Risk Factors Comparison 2024-02-28 to 2023-02-24 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 Termination or interruption of our supply relationships and increases in ~~labor~~ **the** ~~costs~~ - **cost** ~~and the prices~~ of ~~our~~ component parts, finished products, third- party services and raw materials ~~, particularly petroleum- based products,~~ is negatively impacting our business and could have a further adverse effect on our business, operations or financial condition. We rely on raw materials, component parts, finished products and third- party services in connection with our business. For example, substantially all of our products are sterilized by only a few different entities. If any of these ~~sterilizers~~ **entities** 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 to replace them. This could significantly delay or stop production and ~~cause~~ **adversely affect** sales of such products ~~to materially decline~~ . Additionally, many of our products have components that are manufactured using resins, plastics and other petroleum- based materials which are available from a limited number of suppliers. We are experiencing a growing trend among suppliers of polymer resins to refuse to supply resin to ~~the~~ medical device manufacturers or to require such manufacturers to assume additional risks ~~due to the potential for product liability claims~~ . Additionally, there is no assurance that crude oil supplies will be uninterrupted or that petroleum- based manufacturing materials will be available for purchase in the future. The **escalating tensions in the Middle East and the** military conflict **in** ~~between Russia and~~ Ukraine may increase the likelihood of supply interruptions and ~~further~~ hinder our ability to ~~find~~ **obtain** the materials we need to make our products. Supply disruptions are making it harder for us to find ~~favorable pricing and~~ reliable sources for the materials we need, putting upward pressure on our costs and increasing the risk that we may be unable to acquire the materials and services we need to continue to manufacture certain products. The availability and price of these materials, parts, products and services are affected by a variety of factors beyond our control, including the willingness of suppliers to sell into the medical device industry, changes in supply and demand, general economic conditions, labor costs, fuel- related transportation costs, liability concerns, climate change (including ~~new and~~ existing **and prospective** laws and regulations ~~to address climate change~~), competition, import duties, tariffs, currency exchange rates and political uncertainty around the world. During ~~2022~~ **2023** , we experienced significantly elevated commodity and supply chain costs, including the costs of labor, raw materials, energy, ~~fuel,~~ packaging materials and other inputs necessary for the production and distribution of our products **. Those** ~~, and we expect~~ elevated **costs may** ~~levels of inflation to~~ continue in ~~2023~~ **2024** ~~. Our suppliers often pass some of their cost increases on to us, and if such increased costs are sustained or increase further, our suppliers may pass further cost increases on to us~~ . In addition to the effect on resin prices, transportation costs have generally increased and may further increase if crude oil prices increase. Our transportation and service providers ~~are~~ typically ~~able to~~ pass any significant increases in oil prices on to us. Our ability to recover such increased costs may depend upon our ability to raise prices on our products. Due to the highly competitive nature of the healthcare industry and the cost- containment efforts of our customers and third- party payers, we may be unable to pass along cost increases through higher prices. If we are unable to ~~fully~~ recover these costs through price increases or offset these increases through cost reductions, or we experience terminations or interruption of our relationships with our suppliers, we could experience lower margins and profitability, and our ~~results of~~ **business,** operations ~~,~~ **or** financial condition ~~and cash flows~~ could be materially harmed. Changes in ~~general~~ economic **and** ~~conditions,~~ geopolitical conditions, domestic and foreign trade policies, monetary policies and other factors beyond our control may adversely impact our business ~~and~~ **,** ~~operating~~ **operations** ~~results~~ **and financial condition** . Our operations and performance depend significantly on global, regional and U. S. economic and geopolitical conditions. The global macroeconomic environment continues to be challenging due to the effects of ~~the COVID- 19 pandemic and government responses,~~ increases in inflation globally, instability in ~~the~~ global credit markets, ~~the impact of~~ uncertainty regarding global central bank monetary policy, ~~the~~ instability in the geopolitical environment in many parts of the world ~~(including~~ **, current economic challenges in China, and other factors. Periods of diplomatic or armed conflict, such** as ~~a result of~~ the ~~on- going~~ **ongoing** ~~Russia and~~ **conflict in** Ukraine ~~war~~ **, tensions in the Middle East** and China- Taiwan relations ~~), the current economic challenges in China, and other disruptions. Periods of intense diplomatic or armed conflict, such as the ongoing conflict inUkraine~~ , may result in (i) new and rapidly evolving sanctions and trade restrictions, which may impair trade with sanctioned individuals and countries, and (ii) negative impacts to regional trade ecosystems among our customers, partners, and us. Non- compliance with sanctions **,** as well as general ecosystem disruptions **,** could result in reputational harm, operational delays, monetary fines, ~~loss~~ **lost** ~~of~~ revenues, increased costs, ~~loss~~ **lost** ~~of~~ export privileges ~~,~~ or criminal sanctions. Furthermore, U. S. trade **policycould** ~~policy could~~ trigger retaliatory actions by other countries, including China, resulting in a " trade war. " A trade war could result in increased costs for raw materials we use in our manufacturing **,** ~~and could result in~~ foreign governments imposing tariffs on products that we export outside the U. S. or ~~otherwise limiting~~ **limitations on** our ability to sell our products abroad. These increased costs would have a negative effect on our financial condition and profitability. ~~Furthermore, if the conflict between Russia and Ukraine continues for a long period of time, or if other countries, including the U. S., become further involved in the conflict, we could face significant adverse effects to our business and financial condition. The occurrence of regional epidemics or a global pandemic, such as COVID- 19, may adversely affect our operations, financial condition, and results of operations. The COVID- 19 pandemic and governmental~~

~~responses have had widespread, rapidly evolving, and unpredictable impacts on global society, economies, financial markets, and business practices. The extent to which global pandemics impact our business going forward will depend on factors such as the duration and scope of the pandemic; governmental, business, and individuals' actions in response to the pandemic; and the impact on economic activity, including the possibility of recession or financial market instability.~~ The above factors, **as well as** ~~including a number of~~ other economic and geopolitical factors ~~both~~ in the U. S. and abroad, could ~~ultimately~~ have **a** material adverse ~~effects~~ **effect** on our business, **operations and** financial condition, ~~results of operations or cash flows,~~ including ~~the following~~ : ● ~~effects of significant~~ changes in economic, monetary and fiscal policies in the U. S. and abroad including currency fluctuations, inflationary pressures and significant income tax changes; ● **a** global ~~increases~~ **or regional economic slowdown** in ~~inflation~~ **any of our market segments** ; ● a **regional epidemic or a** global ~~or regional economic slowdown in any of our market segments~~ **pandemic, such as COVID- 19, and government and social responses** ; ● changes in government policies and regulations affecting the Company or its significant customers; ● ~~industrial~~ policies in various countries that favor domestic industries ~~over multinationals~~ or ~~that~~ restrict foreign companies ~~altogether~~ ; ● ~~new or stricter~~ trade policies and tariffs enacted by countries ~~, such as China,~~ in response to changes in U. S. trade policies and tariffs; ● postponement of spending, in response to tighter credit, financial market volatility and other factors; ● rapid ~~material~~ escalation of the cost of regulatory compliance and litigation; **and** ● **credit risks,** ~~difficulties protecting intellectual property; ●~~ longer payment cycles ~~; ● credit risks~~ and other challenges in collecting accounts receivable **. The military conflict between Russia and Ukraine, and the global response to it, has adversely affected, and will likely continue to adversely affect our 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 ~~of each of~~ the ~~foregoing~~ **conflict may have** on ~~outsourcing~~ **the global economy or our business, financial condition** and ~~procurement arrangements~~ **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 ~~, infrastructure~~ , manufacturing processes or information technology systems, or those of our suppliers, ~~including as a result of our facility consolidation initiatives,~~ could **have** ~~result in lost revenues and~~ **an adverse effect on** our business ~~could be seriously harmed~~ **, operations or financial condition** . Damage or interruption to our facilities or systems ~~relating to manufacturing, distribution, research and development, or information technology~~ because of fire, extreme weather conditions, natural disaster, power loss, communications failure, geopolitical disruption, labor strikes, riots, cyber-attack, health epidemics ~~and~~ **or** pandemics, unauthorized entry or other events could significantly disrupt our operations, the operations of suppliers and critical infrastructure. These events may also delay or prevent product manufacturing and shipment during the time required to repair, rebuild or replace the damaged facilities or systems. We have recently closed or reduced the operations of certain facilities and moved operations and resources to other facilities, and we are in the process of other facility consolidation initiatives. The resulting concentration of resources and the potential disruption and logistical challenges resulting from those initiatives may further exacerbate the adverse effects of these events or make it more difficult for us to respond to the effects of these events. Those initiatives may also divert the attention of our management team or other personnel, result in unanticipated expense and disrupt our operations. Climate change may increase both the frequency and severity of natural disasters and, ~~23consequently~~ **consequently** , risks to our operations and growth. Although we maintain property damage and business interruption insurance coverage on our facilities, our insurance might not cover all losses under such circumstances, and we may not be able to renew or obtain such insurance in the future on acceptable terms with adequate coverage or at reasonable costs. Consolidation in the healthcare industry, group purchasing organizations and public procurement policies have ~~lead~~ **led** to demands for price concessions, which **may** ~~reduces~~ **reduce** our revenues and ~~may~~ harm our ability to sell our products at prices necessary to support our current business strategies. ~~Healthcare~~ **21Healthcare** costs have risen significantly over the past decade, which has ~~resulted in or~~ led to numerous cost reform initiatives by legislators, regulators and third- party payers. Cost reform has triggered a consolidation trend in the healthcare industry to aggregate purchasing power, which has created more requests for pricing concessions and is expected to continue in the future. Additionally, many of our customers belong to group purchasing organizations or integrated delivery networks that use their market power to consolidate purchasing decisions for these hospitals and healthcare ~~service~~ providers. These customers are often able to obtain lower prices and more favorable terms because of the potential sales volume they represent, which has ~~lead~~ **led** to lower revenues and required us to take on additional liability. We expect that market demand, government regulation, third- party coverage and reimbursement policies and societal pressures will continue to change the healthcare industry worldwide, resulting in further business consolidations and alliances among our customers, which may exert further downward pressure on the prices of our products. We may be unable to compete in our markets, particularly if there is a significant change in ~~relevant~~ practices or technology. The markets in which our products compete are highly competitive. We face competition from many companies which are larger, better established, have greater financial, technical and other resources and possess a greater market presence than we do. Such resources and market presence may enable our competitors to more effectively market competing products or to market competing products at reduced prices in order to gain market share. In addition, our ability to compete successfully is dependent, in part, upon our response to changes in technology and upon our efforts to develop and market new products which achieve

significant market acceptance. ~~Competing companies~~ **Companies** with substantially greater resources than us are actively engaged in research and development of new methods, treatments, drugs, and procedures to treat or prevent cardiovascular disease that could limit the market for our products and eventually make some of our products obsolete. A reduction in the demand for ~~a significant number of our products, or~~ **our** ~~a few key~~ products, could have a material adverse effect on our business, operations or financial condition ~~. COVID- 19 RisksThe COVID- 19 pandemic and related ongoing implications have negatively impacted our business and operations around the world and may continue to materially and adversely impact our business, operations and financial results. The COVID- 19 pandemic and the resulting containment measures created significant disruption and uncertainty in the global economy and negatively impacted our business, results of operations and financial condition during 2020, 2021 and 2022. Although the impact of COVID- 19 and the resulting containment measures decreased during 2022, they have the potential to continue to negatively impact our business, results of operations and financial condition in the future. Numerous national, international, state and local jurisdictions imposed a variety of government orders and restrictions for their residents to control the spread of COVID- 19. In 2020, such orders and restrictions caused significant alterations of our operations, work stoppages, slowdowns and delays, travel restrictions and event cancellations, among other effects, thereby significantly and negatively impacting our financial condition. In 2021 and 2022, these conditions continued at varying levels. Other disruptions that we experienced include (i) restrictions on our personnel and personnel of business partners to travel and access customers for training and ease support ; (ii) supply chain delays and disruptions, logistical challenges and increased freight, transportation and other expenses; (iii) delays in regulatory approvals by governmental and regulatory bodies; (iv) reductions in spending by our customers; (v) diversion of or limitations on employee resources that would otherwise be focused on the operations of our business, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people ; (vi) fluctuations in the availability of employees and potential employees ; (vii) additional government requirements or other incremental mitigation efforts that 24may further impact our or our suppliers' capacity to manufacture our products; (viii) disruption of our research and development activities; and (ix) delays in ongoing studies and pre- clinical trials. Although some of these disruptions diminished in 2021 and the impact lessened further during 2022, they may again return or further intensify their effect on our operations, whether as a direct result of COVID- 19 or other factors exacerbated by the effects of COVID- 19. In addition, elective procedures that use our products significantly decreased in number during much of 2020 as health care organizations around the world prioritized the treatment of patients with COVID- 19 and reduced spending in other areas. For example, in the United States, governmental authorities recommended, and in certain cases required, that elective, deferrable, specialty and other procedures and appointments (many of which use our products), be suspended or canceled to avoid non- essential patient exposure to medical environments and potential infection with COVID- 19 and to focus limited resources and personnel capacity toward the treatment of COVID- 19 patients. In 2021, these procedures resumed in many locations, and overall, we saw significant improvement in our business during 2021. We saw further improvement in the availability of elective procedures during 2022. It is possible, however, that a resurgence of COVID- 19, or increased spread of its variants, could again cause a rise in severe infections and force authorities and customers to impose restrictions that would negatively impact our operations. All of these factors have also caused or contributed to disruptions and delays in our logistics and supply chain, and we may continue to experience these disruptions and delays. The full extent to which COVID- 19 and resulting containment measures impact our business, operations and financial results will depend on future developments that are uncertain and cannot be predicted, including new information that may emerge concerning the severity and spread of the virus and its variants. To the extent COVID- 19 (including existing variants and any new variants) and resulting containment measures continue to adversely affect our business, operations and financial results, they may also have the effect of heightening other risks described herein, such as those relating to general economic conditions, demand for our products, relationships with suppliers and sales efforts .** Strategic, Business Development and Employee Attraction and Retention 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 the Company grows, we are often faced with decisions to (i) expand certain product lines and discontinue others, (ii) open or expand new facilities and close others, (iii) allocate resources between new and established markets, or (iv) allocate resources between the expansion of organic business and the acquisition of new product lines. The outcome of each of these decisions is uncertain, and even with the exercise of excellent business judgment, results may not align with expectations because of the many factors listed in this section. In addition, our management will need to continue to implement changes in certain aspects of our business, improve our information systems, infrastructure and operations to respond to increased demand, attract and retain qualified personnel, and develop, train, and manage an increasing number of employees. We may not have the resources available to implement certain necessary changes, and as a result, growth may be delayed or we may not be able to take advantage of certain business opportunities. Growth has placed, and will likely continue to place, an increasing strain on our management, sales and other personnel, and on our financial, product design, marketing, distribution, technology and other resources. Any failure to manage growth effectively could have a material adverse effect on our business, operations or financial condition. **We may incur** ~~Substantial~~ **substantial** costs ~~are incurred~~ when ~~identifying,~~ 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 have completed a series of **strategic acquisitions and transactions, some of which have been** significant ~~acquisitions and~~ , **and** continue to evaluate other potential acquisitions and ~~strategic~~ transactions, certain of which may also be significant. We have incurred, and will likely continue to incur, significant expenses in connection with evaluating, negotiating and consummating various acquisition and other ~~strategic~~ transactions. As we grow through acquisitions, we face the additional challenges of integrating the operations, culture, ~~information management~~ systems and other characteristics of the acquired ~~entity~~ **enterprises** with our own ~~, including sales models related to capital equipment~~ . Our efforts to integrate acquisitions **and transactions** may be hampered by delays,

the loss of certain employees, suppliers or ~~25customers~~ -- **customers** , proceedings resulting from employment terminations, culture clashes, unbudgeted costs, and other issues, which may occur at levels that are more severe or prolonged than anticipated. ~~Additionally~~ **22Additionally** , 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 sales personnel and limited expertise. Further, as a result of certain acquisitions, we are selling capital equipment, in addition to our historical sales of disposable medical devices. The sale of capital equipment may create additional risks and potential liability, which may negatively affect our business, operations or financial condition. In addition, we may not realize competitive advantages, synergies or other benefits anticipated in connection with any such acquisition or other transaction. If we do not adequately identify and value targets for, or manage issues related to, acquisitions and ~~strategic~~ **other** transactions, such transactions may not produce the anticipated benefits and have an adverse effect on our business, operations or financial condition. We have incurred expenses in connection with the disposition of businesses and assets which we acquired but determined that they did not produce the benefits contemplated at the time of acquisition. We may incur similar expenses in the future. ~~We~~ **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 to develop new products 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 we are preparing for launch, now developing or that we may seek to develop in the future,** will **achieve technological feasibility** ~~be required to expend significant resources for research~~ , **obtain** ~~development, testing and~~ regulatory approval or ~~clearance of~~ **gain market acceptance. If we are unable to develop and launch new products and enhanced products, our ability to maintain** ~~our~~ - **or** ~~products under~~ **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 ™ 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** ~~may not be developed successfully or approved for commercial use. Most of our products under~~ development **timelines or growth projections** ~~will require significant additional research~~ , **poor** ~~development, engineering and, in some cases, preclinical and~~ clinical ~~testing~~ **outcomes** , **increasing** ~~as well as regulatory approval or clearance and a commitment of significant additional resources prior to their commercialization. It is possible that our products may not: ● be developed successfully; ● be proven safe or effective in clinical trials; ● offer therapeutic or other improvements over current treatments and products; ● meet applicable regulatory standards or receive regulatory approvals or clearances; ● be capable of production in commercial quantities at acceptable costs and in compliance with~~ regulatory requirements ~~; ● be successfully~~ **, launch delays and inability to effectively scale manufacturing and achieve** ~~marketed~~ **targeted** ~~;~~ **margins with respect to any of these products or groups of products in particular may adversely impact** ~~or~~ **our business, operations and financial condition** ~~● be covered by private or public insurers~~ . We may be unable to accurately forecast customer demand for our products and manage our inventory. To ensure adequate supply, we must forecast our inventory needs and place orders with our suppliers based on estimates of future demand for particular products. Our ability to accurately forecast demand for our products could be negatively affected by many factors, including our failure to accurately manage our ~~expansion~~ **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, ~~effects of COVID- 19~~ or decreased consumer confidence ~~in future economic conditions~~ . Inventory levels in excess of customer demand may result in inventory write- downs or write- offs, which would impact our gross margin. Conversely, if we underestimate customer demand ~~for our products~~ , our manufacturing facilities may not be able to deliver products to meet our order requirements, which could damage our reputation and customer relationships. ~~Our forecasts of customer demand and related decisions that we make about production levels may take into account potential opportunities created by regulatory issues, supply disruptions or other challenges experienced by our competitors.~~ We ~~generally~~ do not **maintain** ~~know the extent and cannot predict the duration of these challenges experienced by our competitors. As a result, our estimates about related increased demand for our products are inherently uncertain and subject to change. If our estimates incorrectly forecast the extent or duration of this increased demand, or the product types to which it relates, our revenues, margins and earnings could be adversely affected. 26We lack~~ direct sales and marketing capabilities in many countries and are dependent on our distributors for the commercialization of our products in ~~these~~ **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 ~~any of~~ our products in those countries. We have no or limited direct sales or marketing capabilities in some of the regions and countries in which our products are sold, including, among others, China, Japan, ~~Russia~~ and India. We have entered into distribution agreements with third parties to market and sell our products in those countries in which we do not have a direct sales force and in those countries in ~~which~~ **23which** we utilize a " modified direct " sales approach. If we are unable to ~~maintain or~~ enter into **or maintain** such distribution arrangements on acceptable terms ~~, or at all~~ , we may not be able to successfully commercialize our products in certain countries. Moreover, to the extent that we enter into distribution arrangements with other

companies, our revenues, if any, will depend on the terms of any such arrangements and the efforts of others. These efforts may turn out not to be sufficient and our third- party distributors may not effectively sell our products **or may choose to instead sell competing products** . In addition, although our contract terms require our distributors to comply with ~~all~~ applicable laws regarding the sale of our products, including anti- competition, anti- corruption, anti- money laundering and sanctions laws, we may not be able to ensure proper compliance. If our distributors fail to effectively market and sell our products in ~~full~~ compliance with applicable laws, our results of operations and business could be impacted. We are dependent upon key personnel **and have announced the anticipated retirement of our Chief Executive Officer** . Our success is dependent on key management personnel, including Fred P. Lampropoulos, our Chairman of the Board, President and Chief Executive Officer. **We** ~~Mr. Lampropoulos is not subject to any agreement prohibiting his departure, and we~~ do not maintain key man life insurance on ~~his life~~ **Mr. Lampropoulos** . The loss of Mr. Lampropoulos, or of certain other key management personnel, could have a materially adverse effect on our business ~~and~~ **,** operations **and financial condition. We have announced that a committee of our independent directors is developing and will oversee a succession plan in preparation for Mr. Lampropoulos' retirement, which we currently anticipate will occur 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, 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 ~~success~~ **technical, sales, marketing and other specialized personnel** also **play** ~~depends on, among other factors, the successful recruitment and~~ ~~retention~~ **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** ~~operating, manufacturing, sales and other personnel~~ . 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 ~~caused~~ **negatively impacted** , and are likely to continue to ~~cause~~ **negatively impact** our sales ~~to decline~~ in such countries. ~~These regulations~~ **Regulations** and **trade** policies **implemented by foreign governments have** ~~result~~ **resulted** in increased costs, lower margins and lower sales than we **had forecast** ~~would otherwise expect~~ , ~~which~~ **and** have ~~a material~~ **had an** adverse effect on our business ~~, financial condition, results of operations, or cash flows~~ . Our customers and suppliers may also be affected by these events **. Thus** , ~~so~~ even if we are not directly impacted **by these regulations and policies** , we may still experience lower demand for our products ~~and~~ **,** 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 ~~a volume- based procurement process designed to~~ **the VBP policy which has the specific aim of** ~~decrease~~ **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** ~~other~~ -- **the** ~~products. This~~ **application of the VBP tender** process ~~has had~~ **, 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 ~~our revenues in China and we expect it will continue to cause a decrease in~~ 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** . The FDA regulatory clearance process is expensive, time-consuming and uncertain, and the failure to obtain and maintain required regulatory clearances and approvals could prevent us from commercializing our products. Before we can introduce a new device or a new use of or a claim for ~~a cleared~~ **an existing** device in the U. S., we must generally obtain clearance from the FDA, unless an exemption from premarket review or an alternative procedure, such as a de novo risk- based classification or a humanitarian device exemption, applies. The FDA clearance and approval processes for medical devices are expensive, ~~uncertain and~~ time- consuming **and uncertain** . ~~We~~ **24We** may make changes to our cleared ~~products~~ **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 pay significant regulatory fines or penalties. In addition, the FDA may not approve or clear our products for the indications that are necessary or desirable for successful commercialization. ~~In particular, we are currently conducting a large, multinational pivotal human clinical trial of the Wrapsody Endoprosthesis. A successful outcome of this trial is required to obtain approval from the FDA and some international 27regulatory agencies. However, there is no assurance that we will be able to obtain the necessary regulatory clearances or approvals for the Wrapsody Endoprosthesis or any other products on a timely basis or at all.~~ Further, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared products on a timely basis. Delays in receipt of, or failure to obtain, regulatory clearances for any product enhancements or new products we develop would result in delayed or no realization of revenue from such product enhancements or new products and in substantial additional costs, which could decrease our profitability. In addition, we are required to continue to comply with applicable FDA and other regulatory requirements once we have obtained clearance or approval for a product **, including good manufacturing practices, timely adverse event reporting and 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 ~~generally~~ subject to ~~regulatory~~ **regulation** ~~requirements~~ in foreign countries in which we sell them. We have ~~experienced delays and~~ expended significant resources **and experienced delays** in obtaining ~~those~~ **foreign** approvals and clearances and we will likely continue to **incur significant expense, and** experience delays and uncertainty, **as we seek to** ~~and incur significant expenses, in obtaining~~ --- **obtain** ~~those~~ **further** approvals or clearances. In order to sell our products in foreign countries, generally we must obtain regulatory approvals and comply with ~~the~~ **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 ~~EU~~ **E. U.** ahead of expiry dates; however for multiple reasons, including but not limited to changing business strategies, limited labor pool and contract resources, administrative delays, increased costs of obtaining MDR certification, availability of necessary data and notified body capacity, there will be some products that will not be fully compliant at the time of expiry. The additional time and resources required to obtain MDR certification has been a significant factor in, and will likely continue to influence, our decisions to discontinue sales and distribution of certain products in the ~~EU~~ **E. U** . 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 ~~operating profits~~ **financial results** from our international operations **. Some of our products are subject to clinical trials and other analyses, the results of which may be unexpected, or perceived as unfavorable by the market, and could have a material adverse effect on our business, operations or financial condition. As a part of the regulatory process of obtaining marketing clearance 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. 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 will necessitate clinical trials and other analyses relating to many of these therapeutic products. In particular, we are currently conducting a large, multinational pivotal human clinical trial of the Wrapsody Endoprosthesis. A successful outcome of this trial is required to obtain approval from the FDA and some international regulatory authorities. However, there is no assurance that we will be able to obtain the necessary regulatory clearances or approvals for the Wrapsody Endoprosthesis or any other products on a timely basis or at all** . 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 ~~governmental~~ authorities. These authorities and domestic and foreign legislators continue to scrutinize the medical device industry. In recent years, the U. S. Congress, DOJ, OIG, SEC and the Department of Defense, as well as foreign counterparts, have issued subpoenas and other requests for information to medical device manufacturers, primarily related to financial arrangements with healthcare providers, regulatory compliance and product promotional practices. In October 2020, we entered into a Settlement Agreement with the DOJ to resolve their investigation into our past marketing transactions and practices. Under the Settlement Agreement and related agreements, we paid $ 18. 7 million (which includes interest and certain fees) in exchange for a release from liability for the alleged conduct. The settlement was also conditioned upon our entering into the CIA. Please refer to the discussion in Item 1. " Business- Regulation- Corporate Integrity Agreement. " Even if we fully comply with the CIA, we have incurred, and anticipate that we will continue to incur, substantial costs in connection with the settlement and compliance with the CIA. It is unclear what impact the settlement has had and may have on our reputation. This matter has consumed a significant amount of our resources and management' s attention. ~~28We~~ **We** anticipate that government authorities will continue to scrutinize our industry closely, and that additional regulation by government authorities may increase compliance costs, exposure to litigation and other adverse effects on our operations. If we fail to comply with applicable regulatory requirements, including the terms of the CIA, we may be subjected to a wide variety of sanctions and enforcement actions, including warning letters that require corrective action, injunctions, product seizures or recalls, suspension of product manufacturing, revocation of approvals, import or export prohibitions, exclusion from participation in government healthcare programs, civil fines and / or criminal penalties, which in turn may have a negative impact on our business, results of operations, financial condition and ability to obtain financing on reasonable terms. We are subject to laws targeting fraud and abuse in the healthcare industry, the violation of which could adversely affect our business **, operations** or financial ~~results~~ **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 ~~fraud and abuse- related~~ laws are punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in healthcare programs such as Medicare and Medicaid, any of which could harm our business or negatively impact our financial results. Allegations of such violations could lead to expensive

and time- consuming investigations by government authorities and result in conviction of these violations or settlement costs and additional restrictions, like the CIA discussed above under Item 1. " Business- Regulation- Corporate Integrity Agreement. " Furthermore, our contracts with government- sponsored healthcare entities are subject to specific procurement requirements. Failure to comply with applicable rules or regulations or with contractual or other requirements may result in monetary damages and criminal or civil penalties as well as termination of our government contracts or our suspension or debarment from government contract work. **26We are** ~~Our international operations make us~~ subject to the U. S. Foreign Corrupt Practices Act and similar anti- bribery laws in non- U. S. jurisdictions, and our failure, or the failure of our distributors ~~and~~ **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 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, ~~results of~~ operations ~~,~~ **or** financial condition ~~or cash flows~~ . Limits on reimbursement imposed by governmental and other programs may adversely affect our business and results of operation. We sell our products to hospitals and other healthcare providers around the world that typically receive reimbursement for the services provided to patients, which incorporate the use of our products, from third- party payers such as government programs (e. g., Medicare and Medicaid in the U. S.) and private insurance programs. The ability of our customers to obtain adequate reimbursement for the health care procedures that use our products, such that the cost of our products is covered, is critical to our business. Limits on reimbursement imposed by such third- party payers may adversely affect our ~~29customers~~ -- **customers** , such as hospitals, physicians and other healthcare providers, to purchase our products, which could adversely affect our business and results of operations. Third- party payers, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In general, a third- party payer covers a medical procedure only when the plan administrator is satisfied that the product or procedure is reasonable and necessary to the patient' s treatment; however, for certain payers (such as foreign governments and some commercial insurers) the cost- effectiveness of the treatment may also be a condition. In addition, in the U. S., no uniform policy of coverage and reimbursement for procedures using our products exists among third- party payers. Therefore, coverage and reimbursement for procedures using our products can differ significantly from payer to payer and, in some cases, jurisdiction to jurisdiction. In addition, payers continually review new and existing technologies for possible coverage and can, without notice, deny, change or reverse coverage decisions or alter prior authorization requirements for new or existing products and procedures. We cannot provide assurance that we will be successful in any efforts we may potentially undertake to reverse such non- coverage or unfavorable coverage decisions. If we are not successful in reversing non- coverage or unfavorable coverage policies, or if third- party payers that currently cover or reimburse certain procedures involving the use of our products reverse, change or limit their coverage of such procedures in the future, or if other third- party payers issue similar policies or adopt similar practices, our business **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 ~~complex and~~ evolving **domestic** ~~U. S., state~~ and ~~international~~ **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. ~~The~~ **27The** U. S. and many other countries in which we **operate** ~~conduct our operations~~ have adopted laws and regulations protecting certain data, including medical and personal data (including HIPAA, the HITECH Act and the rules issued thereunder), and requiring data holders and controllers to implement administrative, logical and technical controls and procedures in order to protect the privacy of such data. Individual states have also begun to enact data privacy laws giving consumers the right to demand certain information and actions from companies who collect personal information. Internationally, some countries have also passed laws and regulations that require individually identifiable data on their citizens to be maintained on local servers and that may restrict transfer or processing of that data. In addition, regulatory authorities around the world are considering additional proposals concerning data protection. These laws and regulations have been, and may continue to be, inconsistent with each other, requiring different approaches in different jurisdictions. In addition, the interpretation and application of medical and personal data protection laws and regulations in the U. S., Europe, China and elsewhere are often uncertain and in flux. Further, we have incurred, and will likely continue to incur, significant expense in connection with our efforts to comply with those applicable laws and regulations. It is possible that these laws and regulations may be interpreted and applied in a manner that is inconsistent with our data practices, **may** ~~resulting~~ --- **result** in **significant liability,** fines or orders requiring that we change our data practices, which could **,** in turn **,** ~~(i)~~ cause us to incur substantial costs **and** ~~or (ii)~~ have ~~an~~ **a materially** adverse effect on our business . Legal developments in foreign countries have..... and reductions in our margins and profitability . Use of our products in unapproved circumstances could expose us to liabilities. The marketing clearances and approvals from the FDA and other ~~regulators~~ **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. 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** ~~enforcement agencies~~ that we are not in compliance with applicable laws or regulations or have improperly promoted our products for uncleared or unapproved uses. The FDA or such other ~~agencies~~ **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. ~~Our~~ **The design, manufacture and marketing of medical devices involves various risks. Frequently, our** products are used in connection with invasive procedures and in other medical contexts that entail an inherent risk of product liability claims. If medical personnel or their patients suffer injury or death in connection with the use of our products, whether as a result of a failure of our products to function as designed, an inappropriate design, inadequate disclosure of product- related risks or information, improper use, or for any other reason, we could be subject to lawsuits seeking significant compensatory and punitive damages. Product liability claims may be brought by individuals or by groups seeking to represent a class. We have previously faced, and currently face, claims by patients claiming injuries from our products. To date, these claims have not ~~resulted in~~ **had a** material ~~harm to~~ **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 ~~31coverage~~ -- **coverage** in the future. As a result, any lawsuit seeking significant monetary damages may have a material adverse effect on our business, operations or financial condition. We generally offer a limited warranty for the return of product due to defects in quality and workmanship. We attempt to estimate our potential liability for future product returns and establish reserves on our financial statements in amounts that we believe will be sufficient to address our warranty obligations; however, our actual liability for product returns may significantly exceed the amount of our reserves. If we underestimate our potential liability for future product returns, or if unanticipated events result in returns that exceed our historical experience, our financial condition and operating results could be materially harmed. In addition, the occurrence of such an event or claim could result in a recall of products from the market or a safety alert relating to such products. Such a recall could result in significant costs, reduce our revenue, divert management' s attention from our business, and harm our reputation. ~~Our~~ **28Our** ~~products may cause or contribute to adverse medical events that we are required to report to the FDA or other governmental authorities, and if we fail to do so, we may be subject to sanctions that may materially harm our business. Our products are subject to medical device reporting regulations, which require us to report to the FDA information that reasonably suggests one of our products may have caused or contributed to a death or serious injury, or one of our products malfunctioned and, if the malfunction were to recur, this device or a similar device that we market would be likely to cause or contribute to a death or serious injury. Our obligation to report under the medical device reporting regulations is triggered on the date on which we become aware of information that reasonably suggests a reportable adverse event occurred. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or if the product characteristic that caused the adverse event is removed in time from our products. Inspections by the FDA or other regulators may reveal violations or instances of noncompliance under the QSRs and other post- market requirements. If we fail to comply with our medical device reporting obligations or commit a violation of these requirements, the FDA could issue warning letters or untitled letters, take administrative actions, commence criminal prosecution, impose civil monetary penalties, demand or initiate a product recall, seize our products, or delay the clearance of our future products. Other regulatory authorities could take similar actions within their jurisdictions. Our~~ employees, independent contractors, consultants, manufacturers and distributors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk that our employees, independent contractors, consultants, manufacturers and distributors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct, or unauthorized activities that violate the healthcare laws and regulations of the FDA and other federal, state and international authorities, manufacturing standards, and laws that require the true, complete and accurate reporting of financial information or data. We have adopted a code of business conduct and ethics, and a global anti- corruption policy, but it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties. We ~~may be~~ **are routinely** a party to litigation ~~in the course of our business or otherwise~~ , which could affect our financial condition and results of operations. We are routinely a party **, 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 **time- consuming** ~~take many months, or even years, to reach resolution~~ , with the final outcome depending on a number of variables, some of which are **beyond** ~~not within~~ our control. Litigation is subject to significant uncertainty and may be expensive, time- consuming, and disruptive to our operations. Although it is our intention to

vigorously defend ourselves in such legal proceedings, their ultimate resolution and potential financial and ~~32other~~ **other** impacts on us are uncertain. If a legal proceeding is resolved against us, it could result in significant compensatory damages or injunctive relief that could materially **and** adversely affect our financial condition ~~,~~ **and** results of operations **.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 ~~hazardous~~ materials that are subject to **domestic** ~~various national,federal,state~~ and ~~local~~ **foreign** laws and regulations governing the protection of the environment,health and safety.Moreover, **existing** ~~climate change~~ and ~~sustainability efforts~~ **prospective environmental,health** and ~~potential climate change~~ **safety laws and** ~~regulations~~ **regulation** could lead to business interruption, ~~significantly~~ increased costs and other adverse consequences to our business. ~~While the cost of compliance~~ **Compliance** ~~with such laws and regulations has not had a material adverse effect on our results of operations historically,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 ~~all~~ applicable laws at the time the acts were performed,rendering us liable without regard to our negligence or fault.Because of these **laws,the composition of our products and packaging or any accidental release may have** ~~and~~ **an** ~~cash flows~~ **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 29regulations. 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 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. 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, increased liabilities and decreased revenues than what we have experienced 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 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 ~~effectively~~ protect our intellectual property, which could harm our business and financial condition. Our ability to remain competitive is dependent, in part, upon our ability to protect our intellectual property rights and prevent other companies from infringing our intellectual property rights to produce competing products. We seek to protect our intellectual property rights through a combination of confidentiality and license agreements, maintaining ~~certain~~ trade secrets, and through registrations under patent, trademark, and copyright laws. However, these measures afford only limited protection and may be

challenged, invalidated, or circumvented by third parties. Additionally, these measures may not prevent competitors from duplicating our products or gaining access to our proprietary information and technology. Third parties may copy all or portions of our products or otherwise use our intellectual property without authorization, and we may not be able to prevent the unauthorized disclosure or use of our intellectual property by consultants, vendors ~~,~~ **and** former ~~employees~~ and current employees. Despite our efforts to restrict such unauthorized disclosure or use through nondisclosure agreements and other contractual restrictions, we may not be able to enforce these contractual provisions or we may incur substantial costs enforcing our legal rights. ~~Third~~ **30Third** parties may also develop similar or superior technology independently or by designing around our patents. In addition, the laws of some foreign countries do not offer the same level of protection for our intellectual property as the laws of the U. S. Further, no assurances can be given that any patent application we have filed or ~~will~~ **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 lawsuits that we might initiate could be expensive, ~~take significant~~ 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 ~~33rights~~ -- **rights** of others. We have made and expect to continue making significant expenditures to investigate, defend and settle claims related to the use of technology and intellectual property rights as part of our strategy to manage this risk. Information Technology and Cybersecurity 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 and customer relationships. We rely on information technology systems (including technology from third- party providers) to process, transmit, and store electronic information in our day- to- day operations, including sensitive personal information and proprietary or confidential information. We also rely on our technology infrastructure, among other functions, to interact with customers and suppliers, fulfill orders and bill, collect and make payments, ship products, provide support to customers, fulfill contractual obligations and otherwise conduct business. Our internal information technology systems, as well as those systems maintained by third- party providers, may be subjected to **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 ~~more sophisticated and frequent~~ **increasingly difficult to detect** , ~~and~~ **especially as they relate to attacks on third- party providers or** ~~there~~ **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. There** can be no assurance that our protective measures ~~have~~ **31have** 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** ~~third- party systems~~ could ~~also~~ 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 ~~, as a result,~~ may face risks associated with defects and vulnerabilities in the systems operated by the other parties to those transactions, or difficulties or other breakdowns or disruptions in connection with the integration of the acquired businesses and products into our information technology systems. Cyber- attacks could also result in unauthorized access to our systems and products, including personal information of individuals, which could trigger notification requirements, encourage actions by regulatory

bodies, result in adverse publicity, prompt us to offer credit support products or services to affected individuals and lead to class action or other civil litigation. If we fail to monitor, maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to these systems, we could (i) lose customers, (ii) be subject to fraud, (iii) breach our agreements with or duties toward customers, physicians, other health care professionals and employees, (iv) be subject to regulatory sanctions or penalties, (v) incur expenses or lose revenues, (vi) sustain damage to our reputation, or (vii) suffer other adverse consequences. Unauthorized tampering, adulteration or interference with our products may also create issues with product functionality that could result in a loss of data, risk to patient safety, and product recalls or field actions. Any of these events could have a material adverse effect on our business, operations or financial condition. **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 ~~July 31~~ **June 6** , ~~2019~~ **2023,** we entered into a ~~Third~~ **Fourth** Amended and Restated Credit Agreement (**" Fourth Amended Credit Agreement "), with Wells Fargo Bank, National Association, and other financial institutions named therein. The Fourth Amended Credit Agreement amends and restates in its entirety our previously outstanding Third Amended and Restated Credit Agreement and all amendments thereto (the** " Third Amended Credit Agreement ") ~~, with Wells Fargo Bank, National Association, as administrative agent and a lender, and Wells Fargo Securities, LLC, BOFA Securities, Inc., HSBC Bank USA, National Association, and U. S. Bank National Association as joint lead arrangers and joint bookrunners, and Bank of America, N. A., HSBC Bank USA, National Association and U. S. Bank National Association as co- syndication agents. In addition, Bank of America, N. A., HSBC Bank USA, National Association, U. S. Bank, National Association, BMO Harris Bank, N. A., and MUFG Union Bank, Ltd. are parties to the Third Amended Credit Agreement as lenders. The Third Amended Credit Agreement amends and restates in its entirety our previously outstanding Second Amended and Restated Credit Agreement and all amendments thereto (the " Second Amended Credit Agreement "). The Third Amended Credit Agreement contains a number of significant covenants that 34could adversely affect our ability to operate our business, our liquidity or our results of operations. These covenants restrict, among other things, our incurrence of indebtedness, creation of liens or pledges on our assets, mergers or similar combinations or liquidations, asset dispositions, repurchases or redemptions of equity interests or debt, issuances of equity, payment of dividends and certain distributions and entry into related party transactions~~ . We have pledged substantially all of our assets as collateral for the ~~Third~~ **Fourth** Amended Credit Agreement. Our breach of any covenant in the ~~Third~~ **Fourth** Amended Credit Agreement, not otherwise cured, waived or amended, could result in a default under that agreement and could trigger acceleration of the underlying obligations. Any default under the ~~Third~~ **Fourth** Amended Credit Agreement could adversely affect our ability to service our debt and to fund our planned capital expenditures and ongoing operations. The administrative agent, joint lead arrangers, joint bookrunners and lenders under the ~~Third~~ **Fourth** Amended Credit Agreement have available to them the remedies typically available to lenders and secured parties, including the ability to foreclose on the collateral we have pledged. It could lead to an acceleration of indebtedness and foreclosure on our assets. **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 mature on February 1, 2029, unless earlier repurchased, redeemed or converted in accordance with their terms prior to such date. The Fourth Amended 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, payment of dividends and certain distributions and entry into related party transactions.** As currently amended, the ~~Third~~ **Fourth** Amended Credit Agreement provides for potential borrowings of up to $ ~~750~~ **850** million. Such increased borrowing limits may make it more difficult for us to comply with leverage ratios and other restrictive covenants in the ~~Third~~ **Fourth** Amended Credit Agreement. We may also have less cash available for operations and investments in our business, as we will be required to use additional cash to satisfy the minimum payment obligations associated with this increased indebtedness. **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 Fourth Amended 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 have not identified specific acquisitions or other uses for a significant portion of the proceeds from the sale of the Convertible Notes or borrowed funds under the Fourth Amended 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 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, our total outstanding indebtedness under the Convertible Notes and the Fourth Amended Credit Agreement was $ 846. 6 million. Under the terms of the Fourth Amended Credit Agreement, we are potentially able to borrow up to $ 626 million in additional funds, which could result in total indebtedness under the Convertible Notes and Fourth Amended Credit Agreement of $ 1, 473 million. We depend on ~~generating sufficient cash flow to fund our debt obligations, capital expenditures, and ongoing operations. We are dependent on~~ our cash on hand and free cash flow **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 **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** market price of our common stock has been and may continue to be volatile. The market price of our common stock has at times, been, and may in the future be, volatile for various reasons, including those discussed in these risk factors. Other events that could cause volatility in our stock include, without limitation, variances in our financial results; analysts' and other projections or recommendations regarding our common stock specifically or medical technology stocks generally; any restatement of our financial statements or any investigation of us by the SEC, DOJ, OIG, FDA, or another regulatory authority; actions taken by activist investors or other shareholders, significant litigation or a decline, or rise, of stock prices in capital markets generally. **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 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. ~~As~~ **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** ~~grown outside the U. S., we have also become increasingly subject~~ to ~~market risk relating to~~ **be adversely affected by fluctuations in** foreign currency **exchange rates. These 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 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 **2023,** 2022 ~~,~~ **and** 2021 ~~and 2020~~ , the exchange rate between all applicable foreign currencies and the U. S. Dollar resulted in a decrease in net sales of $ **6. 4 million, a decrease in net sales of $** 23. 8 million, **and** an increase in net sales of $ 10 ~~. 3 million, and a decrease in net sales of $ 1~~ . 3 million, respectively. For the year ended December 31, ~~2022~~ **2023** , $ ~~394~~ **423** . ~~1~~ **4** million, or ~~34~~ **33** . ~~2~~ **7** %, of our net sales were denominated in foreign currencies, with our ~~CNY~~ **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. ~~35~~ **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.