, 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 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.

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.

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 proceedings.

False Claims Laws. The False Claims Acts prohibit 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 claim paid. The Civil False Claims Act can be violated without actual knowledge and only requires reckless disregard or deliberate ignorance, while the Criminal False Claims Act requires a higher knowledge standard of actual knowledge and intent to violate. Manufacturers can be held liable under the False Claims Acts, even if they do not submit claims to the government, if they are found to have caused the submission of false claims (e.g., by third parties such as healthcare providers). The Civil 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 Civil 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 False Claims Acts and similar state laws may include civil monetary penalties, treble damages, criminal fines and/or imprisonment.

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

Privacy and Security. Due to Merit's global presence, we are impacted by the privacy and data security requirements at the international, federal, state and regional level, as well as on an industry specific basis. More privacy and data security laws and regulations are being adopted and enforced, with increasingly significant fines and financial penalties for violations in the jurisdictions in which we conduct our operations. Compliance with these evolving and complex data privacy and cybersecurity laws and regulations has resulted in, and will likely continue to result in new compliance challenges and increased costs. Our business relies on the secure electronic transmission, storage and hosting of personal and sensitive personal information, including protected health information, financial information, intellectual property and other sensitive information related to our customers and workforce.

Internationally, Merit is impacted by a number of stringent privacy regimes, such as the General Data Protection Regulation ("GDPR") in the EU and the Personal Information Protection Law ("PIPL") in China, GDPR applies uniformly across the EU and includes, among other things, a requirement for prompt notice of data breaches to the owner of the personal data and to supervisory authorities in certain circumstances, and the imposition of significant fines for non-compliance. GDPR also requires companies based outside of the EU but processing personal data of individuals residing in the EU to comply with EU privacy and data protection rules. Non-compliance could result in the imposition of significant fines, penalties, and/or orders to stop non-compliant activities.

GDPR provides for a harmonization of the data protection regulations throughout the EU. It imposes a strict data protection compliance regime with severe penalties and includes rights such as the "portability" of personal data and the right of erasure of personal data for the data subject. Although 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 GDPR, which has the potential to create inconsistencies on a country-by-country basis.

As a consequence of Brexit, GDPR no longer directly applies in the United Kingdom. However, the UK has adopted its own UK General Data Protection Regulation ("UKGDPR"). This regulation came into effect on January 1, 2021 and is generally similar to GDPR, while at the same time accommodating applicable laws in the UK.

The People's Republic of China has introduced a comprehensive personal information protection regime by establishing a unified, cross-sector legislation, as the EU does with GDPR. This legislation, called PIPL, went into effect on November 1, 2021, and has many aspects that are similar to GDPR. The PIPL sets rules for personal information processing activities such as collection, use, sharing, transfer, and disclosure of personal information in China. It also applies to personal information processing activities outside of China if relevant business operators (a) aim at providing products or services to individuals in China; or (b) engage in analyzing and evaluating the behavior of individuals in China. Among other provisions, the PIPL requires companies identified as personal information processors (which can be viewed as equivalent to data controllers under GDPR) to obtain informed consents from the data subjects for the processing activities of their personal information, and separate consents under certain circumstances such as cross-border transfer of personal information. The PIPL also requires storage of personal information locally in China if the company is certified as a critical information infrastructure operator or processing personal information exceeding a certain volume threshold. Further, the PIPL grants statutory rights to data subjects, such as the right to information, the right to withdraw consents, the right of data portability, and the right to refuse automated decision-making. In addition, the PIPL also imposes a number of new administrative requirements on the personal information processors, including, among others, designating a data protection officer if certain conditions are met, signing data processing agreements with entrusted processors (which can be viewed as equivalent to data processors under GDPR), preparing data breach notices, conducting a personal information impact assessment as required, and obtaining regulatory approval for certain cross-border data transfer activities. Violations of the PIPL may incur severe penalties, revocation of the company's license to do business in China, and personal liabilities for company executives. As the PIPL is new and relevant implementation rules are to be finalized and released, we are in the process of implementing changes to our business practices to comply with the PIPL while monitoring further developments in the law.

In the U.S., the collection, maintenance, protection, use, transmission, disclosure and disposal of certain personal information and the security of medical devices are regulated at the U.S. federal and state, international and industry levels. U.S. federal and state laws protect the confidentiality of certain patient health information, including patient medical records ("PHI"), and restrict the use and disclosure of patient health information by healthcare providers. "Privacy" and

"Security" Rules under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended, and the Health Information Technology for Economic and Clinical Health Act (the "HITECH Act"), govern the use, disclosure, and security of protected health information by "Covered Entities" (which are healthcare providers, health plans and healthcare clearinghouses), and by their "Business Associates" (which is anyone that performs a service on behalf of a Covered Entity involving the use or disclosure of PHI and is not a member of the Covered Entity's workforce). Regulations under these laws establish standards, including standards regarding the privacy and security of PHI and breach notification requirements. The U.S. Department of Health and Human Services (through the Office of Civil Rights) has direct enforcement authority against Covered Entities and Business Associates with respect to both the Security and Privacy Rules, including both civil and criminal liability. Although Merit is a healthcare provider, Merit is not a Business Associate under the HIPAA/HITECH Act. Our risk is therefore significantly reduced because we do not create, receive, maintain, have access to, use, disclose or transmit PHI. Many state laws also regulate the use and protection of PHI by healthcare providers and may require notification in the event of a breach of such information. Merit may be subject to these laws in certain instances.

With the advent of digital technology, artificial intelligence, social media, and the speed at which information moves, the protection and security of data has become an increasingly important public, media and legislative concern. As a result, and in addition to the U.S. federal regulation of PHI, a number of states have also adopted laws and regulations that may affect our privacy and data security practices for other kinds of personally identifiable information, such as state laws that govern the use, disclosure and protection of personal information and sensitive personal information (such as social security numbers). State consumer protection laws may also establish privacy and security standard for the storage, use and management of personally identifiable information, including information related to consumers or employees (which include job applicants, employees, owners, officers, directors, and medical staff members of Merit).

As of December 31 2022, five U.S. states had enacted comprehensive data privacy laws. In general, these state laws (California, Colorado, Connecticut, Utah and Virginia) give residents the right to obtain their personal information from companies, request to have their personal information deleted, and opt out of having that information sold to third parties. The state laws also compel companies to post clear privacy policies that detail the types of personal information they collect about consumers, with whom they share this data, and how consumers can control their personal data. We post on our websites our privacy notices, policies and practices regarding the collection, use and disclosure of user data, as well as providing our privacy policies to our employees (including job applicants) by linking to the Merit privacy policy (posted on the Merit website) from our Employee Handbook and our job application board. Any failure, or perceived failure, by us to comply with our posted privacy notices or 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. California's Consumer Protection Act ("CCPA") went into effect on January 1, 2020, giving consumers the right to (i) prevent businesses from sharing their personal information, (ii) correct inaccurate personal information, and (iii) restrict companies from utilizing sensitive data and personal information. The California Privacy Rights Act ("CPRA"), which went into effect on January 1, 2023, amended the CCPA to include job applicants, employees, owners, officers, directors, and medical staff members of a business (collectively "employees"), give consumers even more control over their data, and increase the maximum penalties for violations against consumers who are less than 16 years old. The CPRA also prevents companies from keeping personal data longer than necessary. The addition of employees to the protections afforded by the CCPA can cause business concerns because we also have legal requirements to retain certain employee data, such as confidential disciplinary files, as well as legal document retention requirements. Virginia's Consumer Data Protection Act, which also went into effect on January 1, 2023, sets forth regulations regarding how we can control and process data, giving consumers the right to access, delete, and correct their data, as well as opt-out of personal data processing for advertising purposes. The Colorado Privacy Act and the Connecticut Personal Data Privacy and Online Monitoring law, both of which establish standards for how companies control and process consumer personal data, are both scheduled to take effect July 1, 2023. The Utah Consumer Privacy Act, which is scheduled to take effect on December 31, 2023, gives consumers the right to know what type of data businesses collect about them, how their data is being used and whether or not businesses intend to sell their data to third parties. All five of these state laws let consumers access and delete their personal data that the business has collected on them and opt out of data collection.

Because privacy and data security laws and regulations continue to expand, differ from jurisdiction to jurisdiction, and are subject to evolving (and at times inconsistent) governmental interpretation, compliance with these laws and regulations may require significant additional cost expenditures or changes in products or business that increase competition or reduce revenue. Noncompliance with such laws or regulations could result in the imposition of fines, penalties, or orders to stop noncompliant activities, as well as 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.

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 deferred payment of the employer's portion of social security payroll tax payments and made a payment equal to one half of the deferred amount during each of the years ended December 31, 2021 and 2022.

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

Under the oversight of our Board of Directors and management team, we continue to make sustainability a key focus of our business. We have a cross-functional Corporate Sustainability Council that is driving long-term Environment, Social and Governance ("ESG") goals across our enterprise. These efforts have included proactive actions to address 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 materials 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. We continually look for opportunities to deliver sustainable, long-term growth of our business. Our sustainability practices are an integral component of our business strategy.

We have identified our sustainability opportunities, and have developed areas of focus where we are positioned to make a positive impact. These include programs designed to reduce waste, improve efficiencies, reduce greenhouse gas emissions, and protect the environment. Our sustainability values in action include:

- achievement of ISO 14001 certification at all of our largest manufacturing facilities (seven in scope) with the goal of continual improvement of our environmental management system (ISO 14001 is the international standard that specifies requirements for an effective environmental management system);
- achievement of ISO 45001 certification at all of our largest manufacturing facilities (seven in scope) with the goal of continual improvement to our occupational health and safety management system (ISO 45001 is the international standard that specifies requirements for an effective safety management system);
- achievement of ISO 50001 certification at five of our largest manufacturing facilities (seven in scope), and our goal is to achieve ISO 50001 certification at all our in scope manufacturing facilities by the end of 2024 (ISO 50001 is the international standard that specifies requirements for an effective energy management system);

- establishment and support of 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 reusable bulk containers, reducing intra-company shipping materials;
- reduction in water consumption at our water-stressed location in South Jordan, Utah by investing in campus-wide xeriscaping and water recirculation systems within our most water intensive operations;
- reduction in packaging materials by implementing product family packaging reviews to consolidate shipments by better understanding our customers' purchasing practices—these reviews often allow us to increase quantities per box, eliminate the usage of intermediate packaging, reducing film thickness and use original product packaging where possible;
- transition from paper work orders to electronic work orders through our internally designed eWorq program—at full completion, this project will save millions of pieces of paper and thousands of plastic sleeves annually—currently we are working to implement this program at our largest manufacturing facilities in South Jordan, Utah and Tijuana, Mexico, with plans to continue the roll-out to other sites thereafter;
- recycling programs where our employees recycle materials, including food waste, paper, plastic, cardboard, food waste and beverage containers, scrap metal, and pallets, and re-use of our plastic scrap waste leftover from the manufacturing process of our molded parts;
- placement of free car charging stations for employees who have transitioned to electric vehicles;
- installation of 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;
- operation of an environmental tracking system at our world-wide facilities to facilitate monthly reporting and accountability for energy, water, waste, recycling, and scope 1 and 2 greenhouse gas emissions metrics—this system supports our 2030 operational sustainability goals; and
- engaged in a comprehensive materiality assessment to better align ESG expectations from our internal and external stakeholders.

To learn more about our sustainability programs and accomplishments, you may visit www.merit.com/about/corporate-sustainability/; however, the information on this website is not, and will not be deemed, a part of this report or incorporated into any other filings we make with the SEC.

Human Capital Management

As of December 31, 2022, we had 6,846 employees located in approximately 40 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, our Chief Human Resources Officer 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. Over 50% of our U.S. employee population identifies as non-white. To further promote a culture of inclusion, during 2021 we started the Women's Leadership Initiative ("WLI"), our first ever affinity group led by women and open to all Merit employees.

The WLI contributes to our long-term strategies by promoting a culture of diversity, equity and inclusion through (i) sponsoring professional development activities focused on overcoming barriers and restraints to the advancement of women's careers, (ii) facilitating external interactions with organizations and thought leaders, and (iii) providing resources focused on improving diversity, equity, and inclusion.

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 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. Since 2021 we have substantially strengthened our employee communications capabilities through the addition of dedicated internal resources and programs aimed at doing even more to communicate with and engage our workforce. In partnership with the Gallup organization, in 2022 we launched our first ever global employee engagement survey. This survey provided us with many insights into the engagement of our employees from which we have been able to develop action plans at the team and company level in order to further strengthen employee engagement.

Compensation and Benefits. Because our mission is to create innovative medical devices that improve lives, we aim to hire and develop employees who want to build something special through hard work, team effort, and commitment. That is why we provide all our employees with competitive benefit packages and strive to provide the most cost-effective medical benefits and wellness programs. As a result of our focus on competitive health and wellness benefits, we have achieved our eighth consecutive year of zero health care plan cost increases for our U.S. employees who participate in our group healthcare plans. Our benefits include competitive pay, annual incentive awards and bonus opportunities, healthcare and retirement benefits, an Employee Stock Purchase Plan, paid time off and sick leave, paid parental leave, flexible work schedules, remote working opportunities, and a wellness program.

Talent Development. In 2021, we hired our first ever Director of Global Talent Management who continues to be focused on building and strengthening global programs around strategic talent management, employee performance, development and engagement. To improve employee performance, we have begun building out a global performance management program which will be officially launched in 2023 alongside our new human resources information system. Employee development programs are also being executed at different regional and local levels with a focus on management and leadership development.

Community. Our employees are actively involved in their communities and supporting causes. At our headquarters, we provide an onsite garden where employees take part in growing and distributing produce to employees and to the local community. Employees also actively support causes by raising awareness and funds for non-profit organizations. Areas that our employees have supported in recent years include Breast Cancer Awareness Month, Heart Health Month, children's charities and supporting those in need. In 2022, we continued our support of humanitarian missions through Merit product donations in Haiti, Kenya, Honduras, Nicaragua, and Tanzania. Merit also conducts and/or participates in medical education conferences around the globe.

Wellness. Wellness is at the foundation of creating a positive employee experience. At our company headquarters in Utah, we have an onsite medical clinic available for our employees and their families where we provide preventative and general medical care. In addition, we have a Chief Wellness Officer dedicated to designing programs and initiatives that support the physical, emotional, and mental health of our employees. We have a monthly wellness committee meeting and create a "Get Healthy" wellness program available to all sites across the globe. Programs include providing health information from medical and nutrition experts, newsletters with wellness and dietary tips, and activities promoting health and wellbeing such as walking groups and fitness challenges. Some programs include suicide prevention awareness, on-site diabetes screenings, mental health awareness, lifestyle modification to prevent diseases, tobacco cessation, breast cancer awareness, and our Smart Choice meal program designed by our onsite nutritionist and chef to provide free heart healthy meals to employees in our Utah headquarters.

COVID-19 Response; Health and Safety. During the COVID-19 pandemic, the majority of our manufacturing employees continued to work from our facilities, where we adopted health screening, implemented social distancing and personal protective equipment requirements, enhanced food service, cleaning and sanitation procedures, and modified workspaces to reduce the potential for disease transmission, and implemented a COVID-19 vaccine mandate for our U.S.

employees. During 2022 most employees who do not require access to our facility to perform their work continued to work remotely, 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. We conduct periodic phishing testing on all our employees with e-mail access and emphasize information security in training events and programs we host throughout the year.

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 is responsible for enterprise risk management, including our approach to managing cybersecurity risk, and has delegated oversight responsibility of information security risks to its Audit Committee. 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 its 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 cyber insurance coverage that may, subject to policy terms, conditions and limitations, 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. During the last three years, we have not experienced a material security breach and, as a result, we have not incurred any material expenses from such a breach. Furthermore, during such time, we have not been penalized or paid any amount under any information security breach settlement.

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:

Business, Economic, Industry and Operational Risks

Termination or interruption of our supply relationships and increases in labor costs and the prices of our component parts, finished products, third-party services and raw materials, particularly petroleum-based products, is negatively impacting our business and could have a further 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. The military conflict between Russia and Ukraine may increase the likelihood of supply interruptions and further hinder our ability to find the materials we need to make our products. Supply disruptions are making it harder for us to find favorable pricing and reliable sources for the materials we need, putting upward pressure on our costs and increasing the risk that we may be unable to acquire the materials and services we need to continue to manufacture certain 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. During 2022, we experienced significantly elevated commodity and supply chain costs, including the costs of labor, raw materials, energy, fuel, packaging materials and other inputs necessary for the production and distribution of our products, and we expect elevated levels of inflation to continue in 2023. 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 have generally increased and may further increase if crude oil prices increase. Our transportation and service providers are typically able to pass any significant increases in oil prices on to us.

Our ability to recover such increased costs may depend upon our ability to raise prices on our products. Due to the highly competitive nature of the healthcare industry and the cost-containment efforts of our customers and third-party payers, we may be unable to pass along cost increases through higher prices. If we are unable to fully recover these costs through price increases or offset these increases through cost reductions, or we experience terminations or interruption of our relationships with our suppliers, we could experience lower margins and profitability, and our results of operations, financial condition and cash flows could be materially harmed.

Changes in general economic conditions, geopolitical conditions, domestic and foreign trade policies, monetary 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. The global macroeconomic environment continues to be challenging due to the effects of the COVID-19 pandemic and government responses, increases in inflation globally, instability in the global credit markets, the impact of uncertainty regarding global central bank monetary policy, the instability in the geopolitical environment in many parts of the world (including as a result of the on-going Russia and Ukraine war and China-Taiwan relations), the current economic challenges in China, and other disruptions. Periods of intense diplomatic or armed conflict, such as the ongoing conflict

in Ukraine, may result in (i) new and rapidly evolving sanctions and trade restrictions, which may impair trade with sanctioned individuals and countries, and (ii) negative impacts to regional trade ecosystems among our customers, partners, and us. Non-compliance with sanctions as well as general ecosystem disruptions could result in reputational harm, operational delays, monetary fines, loss of revenues, increased costs, loss of export privileges, or criminal sanctions. Furthermore, U.S. trade policy could trigger retaliatory actions by other countries, including China, resulting in a "trade war." A trade war could result in increased costs for raw materials we use in our manufacturing and could result in foreign governments imposing tariffs on products that we export outside the U.S. or otherwise limiting our ability to sell our products abroad. These increased costs would have a negative effect on our financial condition and profitability. Furthermore, if the conflict between Russia and Ukraine continues for a long period of time, or if other countries, including the U.S., become further involved in the conflict, we could face significant adverse effects to our business and financial condition.

The occurrence of regional epidemics or a global pandemic, such as COVID-19, may adversely affect our operations, financial condition, and results of operations. The COVID-19 pandemic and governmental responses have had widespread, rapidly evolving, and unpredictable impacts on global society, economies, financial markets, and business practices. The extent to which global pandemics impact our business going forward will depend on factors such as the duration and scope of the pandemic; governmental, business, and individuals' actions in response to the pandemic; and the impact on economic activity, including the possibility of recession or financial market instability.

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:

- effects of significant changes in economic, monetary and fiscal policies in the U.S. and abroad including currency fluctuations, inflationary pressures and significant income tax changes;
- global increases in inflation;
- a global or regional economic slowdown in any of our market segments;
- 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;
- new or stricter trade policies and tariffs enacted by countries, such as China, in response to changes in U.S. trade policies and tariffs;
- postponement of spending, in response to tighter credit, financial market volatility and other factors;
- rapid material escalation of the cost of regulatory compliance and litigation;
- difficulties protecting intellectual property;
- longer payment cycles;
- credit risks and other challenges in collecting accounts receivable; and
- the impact of each of the foregoing on outsourcing and procurement arrangements.

Any damage or interruption to our operations, facilities, infrastructure, manufacturing processes or information technology systems, or those of our suppliers, including as a result of our facility consolidation initiatives, 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 or reduced the operations of certain facilities and moved operations and resources to other facilities, and we are in the process of other facility consolidation initiatives. The resulting concentration of resources and the potential disruption and logistical challenges resulting from those initiatives may further exacerbate the adverse effects of these events or make it more difficult for us to respond to the effects of these events. Those initiatives may also divert the attention of our management team or other personnel, result in unanticipated expense and disrupt our operations. 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.

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.

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.

COVID-19 Risks

The COVID-19 pandemic and related ongoing implications have 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 and the resulting containment measures created significant disruption and uncertainty in the global economy and negatively impacted our business, results of operations and financial condition during 2020, 2021 and 2022. Although the impact of COVID-19 and the resulting containment measures decreased during 2022, they have the potential to continue to negatively impact our business, results of operations and financial condition in the future.

Numerous national, international, state and local jurisdictions imposed a variety of government orders and restrictions for their residents to control the spread of COVID-19. In 2020, such orders and restrictions caused significant alterations of our operations, work stoppages, slowdowns and delays, travel restrictions and event cancellations, among other effects, thereby significantly and negatively impacting our financial condition. In 2021 and 2022, these conditions continued at varying levels. Other disruptions that we experienced include (i) restrictions on our personnel and personnel of business partners to travel and access customers for training and case support; (ii) supply chain delays and disruptions, logistical challenges and increased freight, transportation and other expenses; (iii) delays in regulatory approvals by governmental and regulatory bodies; (iv) reductions in spending by our customers; (v) 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; (vi) fluctuations in the availability of employees and potential employees; (vii) additional government requirements or other incremental mitigation efforts that

may further impact our or our suppliers' capacity to manufacture our products; (viii) disruption of our research and development activities; and (ix) delays in ongoing studies and pre-clinical trials. Although some of these disruptions diminished in 2021 and the impact lessened further during 2022, they may again return or further intensify their effect on our operations, whether as a direct result of COVID-19 or other factors exacerbated by the effects of COVID-19.

In addition, elective procedures that use our products significantly decreased in number during much of 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 recommended, and in certain cases required, that elective, deferrable, specialty and other procedures and appointments (many of which use our products), 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. In 2021, these procedures resumed in many locations, and overall, we saw significant improvement in our business during 2021. We saw further improvement in the availability of elective procedures during 2022. It is possible, however, that a resurgence of COVID-19, or increased spread of its variants, could again cause a rise in severe infections and force authorities and customers to impose restrictions that would negatively impact our operations.

All of these factors have also caused or contributed to disruptions and delays in our logistics and supply chain, and we may continue to experience these disruptions and delays. The full extent to which COVID-19 and resulting containment measures impact 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 its variants. To the extent COVID-19 (including existing variants and any new variants) and resulting containment measures continue to adversely affect our business, operations and financial results, they 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.

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 of 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.

We have completed a series of significant acquisitions and, continue to evaluate 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 evaluating, 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 have incurred expenses in connection with the disposition of businesses and assets which we acquired but determined that they did not produce the benefits contemplated at the time of acquisition. We may incur similar expenses in the future.

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 COVID-19 or decreased 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.

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.

Regulatory, Litigation, Tax and Legal Compliance Risks

Regulations and trade policies implemented by foreign governments to reduce the costs of healthcare or promote business in their countries have caused, and are likely to continue to cause our sales to decline in such countries.

These regulations and policies result in increased costs, lower margins and lower sales than we would otherwise expect, which 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. For example, China has implemented a volume-based procurement process designed to decrease prices for medical devices and other products. This process has had a negative impact on our revenues in China and we expect it will continue to cause a decrease in the revenue we are able to generate in China.

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 Endoprosthesis. 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 Endoprosthesis 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 them. We have experienced delays and expended significant resources in obtaining those approvals and clearances and we will likely continue to experience delays and uncertainty, and incur significant expenses, 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. See our related discussion under Item 1. "Business – Regulation - Regulatory Approvals."

In general, we intend to obtain MDR approvals for our principal products sold in the EU ahead of expiry dates; however for multiple reasons, including but not limited to changing business strategies, limited labor pool and contract resources, administrative delays, increased costs of obtaining MDR certification, availability of necessary data and notified body capacity, there will be some products that will not be fully compliant at the time of expiry. The additional time and resources required to obtain MDR certification has been a significant factor in, and will likely continue to influence, our decisions to discontinue sales and distribution of certain products in the EU.

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

The medical device industry is subject to extensive scrutiny and regulation by governmental authorities 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 products 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, OIG, SEC 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 $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 the CIA. Please refer to the discussion in Item 1. "Business - Regulation - Corporate Integrity Agreement." 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, including 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 on 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 negatively impact our 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 the CIA discussed above under Item 1. “Business - Regulation - Corporate Integrity Agreement.”

Furthermore, our contracts with government-sponsored healthcare entities are subject to specific procurement requirements. Failure to comply with applicable rules or regulations or with contractual or other requirements may result in monetary damages and criminal or civil penalties as well as termination of our government contracts or our suspension or debarment from government contract work.

Our international operations make us subject to the U.S. Foreign Corrupt Practices Act and similar anti-bribery laws in non-U.S. jurisdictions, and our failure, or the failure of our distributors and agents, to comply with these laws could subject us to civil and criminal penalties and adversely affect our business.

We currently conduct our business in various foreign countries, and we expect to continue to expand our foreign operations. As a result, we are 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.

Compliance with the FCPA and other anti-bribery laws presents challenges to our operations. Our policies mandate compliance with the FCPA and all other applicable anti-bribery laws. Further, we expect our employees, distributors, agents and others who work for us or on our behalf to comply with these anti-bribery laws. Despite our training and compliance programs, our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employees, distributors or agents. If our employees, distributors or agents violate the provisions of the FCPA or other anti-bribery laws, or even if there are allegations of such violations, we could be subject to investigations or civil and criminal penalties or other sanctions, which could have a material, adverse effect on our reputation, business, results of operations, financial condition or cash flows.

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, which incorporate the use of our products, 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 adequate reimbursement for the health care procedures that use our products, such that the cost of our products is covered, is critical to our business. Limits on reimbursement imposed by such third-party payers may adversely affect our

customers, such as hospitals, physicians and other healthcare providers, 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, for certain payers (such as foreign governments and some commercial insurers) 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 and, in some cases, jurisdiction to jurisdiction. In addition, payers continually review new and existing technologies for possible coverage and can, without notice, deny, change or reverse coverage decisions or alter prior 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 or unfavorable coverage decisions. If we are not successful in reversing non-coverage or unfavorable coverage policies, or if third-party payers that currently cover or reimburse certain procedures involving the use of our products reverse, change or limit their coverage of such procedures in the future, or if other third-party payers issue similar policies or adopt similar practices, our business could be adversely impacted.

Further, we believe that future coverage and reimbursement may be subject to increased restrictions, such as additional prior authorization 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 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 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, resulting in fines or orders requiring that we change our data practices, which could in turn (i) cause us to incur substantial costs or (ii) have an adverse effect on our business.

Legal developments in foreign countries have created uncertainty regarding certain transfers of personal data from certain countries to the U.S. or other foreign countries. For example, GDPR applies to the processing of personal data related to: (i) the activities of an establishment in the EU or (ii) the processing of personal data of data subjects who are in the EU where this is related to products and services that we offer to EU users. GDPR includes compliance obligations, which could cause us to change our business practices, and significantly increases financial penalties for noncompliance. In addition, the PIPL, similar to GDPR, applies to personal information processing activities outside of China if companies provide products or services to individuals in China or analyze and evaluate the behavior of individuals in China. If we fail to comply with the requirements of the PIPL, we could incur severe penalties. If we incur any of these penalties in the EU or China for violations of GDPR or the PIPL, our business and operations in those areas could be adversely affected and have a material adverse effect on our financial results.

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 or other expenses. 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, and currently face, 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. Inspections by the FDA or other regulators may reveal violations or instances of noncompliance under the QSRs and other post-market requirements. If we fail to comply with our medical device reporting obligations or commit a violation of these requirements, 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. Other regulatory authorities could take similar actions within their jurisdictions.

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 unauthorized activities that violate the 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 are routinely a party to or otherwise involved in legal proceedings, claims or other legal matters, arising in the course of our business. 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.

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 infringing our intellectual property rights to produce competing products. We seek to protect our intellectual property rights through a combination of confidentiality and license agreements, maintaining certain trade secrets, and through registrations under patent, trademark, and copyright 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 and copyrights 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, trade secrets, and confidential information. 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.

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 at times, been, and may in the future be, volatile for various reasons, including those discussed in these risk factors. Other events that could cause volatility in our stock include, without limitation, variances in our financial results; analysts' and other projections or recommendations regarding our common stock specifically or medical technology stocks generally; any restatement of our financial statements or any investigation of us by the SEC, DOJ, OIG, FDA, or another regulatory authority; actions taken by activist investors or other shareholders, 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 2022, 2021 and 2020, the exchange rate between all applicable foreign currencies and the U.S. Dollar resulted in a decrease in net sales of $23.8 million, an increase in net sales of $10.3 million, and a decrease in net sales of $1.3 million, respectively.

For the year ended December 31, 2022, $394.1 million, or 34.2%, 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.

We are subject to changes in tax laws, fluctuations in tax rates, the adoption of new tax legislation or exposure to additional tax liabilities, which may adversely affect our effective tax rate, business, financial condition, or results of operations.

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.

In many countries, including the United States, we are subject to transfer pricing and other tax regulations designed to ensure that appropriate levels of income are reported as earned by our U.S. or local entities and are taxed accordingly. Although we believe we are in substantial compliance with applicable regulations and restrictions, we are subject to the risk that governmental authorities could assert that we owe additional taxes. In the event that audits, assessments, or other determinations by governmental authorities are concluded adversely to us, they could have an adverse effect on our business, financial condition or results of operation.

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, Canada, Brazil, Malaysia, South Korea, Japan, South Africa, Singapore, Great Britain, Vietnam, Taiwan, New Zealand, Indonesia, and France, as well as in 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 1.9 million square feet, of which approximately 1.0 million square feet is owned, and 0.9 million square feet is leased.

The following is a summary of the approximate square footage of our key facilities as of December 31, 2022:

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	Manufacturing, Distribution	136,501
Texas	Manufacturing, Research	94,000
Singapore	Manufacturing, Research	68,000
China	Distribution	50,290

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.

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

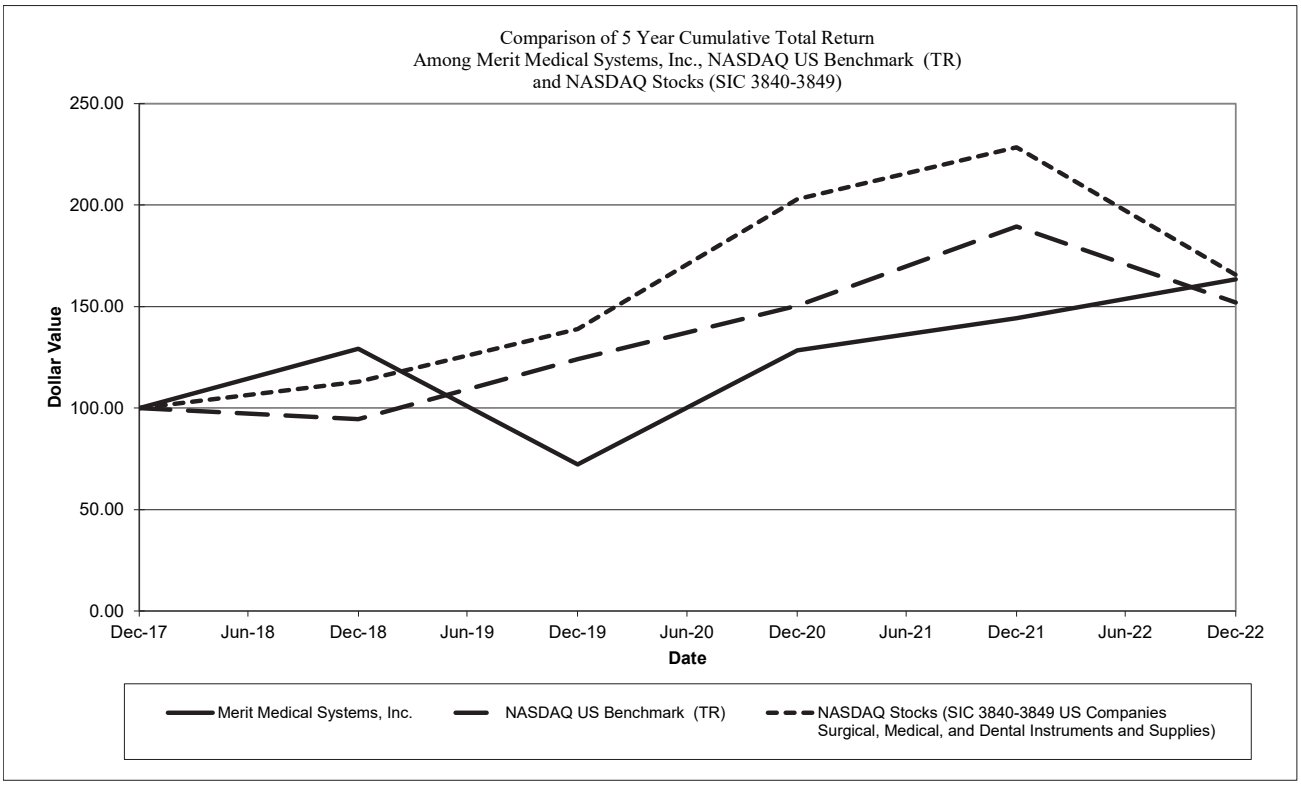
Item 5. **Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.**

Market Price for the Common Stock

Our common stock is traded on the NASDAQ Global Select Market under the symbol "MMSI." As of February 22, 2023, the number of shares of our common stock outstanding was 57,318,032 held by approximately 96 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, 2022, 2021 and 2020.

Performance

The following graph compares the performance of our common stock with the performance of the NASDAQ US Benchmark TR Index 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, 2017 to December 31, 2022.



	12/2017	12/2018	12/2019	12/2020	12/2021	12/2022
Merit Medical Systems, Inc.	$ 100.00	$ 129.19	$ 72.27	$ 128.50	$ 144.21	$ 163.45
NASDAQ US Benchmark (TR)	100.00	94.56	124.03	150.41	189.36	152.00
NASDAQ Stocks (SIC 3840-3849 U.S. Companies)	100.00	112.98	138.90	202.84	228.47	165.59

The stock performance graph assumes for comparison that the value of our common stock and of each index was $100 on December 31, 2017 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. Corporate Performance Graph with peer group uses peer group only performance (excludes only Merit). Peer group indices use beginning of period market capitalization weighting. Prepared by Zacks Investment Research, Inc. Used with permission. All rights reserved. Copyright 1980-2023. Used with permission. All rights reserved. Index Data: Copyright NASDAQ OMX, Inc. Used with permission. All rights reserved.

Item 6. **Reserved.**

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, 2022, we reported sales of $1.151 billion, up $76.2 million or 7.1%, compared to 2021 sales of $1.075 billion. Our revenue results for the year ended December 31, 2022 were driven primarily by stronger-than-anticipated demand in the U.S. and more favorable than anticipated international sales trends, particularly in the EMEA and "Rest of World" ("ROW") regions.

Gross profit as a percentage of sales was 45.1% for the year ended December 31, 2022 as compared to 45.2% for the year ended December 31, 2021.

Net income for the year ended December 31, 2022 was $74.5 million, or $1.29 per share, as compared to $48.5 million, or $0.84 per share, for the year ended December 31, 2021.

During 2022 we received "Breakthrough Device Designation" for Embosphere Microspheres for use in genicular artery embolization for symptomatic knee osteoarthritis. We also received FDA clearance for the SCOUT Bx Delivery System, the first wire-free breast localization solution that can be deployed at the time of stereotactic or MRI-guided biopsy representing a notable addition to the Merit Oncology portfolio.

We have launched eight new products during 2022 including the basixALPHA inflation device, PreludeSYNC EZ™ Radial Compression Device, TEMNO Elite™ Soft Tissue Biopsy System, Prelude Roadster™ Guide Sheath, SafeGuard Focus Cool™ Compression Device, SCOUT® Mini Reflector, ReSolve® Thoracostomy Tray and the commercial release of the smallest and shortest configuration in the Elation Pulmonary Balloon Dilator portfolio.

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 for the three-year period ending December 31, 2023. As part of this initiative, we continue to 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. Our dedication to the Foundations for Growth program has helped offset inflationary cost pressures in certain raw materials, shipping, and freight expenses.

Results of Operations

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

	2022	2021	2020
Net sales	100 %	100 %	100 %
Gross profit	45.1	45.2	41.6
Selling, general and administrative expenses	29.8	31.2	30.9
Research and development expenses	6.6	6.6	6.0
Legal settlement	—	0.9	1.9
Impairment charges	0.2	0.4	3.8
Contingent consideration expense (benefit)	0.4	0.3	(0.8)
Acquired in-process research and development expense	0.6	—	0.0
Income (loss) from operations	7.6	5.7	(0.2)
Income (loss) before income taxes	7.2	5.0	(1.4)
Net income (loss)	6.5	4.5	(1.0)

Sales

Listed below are the sales by product category within each operating segment for the years ended December 31, 2022, 2021 and 2020 (in thousands, other than percentage changes):

	% Change	2022	% Change	2021	% Change	2020
Cardiovascular						
Peripheral Intervention	8.6 %	$ 439,810	18.6 %	$ 405,116	(2.7)%	$ 341,568
Cardiac Intervention	7.0 %	343,186	14.6 %	320,641	(8.2)%	279,671
Custom Procedural Solutions	(1.9)%	190,194	(4.6)%	193,942	8.5 %	203,196
OEM	17.4 %	145,034	12.5 %	123,528	(6.9)%	109,767
Total	7.2 %	1,118,224	11.7 %	1,043,227	(2.8)%	934,202
Endoscopy						
Endoscopy Devices	3.9 %	32,757	6.2 %	31,524	(12.4)%	29,673
Total	7.1 %	$ 1,150,981	11.5 %	$ 1,074,751	(3.1)%	$ 963,875

Cardiovascular Sales. Our cardiovascular sales for the year ended December 31, 2022 were $1.118 billion, up 7.2%, when compared to the year ended December 31, 2021 of $1.043 billion. Sales for the year ended December 31, 2022 were favorably affected by increased sales of:

(a) Peripheral intervention products, which increased by $34.7 million, or 8.6%, from the corresponding period of 2021. This increase was driven primarily by sales of our access, embolotherapy, and radar localization products.

(b) Cardiac intervention products, which increased by $22.5 million, or 7.0%, from the corresponding period of 2021. This increase was driven primarily by sales of our intervention, cardiac rhythm management/electrophysiology ("CRM/EP"), and angiography products, partially offset by a decrease in sales of our fluid management products.

(c) OEM products, which increased by $21.5 million, or 17.4% from the corresponding period of 2021. This increase was driven primarily by sales of our access, angiography, fluid management, intervention, coating products and kits, partially offset by a decrease in sales of our CRM/EP products.

The foregoing increase in sales for the year ended December 31, 2022 was partially offset by decreased sales of:

(d) Custom procedural solutions products, which decreased by $(3.7) million, or (1.9)% from the corresponding period of 2021. This decrease was driven primarily by decreased sales of our critical care products, offset partially by increased sales of trays.

Our cardiovascular sales for the year ended December 31, 2021 were $1.043 billion, up 11.7%, when compared to the year ended December 31, 2020 of $934.2 million. Sales for the year ended December 31, 2021 were favorably affected by increased sales of:

(a) Peripheral intervention products, which increased by $63.5 million, or 18.6%, from the corresponding period of 2020. This increase was driven primarily by sales of our radar localization, embolotherapy, drainage, biopsy, angiography, access and intervention products.

(b) Cardiac intervention products, which increased by $41.0 million, or 14.6%, from the corresponding period of 2020. This increase was driven primarily by sales of our intervention, fluid management (including our Medallion Syringes, which saw increased demand due to COVID-19 vaccination efforts) and angiography products.

(c) OEM products, which increased by $13.8 million, or 12.5% from the corresponding period of 2020. This increase was driven primarily by sales of our CRM/EP, angiography products and kits.

The foregoing increase in sales for the year ended December 31, 2021 was partially offset by decreased sales of:

(d) Custom procedural solutions products, which decreased by $(9.3) million, or (4.6)% from the corresponding period of 2020. This decrease was driven primarily by decreased sales of our critical care products (including a $(15.9) million decrease in Cultura® nasopharyngeal swab and test kit sales) and trays, offset partially by sales of kits.

Endoscopy Sales. Our endoscopy sales for the year ended December 31, 2022 were $32.8 million, up 3.9%, when compared to sales for the year ended December 31, 2021 of $31.5 million. Sales for the year ended December 31, 2022 were favorably affected by increased sales of our Elation Balloon Dilator and other stents, partially offset by a decrease in sales of our EndoMAXX fully covered esophageal stent. Our endoscopy sales for the year ended December 31, 2021 were $31.5 million, up 6.2%, when compared to sales for the corresponding period in 2020 of $29.7 million. Sales for the year ended December 31, 2021 were favorably affected by increased sales of our Elation Balloon Dilator and our EndoMAXX fully covered esophageal stent.

Geographic Sales

Sales trends for the years ended December 31, 2022, 2021, and 2020 were influenced by the incidence and timing of COVID-19 infections and the associated governmental and patient responses, which varied between countries and regions in both the current and prior-year periods. Listed below are sales by geography for the years ended December 31, 2022, 2021, and 2020 (in thousands, other than percentage changes):

	% Change	2022	% Change	2021	% Change	2020
United States	6.8 %	650,559	10.7 %	608,878	(4.5)%	550,061
International	7.4 %	500,422	12.6 %	465,873	(1.3)%	413,814
Total	7.1 %	$ 1,150,981	11.5 %	$ 1,074,751	(3.1)%	$ 963,875

United States Sales: U.S. sales for the year ended December 31, 2022 were $650.6 million, or 56.5% of net sales, up 6.8% when compared to 2021. The increase in our domestic sales in 2022 was driven primarily by our U.S. direct, sensors and OEM businesses. U.S. sales for the year ended December 31, 2021 were $608.9 million, or 56.7% of net sales, up 10.7% when compared to 2020. The increase in our domestic sales in 2021 was driven primarily by our U.S. direct and OEM businesses.

International Sales. International sales for the year ended December 31, 2022 were $500.4 million, or 43.5% of net sales, up 7.4% when compared to 2021. The increase in our international sales during 2022 was primarily a result of higher sales

in APAC, which increased $13.3 million or 5.9%, higher sales in EMEA, which increased $11.4 million or 5.5%, and higher rest of world sales which increased $9.9 million or 30.8%, compared to the corresponding period of 2021. International sales for the year ended December 31, 2021 were $465.9 million, or 43.3% of net sales, up 12.6% when compared to 2020. The increase in our international sales during 2021 was primarily a result of higher sales in APAC, which increased 12.8% or $25.9 million, higher sales in EMEA, which increased 11.8% or $21.7 million, and higher rest of world sales which increased 16.2% or $4.5 million, compared to the corresponding period of 2020.

Our international sales 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, calculated by using the applicable average foreign exchange rates for the prior year decreased sales (2.2)% for the year ended December 31, 2022 compared to 2021 and increased sales 1.1% for the year ended December 31, 2021 compared to 2020.

Gross Profit

Our gross profit as a percentage of sales was 45.1%, 45.2%, and 41.6% for the years ended December 31, 2022, 2021 and 2020, respectively. The decrease in gross profit as a percentage of sales for 2022, as compared to 2021, was primarily due to less favorable manufacturing variances and higher freight costs as a percentage of sales, partially offset by more favorable changes in standard cost and product mix, decreased intangible amortization expense as a percentage of sales, and lower obsolescence expense, among other factors. The increase in gross profit as a percentage of sales for 2021, as compared to 2020, was primarily due to decreased amortization expense associated with acquisitions ($42.5 million in 2021 compared to $50.7 million in 2020), changes in product mix, improvements in manufacturing variances, and decreased obsolescence expense as a percentage of sales, partially offset by higher shipping and freight costs, among other factors.

Operating Expenses

Selling, General and Administrative Expenses. Our selling, general and administrative ("SG&A") expenses increased $6.8 million, or 2.0%, for the year ended December 31, 2022 compared to 2021 and increased $38.0 million, or 12.8%, for the year ended December 31, 2021 compared to 2020. SG&A expenses as a percentage of sales were 29.8%, 31.2% and 30.9% for the years ended December 31, 2022, 2021 and 2020, respectively.

The increase in SG&A expenses for the year ended December 31, 2022 compared to the year ended December 31, 2021 was primarily related to an increase in labor-related costs, including a $6.6 million increase for severance associated with restructuring and site closures, and higher travel related expenses as restrictions from the pandemic continued to decline; partially offset by a decrease of approximately $6 million for contract termination costs incurred in 2021 to renegotiate certain terms of our September 1, 2017 share purchase agreement with IntelliMedical Technologies Pty. Ltd. ("IntelliMedical"). In addition, for the year ended December 31, 2022, we recorded $1.0 million of expense in connection with the negotiated settlement of a shareholder derivative lawsuit filed in the United States District Court for the District of Utah against Merit, our Chief Executive Officer, our Chief Financial Officer and certain of our directors.

The increase in SG&A expenses for the year ended December 31, 2021 compared to the year ended December 31, 2020 was primarily related to labor-related costs, which increased due primarily to higher commissions and bonus expense in the current-year period, in contrast to temporary salary cuts and furloughs in 2020. During the year ended December 31, 2021, we incurred approximately $6 million of contract termination costs in SG&A to renegotiate certain terms of our September 1, 2017 share purchase agreement with IntelliMedical and $18.6 million of corporate transformation and restructuring costs, including consulting charges, in connection with our Foundations for Growth program.

Research and Development Expenses. Our research and development ("R&D") expenses as a percentage of sales were 6.6%, 6.6% and 6.0% for the years ended December 31 2022, 2021, and 2020, respectively. R&D expenses increased by $4.3 million or 6.0% to $75.5 million for the year ended December 31, 2022, compared to $71.2 million in 2021. The increase in R&D expenses for the year ended December 31, 2022 compared to the year ended December 31, 2021 was primarily related to labor-related costs consistent with an increase in headcount. We also incurred increased outside service and consulting costs due to higher costs from clinical trials and the implementation of the MDR in the European Union.

R&D expenses increased by $13.7 million or 23.8% to $71.2 million for the year ended December 31, 2021, compared to $57.5 million for the year ended December 31, 2020. The increase in R&D expenses for the year ended December 31, 2021 compared to the year ended December 31, 2020 was primarily related to labor-related costs, which increased due to higher bonus expense in the current-year period, in contrast to temporary salary cuts and furloughs in the prior year. We also incurred increased clinical expenses for certain R&D projects (including our Wrapsody AV Access Efficacy Study) and higher expenses related to implementation of the MDR in the European Union.

Legal Settlement. For the year ended December 31, 2021, we recorded approximately $10 million of net expense in connection with an agreement in principle to settle the securities class action lawsuit in December 2019 against Merit, our Chief Executive Officer and our Chief Financial Officer in the United States District Court for the Central District of California (the "Class Action Litigation"). This expense includes $18.25 million of settlement related costs, net of $8.2 million of insurance proceeds.

For the year ended December 31, 2020, we recorded $18.7 million of expense in connection with a settlement agreement with the United States Department of Justice ("DOJ") to resolve the DOJ's investigation of certain marketing and promotional practices.

Impairment Charges. For the year ended December 31, 2022, we recorded impairment charges of $2.2 million. These impairments included $1.7 million of intangible assets for our divestiture of STD Pharmaceutical Products Limited ("STD Pharmaceutical") business acquired in our August 2019 acquisition of Fibrovein Holdings and $0.5 million impairment of our equity investment in XableCath, Inc. as this business ceased operations.

For the year ended December 31, 2021 we recorded impairment charges of $4.3 million. These impairments included $1.6 million of intangible asset and $1.3 million of property and equipment due to the planned discontinuance of the Advocate™ Peripheral Angioplasty Balloon product line, sold under our license agreements with ArraVasc Limited ("ArraVasc") and $1.4 million of impairments of certain right-of-use ("ROU") operating lease assets due to site consolidation decisions and changes in our projected cash flows for the underlying lease assets.

For the year ended December 31, 2020 we recorded impairment charges of $36.5 million, which included $1.8 million related to certain ROU 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, 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, 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").

Contingent Consideration Expense (Benefit). For the years ended December 31, 2022, 2021 and 2020, we recorded $4.6 million, $3.2 million and $(8.0) million, respectively, of net contingent consideration expense (benefit) from changes in the estimated fair value of our contingent consideration obligations stemming from our previously disclosed business acquisitions. The expense (benefit) in each fiscal year relates to changes in the probability and timing of achieving certain revenue and operational milestones, as well as expense for the passage of time.

Acquired In-process Research and Development. During the year ended December 31, 2022, we incurred in-process research and development charges of $6.7 million primarily associated with our acquisition of Restore Endosystems, LLC ("Restore Endosystems"). We did not incur in-process research and development charges during the year ended December 31, 2021. We incurred $0.3 million for in-process research and development associated with various asset acquisitions during the year ended December 31, 2020.

Operating Income (Loss)

Our operating profit by operating segment for the years ended December 31, 2022, 2021 and 2020 was as follows (in thousands):

Operating Income (Loss)	2022	2021	2020
Cardiovascular	$ 80,946	$ 53,415	$ (7,042)
Endoscopy	6,617	7,501	5,480
Total operating income (loss)	$ 87,563	$ 60,916	$ (1,562)

Cardiovascular Operating Income (Loss). Our cardiovascular operating income for the year ended December 31, 2022 was $80.9 million, compared to cardiovascular operating income of $53.4 million for the year ended December 31, 2021. This increase in cardiovascular operating income was primarily related to higher sales, decreased legal settlement costs, including $10 million in 2021 in connection with an agreement in principle to settle a securities class action lawsuit, and decreased impairment charges within our cardiovascular operating segment ($2.2 million in 2022 compared to $4.3 million in 2021), partially offset by increased labor-related and travel costs, and increased contingent consideration expense ($4.6 million in 2022, compared to $3.2 million in 2021).

Our cardiovascular operating income for the year ended December 31, 2021 was $53.4 million, compared to cardiovascular operating loss of $(7.0) million for the year ended December 31, 2020. This increase in cardiovascular operating income was primarily related to higher sales and increased gross margin percentage, decreased legal settlement costs ($10 million in 2021, compared to $18.7 million in 2020) and decreased impairment charges within our cardiovascular operating segment ($4.3 million in 2021 compared to $36.5 million in 2020), partially offset by increased labor-related costs, approximately $6 million of contract termination costs to renegotiate certain terms of our share purchase agreement with IntelliMedical, increased corporate transformation costs, including consulting charges, in connection with our Foundations for Growth program and increased contingent consideration ($3.2 million of expense in 2021, compared to a benefit of $(8.0) million in 2020).

Endoscopy Operating Income. Our endoscopy operating income for the year ended December 31, 2022 was $6.6 million, compared to operating income of $7.5 million for the year ended December 31, 2021. This decrease in endoscopy operating income relative to 2021 was primarily due to decreased gross margin percentage as a result of changes in product mix and higher shipping costs and higher labor-related costs, partially offset by higher sales.

Our endoscopy operating income for the year ended December 31, 2021 was $7.5 million, compared to operating income of $5.5 million for the year ended December 31, 2020. This increase in endoscopy operating income relative to 2020 was primarily due to higher sales and increased gross margin percentage, partially offset by increased labor-related costs.

Other Income (Expense)

Our other expense for the years ended December 31, 2022, 2021 and 2020 was $4.9 million, $7.0 million, and $11.7 million, respectively. The decrease in other expense for 2022 compared to 2021 was principally the result of an increase in other income associated with realized and unrealized foreign currency gain (loss), partially offset by an increase in interest expense associated with rising interest rates and an increase in other expense related to the divestiture of the STD Pharmaceutical business.

The decrease in other expense for 2021 compared to 2020 was principally the result of decreased interest expense due to lower average debt balances and a lower average interest rate during 2021 partially offset by a gain of $0.5 million on the sale of the assets associated with our Hypotube™ product line in 2020.

Effective Tax Rate

Our provision for income taxes for the years ended December 31, 2022, 2021 and 2020 was a tax expense (benefit) of $8.1 million, $5.5 million and $(3.4) million, respectively, which resulted in an effective income tax rate of 9.8%, 10.1%, and 25.6%, respectively. The decrease in the effective income tax rate for 2022 compared to 2021 was primarily the result of

a benefit from the change in foreign withholding taxes on unremitted foreign earnings due to the restructuring of our foreign entities, more foreign tax credits being utilized, as well as additional benefit from the foreign-derived intangible income (FDII) deduction. The decrease in the effective income tax rate for 2021 compared to 2020 was primarily the result of a change in the jurisdictional mix of earnings, additional benefit from stock-based compensation awards, as well as more foreign tax credits being utilized.

Net Income (Loss)

Our net income (loss) for the years ended December 31, 2022, 2021 and 2020 was $74.5 million, $48.5 million, and $(9.8) million, respectively. The increase in net income for 2022, when compared to 2021, was primarily related to higher sales, decreased legal settlement costs primarily due to the $10.0 million settlement in 2021 in connection with an agreement in principle to settle a securities class action lawsuit, and decreased impairment charges ($2.2 million in 2022 compared to $4.3 million in 2021); partially offset by higher SG&A expenses due to higher labor-related and travel costs, as well as increased contingent consideration expense of $4.6 million in 2022 compared to $3.2 million in 2021.

The increase in net income for 2021, when compared to 2020, was primarily related to higher sales and increased gross margin percentage, as we observed an operating environment with fewer COVID-19 related restrictions throughout the year. Legal settlement costs decreased to $10 million in 2021, compared to $18.7 million in 2020, and impairment charges decreased to $4.3 million in 2021 compared to $36.5 million in 2020. This was partially offset by higher SG&A expenses due to higher labor-related costs, $6 million of contract termination costs to renegotiate certain terms of an acquisition agreement, increased corporate transformation costs, including consulting charges, in connection with our Foundations for Growth program, as well as contingent consideration expense of $3.2 million in 2021 compared to a benefit of $(8.0) million in 2020.

Liquidity and Capital Resources

Capital Commitments and Contractual Obligations

Our most significant contractual obligations as of December 31, 2022 included long-term debt of $198.2 million, of which $11.3 million is recorded in current liabilities, interest payments on this debt, operating lease liabilities of $70.7 million, of which $11.0 million is recorded in current liabilities, and contingent consideration liabilities of $18.1 million, of which $15.8 million is recorded in current liabilities. Additional information about these obligations is contained in Notes 8, 15 and 17 to our consolidated financial statements set forth in Item 8 of this report.

Cash Flows

At December 31, 2022 and 2021, we had cash, cash equivalents and restricted cash of $60.6 million and $67.8 million respectively, of which $49.6 million and $55.7 million, respectively, were held by foreign subsidiaries. We do not consider our foreign earnings to be permanently reinvested. As of December 31, 2022 and 2021, approximately $2.1 million and $1.9 million respectively, of our cash and cash equivalents represents restricted cash for the payment of certain import and other taxes for our subsidiary in China. 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, 2022 and 2021, we had cash and cash equivalents, including restricted cash, of $26.1 million and $28.5 million, respectively, held by our subsidiary in China.

Cash flows provided by operating activities. We generated cash from operating activities of $114.3 million, $147.2 million and $165.3 million during the years ended December 31, 2022, 2021 and 2020, respectively. Net cash provided by operating activities decreased $32.9 million for the year ended December 31, 2022 compared to the year ended December 31, 2021. Significant changes in operating assets and liabilities affecting cash flows during these years included:

- Net income was $74.5 million and $48.5 million for the years ended December 31, 2022 and 2021, respectively. This improvement in net income was partially offset by an increase in the non-cash adjustment for deferred income taxes within the statement of cash flows of $(14.9) million and $(4.6) million for the years ended December 31, 2022 and 2021, respectively.

- Cash (used for) accounts receivable was $(15.1) million and $(8.6) million for the years ended December 31, 2022 and 2021, respectively, due primarily to increases in sales volume,
- Cash provided by (used for) other receivables was $4.2 million and $(10.4) million for the years ended December 31, 2022 and 2021, respectively, due primarily to the collection of approximately $8.2 million of insurance proceeds in connection with the consolidated securities class action lawsuit we settled in April 2022,
- Cash (used for) inventories was $(47.9) million and $(25.2) million for the years ended December 31, 2022 and 2021, respectively, due primarily to efforts to normalize inventory levels as well as build bridge inventory for production line transfers and increases in safety stock due to vendor supply delays, and
- Cash provided by (used for) accrued expenses was $(16.4) million and $36.5 million for the years ended December 31, 2022 and 2021, respectively, primarily related to payment of a legal settlement accrual of $18.25 million in 2022 associated with the agreement in principle to settle the Class Action Litigation and increased labor-related cost accruals associated with higher commissions and bonus expense in the prior-year period, among other items.

Net cash provided by operating activities decreased $18.0 million for the year ended December 31, 2021 compared to the year ended December 31, 2020. Significant changes in operating assets and liabilities affecting cash flows during these years included:

- Net income (loss) was $48.5 million and $(9.8) million for the years ended December 31, 2021 and 2020, respectively. This improvement in net income was offset by a decrease in the non-cash adjustment for the write-off of certain intangible and other long-term assets within the statement of cash flows of $4.4 million and $36.6 million for the years ended December 31, 2021 and 2020, respectively.
- Cash provided by (used for) accounts receivable was $(8.6) million and $10.4 million for the years ended December 31, 2022 and 2021, respectively, due primarily to increases in sales volume,
- Cash provided by (used for) other receivables was $(10.4) million and $1.7 million for the years ended December 31, 2021 and 2020, respectively, due primarily to an increase in an insurance receivable associated with the agreement in principle to settle the Class Action Litigation,
- Cash provided by (used for) inventories was $(25.2) million and $29.4 million for the years ended December 31, 2021 and 2020, respectively, due primarily to efforts to manage inventory levels to support the growth in sales and reduced production in the prior-year period during the economic downturn related to the COVID-19 pandemic, and
- Cash provided by accrued expenses was $36.5 million and $4.6 million for the years ended December 31, 2021 and 2020, respectively, related to increased labor-related cost accruals associated with higher commissions and bonus expense in the current-year period and a legal settlement accrual of $18.25 million in 2021 associated with the agreement in principle to settle the Class Action Litigation, among other items.

Cash flows used in investing activities. We used cash in investing activities of $57.4 million, $37.2 million, and $58.7 million for the years ended December 31, 2022, 2021 and 2020, respectively. We invested in capital expenditures for property and equipment of $45.0 million, $27.9 million, and $46.0 million for the years ended December 31, 2022, 2021 and 2020, respectively. Capital expenditures in each period were primarily related to investment in property and equipment to support development and production of our 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 $55 to $60 million in 2023 for property and equipment.

Cash outflows invested in acquisitions for the year ended December 31, 2022 were $8.3 million and were primarily related to our $3.0 million upfront payment in our purchase of Restore Endosystems, our $2.5 million payment in our purchase of BioTrace Medical, Inc., and our additional equity investment in FluidX Medical Technology, Inc. ("Fluidx") of $1.4 million. Cash outflows invested in acquisitions for the year ended December 31, 2021 were $7.2 million and were primarily related to $4.1 for the settlement of deferred payments and the working capital adjustment associated with our acquisition of KA Medical, LLC ("KA Medical") completed in November 2020 and $2.7 million for an equity investment in FluidX. Cash outflows invested in acquisitions for the year ended December 31, 2020 were $11.0 million and were primarily related to our acquisition of KA Medical. For further discussion, refer to Note 3 to our consolidated financial statements set forth in Item 8 of this report.

Cash flows used in financing activities. Cash used in financing activities for the years ended December 31, 2022, 2021 and 2020 was $60.3 million, $98.4 million, and $95.7 million, respectively. In 2022 we decreased our net borrowings under our Third Amended Credit Agreement by $44.9 million and paid contingent consideration of $32.9 million, which is classified as a financing activity, principally related to our acquisitions of Cianna Medical Inc. ("Cianna Medical") and Vascular Insights LLC ("Vascular Insights"). In 2021 we decreased our net borrowings under our Third Amended Credit Agreement by $108.5 million and paid contingent consideration of $10.7 million, which is classified as a financing activity, principally related to our acquisition of Vascular Insights. In 2020 we decreased our net borrowings by $88.4 million and paid contingent consideration of $13.1 million, which is classified as a financing activity, principally related to our acquisition of Cianna Medical.

As of December 31, 2022, we had outstanding borrowings of $198.2 million and issued letter of credit guarantees of $3.2 million under the Third Amended Credit Agreement, with additional available borrowings of approximately $523 million, based on the leverage ratio required pursuant to the Third Amended Credit Agreement. Our interest rate as of December 31, 2022 was a fixed rate of 2.71% on $75 million as a result of an interest rate swap and a variable floating rate of 5.38% on $123.2 million. Our interest rate as of December 31, 2021 was a fixed rate of 2.71% on $75 million as a result of an interest rate swap and a variable floating rate of 1.10% on $168.1 million. The foregoing fixed rates are exclusive of 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 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:

Inventory Obsolescence. Our management reviews inventory quantities on hand and records provisions for estimated excess, slow moving and obsolete inventory. Based on this review, we provide adjustments for any slow-moving finished good products or raw materials that we believe will expire prior to being sold or used to produce a finished good and any

products that are unmarketable. This review of inventory quantities for unmarketable and/or slow moving products is based on forecasted product demand derived from our historical experience of product sales and production raw material usage. If market conditions become less favorable than those projected by our management, additional inventory write-downs may be required. During the years ended December 31, 2022, 2021 and 2020, we recorded obsolescence expense of approximately $9.8 million, $10.9 million, and $14.1 million, respectively, and wrote off approximately $10.2 million, $11.6 million, and $8.9 million, respectively. Based on this historical trend, we believe that our inventory balances as of December 31, 2022 have been accurately adjusted for any unmarketable and/or slow moving products that may expire prior to being sold.

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. 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 2022, which was completed during the third quarter of 2022, we determined that the fair value of each reporting unit with goodwill exceeded the carrying amount by a significant amount.

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 is largely independent of the cash flows of other assets and liabilities. We first compare undiscounted cash flows to the carrying amount of the asset group to determine if impairment exists, and then 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. This analysis requires similar significant judgments as those discussed above regarding goodwill. 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, 2022, 2021 and 2020, we identified indicators of impairment associated with certain acquired intangible assets within the asset groups based on our qualitative assessment. During the years ended December 31, 2022, 2021 and 2020 we recorded total impairment charges associated with intangible assets in our cardiovascular segment of $1.7 million, $1.6 million, and $28.7 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 planned closure and restructuring activities and uncertainty about future product development and commercialization associated with certain acquired technologies, due in part to the economic impacts of 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.

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 (loss). Significant increases or decreases in our estimates could result in changes to the estimated fair value of our contingent consideration liability, as well as the result of changes in the timing and amount of revenue estimates and 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 Medical, Inc. includes 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, 2022, 2021 and 2020, we recognized contingent consideration expense (benefit) of $4.6 million, $3.2 million and $(8.0) 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 changes in anticipated sales growth in the acquired products and the anticipated timing of milestone payments. See Note 15 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, 2022, a portion of our net sales ($394.1 million, representing 34.2% of our aggregate net sales), was attributable to sales that were denominated in foreign currencies. All other international sales were denominated in U.S. Dollars. Our principal market risk relates to changes in the value of the Chinese Yuan Renminbi (CNY) and Euro (EUR) relative to the 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, 2022 and 2021, we had entered into foreign currency forward contracts, which qualified as cash flow hedges, with aggregate notional amounts of $87.8 million and $123.0 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, 2022 and 2021, 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 $92.4 million and $86.0 million, respectively.

A sensitivity analysis of changes in the fair value of all currency exchange rate derivative contracts at December 31, 2022 and 2021 indicates that, if the U.S. Dollar strengthened or weakened by 10% against all currencies, it would have the following impact on the fair value of these contracts (in thousands):

	2022	2021
10% Strengthening	$ 4,660	$ 3,470
10% Weakening	$ (4,660)	$ (3,470)

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, 2022, we had outstanding borrowings of $198.2 million under the Third Amended Credit Agreement. Accordingly, our earnings and after-tax cash flow are affected by changes in interest rates. 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. This interest rate swap is intended to reduce our exposure to interest rate fluctuations and was not entered into for speculative purposes. Excluding the amount that is subject to a fixed rate under the interest rate swap and assuming the current level of borrowings remained the same, it is estimated that our interest expense and income before income taxes would change by approximately $1.2 million annually for each one percentage point change in the average interest rate under these borrowings.

Certain of the interest rates applicable to our Third Amended Credit Agreement and to hedging instruments we have purchased to offset interest rate risk under our Third Amended Credit Agreement, are LIBOR-based. We anticipate replacement rates will be identified, as provided for in our Third Amended Credit Agreement, as LIBOR-based rates become unavailable.

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, 2022 and 2021, 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, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, 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, 2022, 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 February 24, 2023, expressed an unqualified opinion on the Company's internal control over financial reporting.

Basis for Opinion

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

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

Critical Audit Matter

The critical audit matter communicated below is a matter 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.

Inventories - Provision for estimated excess, slow moving and obsolete inventories – Refer to Note 1 to the financial statements

Critical Audit Matter Description

Inventories are valued at the lower of cost, at approximate costs determined on a first-in, first-out method, or net realizable value. The Company reviews inventories on hand and records provisions based on estimated excess, slow moving and obsolete inventories. The inventories valuation reviews include an assessment of future product demand based on historical sales and raw material usage and product expiration. As of December 31, 2022, the Company's inventories were $266.0 million. During the year ended December 31, 2022, the Company recorded obsolescence expense of approximately $9.8 million.

We identified the provision for estimated excess, slow moving and obsolete inventories as a critical audit matter because of management's significant judgment and estimates in determining the provision for estimated excess, slow moving and obsolete inventories primarily around future product demand based on historical sales. This required a high degree of auditor judgment and an increased extent of effort.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to management's estimates of the valuation of excess and obsolete inventories included the following, among others:

- We tested the effectiveness of controls over the provision for estimated excess, slow moving and obsolete inventories.
- We evaluated management's ability to accurately estimate the provision for estimated excess, slow moving and obsolete inventories by comparing actual write-downs of inventories to management's historical estimates.
- We evaluated the reasonableness of the Company's provision for estimated excess, slow moving and obsolete inventories, considering future product demand based on historical sales and raw material usage and product expiration and the underlying assumptions.
- We tested the accuracy and completeness of the underlying data used in the Company's calculations of the valuation of excess and obsolete inventories, including historical usage, quantities on hand, expiration dates, and pricing.
- We assessed the reasonableness of the assumptions used in the calculations of the provision for estimated excess, slow moving and obsolete inventories by developing an independent expectation and comparing our independent expectation to the results of the Company's calculations.
- We tested the mathematical accuracy of the Company's calculations of excess, slow moving and obsolete inventories.

/s/ DELOITTE & TOUCHE LLP

Salt Lake City, Utah
February 24, 2023
We have served as the Company's auditor since 1988.

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

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 58,408	$ 67,750
Trade receivables — net of allowance for credit losses — 2022 — $8,423 and 2021 — $6,767	164,677	152,301
Other receivables	12,992	17,763
Inventories	265,991	221,922
Prepaid expenses and other current assets	22,324	16,149
Prepaid income taxes	3,913	3,550
Income tax refund receivables	779	2,777
Total current assets	529,084	482,212
Property and equipment:		
Land and land improvements	25,940	25,287
Buildings	189,148	190,044
Manufacturing equipment	299,089	277,976
Furniture and fixtures	61,128	61,446
Leasehold improvements	49,673	46,341
Construction-in-progress	61,269	51,182
Total property and equipment	686,247	652,276
Less accumulated depreciation	(303,271)	(280,618)
Property and equipment — net	382,976	371,658
Other assets:		
Intangible assets:		
Developed technology — net of accumulated amortization — 2022 — $274,570 and 2021 — $234,016	237,522	276,833
Other — net of accumulated amortization — 2022 — $69,780 and 2021 — $65,053	38,350	42,436
Goodwill	359,821	361,741
Deferred income tax assets	6,599	6,080
Right-of-use operating lease assets	65,262	65,913
Other assets	44,352	41,421
Total other assets	751,906	794,424
Total assets	$ 1,663,966	$ 1,648,294

See notes to consolidated financial statements.

(continued)

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

	December 31, 2022	December 31, 2021
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Trade payables	$ 68,504	$ 55,624
Accrued expenses	123,189	159,014
Current portion of long-term debt	11,250	8,438
Short-term operating lease liabilities	11,005	10,668
Income taxes payable	6,697	2,536
Total current liabilities	220,645	236,280
Long-term debt	186,759	234,397
Deferred income tax liabilities	18,462	31,503
Long-term income taxes payable	347	347
Liabilities related to unrecognized tax benefits	1,912	932
Deferred compensation payable	15,264	18,111
Deferred credits	1,708	1,815
Long-term operating lease liabilities	59,736	61,526
Other long-term obligations	14,736	23,584
Total liabilities	519,569	608,495
Commitments and contingencies		
Stockholders' equity:		
Preferred stock — 5,000 shares authorized as of December 31, 2022 and December 31, 2021; no shares issued	—	—
Common stock, no par value; 100,000 shares authorized; issued and outstanding as of December 31, 2022 - 57,306 and December 31, 2021 - 56,570	675,174	641,533
Retained earnings	480,773	406,257
Accumulated other comprehensive loss	(11,550)	(7,991)
Total stockholders' equity	1,144,397	1,039,799
Total liabilities and stockholders' equity	$ 1,663,966	$ 1,648,294

See notes to consolidated financial statements. (concluded)

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

	2022	2021	2020
Net sales	$ 1,150,981	$ 1,074,751	$ 963,875
Cost of sales	631,882	589,418	562,698
Gross profit	519,099	485,333	401,177
Operating expenses:			
Selling, general and administrative	342,525	335,690	297,724
Research and development	75,510	71,247	57,537
Legal settlement	—	10,036	18,684
Impairment charges	2,219	4,283	36,504
Contingent consideration expense (benefit)	4,611	3,161	(7,960)
Acquired in-process research and development	6,671	—	250
Total operating expenses	431,536	424,417	402,739
Income (loss) from operations	87,563	60,916	(1,562)
Other income (expense):			
Interest income	439	769	604
Interest expense	(6,339)	(5,261)	(9,994)
Other income (expense) — net	966	(2,507)	(2,279)
Total other expense — net	(4,934)	(6,999)	(11,669)
Income (loss) before income taxes	82,629	53,917	(13,231)
Income tax expense (benefit)	8,113	5,463	(3,388)
Net income (loss)	$ 74,516	$ 48,454	$ (9,843)
Earnings (loss) per common share			
Basic	$ 1.31	$ 0.86	$ (0.18)
Diluted	$ 1.29	$ 0.84	$ (0.18)
Weighted average shares outstanding			
Basic	56,806	56,145	55,434
Diluted	57,671	57,359	55,434

See notes to consolidated financial statements.

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

	2022	2021	2020
Net income (loss)	$ 74,516	$ 48,454	$ (9,843)
Other comprehensive income (loss):			
Cash flow hedges	9,007	5,965	(9,523)
Income tax benefit (expense)	(2,177)	(1,489)	2,365
Foreign currency translation adjustment	(10,491)	(7,704)	7,786
Income tax benefit (expense)	102	689	(786)
Total other comprehensive loss	(3,559)	(2,539)	(158)
Total comprehensive income (loss)	$ 70,957	$ 45,915	$ (10,001)

See notes to consolidated financial statements.

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

	Common Stock		Retained	Accumulated Other Comprehensive	
	Shares	Amount	Earnings	Income (Loss)	Total
BALANCE — January 1, 2020	55,213	$ 587,017	$ 368,221	$ (5,294)	$ 949,944
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	442	6,948			6,948
Issuance of common stock under Employee Stock Purchase Plans	30	1,159			1,159
Shares surrendered in exchange for payment of payroll tax liabilities	(23)	(866)			(866)
Shares surrendered in exchange for exercise of stock options	(39)	(1,467)			(1,467)
BALANCE — December 31, 2020	55,623	606,224	357,803	(5,452)	958,575
Net income			48,454		48,454
Other comprehensive loss				(2,539)	(2,539)
Stock-based compensation expense		14,579			14,579
Options exercised	883	20,374			20,374
Issuance of common stock under Employee Stock Purchase Plans	18	1,112			1,112
Shares issued from time-vested restricted stock units	59	—			—
Shares surrendered in exchange for payment of payroll tax liabilities	(10)	(576)			(576)
Shares surrendered in exchange for exercise of stock options	(3)	(180)			(180)
BALANCE — December 31, 2021	56,570	641,533	406,257	(7,991)	1,039,799
Net income			74,516		74,516
Other comprehensive loss				(3,559)	(3,559)
Stock-based compensation expense		16,045			16,045
Options exercised	703	20,092			20,092
Issuance of common stock under Employee Stock Purchase Plans	19	1,118			1,118
Shares issued from time-vested restricted stock units	70	—			—
Shares surrendered in exchange for payment of payroll tax liabilities	(38)	(2,474)			(2,474)
Shares surrendered in exchange for exercise of stock options	(18)	(1,140)			(1,140)
BALANCE — December 31, 2022	57,306	$ 675,174	$ 480,773	$ (11,550)	$ 1,144,397

See notes to consolidated financial statements.

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

	2022	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income (loss)	$ 74,516	$ 48,454	$ (9,843)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	81,804	84,066	94,070
Loss (gain) on disposition of business	1,417	—	(517)
Loss on sale or abandonment of property and equipment	380	1,303	2,159
Write-off of certain intangible assets and other long-term assets	2,281	4,412	36,609
Acquired in-process research and development	6,671	—	250
Amortization of right-of-use operating lease assets	10,394	11,718	12,746
Adjustments related to contingent consideration liabilities	4,611	3,161	(7,960)
Amortization of deferred credits	(107)	(108)	(130)
Amortization of long-term debt issuance costs	604	604	604
Deferred income taxes	(14,924)	(4,631)	(11,295)
Stock-based compensation expense	18,042	16,090	14,339
Changes in operating assets and liabilities, net of acquisitions and divestitures:			
Trade receivables	(15,116)	(8,618)	10,425
Other receivables	4,154	(10,418)	1,668
Inventories	(47,929)	(25,183)	29,429
Prepaid expenses and other current assets	(1,798)	(3,555)	(446)
Prepaid income taxes	(379)	125	(162)
Income tax refund receivables	1,952	739	(339)
Other assets	657	(1,670)	(3,511)
Trade payables	12,661	6,050	333
Accrued expenses	(16,379)	36,462	4,603
Income taxes payable	4,521	(119)	(86)
Liabilities related to unrecognized tax benefits	(45)	314	(576)
Deferred compensation payable	(2,848)	1,303	1,953
Operating lease liabilities	(11,127)	(12,410)	(12,659)
Other long-term obligations	278	(858)	3,606
Total adjustments	39,775	98,777	175,113
Net cash, cash equivalents, and restricted cash provided by operating activities	114,291	147,231	165,270
CASH FLOWS FROM INVESTING ACTIVITIES:			
Capital expenditures for:			
Property and equipment	(45,029)	(27,939)	(45,988)
Intangible assets	(3,175)	(2,834)	(3,288)
Proceeds from the sale of property and equipment	65	1,037	42
Proceeds (payments) from disposition of business	(971)	—	1,285
Cash received for settlement of note receivable	—	2,000	250
Issuance of note receivable	—	(2,254)	—
Cash paid in acquisitions, net of cash acquired	(8,287)	(7,171)	(10,953)
Net cash, cash equivalents, and restricted cash used in investing activities	$ (57,397)	$ (37,161)	$ (58,652)

See notes to consolidated financial statements.

(continued)

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

	2022	2021	2020
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock	$ 20,070	$ 21,306	$ 6,635
Proceeds from issuance of long-term debt	215,205	98,421	68,625
Payments on long-term debt	(260,143)	(206,921)	(157,000)
Contingent payments related to acquisitions	(32,918)	(10,665)	(13,100)
Payment of taxes related to an exchange of common stock	(2,474)	(576)	(866)
Net cash, cash equivalents, and restricted cash used in financing activities	(60,260)	(98,435)	(95,706)
Effect of exchange rates on cash, cash equivalents, and restricted cash	(3,826)	(801)	1,684
Net increase (decrease) in cash, cash equivalents and restricted cash	(7,192)	10,834	12,596
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:			
Beginning of period	67,750	56,916	44,320
End of period	$ 60,558	$ 67,750	$ 56,916
RECONCILIATION OF CASH, CASH EQUIVALENTS AND RESTRICTED CASH TO THE CONSOLIDATED BALANCE SHEETS:			
Cash and cash equivalents	58,408	67,750	56,916
Restricted cash reported in prepaid expenses and other current assets	2,150	—	—
Total cash, cash equivalents and restricted cash	$ 60,558	$ 67,750	$ 56,916
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION			
Cash paid during the period for:			
Interest (net of capitalized interest of $858, $480 and $813, respectively)	$ 6,258	$ 5,261	$ 10,077
Income taxes	17,092	8,828	8,918
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES			
Property and equipment purchases in accounts payable	$ 3,702	$ 2,558	$ 2,180
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	3,526	—	4,358
Merit common stock surrendered (18, 3, and 39 shares, respectively) in exchange for exercise of stock options	1,140	180	1,467
Right-of-use operating lease assets obtained in exchange for operating lease liabilities	11,130	1,524	10,938

See notes to consolidated financial statements. (concluded)

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

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization. Merit Medical Systems, Inc. ("Merit," "we," or "us") designs, develops, manufactures and markets single-use medical products for interventional and diagnostic procedures. For financial reporting purposes, we report our operations in two operating segments: cardiovascular and endoscopy. Our cardiovascular segment consists of cardiology and radiology medical device products which assist in diagnosing and treating coronary artery disease, peripheral vascular disease and other non-vascular diseases and includes embolotherapeutic, cardiac rhythm management, electrophysiology, 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, Japan, China, Malaysia, South Korea, UAE, India, New Zealand and South Africa (see Note 13). Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The following is a summary of the more significant of such policies.

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

Principles of Consolidation. The consolidated financial statements include our wholly owned subsidiaries. Intercompany balances and transactions have been eliminated. Amounts presented in this report are rounded, while percentages and earnings per share amounts presented are calculated from the underlying amounts.

Cash and Cash Equivalents. We consider interest-bearing deposits with an original maturity date of three months or less to be cash equivalents. As of December 31, 2021, approximately $1.9 million, respectively, of our cash and cash equivalents represents restricted cash for the payment of certain import and other taxes for our subsidiary in China.

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 and record provisions based on estimated excess, slow moving and obsolete inventory, as well as inventories with a carrying value in excess of net realizable value. The regular and systematic review of the valuation of inventories includes an assessment of future product demand based on historical sales and raw material usage 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 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 asset group 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 each asset group 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 undiscounted 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, 2022, 2021 and 2020 was $33.4 million, $34.5 million, and $35.4 million, respectively.

Deferred Compensation. We have a deferred compensation plan that permits certain management employees to defer a portion of their salary until the future. We established a Rabbi trust to finance obligations under the plan with corporate-owned variable life insurance contracts. The cash surrender value totaled $15.8 million and $19.1 million at December 31, 2022 and 2021, respectively, which is included in other assets in our consolidated balance sheets. We have recorded a deferred compensation payable of $15.3 million and $18.1 million at December 31, 2022 and 2021, respectively, to reflect the liability to our employees under this plan.

Other Assets. Other assets as of December 31, 2022 and 2021 consisted of the following (in thousands):

	2022	2021
Investments in privately held companies	$ 15,576	$ 14,711
Deferred compensation plan assets	15,767	19,126
Long-term notes receivable, net	2,397	2,345
Other	10,612	5,239
Total	$ 44,352	$ 41,421

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, 2022 and 2021 consisted of the following (in thousands):

	2022	2021
Contingent consideration liabilities	$ 2,260	$ 13,500
Other long-term obligations	12,476	10,084
Total	$ 14,736	$ 23,584

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. We generally satisfy performance obligations at a point in time upon either shipment or delivery of goods, in accordance with the terms of each contract with the customer. We do not have significant service revenue. 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, 2022, 2021 and 2020. 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. Such differences could have a material impact on our income tax provisions and operating results in the periods 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. Total stock-based compensation expense for the years ended December 31, 2022, 2021 and 2020 was $18.0 million, $16.1 million, and $14.3 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. In March 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("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. In December 2022, the FASB issued ASU 2022-06, *Deferral of the Sunset Date of Topic 848*, which defers the sunset date of the guidance in ASC 848 to December 31, 2024. ASU 2020-04 and ASU 2021-01 were effective as of March 12, 2020; ASU 2022-06 was effective upon its issuance in December 2022. The provisions of these updates may be applied prospectively to transactions through December 31, 2024, when reference rate reform activity is expected to be completed. As of December 31, 2022, we had not modified any contracts as a result of reference rate reform. 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 materially relevant to our financial statements.

2. REVENUES

Disaggregation of Revenue. Our revenue is disaggregated based on reporting segment, product category and geographical region.

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, 2022, 2021 and 2020 (in thousands).

	Year Ended December 31, 2022			Year Ended December 31, 2021			Year Ended December 31, 2020		
	United States	International	Total	United States	International	Total	United States	International	Total
Cardiovascular									
Peripheral Intervention	$ 263,602	$ 176,208	$ 439,810	$ 244,459	$ 160,657	$ 405,116	$ 211,999	$ 129,569	$ 341,568
Cardiac Intervention	128,711	214,475	343,186	122,452	198,189	320,641	108,109	171,562	279,671
Custom Procedural Solutions	108,778	81,416	190,194	108,068	85,874	193,942	110,269	92,927	203,196
OEM	118,869	26,165	145,034	104,436	19,092	123,528	91,826	17,941	109,767
Total	619,960	498,264	1,118,224	579,415	463,812	1,043,227	522,203	411,999	934,202
Endoscopy									
Endoscopy Devices	30,599	2,158	32,757	29,463	2,061	31,524	27,858	1,815	29,673
Total	$ 650,559	$ 500,422	$ 1,150,981	$ 608,878	$ 465,873	$ 1,074,751	$ 550,061	$ 413,814	$ 963,875

3. ACQUISITIONS AND OTHER STRATEGIC TRANSACTIONS

2022 Acquisitions

On October 3, 2022, we entered into an asset purchase agreement with BioTrace Medical, Inc., developer of the Tempo® Temporary Pacing Lead device, for a purchase price of $2.5 million. We are also required to pay a total of six annual royalty payments between 5% and 10% of net sales, dependent on net sales goal achievement, upon achievement of the first device sold in the United States. We accounted for this transaction as an asset purchase. We recorded the amount paid upon closing as a developed technology intangible asset, which we are amortizing over 10 years.

On April 30, 2022, we acquired the Restore Endosystems Bifurcated Stent System pursuant to the terms of a unit purchase agreement we executed with all of the members of Restore Endosystems. Subject to the terms and conditions of the unit purchase agreement, we paid $3 million in cash at closing. We also accrued $3.5 million of other long-term obligations, which represents the fair value of two separate $2 million payments which are payable no later than two and four years following the closing of the acquisition, respectively, or earlier upon the achievement of specified milestones. We will impute interest on these liabilities with the passage of time. We have accounted for this transaction as an asset purchase and recorded $6.5 million of acquired in-process research and development expense because the technological feasibility of the underlying research and development project has not yet been reached and such technology has no identified future alternative use as of the date of acquisition.

During April 2022, we paid $1.4 million to acquire shares of series A preferred stock of Fluidx Medical Technology, Inc.("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. We had previously purchased, and continue to hold, $4.7 million of participating preferred shares of Fluidx. Our investments have been recorded as equity investments 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 Fluidx. Our total current investment in Fluidx represents an ownership of approximately 17% of its outstanding capital stock.

2021 Acquisitions

During September 2021, we paid $2.7 million to acquire series A preferred shares of Fluidx. We had previously purchased $2 million of participating preferred shares during 2019. 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 Fluidx. Our total current investment in Fluidx represents an ownership of 15.0% of the outstanding stock.

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 $14.6 million in cash, net of cash acquired, including adjustments for working capital and deferred payments of $4 million. 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 for the years ended December 31, 2022, 2021 and 2020. Acquisition-related costs associated with the KA Medical acquisition, which were included in selling, general and

administrative expenses, were not material. During the fourth quarter of 2021, certain immaterial measurement period adjustments were recorded to our purchase price allocation. The purchase price was allocated as follows (in thousands):

Assets Acquired	
Trade receivables	$ 24
Other receivables	13
Inventories	211
Property and equipment	298
Other long-term assets	10
Intangible assets	
Developed technology	6,000
Goodwill	8,570
Total assets acquired	15,126
Liabilities Assumed	
Trade payables	(31)
Accrued expenses	(507)
Total liabilities assumed	(538)
Total net assets acquired	**$ 14,588**

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. We do not deem the pro forma effects to our consolidated results of operations of the KA Medical acquisition to be material.

4. INVENTORIES

Inventories at December 31, 2022 and 2021, consisted of the following (in thousands):

	2022	2021
Finished goods	$ 147,051	$ 132,403
Work-in-process	29,534	22,160
Raw materials	89,406	67,359
Total inventories	$ 265,991	$ 221,922

5. GOODWILL AND INTANGIBLE ASSETS

The changes in the carrying amount of goodwill for the years ended December 31, 2022 and 2021, are as follows (in thousands):

	2022	2021
Goodwill balance at January 1	$ 361,741	$ 363,533
Effect of foreign exchange	(1,920)	(2,078)
Additions and adjustments as the result of acquisitions	—	286
Goodwill balance at December 31	$ 359,821	$ 361,741

Total accumulated goodwill impairment losses aggregated to $8.3 million as of December 31, 2022 and 2021. We did not have any goodwill impairments for the years ended December 31, 2022, 2021 and 2020. The total goodwill balance as of December 31, 2022 and 2021 is related to our cardiovascular segment.

Other intangible assets at December 31, 2022 and 2021, consisted of the following (in thousands):

	December 31, 2022		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patents	$ 29,445	$ (10,203)	$ 19,242
Distribution agreements	3,250	(2,715)	535
License agreements	11,109	(7,250)	3,859
Trademarks	30,221	(17,863)	12,358
Customer lists	34,105	(31,749)	2,356
Total	$ 108,130	$ (69,780)	$ 38,350

	December 31, 2021		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patents	$ 26,349	$ (8,315)	$ 18,034
Distribution agreements	3,250	(2,519)	731
License agreements	12,663	(7,768)	4,895
Trademarks	30,242	(15,256)	14,986
Customer lists	34,985	(31,195)	3,790
Total	$ 107,489	$ (65,053)	$ 42,436

Aggregate amortization expense for the years ended December 31, 2022, 2021 and 2020 was $48.4 million, $49.6 million, and $58.6 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, 2022 (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2023	$ 47,496
2024	44,434
2025	42,610
2026	32,040
2027	28,966

During the years ended December 31, 2022, 2021 and 2020, we identified indicators of impairment associated with certain acquired intangible assets based on our qualitative assessment that carrying amounts may not be recoverable, which required us to then complete a quantitative impairment assessment. The primary indicators of impairment were planned closure and restructuring activities and uncertainty about future product development and commercialization associated with certain acquired technologies, due in part to the economic impacts of the COVID-19 pandemic in 2021 and 2020.

During the year ended December 31, 2022, we recorded total impairment charges related to our intangible assets of $1.7 million for our divestiture on April 30, 2022 of the STD Pharmaceutical Products Limited ("STD Pharmaceutical") business acquired in our August 2019 acquisition of Fibrovein Holdings Limited.

During the year ended December 31, 2021, we recorded total impairment charges related to our intangible assets of $1.6 million for the remaining carrying value of ArraVasc license agreements.

During the year ended December 31, 2020, we recorded total impairment charges related to our intangible assets of $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").

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 and made a payment equal to one half of the deferred amount during the year ended December 31, 2021. The remaining half was paid during the year ended December 31, 2022.

On August 16, 2022, the Inflation Reduction Act of 2022 was signed into law. We currently do not anticipate the recently enacted law, including the corporate alternative minimum tax, one percent excise tax on stock repurchases, or tax incentives to promote clean energy, to have a material impact on our consolidated financial statements.

For the years ended December 31, 2022, 2021 and 2020, income (loss) before income taxes is broken out between U.S. and foreign-sourced operations and consisted of the following (in thousands):

	2022	2021	2020
Domestic	$ 77,562	$ 21,328	$ (32,216)
Foreign	5,067	32,589	18,985
Total	$ 82,629	$ 53,917	$ (13,231)

The components of the provision for income taxes for the years ended December 31, 2022, 2021 and 2020, consisted of the following (in thousands):

	2022	2021	2020
Current expense (benefit):			
Federal	$ 9,584	$ 808	$ (937)
State	3,162	806	437
Foreign	10,291	8,480	8,407
Total current expense	23,037	10,094	7,907
Deferred expense (benefit):			
Federal	(10,438)	(468)	(2,688)
State	(3,615)	(1,845)	(4,524)
Foreign	(871)	(2,318)	(4,083)
Total deferred benefit	(14,924)	(4,631)	(11,295)
Total income tax expense (benefit)	$ 8,113	$ 5,463	$ (3,388)

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, 2022, 2021 and 2020, consisted of the following (in thousands):

	2022	2021	2020
Computed federal income tax expense (benefit) at applicable statutory rate of 21%	$ 17,352	$ 11,323	$ (2,778)
State income tax benefit	35	(283)	(1,448)
Tax credits	(1,978)	(2,507)	(2,391)
Tax effect of international items	(10,698)	(281)	4,705
Uncertain tax positions	(47)	401	(455)
Deferred compensation insurance assets	706	(413)	(290)
Stock-based compensation	(3,423)	(5,571)	(1,822)
Valuation allowance	3,523	—	1,257
DOJ settlement	—	—	1,890
Remeasurement of state deferred taxes	(375)	(526)	(1,765)
Non-deductible expenses	2,027	2,455	1,077
Remeasurement of contingent consideration liabilities	1,061	733	(1,185)
Other — including the effect of graduated rates	(70)	132	(183)
Total income tax expense (benefit)	$ 8,113	$ 5,463	$ (3,388)

Deferred income tax assets and liabilities at December 31, 2022 and 2021, consisted of the following temporary differences and carry-forward items (in thousands):

	2022	2021
Deferred income tax assets:		
Allowance for credit losses on trade receivables	$ 1,925	$ 1,494
Accrued compensation expense	9,968	11,063
Inventory differences	5,712	4,887
Net operating loss carryforwards	11,117	14,833
Stock-based compensation expense	7,167	6,388
Operating lease assets	12,801	13,431
Federal R&D tax credit	634	5,003
UT R&D Credit	4,679	4,126
IRC section 174 capitalized R&D	15,012	—
Other	8,827	9,939
Total deferred income tax assets	77,842	71,164
Deferred income tax liabilities:		
Prepaid expenses	(1,568)	(1,047)
Property and equipment	(20,925)	(20,797)
Intangible assets	(38,547)	(42,888)
Foreign withholding tax	(1,571)	(5,575)
Operating lease liabilities	(11,527)	(11,938)
Other	(2,040)	(3,556)
Total deferred income tax liabilities	(76,178)	(85,801)
Valuation allowance	(13,527)	(10,786)
Net deferred income tax liabilities	$ (11,863)	$ (25,423)
Reported as:		
Deferred income tax assets	$ 6,599	$ 6,080
Deferred income tax liabilities	(18,462)	(31,503)
Net deferred income tax liabilities	$ (11,863)	$ (25,423)

Deferred tax assets and liabilities are netted on the balance sheet by separate tax 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 $2.7 million during the year ended December 31, 2022, increased by $573,000 during the year ended December 31, 2021, and increased by $5.6 million during the year ended December 31, 2020.

As of December 31, 2022, we had U.S federal net operating loss carryforwards of $29.7 million, which were generated by Cianna Medical, Vascular Access Technologies, Inc., DFINE Inc., and Biosphere Medical, Inc., 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 $29.6 million of the NOLs will expire between 2025 and 2037. Of the NOLs incurred post-2017, $97,000 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 13 years. We utilized a total of $15.9 million in U.S. federal net operating loss carryforwards during the year ended December 31, 2022.

As of December 31, 2022, we had $22.2 million of non-U.S. net operating loss carryforwards, of which $21.1 million have no expiration date and $1.1 million expire at various dates through 2034. Non-U.S. net operating loss carryforwards utilized during the year ended December 31, 2022 were not material.

We do not consider our foreign earnings to be permanently reinvested. Consequently, we have recorded tax expense of $320,000, $288,000 and $228,000 for foreign withholding taxes on unremitted foreign earnings during the years ended December 31, 2022, 2021 and 2020, respectively. Additionally, for the year ended December 31, 2022, a tax benefit of $4.3 million was recorded with respect to the restructuring of our foreign entities and the associated change in foreign withholding taxes on the unremitted foreign earnings.

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 2019. In foreign jurisdictions, we are no longer subject to income tax examinations for years before 2016.

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, 2022, including interest and penalties, was $1.9 million, of which $1.9 million would favorably impact our effective tax rate if recognized. At December 31, 2022, none of the total liability 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, 2021, including interest and penalties, was $2.0 million, of which $2.0 million would favorably impact our effective tax rate if recognized. At December 31, 2021, $1.0 million of the total liability was presented as a reduction to non-current deferred income tax assets on our consolidated balance sheet. As of December 31, 2022 and 2021, we had accrued $336,000 and $322,000 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, 2022, 2021 and 2020, our liability for unrecognized tax benefit was increased (decreased) for interest and penalties by $14,000, $46,000, and $(90,000), respectively. We estimate it is reasonably possible that within the next 12 months the total liability for unrecognized tax benefits may decrease, including expirations related to statutes of limitation, up to $109,000.

A reconciliation of the beginning and ending amount of liabilities associated with uncertain tax benefits for the years ended December 31, 2022, 2021 and 2020, consisted of the following (in thousands):

	2022	2021	2020
Unrecognized tax benefits, opening balance	$ 1,635	$ 1,674	$ 2,161
Gross increases (decreases) in tax positions taken in a prior year	(10)	82	115
Gross increases in tax positions taken in the current year	294	316	283
Lapse of applicable statute of limitations	(343)	(437)	(885)
Unrecognized tax benefits, ending balance	$ 1,576	$ 1,635	$ 1,674

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, 2022 and 2021, consisted of the following (in thousands):

	2022	2021
Payroll and related liabilities	$ 58,620	$ 59,435
Current portion of contingent liabilities	15,813	34,735
Advances from employees	165	201
Accrued rebates payable	10,925	11,271
Accrued legal settlement	1,000	18,250
Other accrued expenses	36,666	35,122
Total	$ 123,189	$ 159,014

8. REVOLVING CREDIT FACILITY AND LONG-TERM DEBT

Principal balances outstanding under our long-term debt obligations as of December 31, 2022 and 2021, consisted of the following (in thousands):

	2022	2021
Term loans	$ 124,688	$ 133,125
Revolving credit loans	73,500	110,000
Less unamortized debt issuance costs	(179)	(290)
Total long-term debt	198,009	242,835
Less current portion	11,250	8,438
Long-term portion	$ 186,759	$ 234,397

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, 2022, we believe we were in compliance with all covenants set forth in the Third Amended Credit Agreement.

As of December 31, 2022, we had outstanding borrowings of $198.2 million and issued letter of credit guarantees of $3.2 million under the Third Amended Credit Agreement, with additional available borrowings of approximately $523 million, based on the leverage ratio required pursuant to the Third Amended Credit Agreement. Our interest rate as of December 31, 2022 was a fixed rate of 2.71% on $75 million as a result of an interest rate swap (see Note 9) and a variable floating rate of 5.38% on $123.2 million. Our interest rate as of December 31, 2021 was a fixed rate of 2.71% on $75 million as a result of an interest rate swap and a variable floating rate of 1.10% on $168.1 million. The foregoing fixed rates are exclusive of potential future changes in the applicable margin.

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. We anticipate replacement rates will be identified, as provided for in our Third Amended Credit Agreement, as LIBOR-based rates become unavailable.

Future Payments

Future minimum principal payments on our long-term debt as of December 31, 2022, are as follows (in thousands):

Years Ending December 31,	Future Minimum Principal Payments
2023	$ 11,250
2024	186,938
Total future minimum principal payments	$ 198,188

9. DERIVATIVES

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

We formally document, designate and assess the effectiveness of transactions that receive hedge accounting initially and on an ongoing basis. For qualifying hedges, the change in fair value is deferred in accumulated other comprehensive income (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 was tied to the one-month LIBOR rate (the benchmark interest rate). The interest rate swap expired 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 reset, the swap is settled with the counterparty, and interest is paid.

At December 31, 2022 and 2021, our interest rate swaps qualified as cash flow hedges. The fair value of our interest rate swap at December 31, 2022 was an asset of $3.4 million, partially offset by $0.8 million in deferred taxes. The fair value of our interest rate swaps at December 31, 2021 was a liability of $1.4 million, partially offset by $0.4 million in deferred taxes.

Foreign Currency Risk. We operate on a global basis and are exposed to the risk that our financial condition, results of operations, and cash flows could be adversely affected by changes in foreign currency exchange rates. To reduce the potential effects of foreign currency exchange rate movements on net earnings, we enter into derivative financial instruments in the form of foreign currency exchange forward contracts with major financial institutions. Our policy is to enter into foreign currency derivative contracts with maturities of up to two years. We are exposed to foreign currency exchange rate risk with respect to transactions and balances denominated in various currencies, with our most significant exposure related to transactions and balances denominated in Chinese Renminbi and Euros, 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 foreign currencies.

We enter into approximately 100 cash flow foreign currency hedges every month. As of December 31, 2022 and 2021, we had entered into foreign currency forward contracts, which qualified as cash flow hedges, with aggregate notional amounts of $87.8 million and $123.0 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 50 foreign currency fair value hedges every month. As of December 31, 2022 and 2021, we had entered into foreign currency forward contracts related to those balance sheet accounts with aggregate notional amounts of $92.4 million and $86.0 million, respectively.

Balance Sheet Presentation of Derivatives. As of December 31, 2022 and 2021, 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, 2022**	**December 31, 2021**
Assets			
Interest rate swaps	Other assets (long-term)	$ 3,444	$ —
Foreign currency forward contracts	Prepaid expenses and other assets	3,215	1,326
Foreign currency forward contracts	Other assets (long-term)	56	179
(Liabilities)			
Interest rate swaps	Other long-term obligations	—	(1,447)
Foreign currency forward contracts	Accrued expenses	(1,509)	(2,288)
Foreign currency forward contracts	Other long-term obligations	(531)	(502)

Fair Value of Derivative Instruments Not Designated as Hedging Instruments	**Balance Sheet Location**	**December 31, 2022**	**December 31, 2021**
Assets			
Foreign currency forward contracts	Prepaid expenses and other assets	$ 1,512	$ 736
(Liabilities)			
Foreign currency forward contracts	Accrued expenses	(1,946)	(856)

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	2022	2021	2020
Interest rate swaps	$ 4,879	$ 1,402	$ (6,131)
Foreign currency forward contracts	6,263	(1,521)	(5,516)

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			Amount of Gain/(Loss) reclassified from AOCI		
	Year Ended December 31,			Year ended December 31,		
Location in statements of income	2022	2021	2020	2022	2021	2020
Interest expense	$ (6,339)	$ (5,261)	$ (9,994)	$ (12)	$ (1,509)	$ (872)
Revenue	1,150,981	1,074,751	963,875	3,583	(5,592)	36
Cost of sales	(631,882)	(589,418)	(562,698)	(1,436)	1,017	(1,288)

As of December 31, 2022, $2.7 million or $2.1 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, 2022, $2.3 million, or $1.8 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	2022	2021	2020
Foreign currency forward contracts	Other income (expense) — net	$ 1,420	$ (1,598)	$ (2,190)

See Note 15 for additional 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 17 for disclosures regarding these operating leases.

Royalties. As of December 31, 2022, 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, 2022, 2021 and 2020, total royalty expense approximated $7.3 million, $7.6 million and $7.1 million, respectively, and is recorded in cost of sales on the consolidated statement of income (loss). Minimum contractual commitments under royalty agreements to be paid within twelve months of December 31, 2022 were not significant. See Note 15 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 proceedings, actions and claims may involve product liability, intellectual property, contract disputes, employment, governmental

inquiries or other matters, including those more fully described below. The outcomes of these matters will generally not be known for prolonged periods of time. In certain proceedings, the claimants may seek damages as well as other compensatory and equitable relief that could result in the payment of significant claims and settlements and/or the imposition of injunctions or other equitable relief. For legal matters for which our management had sufficient information to reasonably estimate our future obligations, a liability representing management's best estimate of the probable loss, or the minimum of the range of probable losses when a best estimate within the range is not known, is recorded. The estimates are based on consultation with legal counsel, previous settlement experience and settlement strategies. If actual outcomes are less favorable than those estimated by management, additional expense may be incurred, which could unfavorably affect our financial position, results of operations and cash flows. The ultimate cost to us with respect to actions and claims could be materially different than the amount of the current estimates and accruals and could have a material adverse effect on our financial position, results of operations and cash flows.

Shareholder Derivative Action

On June 3, 2021, Steffen Maute filed a complaint, derivatively on behalf of Merit, against Merit (as a nominal defendant), our Chief Executive Officer, our Chief Financial Officer, our former President of EMEA and certain of our directors in the United States District Court for the District of Utah (Case No. 2:21-cv-00346-DBP). The derivative complaint alleged that the individual defendants violated their fiduciary duties owed to Merit and were unjustly enriched at the expense of and to the detriment of Merit between February 2019 and October 2019, and sought unspecified damages, costs, and professional fees. Following mediation, the parties negotiated an agreement to settle the dispute, which, among other provisions, provides for the release of all claims against Merit and the other defendants in exchange for Merit's undertaking to implement certain corporate governance revisions and pay attorneys fees and expenses in the amount of $1.0 million. On February 16, 2023, the court held a hearing and announced approval of the settlement, which has the effect of resolving all claims arising from the litigation. The expense associated with the settlement has been reflected in our financial results reported for the year ended December 31, 2022.

SEC Inquiry

We have received requests from the Division of Enforcement of the U.S. Securities and Exchange Commission ("SEC") seeking the voluntary production of information relating to the business activities of Merit's subsidiary in China, including interactions with hospitals and health care officials in China. We are cooperating with the requests and investigating the matter and, at this time, are unable to predict the scope, timing, significance or outcome of this matter.

It is possible that the ultimate resolution of the foregoing matter, or 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):

	2022	2021	2020
Net income (loss)	$ 74,516	$ 48,454	$ (9,843)
Average common shares outstanding	56,806	56,145	55,434
Basic EPS	$ 1.31	$ 0.86	$ (0.18)
Average common shares outstanding	56,806	56,145	55,434
Effect of dilutive stock awards	865	1,214	—
Total potential shares outstanding	57,671	57,359	55,434
Diluted EPS	$ 1.29	$ 0.84	$ (0.18)
Equity awards excluded as the impact was anti-dilutive [(1)]	1,438	799	4,216

(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 typically vest on an annual basis over a three to five-year life with a contractual life of seven years. As of December 31, 2022, a total of 2,817,861 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, 2022, the 2006 Incentive Plan was no longer being used for new equity award grants. However, as of December 31, 2022, 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, 2022, the total number of shares of common stock that remained available to be issued under our non-qualified plan was 102,739 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, 2022, 2021 and 2020, consisted of the following (in thousands):

	2022	2021	2020
Cost of sales			
Nonqualified stock options	$ 1,606	$ 1,476	$ 1,357
Research and development			
Nonqualified stock options	1,789	1,343	1,157
Selling, general and administrative			
Nonqualified stock options	7,305	6,678	7,332
Performance-based restricted stock units	3,509	3,525	2,829
Restricted stock units	1,836	1,557	758
Cash-settled performance-based share-based awards ("Liability Awards")	1,997	1,511	906
Total selling, general and administrative	14,647	13,271	11,825
Stock-based compensation expense before taxes	$ 18,042	$ 16,090	$ 14,339

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.

Nonqualified Stock Options

As of December 31, 2022, the total remaining unrecognized compensation cost related to non-vested stock options, net of expected forfeitures, was $20.4 million and is expected to be recognized over a weighted average period of 2.1 years.

In applying the Black-Scholes methodology to the option grants, the fair value of our stock-based awards granted was estimated using the following assumptions for the years ended December 31, 2022, 2021 and 2020:

	2022	2021	2020
Risk-free interest rate	1.4% - 4.3%	0.5% - 1.1%	0.3% - 1.7%
Expected option term	4.0 years	4.0 years	4.0 - 5.0 years
Expected dividend yield	—	—	—
Expected price volatility	46.2% - 47.5%	46.1% - 46.7%	38.7% - 45.1%

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 the historical volatility for our stock. We recognize compensation expense for options on a straight-line basis over the service period, which corresponds to the vesting period. During the years ended December 31, 2022, 2021 and 2020, approximately 251,000, 716,000 and 329,000 nonqualified stock option grants were made, respectively, for a total fair value of $6.3 million, $17.5 million and $4.5 million.

The table below presents information related to stock option activity for the years ended December 31, 2022, 2021 and 2020 (in thousands):

	2022	2021	2020
Total intrinsic value of stock options exercised	$ 27,110	$ 36,086	$ 11,733
Cash received from stock option exercises	18,952	20,194	5,481
Excess tax benefit from the exercise of stock options	3,423	5,571	1,815

Changes in stock options for the year ended December 31, 2022, consisted of the following (shares and intrinsic value in thousands):

	Number of Shares	Weighted Average Exercise Price	Remaining Contractual Term (in years)	Intrinsic Value
Beginning balance	3,640	$ 44.70		
Granted	251	63.69		
Exercised	(703)	28.58		
Forfeited/expired	(111)	53.16		
Outstanding at December 31	3,077	49.62	3.51	$ 64,634
Exercisable	1,792	43.50	2.61	48,595
Ending vested and expected to vest	3,013	49.37	3.47	64,026

The weighted average grant-date fair value of options granted during the years ended December 31, 2022, 2021 and 2020 was $24.98, $24.38 and $13.70, respectively.

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

Since 2020, we have granted 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. In 2020, our Board of Directors amended PSUs granted in 2020 with a one-year performance period to adjust the performance targets and reduce 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 accounted for this amendment in accordance with ASC 718 as a "Type I" modification.

The payout for each PSU is equal to one share of common stock multiplied by a FCF multiplier (between 50% and 100% in the case of the 2020 one-year awards, as amended, or 50% and 200% in the case of all other PSU 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, 2022, consisted of the following:

	PSUs		RSUs	
	Stock Units (In Thousands) [1]	Weighted Average Grant Date Fair Value	Stock Units (In Thousands)	Weighted Average Grant Date Fair Value
Beginning nonvested balance	163	$ 53.71	26	$ 61.77
Granted	97	64.54	31	59.02
rTSR adjustment	8 [2]	65.03	—	—
Vested	(44)	65.03	(26)	61.77
Forfeited	(45)	60.81	—	—
Nonvested balance at December 31	179	65.20	31	59.02

(1) Based on the maximum payout, excluding the impact of the rTSR multiplier. The actual number of shares which vest is determined based on the satisfaction of performance conditions and the application of an rTSR multiplier between 75% and 125%.

(2) Represents the application of an rTSR multiplier of 125% to awards vested in 2022 based on the performance of our common stock and the terms of the awards.

The following table summarizes PSUs and RSUs granted during the years ended December 31, 2022, 2021, and 2020 (units and shares in thousands):

	2022	2021	2020
PSUs			
Target units granted	48	52	61
Maximum units granted [1]	97	103	102 [3]
Maximum potential shares [1][2]	121	129	127 [3]
Weighted average grant date fair value	$ 64.54	$ 61.39	$ 43.63
RSUs			
Units granted	31	26	34
Weighted average grant date fair value	$ 59.02	$ 61.77	$ 42.98

(1) Based on the maximum payout, excluding the impact of the rTSR multiplier.

(2) Includes the impact of the maximum potential rTSR multiplier of 125%.

(3) Includes the impact of the 2020 amendment which reduced the maximum FCF multiplier for one-year awards from 200% to 100%.

During the years ended December 31, 2022 and 2021, there were approximately 44,000 and 26,000 shares, respectively, that vested under PSUs, prior to the reduction of shares withheld to satisfy tax withholding obligations. Vested shares were calculated based upon achievement of the maximum performance multiplier, as amended, of 200% and 100% for 2022 and 2021, respectively, and an rTSR multiplier of 125%. There were no shares that vested under PSUs during the year ended December 31, 2020. During the years ended December 31, 2022 and 2021, there were approximately 26,000 and 34,000 shares, respectively, that vested under RSUs. There were no shares that vested under RSUs during the year ended December 31, 2020.

The fair value of each PSU was estimated as of the grant date using the following assumptions for awards granted in the years ended December 31, 2022 and 2021:

	2022	2021
Risk-free interest rate	1.6% - 2.7%	0.1% - 0.3%
Performance period	2.6 - 2.8 years	1.8 - 2.8 years
Expected dividend yield	—	—
Expected price volatility	38.5% - 42.6%	43.7% - 49.3%

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, 2022, the total remaining unrecognized compensation cost related to stock-settled performance stock units and restricted stock units, net of expected forfeitures, was $4.7 million and $0.7 million, respectively, which is expected to be recognized over a weighted average period of 1.6 years and 0.4 years, respectively.

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

During the years ended December 31, 2022, 2021 and 2020, we granted liability awards to certain executive officers. These awards entitle them to cash payments equal to a total target cash incentive of $1.0 million, $1.0 million, and $1.0 million, respectively, multiplied by rTSR and FCF multipliers, as defined in the award agreements. In 2020, our Board of Directors amended the liability awards with a one-year performance period. The potential maximum payout of these liability awards is 125% of the target cash incentive for the 2020 one-year award, as amended, and 250% of the target cash incentive for all other liability awards, resulting in a total potential maximum payout of $2.5 million and $2.5 million for liability awards granted during the years ended December 31, 2022 and 2021, respectively. 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, 2022, our recorded liabilities associated with these awards was $3.2 million, and we had remaining unrecognized compensation cost related to cash-settled performance-based share-based awards of $1.9 million, which is expected to be recognized over a weighted average period of 1.7 years. During 2022 and 2021, we paid $833,000 and $417,000, respectively, in connection with liability awards, and no awards were forfeited. There were no liability awards vested or forfeited in the year ended December 31, 2020.

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 to our consolidated financial statements set forth in Item 8 of this report 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, 2022, 2021 and 2020, we had international sales of $500.4 million, $465.9 million and $413.8 million, respectively, or 43%, 43% and 43%, respectively, of net sales. Our largest international markets include China, Japan, Germany, France and the United Kingdom, with China representing our most significant international sales market with sales of $149.3 million, $138.2 million, and $113.2 million for the years ended December 31, 2022, 2021 and 2020, 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, 2022, 2021 and 2020, consisted of the following (in thousands):

	2022	2021	2020
United States	$ 281,290	$ 275,311	$ 277,643
Ireland	40,749	39,863	42,951
Other foreign countries	60,937	56,484	62,134
Total	$ 382,976	$ 371,658	$ 382,728

Financial information relating to our reportable operating segments and reconciliations to the consolidated totals for the years ended December 31, 2022, 2021 and 2020, are as follows (in thousands):

	2022	2021	2020
Net sales			
Cardiovascular	$ 1,118,224	$ 1,043,227	$ 934,202
Endoscopy	32,757	31,524	29,673
Total net sales	1,150,981	1,074,751	963,875
Income (loss) from operations			
Cardiovascular	80,946	53,415	(7,042)
Endoscopy	6,617	7,501	5,480
Total income (loss) from operations	87,563	60,916	(1,562)
Total other expense — net	(4,934)	(6,999)	(11,669)
Income tax expense (benefit)	8,113	5,463	(3,388)
Net income (loss)	$ 74,516	$ 48,454	$ (9,843)

Total assets by operating segment at December 31, 2022, 2021 and 2020, consisted of the following (in thousands):

	2022	2021	2020
Cardiovascular	$ 1,652,145	$ 1,635,676	$ 1,654,866
Endoscopy	11,821	12,618	9,530
Total	$ 1,663,966	$ 1,648,294	$ 1,664,396

Total depreciation and amortization by operating segment for the years ended December 31, 2022, 2021 and 2020, consisted of the following (in thousands):

	2022	2021	2020
Cardiovascular	$ 80,777	$ 83,000	$ 93,160
Endoscopy	1,027	1,066	910
Total	$ 81,804	$ 84,066	$ 94,070

Total capital expenditures for property and equipment by operating segment for the years ended December 31, 2022, 2021 and 2020, consisted of the following (in thousands):

	2022	2021	2020
Cardiovascular	$ 44,925	$ 27,557	$ 45,803
Endoscopy	104	382	185
Total	$ 45,029	$ 27,939	$ 45,988

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. In September 2019, we ceased discretionary contributions to certain of our defined contribution plans and subsequently reinstated those contributions in May 2021. Total expense for contributions made to these plans for the years ended December 31, 2022, 2021 and 2020 was $7.7 million, $6.5 million and $3.9 million, respectively.

15. 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, 2022 and 2021, consisted of the following (in thousands):

		Fair Value Measurements Using		
	Total Fair Value at December 31, 2022	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Marketable securities [1]	$ 138	$ 138	$ —	$ —
Interest rate contract asset, long-term [2]	$ 3,444	$ —	$ 3,444	$ —
Foreign currency contract assets, current and long-term [3]	$ 4,783	$ —	$ 4,783	$ —
Foreign currency contract liabilities, current and long-term [4]	$ (3,986)	$ —	$ (3,986)	$ —
Contingent consideration liabilities	$ (18,073)	$ —	$ —	$ (18,073)

		Fair Value Measurements Using		
	Total Fair Value at December 31, 2021	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Interest rate contract liability, long-term [2]	$ (1,447)	$ —	$ (1,447)	$ —
Foreign currency contract assets, current and long-term [3]	$ 2,241	$ —	$ 2,241	$ —
Foreign currency contract liabilities, current and long-term [4]	$ (3,646)	$ —	$ (3,646)	$ —
Contingent consideration liabilities	$ (48,234)	$ —	$ —	$ (48,234)

[1] Our marketable securities, which consist entirely of available-for-sale equity securities, are valued using market prices in active markets. Level 1 instrument valuations are obtained from real-time quotes for transactions in active exchange markets involving identical assets.

[2] The fair value of the interest rate contracts is determined using Level 2 fair value inputs and is recorded as accrued expenses or other long-term obligations in the consolidated balance sheets.

[3] 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.

[4] 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. 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, 2022 and 2021, consisted of the following (in thousands):

	2022	2021
Beginning balance	$ 48,234	$ 55,750
Contingent consideration expense	4,610	3,161
Contingent payments made	(34,762)	(10,665)
Effect of foreign exchange	(9)	(12)
Ending balance	$ 18,073	$ 48,234

As of December 31, 2022, $2.3 million in contingent consideration liability was included in other long-term obligations and $15.8 million in contingent consideration liability was included in accrued expenses in our consolidated balance sheet related to contingent liabilities. As of December 31, 2021, $13.5 million in contingent consideration liability was included in other long-term obligations and $34.7 in contingent consideration liability was included in accrued expenses in our consolidated balance sheet related to contingent liabilities.

Cash payments related to the settlement of the contingent consideration liability recognized at fair value as of the applicable acquisition date been reflected as a cash outflow from financing activities in the accompanying consolidated statements of cash flows. Payments related to increases in the contingent consideration liability subsequent to the date of acquisition of $1.8 million for the year ended December 31, 2022 are reflected as operating cash flows.

The recurring Level 3 measurement of our contingent consideration liabilities includes the following significant unobservable inputs at December 31, 2022 and 2021 (amounts in thousands):

Contingent consideration liability	Fair value at December 31, 2022	Valuation technique	Unobservable inputs	Range	Weighted Average[(1)]
Revenue-based royalty payments contingent liability	$ 2,097	Discounted cash flow	Discount rate	14% - 17%	15.7%
			Projected year of payments	2023-2034	2026
Revenue milestones contingent liability	$ 13,064	Monte Carlo simulation	Discount rate	5.1% - 14.0%	5.2%
			Projected year of payments	2023-2033	2023
Regulatory approval contingent liability	$ 2,912	Scenario-based method	Discount rate	5.7%	
			Probability of milestone payment	90%	
			Projected year of payment	2023-2030	2024

(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, 2021	Valuation technique	Unobservable inputs	Range	Weighted Average[1]
Revenue-based royalty payments contingent liability	$ 2,870	Discounted cash flow	Discount rate	13% - 16%	14.7%
			Projected year of payments	2022-2034	2026
Revenue milestones contingent liability	$ 41,671	Monte Carlo simulation	Discount rate	7.5% - 12.5%	8.2%
			Projected year of payments	2022-2031	2022
Regulatory approval contingent liability	$ 3,693	Scenario-based method	Discount rate	2.6%	
			Probability of milestone payment	80%	
			Projected year of payment	2024-2025	2025

(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.

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 (increase) in the probability of any milestone payment may result in lower (higher) 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, 2022 and 2020, we made contingent payments of approximately $1.6 million and $800,000 to a former director of Merit and former shareholder of Cianna Medical which we acquired in 2018. We made no such payments in 2021. In 2023, the Company expects to make additional payments consistent with prior years. 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 former 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, 2022, 2021 and 2020, we had losses of $1.7 million, $1.6 million and $28.7 million, respectively, related to certain acquired intangible assets (see Note 5).

Right of Use Operating Lease Assets. We identified changes in events and circumstances relating to certain right-of-use ("ROU") operating lease assets. 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 values were not recoverable. Consequently, we recorded impairment losses during the years ended December 31, 2021 and 2020 of $1.4 million and $1.5 million, respectively, which is equal to the excess of the carrying value of the assets over their estimated fair value. The impairment losses were driven primarily 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. The ROU operating lease asset impairment losses pertained to our cardiovascular segment. We had no such losses during the year ended December 31, 2022.

Property and Equipment. During the year ended December 31, 2021, we had losses of $1.3 million related to the measurement of property and equipment at fair value based on the planned discontinuance of the Advocate™ Peripheral Angioplasty Balloon product line, sold under our license agreements with ArraVasc, which pertained to our cardiovascular segment. During the year ended December 31, 2020, we had losses of $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, which pertained to our endoscopy segment. We had no such losses during the year ended December 31, 2022.

Equity Investments, Purchase Options and Notes Receivable. During the year ended December 31, 2022, we recognized $0.5 million of impairment expense related to our equity method investment in XableCath, as business ceased operations. 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. We had no such losses during the year ended December 31, 2021. Our equity investments in privately held companies were $15.6 million and $14.7 million at December 21, 2022 and 2021, 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.

Current Expected Credit Losses

Our outstanding long-term notes receivable, including accrued interest and our allowance for current expected credit losses, were $2.4 million and $2.3 million, as of December 31, 2022 and 2021, respectively. As of December 31, 2022 and 2021, we had an allowance for current expected credit losses of $281,000 and $199,000, respectively, associated with these notes receivable. 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, 2021, we collected $2.8 million from Bluegrass Vascular Technologies, Inc. pursuant to the terms of a note receivable, which represents the entire principal balance and all accrued interest payable pursuant to that note.

The table below presents a rollforward of the allowance for current expected credit losses on our notes receivable for the years ended December 31, 2022 and 2021 (in thousands):

	2022	2021
Beginning balance	$ 199	$ 730
Provision for credit loss expense	82	(531)
Ending balance	$ 281	$ 199

16. ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)

The changes in each component of Accumulated Other Comprehensive Income (Loss) for the years ended December 31, 2022, 2021 and 2020 were as follows (in thousands):

	Cash Flow Hedges	Foreign Currency Translation	Total
January 1, 2020	**$ 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)**
Other comprehensive income (loss)	(119)	(7,704)	(7,823)
Income taxes	(1,489)	689	(800)
Reclassifications to:			
Revenue	5,592		5,592
Cost of sales	(1,017)		(1,017)
Interest expense	1,509		1,509
Net other comprehensive income (loss)	4,476	(7,015)	(2,539)
December 31, 2021	**(2,464)**	**(5,527)**	**(7,991)**
Other comprehensive income (loss)	11,142	(10,491)	651
Income taxes	(2,177)	102	(2,075)
Reclassifications to:			
Revenue	(3,583)		(3,583)
Cost of sales	1,436		1,436
Interest expense	12		12
Net other comprehensive income (loss)	6,830	(10,389)	(3,559)
December 31, 2022	**$ 4,366**	**$ (15,916)**	**$ (11,550)**

17. 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 ranging from less than one year to approximately 27 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, 2022 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, 2022, 2021 and 2020 was not significant.

The following was included in our consolidated balance sheet as of December 31, 2022 and 2021 (in thousands):

	2022	2021
Assets		
ROU operating lease assets	$ 65,262	$ 65,913
Liabilities		
Short-term operating lease liabilities	$ 11,005	$ 10,668
Long-term operating lease liabilities	59,736	61,526
Total operating lease liabilities	$ 70,741	$ 72,194

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, 2022, 2021 and 2020 was $13.8 million, $15.9 million, and $16.7 million, respectively. The components of lease costs for the years ended December 31, 2022, 2021 and 2020 were as follows, in thousands:

Lease Cost	Classification	2022	2021	2020
Operating lease cost (a)	Selling, general and administrative expenses	$ 14,219	$ 16,013	$ 16,735
Sublease (income) (b)	Selling, general and administrative expenses	(409)	(75)	(15)
Net lease cost		$ 13,810	$ 15,938	$ 16,720

(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, 2022, 2021 and 2020 was as follows, in thousands:

	2022	2021	2020
Cash paid for amounts included in the measurement of lease liabilities	$ 13,710	$ 14,970	$ 15,059
Right-of-use assets obtained in exchange for lease obligations	$ 11,130	$ 1,524	$ 10,938

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, 2022, 2021 and 2020, our lease agreements had the following remaining lease term and discount rates:

	2022	2021	2020
Weighted average remaining lease term	10.4 years	11.4 years	11.5 years
Weighted average discount rate	3.4%	3.4%	3.3%

As of December 31, 2022, maturities of operating lease liabilities were as follows, in thousands:

Year ended December 31,	Amounts due under operating leases
2023	$ 12,638
2024	11,554
2025	8,941
2026	7,523
2027	5,944
Thereafter	37,983
Total lease payments	84,583
Less: Imputed interest	(13,842)
Total	$ 70,741

As of December 31, 2022, we had additional operating leases for office space that had not yet commenced. These leases will commence during 2023 and are not deemed material.

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, 2022. Based on this evaluation, our principal executive officer and principal financial officer concluded that as of December 31, 2022, 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, 2022. 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, 2022, our internal control over financial reporting was effective.

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

During the quarter ended December 31, 2022, 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, 2022, 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, 2022, 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, 2022, of the Company and our report dated February 24, 2023, expressed an unqualified opinion on those financial statements.

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
February 24, 2023

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

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 2023 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, 2022, 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 (PCAOB ID 34) — Internal Control

Report of Independent Registered Public Accounting Firm — Financial Statements

Consolidated Balance Sheets as of December 31, 2022 and 2021

Consolidated Statements of Income (Loss) for the Years Ended December 31, 2022, 2021 and 2020

Consolidated Statements of Comprehensive Income (Loss) for the Years Ended December 31, 2022, 2021 and 2020

Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2022, 2021 and 2020

Consolidated Statements of Cash Flows for the Years Ended December 31, 2022, 2021 and 2020

Notes to Consolidated Financial Statements

(2) Financial Statement Schedules.

— Schedule II - Valuation and qualifying accounts

Years Ended December 31, 2022, 2021 and 2020
(In thousands)

Allowance for Credit Losses:	Balance at Beginning of Year	Additions Charged to Costs and Expenses (a)	Deduction (b)	Balance at End of Year
2020	$ (3,108)	$ (3,115)	$ 910	$ (5,313)
2021	$ (5,313)	$ (2,678)	$ 1,224	$ (6,767)
2022	$ (6,767)	$ (1,858)	$ 202	$ (8,423)

(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.

Years Ended December 31, 2022, 2021 and 2020
(In thousands)

Tax Valuation Allowance:	Balance at Beginning of Year	Additions Charged to Costs and Expenses (a)	Deduction	Balance at End of Year
2020	$ (4,644)	$ (5,569)	$ —	$ (10,213)
2021	$ (10,213)	$ (573)	$ —	$ (10,786)
2022	$ (10,786)	$ (2,741)	$ —	$ (13,527)

(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
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. 2006 Long Term Incentive Plan, dated*†
10.2	First Amendment to the Merit Medical Systems 2006 Long-Term Incentive Plan, dated May 31, 2007*†
10.3	Lease Agreement dated as of June 8, 1993 for office and manufacturing facility*
10.4	Amended and Restated Deferred Compensation Plan, dated January 1, 2004*†
10.5	Merit Medical Systems, Inc. Amended and Restated Deferred Compensation Plan, effective January 1, 2008*†
10.6	Second Amendment to the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan made and adopted effective May 31, 2009*†
10.7	Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan made and adopted effective May 31, 2009*†

10.8 First Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, effective September 19, 2010*†

10.9 Second Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated November 29, 2010 *†

10.10 Third Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, effective October 1, 2010*†

10.11 Fourth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated December 31, 2011*†

10.12 Fifth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated December 28, 2012*†

10.13 Sixth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated December 31, 2013.*†

10.14 Seventh Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated June 10, 2014*†

10.15 Eighth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated December 29, 2014*†

10.16 Second Amended and Restated Credit Agreement dated as of July 6, 2016 by and among Merit Medical Systems, Inc., Wells Fargo Bank, National Association, Well Fargo Securities, LLC and the lenders named therein*

10.17 Form of Employment Agreement, dated May 26, 2016 between the Company and each of the following individuals: Joseph C. Wright, and Brian G. Lloyd*†

10.18 Employment Agreement, dated May 26, 2016 between the Company and Fred P. Lampropoulos*†

10.19 Third Amendment to the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan dated February 13, 2015*†

10.20 Merit Medical Systems, Inc., Restatement of the 1996 Employee Stock Purchase Plan dated July 1, 2000*†

10.21 First Amendment to the Merit Medical Systems, Inc., 1996 Employee Stock Purchase Plan dated April 1, 2001*†

10.22 Second Amendment to the Merit Medical Systems, Inc., 1996 Employee Stock Purchase Plan dated January 1, 2006*†

10.23 Third Amendment to the Merit Medical Systems, Inc., 1996 Employee Stock Purchase Plan dated April 7, 2006*†

10.24 Fourth Amendment to the Merit Medical Systems, Inc., 1996 Employee Stock Purchase Plan dated February 13, 2015*†

10.25 Fifth Amendment to the Merit Medical Systems, Inc., 1996 Employee Stock Purchase Plan dated April 15, 2021*†

10.26 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*†

10.27 Form of First Amendment to Employment Agreement for each of Joseph C. Wright, and Brian G. Lloyd*†

10.28 First Amendment to Lease Agreement dated May 22, 2017 for office and manufacturing facility*

10.29 Merit Medical Systems, Inc. 2018 Long-Term Incentive Plan effective May 24, 2018*†

10.30 First Amendment to the Merit Medical Systems, Inc. 2018 Long-Term Incentive Plan effective December 14, 2018*†

10.31 Second Amendment to the Merit Medical Systems, Inc. 2018 Long-Term Incentive Plan effective April 15, 2021*†

10.32 Employment Agreement made and entered into by and between Merit Medical Systems, Inc. and Raul Parra as of the 1st day of August, 2018.*†

10.33 Merit Medical Systems, Inc. 2019 Executive Bonus Plan, dated January 1, 2019*†

10.34 Ninth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated August 1, 2016*†

10.35 Tenth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated January 1, 2017*†

10.36 Eleventh Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated January 1, 2019*†

10.37 Twelfth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, dated June 1, 2018*†

10.38 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*

10.39 Thirteenth Amendment to the Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan, effective January 1, 2019*†

10.40 Performance Stock Unit Award Agreement (Three Year Performance Period), dated February 26, 2020, by and between Merit Medical Systems, Inc. and Fred Lampropoulos.*†

10.41 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, Joseph C. Wright, and Brian G. Lloyd. *†

10.42 First Amendment to the Merit Medical Systems, Inc. 2019 Executive Bonus Plan, effective June 22, 2020 *†

10.43 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.*

10.44	Corporate Integrity Agreement, dated October 13, 2020, by and between the OIG-HHS and the Company.*
10.45	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 *†
10.46	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 *†
10.47	Form of Indemnification Agreement between the Company and each executive officer. *†
10.48	Indemnification Agreement, dated as of June 17, 2021, between the Company and Stephen C. Evans.*†
10.49	Form of Indemnification Agreement, dated as of May 19, 2022, between the Company and each of Laura Kaiser and Michael McDonnell.*†
10.50	Employment Agreement between the Company and Michel J. Voigt, dated December 11, 2020*†
10.51	Employment Agreement between the Company and Neil Peterson, dated May 19, 2022†
10.52	Performance Stock Unit Award Agreement (Two Year Performance Period), dated March 19, 2021, by and between Merit Medical Systems, Inc. and Fred Lampropoulos.*†
10.53	Performance Stock Unit Award Agreement (Three Year Performance Period), dated March 19, 2021, by and between Merit Medical Systems, Inc. and Fred Lampropoulos.*†
10.54	Form of Performance Stock Unit Award Agreement (Two Year Performance Period), dated March 19, 2021, by and between Merit Medical Systems, Inc. and each of the following individuals: Raul Parra, Brian G. Lloyd, Michel J. Voigt, and Joseph C. Wright.*†
10.55	Form of Performance Stock Unit Award Agreement (Three Year Performance Period), dated March 19, 2021, by and between Merit Medical Systems, Inc. and each of the following individuals: Raul Parra, Brian G. Lloyd, Michel J. Voigt, and Joseph C. Wright.*†
10.56	Performance Stock Unit Award Agreement (Three Year Performance Period), dated February 26, 2022, by and between Merit Medical Systems, Inc. and Fred Lampropoulos.*†
10.57	Performance Stock Unit Award Agreement (Three Year Performance Period), dated February 26, 2022, by and between Merit Medical Systems, Inc. and Raul Parra.*†
10.58	Form of Performance Stock Unit Award Agreement (Three Year Performance Period), dated February 26, 2022, by and between Merit Medical Systems, Inc. and each of the following individuals: Brian G. Lloyd, Michel J. Voigt, and Joseph C. Wright.*†
10.59	Performance Stock Unit Award Agreement (Three Year Performance Period), dated May 19, 2022, by and between Merit Medical Systems, Inc. and Neil Peterson.*†
10.60	Form of Restricted Stock Unit Award Agreement, dated May 24, 2022, by and between Merit Medical Systems, Inc. and each of the following individuals: A. Scott Anderson, Lonny J. Carpenter, Stephen C. Evans, David K. Floyd, James T. Hogan, Thomas J. Gunderson, Laura s. Kaiser, Michael R. McDonnell, F. Ann Millner, and Lynne N. Ward.†
10.61	Second Amendment to Lease Agreement dated March 10, 2022 for office and manufacturing facility.

10.62	Deferred Compensation Plan for Non-Employee Directors.*†
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, 2022, formatted in iXBRL (Inline eXtensible Business Reporting Language): (i) Consolidated Statements of Income (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 February 24, 2023.

MERIT MEDICAL SYSTEMS, INC.

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

ADDITIONAL SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on form 10-K has been signed below by the following persons in the capacities indicated on February 24, 2023.

Signature	Capacity in Which Signed
/s/: FRED P. LAMPROPOULOS Fred P. Lampropoulos	President, Chief Executive Officer and Director (Principal executive officer)
/s/: RAUL PARRA Raul Parra	Chief Financial Officer and Treasurer (Principal financial and accounting officer)
/s/: A. SCOTT ANDERSON A. Scott Anderson	Director
/s/: LONNY J. CARPENTER Lonny J. Carpenter	Director
/s/: STEPHEN C. EVANS Stephen C. Evans	Director
/s/: DAVID K. FLOYD David K. Floyd	Director
/s/: THOMAS J. GUNDERSON Thomas J. Gunderson	Director
/s/: JAMES T. HOGAN James T. Hogan	Director
/s/: LAURA S. KAISER Laura S. Kaiser	Director
/s/: MICHAEL R. MCDONNELL Michael R. McDonnell	Director
/s/: F. ANN MILLNER F. Ann Millner	Director
/s/: LYNNE N. WARD Lynne N. Ward	Director

CORPORATE INFORMATION

EXECUTIVE OFFICERS

Fred P. Lampropoulos
Chairman, Chief Executive Officer

Raul Parra
Chief Financial Officer, Treasurer

Neil W. Peterson
Chief Operating Officer

Joseph C. Wright
Chief Commercial Officer

Brian G. Lloyd
Chief Legal Officer, Corporate Secretary

Michel J. Voigt
Chief Human Resources Officer

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

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

Stephen C. Evans
Founder, Chairman & CEO
Flag Bridge Global Solutions, LLC

David K. Floyd
Former Group President
Stryker Corporation

Thomas J. Gunderson
Director and Former Chair
Minneapolis Heart Institute Foundation

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

Laura S. Kaiser
President and Cheif Executive Officer,
SSM Health

Michael R. McDonnell
Chief Financial Officer
Biogen 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, 2022. 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 on Thursday, May 18, 2023, 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 22, 2023, the number of shares of common stock outstanding was 57,318,032, held by approximately 96 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

Dorsey & Whitney LLP
Intellectual Property Counsel

Understand. Innovate. Deliver.™

MERIT MEDICAL SYSTEMS, INC.
1600 West Merit Parkway
South Jordan, Utah 84095
+1 (801) 253–1600
www.merit.com