Risk Factors Comparison 2025-02-25 to 2024-02-28 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

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 **Disruptions in the** ~~Termination or interruption of our~~ supply **from** ~~relationships and increases in the cost of component parts, finished products,~~ third- party ~~services and raw~~ **vendors of the** materials ~~is negatively impacting~~ **and components used in manufacturing** ~~our~~ **or** ~~business and~~ **sterilizing our products** could ~~have a further adverse~~ **adversely** ~~effect~~ **affect** ~~on~~ our business, operations or financial condition. We rely on ~~raw materials, component parts, finished products and~~ third- party **vendors to supply raw materials, component parts, finished products and** services in connection with our business. **Our reliance on these third- party vendors exposes us to product or service shortages and unanticipated price increases, whether due to inflationary pressure, regulatory changes, geopolitical tensions, the discretion of such vendors or otherwise.** For example, ~~substantially~~ **we rely on a relatively** ~~all~~ **small number** of **service providers to sterilize** our products **prior to sale** ~~are sterilized by only a few different entities~~. If any of these ~~entities~~ **service providers** goes out of business, ceases to provide services to us or fails to comply with quality or regulatory requirements, we may be unable to find a suitable ~~supplier~~ **service provider** to replace them. This could significantly delay or stop production and adversely affect sales of such products. 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 medical device manufacturers or to require such manufacturers to assume additional risks. Additionally, there~~ **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 escalating tensions~~ **Tensions** in the Middle East and the military conflict in Ukraine may increase the likelihood of supply interruptions and hinder our ability to obtain the materials we need to make our products. Supply disruptions are making it harder for us to find 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 **existing and potential tariffs** ~~the willingness of suppliers to sell into the medical device industry~~, changes in supply and demand, general economic conditions, labor **and** ~~costs, fuel- related~~ transportation costs ~~, liability concerns~~, climate change (including existing and prospective laws and regulations), competition, import duties, ~~tariffs,~~ currency exchange rates and political uncertainty around the world. During ~~2023~~ **2024**, we experienced significantly elevated commodity and supply chain costs, including the costs of labor, raw materials, energy, packaging materials and other inputs necessary for the production and distribution of our products. Those elevated costs may continue in ~~2024~~ **2025 , which could adversely** ~~. In addition to the effect~~ **affect our business** ~~on resin prices~~, **operations or financial condition** ~~transportation costs have generally increased and may further increase if crude oil prices increase. Our transportation and service providers typically 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 recover these costs through price increases or offset these increases through cost reductions, or we experience terminations or ~~interruption~~ **interruptions** of our relationships with our suppliers, we could experience lower margins and profitability, and our business, operations or financial condition could be materially harmed. Changes in economic and geopolitical conditions, domestic and foreign trade policies, monetary policies and other factors beyond our control may adversely impact our business, operations and financial condition. Our operations and performance ~~depend~~ **are** significantly ~~on~~ **impacted by** global, regional and U. S. economic and geopolitical conditions. The global macroeconomic environment continues to be challenging due to the effects of ~~increases in~~ inflation globally, instability in global credit markets, uncertainty regarding global central bank monetary policy, instability in the geopolitical environment in many parts of the world, current economic challenges in China, and other factors. Periods of diplomatic or armed conflict, such as the ongoing conflict in Ukraine, tensions in the Middle East and China- Taiwan relations, 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, lost revenues, increased costs, lost export privileges or criminal sanctions. ~~Furthermore,~~ U. S. **President Donald Trump has expressed a strong desire to impose new or increase existing tariffs on selected goods imported into the United States. Accordingly, on February 1, 2025, President Trump issued three executive orders directing the United States to impose new tariffs on imports from Canada, Mexico and China, and on February 3, 2025, President Trump announced his intention to pause these tariffs on Canada and Mexico for approximately 30 days. A significantportion of our raw materials, component parts and finished products are sourced or manufactured in Mexico and China and could be subject to these tariffs, thereby increasing our manufacturing costs. We are currently evaluating the potential impact of the imposition of potential tariffs on our business and financial condition. The ultimate impact of any announced or future tariffs will depend on various factors, including whether such tariffs are ultimately implemented, the timing of implementation and the amount, scope and**

nature of such tariffs and potential exclusions from the application of those tariffs. Additionally, potential tariffs or other U. S. trade ~~policycould~~ **policy measures could** trigger retaliatory actions by other countries, including ~~China~~ **by countries that are significant markets for our products** , resulting in a " trade war. " A trade war could **cause** ~~result in~~ increased **manufacturing** costs **, including with respect to** ~~for raw materials we use in~~ our **products** ~~manufacturing~~ **manufactured in Mexico** , foreign governments imposing tariffs on products that we export outside **of** the U. S. **,** or limitations on our ability to sell our products **domestically or** abroad ~~. These increased costs~~ **, any of which** would ~~have a negative~~ **negatively** ~~effect~~ **affect** ~~on~~ our **business, operations and** financial condition ~~and profitability~~ . The above factors, as well as other economic and geopolitical factors in the U. S. and abroad, could have a material adverse effect on our business, operations and financial condition, including: ● changes in economic, monetary and fiscal policies in the U. S. and abroad ~~including currency fluctuations, inflationary pressures and significant income tax changes~~ ; ● a global or regional economic slowdown in any of our market segments; ● **public health crises** ~~a regional epidemic or a global pandemic, such as COVID- 19~~ , and government and social responses; ● ~~changes in~~ government ~~policies and regulations affecting~~ **cost- reduction initiatives, including such initiatives implemented by** the ~~Company or its significant customers~~ **administration of U. S. President Donald Trump** ; ● policies in various countries that favor domestic industries or restrict foreign companies; ● ~~trade policies and tariffs enacted by countries 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 escalation of the cost of regulatory compliance and litigation; and ● credit risks, longer payment cycles and other challenges in collecting accounts receivable. ~~The military~~ **Volatile geopolitical turmoil, including popular uprisings, regional** ~~conflict~~ **conflicts , terrorism and war could result in market instability, which could negatively impact our business results. We are a global company with international operations, and we sell our products in countries throughout the world. Regional conflicts, including the Russian invasion of Ukraine, tensions in the Middle East, and the risk of increased tensions** between ~~Russia~~ **China** and ~~Ukraine~~ **Taiwan** , ~~and the~~ **could limit or prohibit our ability to sell our products in or source materials from sanctioned countries. In addition, international conflicts could further result in** global ~~response to it~~ **or regional market instability; increased energy costs; and increased risk of cybersecurity attacks** , ~~has~~ **any of which could** adversely **impact** ~~affected, and will likely continue to adversely affect~~ our **financial** ~~business, and~~ results ~~of operations. The war between Russia and Ukraine has increased global economic and political uncertainty and created barriers to doing business in Russia. Governments in the U. S., U. K. and E. U. have each imposed controls on certain products and financial and economic sanctions on certain industry sectors and parties. Additional controls and sanctions could be enacted in the future. We continue to actively monitor the situation in Russia and Ukraine and assess its impact on our business, including our suppliers and customers. We have no manufacturing facilities or significant operations in Russia or Ukraine and as such, the conflict has not had a material impact on our manufacturing operations to date; however, our sales into the region have been negatively impacted by expanded controls and sanctions and could be further impacted in the future. It is also possible that the conflict between Russia and Ukraine may escalate or expand, and the scope, extent and duration of the military action, current or future sanctions and resulting market and geopolitical disruptions could be significant. We cannot predict the impact the conflict may have on the global economy or our business, financial condition and operations in the future. The Russia and Ukraine conflict may also heighten the impact of other risks factors described herein~~ . Any damage or interruption to our operations, facilities, manufacturing processes or information technology systems, or those of our suppliers, could have an adverse effect on our business, operations or financial condition. **Our products are designed and manufactured in facilities around the world, either by us or third parties.** Damage or interruption to our facilities or systems **, or those of our suppliers,** because of ~~fire,~~ extreme weather conditions, natural disaster, power loss, communications failure, geopolitical disruption, labor strikes, riots, cyber- attack, **public** health **crises** ~~epidemics or pandemics~~ , unauthorized entry or other events could significantly disrupt our operations, the operations of suppliers ~~and~~ **or** 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~~ **In the event of any such delay or interruption of our operations, facilities or systems, or those of our suppliers,** we ~~maintain property damage~~ **may experience a loss of market share** and **harm to our reputation, which could adversely affect our** business **, operations** ~~interruption insurance coverage on our~~ **or financial condition** ~~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~~ **cost- containment measures** have led to demands for price concessions, which may reduce our revenues and harm our ability to sell our products at prices necessary to support our current business strategies. ~~21Healthcare~~ -- **Healthcare** costs have risen significantly over the past decade, which has led to numerous cost **containment measures and other healthcare** ~~reform~~ **reforms** ~~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 providers. These customers are often able to obtain lower prices and more favorable terms because of the potential sales volume they represent, which has led to lower revenues and required us to take on additional liability. ~~We~~ **21The global trend toward limiting growth of healthcare costs has also impacted us in international**

markets, including China, our largest international market in terms of revenue. China has implemented the VBP policy, which has the specific aim of decreasing prices for medical devices. China' s VBP policy decreased our sales prices in China in 2022, 2023 and 2024, which negatively impacted our revenues. Due to uncertainties with the application of the VBP tender process, we are unable to reliably predict the impact of the VBP policy on our China revenues in 2025. However, we expect that **the VBP tender process in China** ~~market demand, government regulation, third- party coverage and reimbursement policies and societal pressures~~ will continue to ~~change~~ **have a negative impact on the revenue we are able to generate in China in 2025, and** ~~the~~ **there** ~~healthcare industry worldwide, resulting in further~~ **can be no assurance that the VBP policy will not have a materially adverse effect on our** business **, operations** ~~consolidations and alliances among our~~ **or financial condition** ~~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 practices or technology. **We** ~~The markets in which our products compete~~ are ~~highly competitive. We~~ **a global company that** ~~face~~ **faces significant** competition from **a wide range of existing competitors and new market entrants. These include large medical device companies with extensive product lines,** many ~~companies~~ **of** which **may** ~~are larger, better established,~~ have greater financial ~~, technical~~ and other resources **than we do, as well as firms which are more specialized than we are with respect to particular markets or product lines. Nontraditional entrants, such as technology companies, are also entering into the healthcare industry** and ~~possess a~~ **some may have** greater ~~market presence~~ **financial or other resources** than we do. ~~Such resources and market presence may enable our competitors~~ **Additionally, the medical device industry is also subject** to ~~more effectively market competing~~ **rapid technological change and frequent** ~~products~~ **product introductions** ~~or to market competing products at reduced prices in order to gain market share~~. **Our** ~~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. 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. **Furthermore, our existing competitors and new market entrants may respond more quickly to or integrate new or emerging technologies such as artificial intelligence and machine learning in their product offerings, which could also limit the market for our products.** A reduction in ~~the~~ demand for our products ~~,~~ could have a material adverse effect on our business, operations or financial condition. Strategic, Business Development and Employee Attraction and Retention RisksWe 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 **Merit** ~~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~~. **Our** ~~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. We may incur substantial costs when evaluating, negotiating and closing acquisitions, and our failure to integrate acquired businesses may adversely impact our business and financial results. We seek to supplement our internal growth through strategic acquisitions and transactions. We **regularly** ~~have completed a series of strategic acquisitions and transactions, some of which have been significant, and continue to~~ evaluate ~~other~~ potential acquisitions and 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 transactions. ~~As we grow through~~ **Our integration of acquired businesses requires considerable efforts, which may include corporate restructuring and the coordination of information technologies, research and development, sales and marketing, operations, regulatory, supply chain, manufacturing, quality systems and finance. These efforts result in additional expenses and require significant management time. Some of the factors that could affect the success of our** acquisitions **include the effectiveness of our due diligence process** , ~~we face~~ **our ability to execute our business plan for the acquired companies, the strength of the acquired technology, results of clinical trials, regulatory approvals and reimbursement levels of the acquired products and related procedures, the performance of critical transition services, our ability to adequately fund acquired research and 22development projects and retain key employees and our ability to achieve synergies with the acquired businesses. Foreign acquisitions involve unique risks, including** ~~the~~ **those related to integration of operations across different geographies, cultures and languages, currency risks and risks associated with the economic, political, legal and regulatory environment in specific countries. In** ~~additional~~ **addition, we have and may in the future acquire less than full ownership interests in other businesses, which involve unique** challenges ~~of integrating the operations~~ **for effective collaboration. Further** , ~~culture, systems and~~ other ~~characteristics of the acquired enterprises with~~ **parties that hold remaining ownership interests in such businesses may have economic** ~~our~~ **or business goals** ~~own. Our efforts to integrate acquisitions and transactions 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~~ **inconsistent with** ~~or~~ **our** ~~prolonged~~ **goals or the goals of such businesses. Our failure to manage these challenges successfully and coordinate the growth of such businesses or other investments could have an adverse impact on our**

business and our future growth. In addition, we cannot be certain ~~than~~ **that** ~~anticipated. 22Additionally~~ **the businesses we acquire or invest in will become profitable or remain so , and if our acquisitions or investments are not successful, we may record related asset impairment charges in the future or experience other negative consequences on our operating results.** ~~past~~ **Past** and future acquisitions and transactions 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~~ **experienced** 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 other transactions, such transactions may not produce the anticipated benefits and **could** have an adverse effect on our business, operations or financial condition. **Failure to realize the benefits expected from recent acquisitions could adversely affect our business, operating results and financial condition.** We have ~~incurred expenses~~ **completed a series of strategic acquisitions and transactions in recent years, some of which have been significant, such as the acquisitions of assets from each of the following companies: AngioDynamics, Inc. on June 8, 2023; EndoGastric Solutions, Inc. on July 1, 2024; and Cook Medical Holdings, LLC on November 1, 2024 (collectively, the " Recent Acquisitions "). The benefits we expect from the Recent Acquisitions are based on projections and assumptions about the performance of the acquired assets under our ownership and control, which may not materialize as expected or which may prove to be inaccurate. Our business, operating results and financial condition could be adversely affected if we are unable to realize the anticipated benefits, such as the anticipated cost and revenue synergies, from the Recent Acquisitions on a timely basis, if at all. Achieving the benefits of the Recent Acquisitions will depend, in part, on our ability to integrate the acquired businesses and operations successfully and efficiently with our business. The challenges involved in these integrations include the following: ● integrating operations and production lines; ● limiting business disruptions, preserving customer and other important relationships of the acquired businesses, and attracting new business and operational relationships; ● coordinating and integrating research and development and engineering teams across technologies and product lines to enhance product development while reducing costs; ● consolidating and integrating corporate, IT, cybersecurity, finance and administrative infrastructures; ● coordinating branding, sales and marketing efforts to effectively position the products acquired in the Recent Acquisitions; and ● integrating employees and related HR systems and benefits, maintaining employee productivity and retaining key employees. If we do not successfully manage these issues and the other challenges inherent in integrating an acquired business, we may not achieve the anticipated benefits of the Recent Acquisitions on our anticipated timeframe, if at all, and our business, operations and financial condition could be materially adversely affected. 23If we fail to achieve anticipated benefits from business acquisitions or strategic investments or identify underperforming products, we may dispose of the acquired or underperforming assets, which could adversely affect our results of operations. We may acquire businesses or assets which do not produce the benefits projected at the time of acquisition or we may identify legacy operations and products that are underperforming, do not fit with our longer- term business strategy or that become subject to unforeseen operating difficulties. We may seek to divest these underperforming businesses, operations or products. The resulting divestiture may be financially disadvantageous to us, which could adversely affect our results of operations. If we cannot divest an underperforming business, operation or asset on acceptable terms, we may voluntarily cease operations related to that business, operation or asset. In such event, we may be required to take impairment charges or write- downs** in connection with **acquisitions** ~~the disposition of businesses~~ and ~~assets~~ **divestitures,** which **could adversely affect our results** ~~we acquired but determined that they did not produce the benefits contemplated at the time~~ of **operations** ~~acquisition. We may incur similar expenses in the future~~ . Our future growth is dependent in part upon the development of new products and the enhancement of existing products, and there can be no assurance that such products be developed or enhanced. ~~In order~~ **An important component of our business strategy is** to ~~develop~~ **increase revenue growth through innovation and** new ~~products~~ - **product** ~~and enhance existing products, we focus our research and~~ development ~~programs largely on the development of next- generation and novel- technology products~~ . The development of new products and enhancement of existing products requires significant investment in research and development, clinical trials and regulatory approvals. The results of our product development efforts may be affected by a number of factors, including our ability to anticipate customer needs, innovate and develop new products, efficiently conduct and complete clinical trials, obtain regulatory approvals and reimbursement approvals in the U. S. and abroad, manufacture products in a cost- effective manner, obtain and enforce intellectual property rights and gain and maintain market approval of our products. There can be no assurance that any ~~products~~ - **product** we **have recently launched (such as the Wrapsody Device),** are preparing for launch, **are** now developing or that we may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch new products and enhanced products, our ability to maintain or expand our market position in the markets in which we participate may be materially adversely impacted. Additionally, the development or enhancement of certain products or groups of products, for example the ~~Merit~~ Wrapsody **Device** ~~™ Cell- Impermeable Endoprosthesis~~ , may have a disproportionate impact on our business, financial condition and results of operations. We have devoted and currently devote significant research and development resources to certain products and groups of products. In light of the significant investment of financial and personnel resources to the development of these products, failure to meet development timelines or growth projections, poor clinical outcomes, increasing regulatory requirements, launch delays and inability to effectively scale manufacturing and achieve targeted margins with respect to any of these products or groups of products in particular may adversely impact our business, operations and financial condition. 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 growth strategy and customer acceptance of new products,~~ product introductions by our competitors, an increase or decrease in customer demand for our products or for products of our competitors, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions, or decreased consumer confidence. Inventory levels in excess of customer demand may result in inventory write- downs or write- offs, which would impact our ~~gross margin~~ **results of operation** . Conversely, if we underestimate customer demand, our manufacturing facilities may not be able to deliver products to meet our order requirements, which could damage our reputation and customer relationships. **Our reliance** ~~We do not maintain direct sales and marketing capabilities in many countries and are dependent~~ on ~~our distributors for the commercialization of our products in those countries. If we are unable to maintain or establish sales capabilities on our own or through third parties, we may not be able to effectively commercialize 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, 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 23which we utilize a " modified direct " sales approach. If we are unable to enter into or maintain such distribution arrangements on acceptable terms, 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 **in many countries could negatively impact the commercialization of our products in those countries. In many countries, we rely on third- party distributors to market, distribute and sell our products, which exposes us to multiple risks. These distributors are often the main point of contact for the healthcare professionals and healthcare organization customers who buy and use our products. If we are unable to enter into or maintain distribution agreements with these third- party distributors on acceptable terms, we** may not ~~effectively sell~~ **be able to successfully commercialize** our products **in certain countries. The sales of** ~~or~~ **our products in these countries** may **be at risk if third- party distributors become insolvent, cease selling our products or** choose to ~~instead~~ sell competing products. In addition, although our contract terms require our distributors to comply with 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. **Our reliance on third- party 24distributors exposes us to various risks, including commercial, legal, compliance and reputational risks, the realization of any of which could harm our results of operations and business.** If ~~our distributors fail~~ **we are unable** to effectively **execute** ~~market and sell~~ our **leadership succession plans and attract** ~~products in compliance with applicable laws~~ , **develop and retain key employees,** our **business and** results of operations ~~and business~~ could be ~~impacted~~ **harmed** . ~~We are dependent upon key personnel and have announced the anticipated retirement of our Chief Executive~~ **Effective** ~~Officer. Our~~ **succession planning is critical to our long- term** success ~~is dependent on key management personnel, including Fred P~~ . **Failure to ensure** ~~Lampropoulos, our Chairman of~~ the ~~Board, President~~ **transfer of knowledge** and ~~Chief~~ **smooth transitions involving** ~~Executive~~ **executives and** ~~Officer. We do not maintain key man life insurance on Mr. Lampropoulos. The loss of Mr. Lampropoulos, or of certain~~ other key **employees could hinder our strategic planning and execution. Changes in our** management ~~personnel~~ **team may be disruptive to our business** , **and any failure to successfully integrate key new hires or promote employees** could ~~have a materially adverse~~ **adversely** ~~effect~~ **affect** ~~on~~ our ~~business,~~ operations ~~and financial condition~~ . We have announced that a committee of our independent directors is ~~developing and will oversee~~ **overseeing** a succession plan in preparation for ~~Mr~~ **the retirement of Fred P** . Lampropoulos ~~' retirement~~ **, our Chairman of the Board, Chief Executive Officer and President** , which we currently anticipate will occur **around** ~~at the end of the fiscal year ending~~ December 31, 2025. Despite the efforts of that committee and our senior management team to implement an effective succession plan that will position Merit for future growth ~~,~~ **and** development ~~and value creation~~ , there can be no assurance that we will not experience disruption in our management team, departure of key management or other employees, loss of focus on our strategic business objectives or other adverse consequences resulting from the anticipated transition. ~~Our technical~~ **We do not maintain key man life insurance on Mr. Lampropoulos. The loss of Mr. Lampropoulos** , **or of certain** ~~sales, marketing and~~ other ~~specialized~~ **key management** personnel ~~also play an integral role in the development~~ , ~~marketing and sale of new and existing products. If we are unable to hire, develop and retain a competitive work force, or if we are unable to plan effective succession for the future, we may not be able to meet our strategic business objectives. In addition, if we are unable to maintain an inclusive culture that aligns our diverse workforce with our mission and values, this~~ could ~~adversely impact our ability to hire, develop and retain key talent. Regulatory, Litigation, Tax and Legal Compliance RisksRegulations and trade policies implemented by foreign governments to reduce the costs of healthcare or promote business in their countries have negatively impacted, and are likely to continue to negatively impact our sales in such countries. Regulations and trade policies implemented by foreign governments have resulted in increased costs, lower margins and lower sales than we had forecast, and have had an adverse effect on our business. Our customers and suppliers may also be affected by these events. Thus, even if we are not directly impacted by these regulations and policies, we may still experience lower demand for our products, increases in our manufacturing costs and supply chain delays or disruptions because of the effects these events may have on our customers and suppliers. For example, China, one of our largest international markets, has recently implemented the VBP policy which has the specific aim of decreasing prices for medical devices. China' s VBP policy decreased our sales prices and volumes in China in 2022 and 2023, which negatively impacted our revenues in China during those years. Due to uncertainties with the application of the VBP tender process, we are unable to reliably predict the impact of the VBP policy on our China revenues in 2024. However, we expect that the VBP tender process in China will continue to have a negative impact on the revenue we are able to generate in China in 2024, and there can be no assurance that the VBP policy**

~~will not~~ have a materially adverse effect on our business ~~and~~ **,** operations **and financial condition. Our ability to compete effectively depends on our ability to attract, develop and retain executives and key employees** . The **market for experienced and talented employees, particularly for persons with certain technical competencies, is highly competitive. Inflationary pressures, labor demand and shortages and other macroeconomic factors have increased and could further increase the cost of labor, particularly in Mexico, and could harm our ability to recruit, hire and retain talented employees. Further, if we are unable to maintain (i) competitive and equitable compensation and benefit programs, including incentive programs which reward financial and operational performance, and (ii) an inclusive work culture that aligns our diverse workforce with our mission and values, our ability to recruit, hire, develop, engage, motivate and retain talented and experienced employees could be negatively affected, which could adversely impact our operating results and financial condition. Regulatory, Litigation, Tax and Legal Compliance RisksThe** FDA regulatory clearance process is ~~expensive~~ **extensive** ~~, time- consuming~~ and ~~uncertain~~ **dynamic** , 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 an existing device in the U. S., we must generally obtain clearance **or approval** from the FDA, unless an exemption from premarket review or an alternative **clearance or approval** procedure ~~, such as a de novo risk- based classification or a humanitarian device exemption,~~ applies. The **process of obtaining and maintaining** FDA ~~clearance~~ **clearances** and ~~approval~~ **approvals** ~~processes~~ for **our** medical devices ~~are expensive,~~ **could require a significant period of** time **, require the expenditure of substantial resources, involve rigorous clinical testing and post** - ~~consuming and uncertain~~ **market surveillance, require changes to our products or result in limitations on the indicated uses of our products** . ~~24We~~ **We** may make changes to our cleared **or approved** devices 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~~ **or** 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. 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. **Additionally, the recent reductions in the FDA workforce imposed by the administration of President Trump could cause delays in the product approval or clearance process of the FDA.** Delays in receipt of, or failure to obtain, regulatory clearances **or approvals** for any product enhancements or new products we develop ~~would~~ **could** 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, including good manufacturing practices, timely adverse event reporting **, completion of required post- market studies, timely annual and other periodic reports, submission of significant changes** ~~and~~ **25and** other post- market requirements. We cannot provide assurance that we will comply with all of these requirements or 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 subject to regulation in foreign countries in which we sell them. We have expended significant resources and experienced delays in obtaining foreign approvals and clearances and we will likely continue to incur significant expense, and experience delays ~~and uncertainty~~ , as we seek to obtain further approvals or clearances. In order to sell our products in foreign countries, generally we must obtain regulatory approvals and comply with applicable 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 E. U. ahead of ~~expiry dates~~ **transition deadlines** ; 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~~ **by** the **transition deadline** ~~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 E. U. **The global regulatory environment is becoming increasingly stringent and unpredictable.** Complying with and obtaining regulatory approval in foreign countries, including our efforts to comply with changing requirements and 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 on our net sales, market share and financial results from our international operations. ~~Some of our products are subject to~~ **Unsuccessful pre- and post- market** clinical trials **relating to** ~~and other analyses, the results of which may be unexpected, or~~ **our products** ~~perceived as unfavorable by the market, and~~ could have a material adverse effect on our **prospects** ~~business, operations or financial condition~~ . As a part of the regulatory process of obtaining ~~marketing~~ **regulatory** clearance **or approval** for new products and new indications for existing products, we conduct and participate in clinical trials ~~and other analyses~~ with a variety of study designs and patient populations. **We** ~~Pursuit of our business strategy will likely increase our need for, and dependance on, clinical trials and other analyses. Unexpected or inconsistent clinical data from existing or future clinical trials or other analyses conducted by us, by our competitors or by third parties, including acquired businesses prior to acquisition by us, or the FDA' s, foreign regulatory authorities' or the market' s perception of this clinical data, may adversely impact our ability to obtain product approvals, our position in, and share of, the markets in which we participate and our business, financial condition, results of operations or future prospects. 25We~~ are

developing and expect to continue to develop products that are increasingly therapeutic in nature. ~~We anticipate that applicable regulatory requirements~~ **Pursuit of our business strategy for therapeutic products** will ~~necessitate~~ **likely increase our need for, and dependance on,** clinical trials ~~and other analyses relating to many of these therapeutic products~~. **Such clinical trials** ~~In particular, we~~ are **inherently uncertain** ~~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 authorities. However,~~ there ~~is~~ **can be** no assurance that ~~we~~ **these trials** will be **sufficiently enrolled** ~~able to obtain the necessary regulatory clearances or approvals for~~ **or completed in** ~~the Wrapsody Endoprosthesis or any other products on~~ a timely ~~basis~~ **or cost- effective manner or result in a commercially viable product or indication. Unfavorable, unexpected or inconsistent clinical data from existing or future clinical trials conducted by us, by** ~~or~~ **our** ~~at all~~ **competitors or by third parties, or the FDA' s, foreign regulatory authorities' or the market' s perception of this clinical data, may adversely impact our ability to obtain and maintain product clearances and approvals, our position in, and share of, the markets in which we participate and our business, financial condition, results of operations or future prospects** . The medical device industry is subject to extensive scrutiny and regulation by governmental and other 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 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 **multiple federal agencies** ~~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. " **Our** ~~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~~ **26We** 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 ~~,~~ **or** 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, operations or financial condition. Our operations are subject to various state and federal laws targeting fraud and abuse in the healthcare industry, including the U. S. 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 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. ~~26We~~ **We** are 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 or agents, to comply with these laws could subject us to civil and criminal penalties and adversely affect our business, operations or financial condition. 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 **negligent,** reckless or criminal acts or other violations 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, operations or financial condition. Limits on reimbursement imposed by governmental and other programs may adversely affect our business and results of operation. We sell our products to hospitals and other healthcare providers around the world that typically receive reimbursement for the services provided to patients,

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~~ **27also** 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 and results of operation 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 evolving domestic and foreign 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. ~~27The~~ -- **The** U. S. and many other countries in which we operate have adopted laws and regulations protecting certain data, including medical and personal data (including HIPAA ~~,~~ **and** 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~~ **A significant number of** countries **where we operate** have **enacted privacy** ~~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 **laws, rules and regulations, many of which restrict outbound data transfers and have extraterritorial scope, creating significant compliance challenges as we seek to maintain our global reach, with significant penalties for non- compliance** . These **domestic and international** 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, may result in significant liability, fines or orders requiring that we change our data practices, which could, in turn, ~~cause us to incur substantial costs and~~ have a materially adverse effect on our business. Use of our products in unapproved circumstances could expose us to liabilities. The marketing clearances and approvals from the FDA and other authorities 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~~ **products** . 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 third- party distributors violating our policies by providing information or recommendations about such unauthorized uses. Consequently, claims may be asserted by the FDA or other authorities 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 authorities 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. The design, manufacture and marketing of medical devices involves various risks. Frequently, our products are used in connection with invasive procedures **, surgical and intensive care settings with seriously ill patients** 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 ~~.~~ **, safety alerts or** ~~Product~~ **product recalls** ~~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 had a material adverse effect on our business, 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. **28We** ~~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~~ **products** 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. ~~28Our~~ -- **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 are routinely a party to litigation, which could affect our financial condition and results of operations. We are routinely a party, including as a defendant to or otherwise involved in legal proceedings, claims or other legal matters ~~, arising in the course of our business~~. Although we endeavor to mitigate our legal risk, we are potentially subject to a wide variety of claims in the conduct of our business, including claims relating to products liability, labor matters, securities laws, regulatory compliance and breach of contract. Legal proceedings can be complex ~~and~~ **, expensive,** time- consuming **and disruptive to our operations** , with the final outcome depending on a number of variables, ~~some~~ **many** of which are beyond our control. **The** ~~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~~ -- **impact of any such proceedings** 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 and adversely affect our financial condition and results of operations. 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. Environmental, Health and Safety and Corporate Social Responsibility RisksOur failure to comply with applicable environmental, health and safety laws and regulations could negatively affect our business, operations or financial condition. We manufacture and assemble certain products that require the use of materials that are subject to domestic and foreign laws and regulations governing the protection of the environment, health and safety. ~~Moreover, existing~~ **Existing** and prospective environmental, health and safety laws and ~~regulation~~ **regulations** could lead to business interruption, increased costs and other adverse consequences ~~to our business~~. Compliance with future regulations may also 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 applicable laws at the time the acts were performed, rendering us liable without regard to our negligence or fault. ~~Because of~~ **Our failure to comply with** these laws ~~, the composition of our products~~ and **regulations** ~~packaging or any accidental release~~ may have an adverse effect on our business, operations or financial condition. Some of our products are composed of materials that contain per- and polyfluoroalkyl substances (" PFAS "). Regulations are being considered in the European Union and other countries that would limit or ban the use of PFAS in consumer and medical products. If these regulations were to restrict our use of PFAS in the production of our products, our business, operations and financial condition could be materially harmed. Environmental laws and regulations could also impact the way in which our ~~finished~~ products are sterilized. Most of our products are sterilized using Ethylene Oxide (" EtO "). Regulations are being considered in the U. S., EU and other countries that would limit the use

of EtO for the sterilization of medical products. The impact of these regulations could have a material adverse effect on our business. Our operations are also subject to various laws and regulations relating to occupational health and safety. We maintain safety, training and maintenance programs as part of our ongoing efforts to ensure compliance with applicable laws and ~~29~~regulations ~~--~~ **regulations** . Compliance with applicable health and safety laws and regulations has required and continues to require significant expenditures. We could be negatively impacted by corporate social responsibility laws, regulations, practices and expectations. We are 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 ~~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 or customers, and reductions in our margins and profitability. Governments, investors, customers, employees and other stakeholders **have focused** ~~are increasingly focusing~~ on CSR practices and disclosures, and expectations in this area are rapidly evolving. ~~On occasion, we announce new initiatives, including goals, under our corporate responsibility framework. This framework is aligned with areas of interest to us, which include sustainability, social impact, diversity, equity and inclusion and supply chain management, among others.~~ The criteria by which our CSR practices are assessed may change due to ~~the quickly~~ evolving social and regulatory landscape, which could result in greater regulatory requirements or expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. ~~Moreover, the increasing attention on CSR initiatives could also result in reduced demand for our products, reduced profits and increased investigations and litigation.~~ If we are unable to satisfy evolving criteria, investors may conclude that our policies and actions with respect to CSR matters are inadequate **and** ~~. If we fail or are perceived to have failed to achieve previously announced initiatives or goals or to accurately disclose our progress,~~ our reputation, business, financial condition and results of operations could be adversely impacted. Our business and operations are subject to risks related to climate change. Risks associated with climate change are subject to increasing societal, regulatory and political focus in the United States and globally. Shifts in weather patterns caused by climate change are projected to increase the frequency, severity or duration of certain adverse weather conditions and natural disasters, such as hurricanes, tornadoes, earthquakes, wildfires, droughts, extreme temperatures or flooding, which could cause ~~more~~ significant business and supply chain interruptions, damage to our products and facilities as well as the infrastructure of hospitals, medical care facilities and other customers, reduced workforce availability, increased costs of raw materials and components ~~,~~ **and** increased liabilities **, compared to our historical** ~~and decreased revenues than what we have experienced~~ - **experience with** ~~in the past from~~ such events. In addition, increased public concern over climate change could result in new legal or regulatory requirements designed to mitigate the effects of climate change ~~, which could include the adoption of more stringent environmental laws and regulations or stricter enforcement of existing laws and regulations~~ . Such developments could result in increased ~~compliance~~ **30compliance** costs and adverse impacts on raw material sourcing, manufacturing operations and the distribution of our products, which could adversely affect our operations and operating results. Intellectual PropertyWe may not be able to 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 **those rights. We seek to protect** 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 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 and former 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. ~~30Third~~ ~~--~~ **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 may 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 **litigation** ~~lawsuits that we might initiate~~ could be expensive, time consuming 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~~ **31Information** Technology and Cybersecurity RisksWe 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 **, reputation** and ~~customer relationships~~ **financial condition** . 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 inadvertent leaks, computer viruses or other malicious code, unauthorized access attempts, and ransom or other cyber- attacks (including through phishing emails, attempts to ~~fraudulently~~ induce employees ~~or others~~ to disclose information, and the exploitation of software and operating vulnerabilities), any of which could result in data leaks or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyber- attacks continue to increase in frequency, sophistication and intensity, and are becoming increasingly difficult to detect ~~,~~ ~~especially as they relate to attacks on third- party providers or their vendors~~ . Such attacks are often carried out by motivated and highly skilled actors, who are increasingly well- resourced. Geopolitical events have also increased cybersecurity risks on a global basis. **Additionally, the continuing evolution of technology we use, including cloud- based computing, data hosting and artificial intelligence, create additional exposure to security breaches and loss of access to our confidential or proprietary information.** There can be no assurance that our protective measures ~~31have~~ -- **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 vendors could become vulnerable to cyber- attacks, malicious intrusions, breakdowns, interference or other significant disruptions, and their systems 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 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 **parties** ~~health care professionals and employees~~ , ~~(iv)~~ be ~~subject~~ **subjected** 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~~ **reputation** or financial condition. The SEC has adopted new rules that require us to provide greater disclosure regarding cybersecurity risk management, strategy and governance, as well as disclosure of material cybersecurity incidents. We cannot predict or estimate the amount of additional costs we will incur in order to comply with these rules or the timing of such costs. These rules may also require us to report a cybersecurity incident before we have been able to fully assess its impact or remediate the underlying issue. Efforts to comply with such reporting requirements could divert management' s attention from our incident response and could potentially reveal system vulnerabilities to threat actors. Failure to timely report incidents under these or other similar rules could also result in monetary fines, sanctions or subject us to other forms of liability. Market, Liquidity and Credit RisksThe 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 June 6, 2023, we entered into a Fourth Amended and Restated Credit Agreement (" Fourth ~~Amended~~ **A & R** Credit Agreement "), with Wells Fargo Bank, National Association, and other financial institutions named therein. ~~The~~ **On December 5, 2023, we 32executed an amendment to the** Fourth ~~Amended~~ **A & R** Credit Agreement **(as** ~~amends~~ **amended , the"** ~~and restates in its entirety our previously outstanding Third~~ Amended **Fourth A & R** ~~and Restated Credit Agreement and all amendments thereto (the " Third Amended~~ Credit Agreement ") **to facilitate the issuance of our Convertible Notes described below** . We have pledged substantially all of our assets as collateral for the **Amended** Fourth ~~Amended~~ **A & R** Credit Agreement. Our breach of any covenant in the **Amended** Fourth ~~Amended~~ **A**

& R 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 **Amended** Fourth ~~Amended~~ **A & R** 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 **Amended** Fourth ~~Amended~~ **A & R** 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~~. On December 8, 2023, we issued $ 747. 5 million aggregate principal amount of 3. 00 % Convertible Senior Notes due 2029 (the " Convertible Notes ") ~~to persons reasonably believed to be " qualified institutional buyers "~~ pursuant to Rule 144A of the Securities Act of 1933, as amended. The Convertible Notes are unsecured and bear interest at 3. 00 % per year, payable semi- annually in arrears on February 1 and August 1 of each year, beginning on August 1, 2024. The Convertible Notes ~~32will~~ -- **will** mature on February 1, 2029, unless earlier repurchased, redeemed or converted in accordance with their terms prior to such date. The **Amended** Fourth ~~Amended~~ **A & R** Credit Agreement and the Indenture which governs the Convertible Notes (the " Note Indenture ") contain restrictive 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 ~~,~~ **and** payment of dividends and certain distributions ~~and entry into related party transactions~~. As currently amended, the **Amended** Fourth ~~Amended~~ **A & R** Credit Agreement provides for potential borrowings of up to $ 850 million. Such increased borrowing limits may make it more difficult for us to comply with leverage ratios and other restrictive covenants in the **Amended** Fourth ~~Amended~~ **A & R** 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. Our management has broad discretion regarding the use of proceeds of the Convertible Notes and other borrowed funds. Our management has broad discretion with respect to the use of the proceeds from the sale of the Convertible Notes and borrowed funds under the **Amended** Fourth ~~Amended~~ **A & R** Credit Agreement ~~, including uses for acquisitions, capital expenditures, technological improvements, research and development projects and other items~~. Some of these uses could prove to be ineffective or unproductive and could negatively impact our business. We **used a portion of the proceeds from the sale of the Convertible Notes and borrowed funds under the Amended Fourth A & R Credit Agreement to finance the Recent Acquisitions, but** have not identified ~~specific~~ **additional** acquisitions or other uses for a significant portion of the proceeds from the sale of the Convertible Notes or borrowed funds under the **Amended** Fourth ~~Amended~~ **A & R** Credit Agreement ~~. Investors will not have the opportunity to evaluate in advance the allocation of our available funds that our management decides to deploy. Rather, investors will rely on the judgment of our management regarding the application of our available funds~~. Our failure to utilize borrowed funds effectively and productively or find suitable investments or assets to acquire in a timely manner or on acceptable terms could result in financial losses, violation of financial covenants ~~to which we are subject~~, ~~harm~~ **limitations on** our ability to access additional liquidity resources or have other negative consequences, any of which could result in a material adverse effect on our business, operations or financial condition. We may not be able to service all of our indebtedness. As of December 31, ~~2023~~ **2024**, our total outstanding indebtedness under the Convertible Notes and the **Amended** Fourth ~~Amended~~ **A & R** Credit Agreement was $ ~~846~~ **747**. ~~6~~ **5** million. Under the terms of the **Amended** Fourth ~~Amended~~ **A & R** Credit Agreement, we are potentially able to borrow up to $ ~~626~~ **697** million in additional funds, which could result in total indebtedness under the Convertible Notes and **Amended** Fourth ~~Amended~~ **A & R** Credit Agreement of **up to** $ 1, ~~473~~ **444. 5** million. We depend on our cash on hand and free cash flow from operations 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 which, in turn, is dependent on a range of economic, competitive, and business factors, many of which are outside our control. 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, any of which could have a material adverse effect on our business, financial condition or results of operations. ~~The~~ **33The** fundamental change repurchase feature of the Convertible Notes may delay or prevent an otherwise beneficial attempt to acquire us. Certain provisions in the Note Indenture may make it more difficult or expensive for a third party to acquire us. For example, the Note Indenture requires us, in certain circumstances, to repurchase the Convertible Notes for cash upon the occurrence of a fundamental change and, in certain circumstances, to increase the conversion rate for a holder that converts its Convertible Notes in connection with a make- whole fundamental change. A takeover of Merit may trigger the requirement that we repurchase the Convertible Notes and / or increase the conversion rate, which could make it more costly for a potential acquirer to engage in such takeover. Such additional costs may have the effect of delaying or preventing a takeover of Merit that would otherwise be beneficial to investors. ~~33The~~ -- **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 **; governmental** or ~~any investigation of us by the SEC, DOJ, OIG, FDA, or another~~ regulatory ~~authority~~ **investigations**; actions taken by activist investors or other shareholders ~~,~~ **;** significant litigation or a decline, or rise, of stock prices in capital markets generally. In connection with the sale of the Convertible Notes, we entered into capped call transactions with certain of the initial purchasers of the Convertible Notes and / or their affiliates (the " Option Counterparties "). The capped call transactions are expected generally to reduce potential dilution to our common stock upon conversion of any Convertible Notes and / or offset any cash payments we are required to make in excess of the principal amount of converted Convertible Notes, as the case may be, with such reduction and / or offset subject to

a cap. Certain actions taken by the Option Counterparties, including modifying their hedge positions, purchasing or selling our common stock, or defaulting on their obligations, could **negatively impact** ~~cause or avoid an increase or decrease in~~ the market price of our common stock. Fluctuations in foreign currency exchange rates may negatively impact our financial results. We report our financial results in United States Dollars. However, a substantial amount of our revenue is derived from ~~international~~ sales in foreign currencies. Thus, the revenues we report with respect to our operations outside the U. S. have been and may continue to be adversely affected by fluctuations in foreign currency exchange rates. These **exchange rate** fluctuations ~~in exchange rates~~ are caused by a number of factors, including changes in a country' s political and economic policies and inflationary conditions. ~~Furthermore, currency~~ **Currency** exchange rates have been especially volatile in recent years, and these currency fluctuations have affected, and may continue to affect, the reported value of our assets and liabilities, as well as our cash flows. Those fluctuations could have a negative impact on our margins and financial results. During **2024,** 2023 ~~,~~ **and** 2022 ~~and 2021~~ , the exchange rate between all applicable foreign currencies and the U. S. Dollar resulted in ~~a decrease~~ **decreases** in **our** net sales of $ **7. 2 million, $** 6. 4 million **and** ~~, a decrease in net sales of~~ $ 23. 8 ~~million, and an increase in net sales of $ 10. 3~~ million, respectively. For the year ended December 31, ~~2023~~ **2024** , $ ~~423~~ **464** . ~~4~~ **9** million, or ~~33~~ **34** . ~~7~~ **3** %, of our net sales **,** were denominated in foreign currencies, with our Chinese Yuan- 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..... financial condition or results of operation. 34