Risk Factors Comparison 2024-02-12 to 2023-02-13 Form: 10-K

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Our business and assets are subject to varying degrees of risk and uncertainty. An investor should carefully consider the risks described below, as well as other information contained in this Annual Report on Form 10- K and in our other filings with the SEC. Additional risks not presently known to us or that we currently deem immaterial may also adversely affect our business. If any of these events or circumstances occurs, our business, financial condition, results of operations, or prospects could be materially harmed. In that case, the value of our securities could decline and an investor could lose part or all of his or her investment. In addition, forward- looking statements within the meaning of the federal securities laws that are contained in this Annual Report on Form 10- K or in our other filings or statements may be subject to the risks described below as well as other risks and uncertainties. Please read the cautionary notice regarding forward- looking statements in Part I above. Please note that the headers and summary provided below are only intended to assist the reader in navigating the risk factors; some risks, present or future, may implicate multiple types of risks. Please read all risk factors in their entirety. Summary of Risk Factors ~~We group our risk factors into three principal sections: (1) Business and Operating Risks; (2) Market and Other External Risks and (3) Legal, Compliance and Regulatory Risks.~~ The following summarizes the principal risks and uncertainties affecting our business, financial condition, and results of operations. This summary should not be relied upon as an exhaustive summary of the material risks facing our business and you should read this summary together with the more detailed description of risks and uncertainties discussed below. **Business and Operating Risks** • Failure to successfully innovate and market products • Unsuccessful clinical trials or procedures • Manufacturing, logistics, or quality problems • Public health crises, including pandemics and epidemics • Competition • Dependence on key physicians and research institutions • Reliance on vendors, suppliers, and other third parties • Damage, failure, or interruption of our information technology systems, including due to cyber- based attacks and breaches • Failure to recruit and retain qualified talent or execute management succession plans • Underperforming operations or unsuccessful business acquisitions or strategic alliances • Risks **related to the spin- off of our Critical Care product group Market and Other External Risks • Risks** associated with international sales and operations • Inability to obtain government reimbursement or reductions in reimbursement levels • Industry consolidation **Legal, Compliance and Regulatory Risks** • Inability to protect our intellectual property • Inability to defend against intellectual property claims from third parties • Compliance with government regulations • Losses from product liability claims • Use of products in unapproved circumstances • Substantial costs from environmental, health and safety regulations • Climate change • Regulatory actions relating to animal **-** borne illnesses Failure to successfully innovate and develop new and differentiated products in a timely manner and effectively market these products could have a material effect on our prospects. Our continued growth and success depend on our ability to innovate and develop new and differentiated products in a timely manner and effectively market these products. Without the timely innovation and development of products, our products could be rendered obsolete or less competitive because of the introduction of a competitor' s newer technologies or changing customer preferences. Innovating products requires the devotion of significant financial and other resources to research and development activities; however, there is no certainty that the products we are currently developing will complete the development process, or that we will obtain the regulatory or other approvals required to market such products in a timely manner or at all. Even if we timely innovate and develop products, our ability to successfully market them could be constrained by a number of different factors, including competitive products and pricing, barriers in ~~patients~~ **patient activation** ~~treatment pathway~~ (including disease awareness, detection, and diagnosis), the need for regulatory clearance, restrictions imposed on approved indications, and uncertainty over third- party reimbursement. Failure in any of these areas could have a material effect on our prospects. Unsuccessful clinical trials or procedures relating to products could have a material adverse effect on our prospects. The regulatory approval process for new products and new indications for existing products requires extensive clinical trials and procedures, including early clinical feasibility and regulatory studies. Unfavorable or inconsistent clinical data from current or future clinical trials or procedures conducted by us, our competitors, or third parties, or perceptions regarding this clinical data, could adversely affect our ability to obtain necessary approvals and the market' s view of our future prospects. Such clinical trials and procedures are inherently uncertain and there can be no assurance that these trials or procedures will be enrolled or completed in a timely or cost- effective manner or result in a commercially viable product or indication; failure to do so could have a material adverse effect on our prospects. Clinical trials or procedures may experience significant setbacks even after earlier trials have shown promising results. Further, preliminary results from clinical trials or procedures may be contradicted by subsequent analyses. In addition, results from our clinical trials or procedures may not be supported by actual long- term studies or clinical experience. If preliminary clinical results are later contradicted, or if initial results cannot be supported by actual long- term studies or clinical experience, our business could be adversely affected. Clinical trials or procedures may be delayed, suspended, or terminated by us, the FDA, or other regulatory authorities at any time if it is believed that the trial participants face unacceptable health risks or any other reasons, and any such delay, suspension, or termination could have a material adverse effect on our prospects or the market' s view of our future prospects. If we or one of our suppliers or logistics partners encounters manufacturing, logistics, **safety,** or quality problems, our business could be materially adversely affected. The manufacture and sterilization of many of our products is highly complex due in part to rigorous regulatory requirements. Quality is extremely important due to the serious and costly consequences of a product failure **. Safety is also critically important** . Problems can arise for a number of reasons, including disruption of facility utilities, equipment malfunction, failure to follow protocols and procedures, raw material problems, software problems, cyber incidents, or human error. Disruptions can occur at

any time, including during production line transfers and expansions. Disruptions can also occur if our manufacturing and warehousing facilities are damaged by earthquakes, hurricanes, volcanoes, fires, and other natural disasters or catastrophic circumstances. As we expand into new markets and scale new products for commercial production, we may face unanticipated delays or surges in demand which could strain our production capacity and lead to other types of disruption. If any of these manufacturing, logistics, or quality problems arise or if we or one of our suppliers or logistics partners otherwise fail to meet internal quality standards or those of the FDA or other applicable regulatory body, our reputation could be damaged, we could become subject to a safety alert or a recall, we could incur product liability and other costs, product approvals and production could be delayed, and our business could otherwise be materially adversely affected. We are subject to risks associated with public health crises, **particularly with respect to** ~~including the COVID- 19 pandemic and other~~ -- **the** ~~pandemics or epidemics~~ **pressures that such crises create on the hospital systems and supply chains in which we operate** . We are subject to risks associated with public health crises, including **pandemics and epidemics, such as** ~~the global health concerns related to the~~ COVID- 19 ~~pandemic. The COVID- 19 pandemic has adversely impacted and is likely to further adversely impact nearly all aspects of our business and markets, including our workforce and operations and the operations of our customers, suppliers, and business partners~~ . Other public health crises, including any future epidemics or pandemics, **are highly uncertain and difficult to predict, and** could result in ~~similar~~ **material** adverse impacts on our business and ~~markets. Financial or operational impacts that we have experienced in connection with the COVID- 19 pandemic and may experience as a result of future COVID- 19 outbreaks or other public health crises include: • Staffing shortages at hospitals which can add to the barriers along the patient treatment pathway; • Impacts and delays to clinical trials, our pipeline milestones, or regulatory clearances and approvals; • The inability to meet our customers' needs or other obligations due to disruptions to our operations or the operations of our third- party partners, suppliers, contractors, logistics partners, or customers including disruptions to production, development, manufacturing, administrative, and supply operations and arrangements; or • Significant volatility or reductions in demand for our products. Depending on the severity of the financial and operational impacts, our business,~~ financial condition ~~, and results of operations may be materially adversely impacted. The extent to which the COVID- 19 pandemic or other future public health crises may impact our business, results of operations, and financial condition depends on many factors which are highly uncertain and are difficult to predict. These factors include, but are not limited to, the duration and spread of any outbreak, its severity, the actions to contain or address the impact of the outbreak, the timing, distribution, and efficacy of vaccines and other treatments, United States and foreign government actions to respond to possible reductions in global economic activity, and how quickly and to what extent normal economic and operating conditions can resume~~ . We operate in highly competitive markets, and if we do not compete effectively, our business will be harmed. We face substantial competition and compete with technologies of many types and companies of all sizes on the basis of cost- effectiveness, technological innovations, product performance, brand name recognition, breadth of product offerings, real or perceived product advantages, pricing and availability and rate of reimbursement. In addition, given the trend toward value- based healthcare, if we are not able to continue to demonstrate the full value of our differentiated products to healthcare providers and payors, our competitive position could be adversely affected. See" Competition" under" Business" in Part I, Item 1 included herein. The success of many of our products depends upon certain key physicians and research institutions. We work with leading global physicians and research institutions who provide considerable knowledge and experience. These physicians may assist us as researchers, marketing consultants, product trainers and consultants, inventors, and as public speakers. If new laws, regulations, or other developments limit our ability to appropriately engage these professionals or with the research institutions of which they are a part or to continue to receive their advice and input or we are otherwise unsuccessful in maintaining strong working relationships with these physicians or their research institutions, the development, marketing, and successful use of our products could suffer, which could have a material adverse effect on our business, financial condition, and results of operations. We rely on third parties in the design, manufacture, and sterilization of our products. Any failure by or loss of a vendor could result in delays and increased costs, which may adversely affect our business. We rely on third parties for a broad range of raw and organic materials and other items in the design, manufacture, and sterilization of our products, and we purchase certain supplies and services from single sources for reasons of quality assurance, cost- effectiveness, availability, constraints resulting from regulatory requirements, and other reasons. We experience from time to time, and may continue to experience, supply interruptions due to a variety of factors, including: • General economic conditions that could adversely affect the financial viability of our vendors; • Vendors' election to no longer service or supply medical technology companies, including due to the burdens of applicable quality requirements and regulations or for no reason at all; • The limitation or ban of certain chemicals or other materials used in the manufacture of our products; and • Delays or shortages due to trade or regulatory embargoes. Additionally, any significant increases in the cost of raw materials, whether due to inflationary pressure, supply constraints, regulatory changes, or otherwise, could adversely impact our operating results. A change or addition to our vendors could require significant effort due to the rigorous regulations and requirements of the FDA and other regulatory authorities; it could be difficult to establish additional or replacement sources on a timely basis or at all, which could have a material adverse effect on our business. Failure to protect our information technology infrastructure and our products against cyber- based attacks, network security breaches, service interruptions, or data corruption could materially disrupt our operations and adversely affect our business and operating results. The operation of our business depends on our information technology systems. We rely on our information technology systems to, among other things, effectively manage sales and marketing data, accounting and financial functions, inventory management, product development tasks, clinical data, customer service and technical support functions. Our information technology systems are vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, power losses, computer system or data network failures, security breaches, and data corruption. In addition, our information technology infrastructure and products are vulnerable to cyber- based attacks. Cyber- based attacks can include, but are not limited to, computer viruses, denial- of- service attacks, phishing attacks, ransomware attacks, and other introduction of malware to computers and networks;

unauthorized access through the use of compromised credentials; exploitation of design flaws, bugs, or security vulnerabilities; intentional or unintentional acts by employees or other insiders with access privileges; and intentional acts of vandalism by third parties and sabotage. In addition, United States federal and state laws and regulations, and the laws and regulations of jurisdictions outside of the United States, such as the General Data Protection Regulation (" GDPR") adopted by the European Union and the California Privacy Rights Act (" CRPA") and the California Consumer Privacy Act, as amended by the CRPA (the" CCPA"), can expose us to investigations and enforcement actions by regulatory authorities and claims from individuals potentially resulting in penalties and significant legal liability, if our information technology security efforts are inadequate. In addition, we rely upon technology suppliers, including cloud - based data management applications hosted by third - party service providers, whose security and information technology systems are subject to similar risks. Significant disruption in either our or our service providers' or suppliers' information technology or the security of our products could impede our operations or result in decreased sales, result in liability claims or regulatory penalties, or lead to increased overhead costs, product shortages, loss or misuse of proprietary or confidential information, intellectual property, or sensitive or personal information, all of which could have a material adverse effect on our reputation, business, financial condition, and operating results. Our business and results of operations may be adversely affected if we are unable to recruit and retain qualified talent or are otherwise unsuccessful in the execution of our management succession plans. Our continued success depends, in large part, on our ability to hire and retain qualified people and execute on our talent management and succession plans, and if we are unable to do so, our business and operations may be impaired or disrupted. See" Human Capital Management Strategy" under" Business" in Part I, Item 1 included herein. Competition for highly qualified people is intense, and there is no assurance that we will be successful in attracting or retaining replacements to fill vacant positions, successors to fill retirements or employees moving to new positions, or other highly qualified personnel. If we identify underperforming operations or products or if there are unforeseen operating difficulties and expenditures in connection with business acquisitions or strategic alliances, we may be required, from time to time, to recognize charges, which could be substantial and which could adversely affect our results of operations. We actively manage a portfolio of research and development products, and we regularly explore potential acquisitions of complementary businesses, technologies, services, or products, as well as potential strategic alliances. From time to time, we identify operations and products that are underperforming, do not fit with our longer- term business strategy or there may be unforeseen operating difficulties and significant expenditures during the integration of an acquired business, technology, service, or product into our existing operations. We may seek to dispose of these underperforming operations or products, and we may also seek to dispose of other operations or products for strategic or other business reasons. If we cannot dispose of an operation or product on acceptable terms, we may voluntarily cease operations related to that product. In addition, we may be required to take charges or write- downs in connection with acquisitions and divestitures. In particular, acquisitions of businesses engaged in the development of new products may give rise to developed technology and / or in- process research and development assets. To the extent that the value of these assets decline, we may be required to write down the value of the assets. Also, in connection with certain asset acquisitions, we may be required to take an immediate charge related to acquired in- process research and development assets. Any of these events could result in charges, which could be substantial and which could adversely affect our results of operations. **We may not be able to complete the announced spin- off of our Critical Care product group at all, or within the timeframes we anticipate, or pursuant to the tax- free structure that we anticipate, and we may not realize some or all of the expected benefits of this transaction. On December 7, 2023, we announced our intention to complete a tax- free spin- off of our Critical Care product group at the end of 2024. We also announced our intention to submit a Form 10 with the SEC in mid- year 2024. In connection with this spin- off and the separation of the Critical Care product group from the rest of Edwards, we will be required to satisfy all necessary governance, contractual, and regulatory conditions, among other, including those required by third parties. A failure to satisfy all necessary conditions could delay or prevent the spin- off from occurring or could result in us completing the spin- off on terms less than favorable to us. In addition, we will incur significant costs associated with the spin- off, which may be significantly higher than projected. Our intention is to complete the spin- off on a tax- free basis, however, there is no assurance that the spin- off will qualify tax- free as intended, which may result in a significant tax liability. Lastly, preparing and structuring the spin- off requires significant resources from Edwards, including but not limited to management' s attention, financial support for the new company, and the collective employee effort to separate the Critical Care product group from the rest of Edwards while continuing to operate in the normal course of business. There is no assurance that the spin- off will occur at all or that the execution, timing, and structure of the spin- off will proceed as intended. There may be a sudden or unpredictable reaction to the spin- off by the investors and financial institutions, which would affect our stock market price. If we don' t realize some or all of the benefits of the spin- off, our business and financial condition and those of the newly spun- off company will be materially adversely affected. Assuming the spin- off is successfully completed, the newly spun- off Critical Care company as a standalone public company may not deliver the returns that we or the shareholders anticipate. The Company plans to spin- off the Critical Care product group into a successful independent public company to be able to increase focus and flexibility to build upon its global leadership position in advanced patient monitoring, transforming care through AI- enabled smart monitoring solutions while expanding its reach to millions of patients around the world. The intention for the newly spun- off company is to retain its Chief Executive Officer and other senior leaders, however, there is no assurance that we or the newly spun- off company will be able to do so, which may materially impact the operations of the newly spun- off company. In addition, the new spin- off will result in a smaller, less diversified standalone company than it was as part of Edwards, which may make it more susceptible to macroeconomic trends, geopolitical risks, financial volatility, and changing market and regulatory conditions, any of which could have a material adverse effect on its financial condition and operations. The newly spun- off company will incur ongoing costs related to the separation and its public**

listing, and its transition to a standalone public company, if executed at all, may not be executed as anticipated. Lastly, we cannot predict whether the market value of our stock and the stock of the spun- off company after the completion of the transaction, will be, in the aggregate, less than, equal to, or greater than the market value of our stock prior to the spin- off. There is no assurance that the newly spun- off company will be successful as a standalone public company, and if it is not successful, that would have a material adverse impact on the operations and financial condition of the newly spun- off company. Because we operate globally, our business is subject to a variety of risks associated with international sales and operations. Our extensive global operations and business activity as well as the fact that many of our manufacturing facilities and suppliers are outside of the United States exposes us to certain financial, economic, political, and other risks, including those listed below. Domestic and Global Economic Conditions. We have been impacted and may continue to be negatively impacted by general domestic and global economic conditions, although we cannot predict the extent to which such conditions may negatively impact our business. These include, but are not limited to, conditions impacting inflation, credit and capital markets, interest rates, tax law, including tax rate and policy changes, factors affecting global economic stability, and the political environment relating to health care. These and other conditions could also adversely affect our customers, payers, vendors and other stakeholders and may impact their ability or decision to purchase our products or make payments on a timely basis. Health Care Legislation and Other Regulations. We are subject to various federal and foreign laws that govern our domestic and international business practices. For example, in the United States, the Affordable Care Act, the Medicare Access and CHIP Reauthorization Act of 2015, and the 21st Century Cures Act, or any future legislation, including deficit reduction legislation, could impact medical procedure volumes, reimbursement for our products, and demand for our products or the prices at which we sell our products. In addition, a Mutual Recognition Agreement still under negotiation for the Medical Device Regulation can result in a lack of free movement of medical devices between the European Union and Switzerland, can impact our access in the European Union and can, ultimately, have a material effect on our business, financial condition, and results of operations. For more information about these laws as they relate to our business, see the section entitled " Government Regulation and Other Matters " in Part I, Item 1, " Business. " In addition, the United States Foreign Corrupt Practices Act, the United Kingdom Bribery Act, and similar laws in other jurisdictions contain prohibitions against bribery and other illegal payments, and make it an offense to fail to have procedures in place that prevent such payments. Penalties resulting from any violation of these laws could adversely affect us and our business. Taxes. We are subject to income taxes in the United States as well as other jurisdictions. • Provision for Income Taxes. Our provision for income taxes and our effective tax rate could fluctuate due to changes in the mix of earnings and losses in countries with differing statutory tax rates. Our income tax provision could also be impacted by changes in excess tax benefits of stock- based compensation, federal and state tax credits, non- deductible expenses, changes in the valuation of deferred tax assets and liabilities and our ability to utilize them, the applicability and creditability of withholding taxes, and effects from acquisitions. • Tax Reform. Our provision for income taxes could be materially impacted by changes in accounting principles or evolving tax laws, including, but not limited to, global corporate tax reform and base- erosion and tax transparency efforts. For example, many countries are aligning their international tax rules with the Organisation for Economic Co- operation and Development' s Base Erosion and Profit Shifting recommendations and action plans that aim to standardize and modernize international corporate tax policy, including changes to cross- border taxes, transfer pricing documentation rules, nexus- based tax practices, and taxation of digital activities. The effective dates of implementation, the interactions of tax reforms in multiple jurisdictions, and uncertainty related to dispute resolution mechanisms could impact our provision for income taxes. • Tax Audits. We are subject to ongoing tax audits in the various jurisdictions in which we operate. Tax authorities **have disagreed and** may disagree with certain positions we have taken and assess additional taxes **that could be material. Please review Note 18 (Income Taxes) to our" Consolidated Financial Statements" in this report for information regarding our current audits and disputes with tax authorities** . Although we regularly assess the likely outcomes of the audits and record reserves for potential tax payments, the calculation of tax liabilities involves the application of complex tax laws, and our estimates could be different than the amounts for which we are ultimately liable **. In addition, we may decide to challenge any assessments, if made, and may exercise our right to appeal, which could result in expensive and time- consuming litigation that may ultimately be unsuccessful** . • Tax Incentives. We benefit from various global tax incentives extended to encourage investment or employment. Several foreign jurisdictions have granted us tax incentives which require renewal at various times in the future. If our incentives are not renewed or we cannot or do not wish to satisfy all or part of the tax incentive conditions, we may lose the tax incentives and could be required to refund tax incentives previously realized. As a result, our provision for income taxes could be higher than it would have been had we maintained the benefits of the tax incentives. Other economic, political, and social risks. In addition to the factors enumerated above, we are from time to time impacted by a variety of other factors associated with doing business internationally that can harm our future results, including the following: • trade protection measures, quotas, embargoes, import or export requirements, and duties, tariffs, or surcharges; • cultural or other local factors affecting financial terms with customers; • differing labor regulations; • military conflict, political unrest, or wars; and • currency exchange rate fluctuations; that is, decreases in the value of the United States dollar to the Euro or the Japanese yen, as well as other currencies in which we transact business, have the effect of increasing our reported ~~revenues~~ **sales** even when the volume of sales outside of the United States has remained constant. Increases in the value of the United States dollar relative to the Euro or the Japanese yen, as well as other currencies, have the opposite effect. Significant increases or decreases in the value of the United States dollar could have a material adverse effect on our ~~revenues~~ **sales** , cost of sales, or results of operations. If government and other third- party payors decline to reimburse our customers for our products or impose other cost containment measures to reduce reimbursement levels, our ability to profitably sell our products will be harmed. We sell our products and technologies to hospitals and other health care providers, nearly all of which receive reimbursement for the health care services provided to patients from third- party payors, such as government programs (both domestic and outside of the United States), private insurance plans, and

managed care programs. The ability of customers to obtain appropriate reimbursement for their products from private and governmental third- party payors is critical to our success. The availability of reimbursement affects which products customers purchase and the prices they are willing to pay. Reimbursement varies from country to country and can significantly impact acceptance of new products. Government and other third- party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for medical products and services. Reimbursement levels may be decreased in the future. Additionally, future legislation, regulation, or reimbursement policies of third- party payors may otherwise adversely affect the demand for and price levels of our products. The introduction of cost containment incentives, combined with closer scrutiny of health care expenditures by both private health insurers and employers, has resulted in increased discounts and contractual adjustments to hospital charges for services performed. Hospitals or physicians may respond to such cost- containment pressures by substituting lower cost products or other therapies. Third- party payors may deny reimbursement if they determine that a device used in a procedure was not used in accordance with cost- effective treatment methods as determined by such third- party payors or was used for an unapproved indication. Third- party payors may also deny reimbursement for experimental procedures and devices. We believe that many of our existing products are cost- effective, even though the one- time cost may be significant, because they are intended to improve quality of life and reduce overall health care costs over a long period of time. We cannot be certain that these third- party payors will recognize these cost savings and quality of life benefits instead of merely focusing on the lower initial costs associated with competing therapies. If our products are not considered cost- effective by third- party payors, our customers may not be reimbursed for them, resulting in lower sales of our products. Continued consolidation in the health care industry could have an adverse effect on our sales and results of operations. The health care industry has been consolidating, and organizations such as GPOs, independent delivery networks, and large single accounts, such as the United States Veterans Administration, continue to consolidate purchasing decisions for many of our health care provider customers. As a result, transactions with customers are larger and more complex, and tend to involve more long- term contracts. The purchasing power of these larger customers has increased, and may continue to increase, causing downward pressure on product pricing. If we are not one of the providers selected by one of these organizations, we may be precluded from making sales to its members or participants. Even if we are one of the selected providers, we may be at a disadvantage relative to other selected providers that are able to offer volume discounts based on purchases of a broader range of medical equipment and supplies. Further, we may be required to commit to pricing that has a material adverse effect on our revenues, profit margins, business, financial condition, and results of operations. We expect that market demand, governmental regulation, third- party reimbursement policies, and societal pressures will continue to drive consolidation and increase pricing pressure. Legal, Compliance, and Regulatory Risks Our inability to protect our intellectual property or failure to maintain the confidentiality and integrity of data or other sensitive company information, by cyber- attack or other event, could have a material adverse effect on our business. Our success and competitive position are dependent in part upon our ability to protect our proprietary intellectual property through a combination of patents and trade secrets. We cannot guarantee that the protective steps we take are adequate to protect these rights: • Patents issued to or licensed by us in the past or in the future may be challenged and held invalid. • As our patents expire, we may be unsuccessful in extending their protection through patent term extensions. • Confidentiality agreements with certain employees, consultants, and other third parties intended to protect, in part, trade secrets and other proprietary information could be breached, and we may not have adequate remedies. • Others could independently develop substantially equivalent proprietary information or gain access to our trade secrets or proprietary information, design around our technology, or develop competing technologies. • Our intellectual property, other proprietary technology, and other sensitive company information is dependent on sophisticated information technology systems and is potentially vulnerable to cyber- attacks, loss, theft, damage, destruction from system malfunction, computer viruses, loss of data privacy, or misappropriation or misuse of it by those with permitted access, and other events. • We may not detect infringement. • Intellectual property protection may also be unavailable or limited in some foreign countries. We spend significant resources to protect and enforce our intellectual property rights, sometimes resulting in expensive and time- consuming litigation that is complex and may ultimately be unsuccessful. Our inability to protect our intellectual property could have a material adverse effect on our business or prospects. Third parties may claim we are infringing their intellectual property, and we could suffer significant litigation or licensing expenses or be prevented from selling products. During recent years, we and our competitors have been involved in substantial litigation regarding patent and other intellectual property rights which is typically costly and time- consuming. We may be forced to defend against claims and legal actions alleging infringement of the intellectual property rights of others, and, if our defense is unsuccessful, we could have significant liabilities to third parties or face injunctions that bar the sale of our products, or could require us to seek licenses from third parties. Such licenses may not be available on commercially reasonable terms, may prevent us from manufacturing, selling, or using certain products, or may be non- exclusive, which could provide our competitors access to the same technologies. In addition, third parties could also obtain patents that may require us to either redesign products, negotiate licenses from such third parties, which may be costly, unavailable or require us to exit a particular product offering. We and our customers are subject to rigorous governmental regulations and we may incur significant expenses to comply with these regulations and develop products that are compatible with these regulations. In addition, failure to comply with these regulations could subject us to substantial sanctions which could adversely affect our business, results of operations, and financial condition. The medical technologies we create, study, manufacture, and market globally are subject to rigorous regulation and scrutiny by the FDA and various other federal, state, and foreign governmental authorities, including the European Union' s European Commission who promulgated the European Medical Device Regulation (" EU MDR"). Government regulation applies to nearly all aspects of our products' lifecycles, including testing, clinical study, manufacturing, transporting, sourcing, safety, labeling, storing, packaging, recordkeeping, reporting, advertising, promoting, distributing, marketing, and importing or exporting of medical devices and products. In general, unless an exemption applies, a medical device or product must receive regulatory approval or clearance before it can be

marketed or sold. Modifications to existing products or the marketing of new uses for existing products also may require regulatory approvals, approval supplements, or clearances. If we are unable to obtain these required approvals, we may be required to cease manufacturing and sale, or recall or restrict the use of such modified device, pay fines, or take other action until such time as appropriate clearance or approval is obtained. More specifically relating to the EU MDR which came into effect in May 2017 and became applicable in May 2021 with a staggered transition period, all regulated products must be assessed by notified bodies (organizations designated by EU member states) as to whether they meet the technical requirements of the EU MDR before entering the market in Europe. During the transition period, with the influx of submissions to the notified bodies, any delay on obtaining approvals may result in a disruption of device supply or a further delay in getting a device to market. In addition, in the EU, we import some of our devices through our offices in Switzerland. Switzerland is not a member state of the EU, but is linked to the EU through bilateral treaties; therefore, the free movement of goods, including medical devices, between the EU and Switzerland after implementation of the EU MDR requires a revised MRA. If an MRA covering the EU MDR is not put in place, then non- EU manufacturers may be required to make significant changes, including replacement of Swiss economic operators with operators based in EU member states, and changes will need to be made to our device labeling and / or packaging to satisfy EU MDR requirements. If these measures are unable to be taken, it may no longer be possible to place such devices on the EU market. Regulatory agencies may refuse to grant approval or clearance, or review and disagree with our interpretation of approvals or clearances, or with our decision that regulatory approval is not required or has been maintained. Regulatory submissions may require the provision of additional data and may be time consuming and costly, and their outcome is uncertain. Regulatory agencies may also change policies, adopt additional regulations, or revise existing regulations, each of which could prevent or delay approval or clearance of devices, or could impact our ability to market a previously cleared, approved, or unregulated device. Our failure to comply with these regulatory requirements of the FDA, the European Commission, or other applicable regulatory requirements in the United States or elsewhere might subject us to administratively or judicially imposed sanctions. These sanctions include, among others, warning letters, fines, civil penalties, criminal penalties, injunctions, debarment, product seizure or detention, product recalls and total or partial suspension of production, sale and / or promotion. Any of the foregoing actions could result in decreased sales including as a result of negative publicity and product liability claims, and could have a material adverse effect on our financial condition, results of operations, and prospects. In addition to the sanctions for noncompliance described above, commencement of an enforcement proceeding, inspection, or investigation could divert substantial management attention from the operation of our business and have an adverse effect on our business, results of operations, and financial condition. We are also subject to various United States and foreign laws pertaining to health care pricing, anti- **competition, anti-** corruption, and fraud and abuse, including prohibitions on kickbacks and the submission of false claims laws and restrictions on relationships with physicians and other referral sources. These laws are broad in scope and are subject to evolving interpretation, which could require us to incur substantial costs to monitor compliance. If we are found not to be in compliance, we may be required to alter our practices or have sanctions imposed against us and our officers and employees, including substantial fines, imprisonment, and exclusion from participation in governmental health care programs. In addition, as a global company, we are subject to global data privacy and security laws, regulations and codes of conduct that apply to our businesses. We are required to comply with increasingly complex and changing legal and regulatory requirements that govern the collection, use, storage, security, transfer, disclosure and other processing of personal data in the United States and in other countries, which may include, but are not limited to, The Health Insurance Portability and Accountability Act, as amended (" HIPAA"), The Health Information Technology for Economic and Clinical Health Act, the CCPA, the CRPA, and the GDPR. The GDPR imposes stringent European Union data protection requirements and provides for significant penalties for noncompliance. HIPAA also imposes stringent data privacy and security requirements and the regulatory authority has imposed significant fines and penalties on organizations found to be out of compliance. The CCPA and the CRPA provides consumers with a private right of action against companies who have a security breach due to lack of appropriate security measures. We or our third- party providers and business partners may also be subjected to audits or investigations by one or more domestic or foreign government agencies relating to compliance with information security and privacy laws and regulations, and noncompliance with the laws and regulations could result in substantial and material fines or class action litigation. Additional risks related to government regulation are also described under" Health Care Legislation and Other Regulations" in the risk factor above titled" Because we operate globally, our business is subject to a variety of risks associated with international sales and operations." We may incur losses from product liability or other claims that could adversely affect our operating results. Our business exposes us to potential product liability risks that are inherent in the design, manufacture, and marketing of medical technologies. Our products are often used in surgical and intensive care settings with seriously ill patients. In addition, many of the devices we manufacture and sell are designed to be implanted in the human body for long periods of time. Component failures, manufacturing and assembly flaws, design defects, software defects, medical procedure errors, or inadequate disclosure of product- related risks or information could result in an unsafe condition, injury to, or death of, patients. Such problems could result in product liability, medical malpractice or other lawsuits and claims, safety alerts, or product recalls in the future. We establish reserves and may incur charges in excess of those reserves. Although we maintain product liability and other insurance with coverages we believe are adequate, product liability or other claims may exceed insurance coverage limits, fines, and penalties. In addition, regulatory sanctions may not be covered by insurance, or insurance may not continue to be available or available on commercially reasonable terms. These litigation matters and regulatory actions, recalls or other actions, regardless of outcome, could have a material adverse effect on our business, reputation, and ability to attract and retain customers. Use of our products in unapproved circumstances could expose us to liabilities. The marketing approval from the FDA and other regulators of certain of our products are, or are expected to be, limited to specific indications. We are prohibited from marketing or promoting any unapproved use of our products. Physicians, however, can use these products in ways or circumstances other than those strictly within the scope of the regulatory approval.

Although the product training we provide to physicians and other health care professionals is conducted in compliance with applicable laws, and therefore, is mainly limited to approved uses or for clinical trials, no assurance can be given that claims might not be asserted against us if our products are used in ways or for procedures that are not approved. Our operations are subject to environmental, health, and safety regulations that could result in substantial costs. Our operations are subject to environmental, health, and safety laws, and regulations concerning, among other things, the generation, handling, transportation, and disposal of hazardous substances or wastes, the cleanup of hazardous substance releases, and emissions or discharges into the air or water. We have incurred and may incur in the future expenditures in connection with environmental, health and safety laws, and regulations. New laws and regulations, violations of these laws or regulations, stricter enforcement of existing requirements, or the discovery of previously unknown contamination could require us to incur costs or could become the basis for **litigation or** new or increased liabilities that could be material. Climate change, or legal, regulatory or market measures to address climate change, may materially adversely affect our financial condition and business operations. Climate change resulting from increased concentrations of carbon dioxide and other greenhouse gases in the atmosphere could present risks to our future operations from natural disasters and extreme weather conditions, such as hurricanes, tornadoes, seismic events, wildfires, or flooding. Such extreme weather conditions could pose physical risks to our facilities and disrupt operation of our supply chain and may impact operational costs. Concern over climate change could result in new legal or regulatory requirements designed to mitigate the effects of climate change on the environment. If such laws or regulations are more stringent than current legal or regulatory requirements, we may experience increased compliance burdens and costs to meet the regulatory obligations, and it may adversely affect our raw material sourcing, manufacturing operations, and the distribution of our products. We are subject to risks arising from concerns and / or regulatory actions relating to animal - borne illnesses, including “ mad cow disease. ” Certain of our products, including pericardial tissue valves, are manufactured using bovine tissue. Concerns relating to the potential transmission of animal - borne illnesses, including BSE, commonly known as" mad cow disease," from cows to humans may result in reduced acceptance of products containing bovine materials. Certain medical device regulatory agencies have considered whether to continue to permit the sale of medical devices that incorporate bovine material. We obtain bovine tissue only from closely controlled sources within the United States and Australia. The bovine tissue used in our pericardial tissue valves is from tissue types considered by global health and regulatory organizations to have shown no risk of infectibility for the suspected BSE infectious agent. We have not experienced any significant adverse impact on our sales as a result of concerns regarding BSE, but no assurance can be given that such an impact may not occur in the future.