Risk Factors Comparison 2024-02-20 to 2023-02-21 Form: 10-K

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Our business faces many risks, and you should carefully consider the following risk factors, together with all of the other information included in this report, including the financial statements and related notes contained in **Part II,** Item 8 **– " Financial Statements and Supplementary Data " and the discussion in Part II, Item 7 – " Management' s Discussion and Analysis of Financial Condition and Results of Operations "** of this report, when deciding to invest in us. Any of the risks discussed below, or elsewhere in this report or in our other SEC filings, could have a material impact on our business, financial condition or results of operations. Additional risks not currently known to us or that we currently consider immaterial also may materially adversely affect our business, financial condition or results of operations in the future. **As a result, the trading price of our common stock could decline and you could lose all or part of your investment in our common stock.** Operational Risks ~~Our operations have been and may continue to be adversely impacted by the ongoing global impact of the COVID- 19 pandemic. The global spread of COVID- 19 and its variants has created significant uncertainty and worldwide economic disruption. COVID- 19 has negatively impacted our operating results and may continue to do so in the future. The duration and scope of the impact is uncertain given the evolving health, economic, social and governmental environments. Specific impacts to our business have included delayed and reduced customer orders, increased absenteeism, disruptions in our supply chain, delays in shipments to and from certain countries, and restrictions on our associates' ability to travel or work. We expect delayed and reduced customer demand will continue to impact our operations. The pandemic has affected and continues to affect our manufacturing facilities and our associates' health. If the operations of any of our manufacturing sites are materially impacted as a result of the pandemic, it may not be possible for us to continue to timely manufacture relevant products at required levels, or at all. We have modified, and may further modify, our business practices in response to the COVID- 19 pandemic and related third- party responses, including from government authorities. Any continued or renewed business closures, operating disruptions, or travel or work restrictions that impact our associates, customers, suppliers or manufacturing facilities will likely continue to adversely affect our operations locally and worldwide and could have a material adverse effect on our operating results and financial condition. The ultimate impact of the COVID- 19 pandemic on our operations and financial performance depends on many factors that are not within our control, including, but not limited, to: governmental, business and individuals' actions that have been and continue to be taken in response to the pandemic (including restrictions on travel, transport and workforce pressures); the impact of the pandemic and actions taken in response on global and regional economies, travel, and economic activity; the availability of federal, state, local or non- U. S. funding programs; general economic uncertainty in key global markets and financial market volatility; global economic conditions and levels of economic growth; and the pace of recovery when the COVID- 19 pandemic subsides, which could be impacted by a number of factors, including limited provider capacity to perform procedures using our products that were deferred as a result of the pandemic.~~ We depend heavily on a limited number of customers, and if we lose any of them or they reduce their business with us, we would lose a substantial portion of our revenues. In ~~2022~~ **2023**, our top three customers collectively accounted for approximately ~~46~~ **45** % of our revenues. Reductions in demand from these customers ~~, largely because of reduction in demand for medical procedures during the COVID- 19 pandemic,~~ has negatively impacted our results of operations during prior fiscal years and may impact our future results of operations if material reductions in demand **from these customers** recur. ~~These~~ **We do not have long- term supply agreements with all of our customers, and our** customers may not agree to renew or extend our supply agreements with them. Furthermore, many of our supply agreements do not contain minimum purchase level requirements and therefore there is no guaranteed source of revenue that we can depend upon under these agreements. In addition, we are dependent on the continued growth, viability and financial stability of these customers. The markets in which these customers operate are subject to rapid technological change, vigorous competition and short product life cycles. As a result, when these customers are adversely affected by these factors, we **have in the past been and** may **in the future** be similarly adversely affected. The loss of any large customer, a material reduction of business with that customer, or a delay or failure by that customer to make payments due to us, would harm our business, financial condition and results of operations. We are subject to pricing pressures from customers and contractual pricing constraints, which could harm our operating results and financial condition. Given the highly competitive industry in which we operate, we have reduced prices ~~to~~ **for** some of our customers in recent years **,** and we expect customer pressure for continued price reductions in future periods. These additional price reductions, if they were to occur, may cause our operating results and financial condition to suffer. ~~- 16-~~ We rely on third **-** party suppliers for raw materials, key products and subcomponents. Unavailability of, or increased prices for, these materials, products or subcomponents could adversely affect our results of operations **and financial condition** . Our business depends on a continuous supply of raw materials. The principal raw materials used in our business include platinum, stainless steel, gold, titanium, nitinol, lithium, palladium, iridium, tantalum, nickel cobalt, ruthenium, gallium trichloride, vanadium oxide, CFx and plastics. The supply and price of raw materials may be susceptible to fluctuations due to transportation issues, government regulations, price controls, foreign civil unrest, tariffs, worldwide economic conditions or other unforeseen circumstances, including the continuing impact of the global pandemic. Increasing global demand for raw materials has caused prices of certain materials to increase. Significant increases in the cost of raw materials that cannot be recovered through increases in the prices of our products could adversely affect our results of operations. There can be no assurance that the marketplace will support higher prices or that price increases and productivity gains, procurement deflation projects or savings will fully offset any raw material cost increases in the future. In addition, there are a limited number of worldwide suppliers of several raw materials needed to manufacture our products. For reasons of quality, cost effectiveness or availability, we obtain some raw materials from a single supplier. Although we work closely with our suppliers to seek to ensure continuity of supply, we may not be able to continue to procure raw materials critical to our business at all or to procure them at acceptable price levels. A disruption in deliveries from our suppliers, price increases or decreased availability of raw materials could have an adverse effect on our ability to meet our commitments to our customers and increase our operating costs. **Finally, continued uncertainty around inflationary pressures and macroeconomic conditions have increased the risk of creating new, or exacerbating existing, economic challenges we face with regard to our supply chain. Inflation has the potential to increase our overall cost structure, and sustained inflation has resulted in, and may continue to result in, higher interest rates and capital costs, increased shipping costs, supply shortages, increased costs of labor, weakening exchange rates, and other similar effects. While we have implemented cost containment measures and taken other actions to offset these inflationary pressures in our global supply chain, we may not be able to completely offset all the increases in our operational costs.- 17-** We rely on third **-** party manufacturers to supply many of the products and subcomponents that are incorporated into our products and components. These third **-** party manufacturers have their own complex supply chains and related risks, whether due to the continuing impact of the global pandemic, the **shipping risks described below, the** military conflict between Russia and Ukraine ~~,~~ or other causes. They are subject to raw material price and availability risks similar to those described above. Manufacturing problems may occur with these and other outside sources, as a supplier may fail to develop or manufacture products and subcomponents for us on a timely basis, or may supply us with products and subcomponents that do not meet our quality, quantity and cost requirements. **Our** ~~Third~~ **third -** party suppliers are also subject to shipping risks, including container shortages, blocked shipping lanes, and port backlogs. If any of these problems occur, we may be unable to obtain substitute sources for these products and subcomponents on a timely basis or on terms acceptable to us, which could harm our ability to manufacture our own products and components profitably or on time. In addition, to the extent the processes our **third- party** suppliers use to manufacture products and subcomponents are proprietary, we may be unable to obtain comparable products and subcomponents from alternative suppliers. Our business is also subject to risks associated with U. S. and foreign legislation, regulations and trade agreements relating to the materials we import, including the tariffs on steel that the U. S. has imposed and other quotas, duties, tariffs or taxes or restrictions on imports, which could adversely affect our operations and our ability to import materials used in our products at current or increased levels. We cannot predict whether additional U. S. and foreign customs quotas, duties (including antidumping or countervailing duties), tariffs, taxes or other charges or restrictions, requirements as to where raw materials must be purchased or other restrictions on our imports will be imposed in the future or adversely modified, or what effect such actions would have on our costs of operations. Future quotas, duties or tariffs may adversely affect our business, financial condition, results of operations or cash flows. Future trade agreements could also provide our competitors with an advantage over us, or increase our costs, either of which could adversely affect our business, financial condition, results of operations or cash flows. Interruptions of our manufacturing operations could delay production and adversely affect our operations. Our products are designed and manufactured in facilities located around the world. In most cases, the manufacturing of specific product lines is concentrated in one or a few locations. If an event (including any weather or natural disaster- related event **or a resurgence of the COVID- 19 pandemic**) occurred that resulted in material damage ~~or~~ **,** loss **or incapacitation** of one or more of these manufacturing facilities or **if** we lacked sufficient labor to fully operate the facility, we ~~might~~ **may not** be ~~unable~~ -- **able** to transfer the manufacture of the relevant products to another facility or location in a cost- effective or timely manner, if at all. This potential inability to transfer production could occur for a number of reasons, including but not limited to a lack of necessary relevant manufacturing capability **or capacity** at another facility, or the regulatory requirements of the FDA or other governmental regulatory bodies. Other disruptions in our manufacturing operations for any reason, including equipment malfunction, failure to follow specific protocols and procedures, or environmental factors could lead to an inability to supply our customers with our products, unanticipated costs, lost revenues and damage to our reputation. ~~The ongoing COVID- 19 pandemic has caused, and may continue to cause, delays in production, unanticipated costs and lost revenues.~~ In addition, our business involves complex manufacturing processes and the use of various hazardous materials, chemicals and other regulated substances, such as trichloroethylene, ~~that~~ **which** can be dangerous to our associates. We must also comply with various health and safety regulations in the U. S. and abroad in connection with our operations. Although we employ safety procedures in the design and operation of our facilities, there is a risk that an accident or death could occur. Any accident, such as a chemical spill or fire, could result in significant manufacturing delays or claims for damages resulting from injuries, which would harm our **business, results of** operations and financial condition. The potential liability resulting from any such accident or death, to the extent not covered by insurance, could harm our financial condition or operating results. Any disruption of operations at any of our facilities, and in particular our larger facilities, could result in production delays, which could adversely affect our operations and harm our business. ~~- 17-~~ We may not be able to attract, train and retain a sufficient number of qualified associates to maintain and grow our business. We monitor the markets in which we compete and assess opportunities to better align expenses with revenues, while preserving our ability to make needed investments in RD & E projects, capital and our associates that we believe are critical to our long- term success. Our success **depends, and our continued success** will depend **,** in large part upon our ability to attract, train, retain and motivate highly skilled associates. There is currently aggressive competition for employees who have experience in technology and engineering. We compete intensely with other companies to recruit and hire from this limited pool, which competition has become more acute since the beginning of the COVID- 19 pandemic. The industries in which we compete for employees are characterized by high levels of employee attrition. Although we believe we offer competitive salaries and benefits, we ~~may~~ have **had** to **, and may in the future have to,** increase spending to attract, train and retain qualified personnel. If we are unable to attract, train and retain a sufficient number of qualified associates to maintain and grow our business, it could have an adverse impact on our results of operations. **- 18-** Quality problems with our products could result in warranty claims and additional costs, could harm our reputation and could erode our competitive advantage. Quality is important to us and our customers, and our products are held to high quality and performance standards. In the event our products fail to meet these standards, we generally allow customers to return defective or damaged products under warranty. We carry a safety stock of inventory for our customers that may be impacted by warranty claims. We reserve for our exposure to warranty claims based upon recent historical experience and other specific information as it becomes available. However, these reserves may not be adequate to cover future warranty claims. If our reserves for warranty claims are inadequate, additional warranty costs or inventory write- offs may need to be incurred in the future, which could harm our operating results. We also could be subject to negative publicity and our reputation could be harmed if we fail to meet quality standards. This could erode our competitive advantage over competitors, causing us to lose or see a material reduction in business from customers and resulting in lower revenues. In addition, we might be required to devote significant resources to address any quality issues associated with our products, which could reduce the resources available for product development and other matters. Our operations are subject to cyber- attacks and other information technology disruptions that could have a material adverse effect on our business, ~~consolidated~~ results of operations and ~~consolidated~~ financial condition **. We are a global company with a complex business model** . In the ordinary course of business, our operations are, and in the future are expected to continue to be, dependent on digital technologies and information technology (" IT ") systems. **Due** ~~The COVID- 19 pandemic has caused us~~ to ~~modify~~ **the complex nature of** our business ~~practices~~ , ~~including the requirement that many~~ **and due to policies we have in place allowing certain** of our ~~office- based~~ employees **to** work from home **from** ~~, at least part-~~ time **to time** ~~. As a result~~ , we are increasingly dependent upon our technology systems to operate our business and our ability to effectively manage our business depends on the security, reliability and adequacy of our technology systems and data. We use these technologies and systems for internal purposes, including data storage, processing and transmissions, as well as in our interactions with customers and suppliers. The security of this information and these systems are important to our operations and business strategy. Our IT systems and infrastructure have been, and in the future are expected to continue to be, subject to the risk of cyber- attacks by hackers or malware, or breach due to associate error, malfeasance or other disruptions, including natural disasters, failures in hardware or software ~~,~~ and power fluctuations. As the techniques used to obtain unauthorized access, disable or degrade service ~~,~~ or sabotage infrastructure and systems change frequently and may be difficult to detect for long periods of time, we may be unable to anticipate these techniques or implement adequate preventive measures. If our systems for protecting against cybersecurity risks or other IT disruptions prove insufficient, our business could be disrupted, resulting in numerous consequences, including temporary or permanent loss of, damage to, third party access to, or misappropriation or public disclosure of **our or a third party' s** intellectual property, proprietary or confidential information, or customer, supplier, or employee data; interruption of our business operations; and increased costs required to prevent, respond to, or mitigate such cybersecurity attacks or IT disruptions. In addition, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed or stolen. These risks could harm our reputation and brand, and our relationships with customers, suppliers, employees and other third parties, and may result in claims or proceedings against us. In certain circumstances, we may rely on third **-** party vendors to process, store and transmit data for our business whose operations are subject to similar risks. These risks could have a material adverse effect on our business, financial condition and results of operations. ~~While~~ **If** we ~~maintain insurance~~ **are unable to protect our business against or efficiently respond to cybersecurity attacks, it could have a material adverse impact on our business, results of operations and financial condition. Additionally, the legal and regulatory environment surrounding information security and privacy is increasingly demanding, with the imposition of new and changing requirements across 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 U. S. and in other countries, including, but not limited to, HIPAA, HITECH, the California Privacy Rights Act and the EU' s General Data Protection Regulation (" GDPR "). The GDPR imposes stringent EU data protection requirements and provides** for ~~cyber events, our insurance may not~~ **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 ~~sufficient~~ **out of compliance. We or our third- party providers and business partners may also be subjected** to ~~cover us against all losses that~~ **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 ~~potentially result~~ **results in material fines** ~~from a breach of our~~ - **or litigation** ~~systems or loss of sensitive data~~ . Global climate change and related emphasis on environmental, social and governance (~~"~~ **"** ESG ~~"~~ **"**) matters by various stakeholders could negatively affect our business or **the price of our common** stock ~~price~~ . Customer, investor and employee expectations relating to ESG have been rapidly evolving and increasing. In addition, government organizations are enhancing or advancing legal and regulatory requirements specific to ESG matters. The heightened stakeholder focus on ESG issues related to our business requires the continuous monitoring of various and evolving laws, regulations, standards and expectations and the associated reporting requirements. A failure to adequately meet stakeholder expectations may result in **material** noncompliance, the loss of business, reputational impacts, reduced **investor** demand **to purchase** ~~for~~ - **or continue to hold** our **common** stock, diluted ~~- 18 -~~ market valuation ~~,~~ and an inability to attract customers. In addition, our **- 19-** adoption of certain standards or mandated compliance ~~to~~ **with** certain requirements could necessitate additional investments that could **increase our operating costs and have a negative** impact **on** our profitability. **Global** ~~Climate~~ **climate** ~~changes~~ - **change** could disrupt our operations by impacting the availability and cost of materials within our supply chain and could also increase our other operating costs **. Transition to low- carbon alternatives may result in reduced demand or product obsolescence for certain of our customers' products, which in turn would result in reduced profit margin associated with certain of our customers, or loss of customers that we may not be able to replace** . Further, increased public awareness and concern regarding global climate change may result in new or enhanced legal requirements to reduce or mitigate the effects of greenhouse gas emissions.

There continues to be a lack of consistent climate legislation **and regulation** , which creates economic and regulatory uncertainty. Such uncertainty may have an impact on our business, including increased costs of compliance, which may impact our results of operations. We are dependent upon our senior management team and key technical personnel and the loss of any of them could significantly harm us. Our future performance depends to a significant degree upon the continued contributions of our senior management team and key technical personnel. In general, only highly qualified and trained scientists have the necessary skills to develop our products, which are often highly technical in nature. The loss or unavailability to us of any member of our senior management team or a key technical employee could significantly harm us. We face intense competition for these professionals from our competitors, customers and companies operating in our industry, which competition has become more acute during the term of the COVID- 19 pandemic. To the extent that the services of members of our senior management team and key technical personnel would be unavailable to us for any reason, we would be required to hire other personnel to manage and operate our Company and to develop our products and technology, which could adversely impact our business. We may not be able to locate or employ these qualified personnel on acceptable terms or may need to increase spending to attract these qualified personnel. Our energy market revenues are dependent on conditions in the oil and natural gas industry, which historically have been volatile. Sales of our products into the energy market depend upon the condition of the oil and gas industry. We believe it is likely that oil and natural gas prices will continue to fluctuate in the future. The current and anticipated prices of oil and natural gas influence the oil and gas exploration and production industry and are affected by a variety of political and economic factors, including worldwide demand for oil and natural gas, worldwide and domestic supplies of oil and natural gas, the ability of the Organization of Petroleum Exporting Countries (“ OPEC ”) to set and maintain production levels and pricing, the level of production of non- OPEC countries, the price and availability of alternative fuels, political stability in oil producing regions and the policies of the ~~various~~ **U. S. government and foreign** governments regarding exploration and development of their oil and natural gas reserves. Consolidation in the healthcare industry could result in greater competition and reduce our revenues and harm our business **and our operating results** . Many healthcare industry companies are consolidating to create new companies with greater market power. As the healthcare industry consolidates, competition to provide products and services to industry participants will become more intense. These industry participants may try to use their market power to negotiate price reductions for our products or may undertake additional vertical integration or supplier diversification initiatives. If we are forced to reduce our prices, our revenues would decrease and our operating results would suffer. Strategic Risks If we are unable to successfully market our current or future products, our business will be harmed and our revenues and operating results will be adversely affected. If the markets for our products do not grow as we or industry experts forecast, our revenues could be less than expected. Furthermore, it is difficult to predict the rate at which the markets for our products will grow or if new and increased competition will result in market saturation. Slower growth in the cardiac rhythm management, neuromodulation, cardio and vascular, environmental, military or energy markets in particular would adversely impact our revenues. In addition, we face the risk that our products will lose widespread market acceptance. Our customers may not continue to utilize the products we offer and a market may not develop for our future products. We may at times determine that it is not technically or economically feasible for us to continue to manufacture certain products and we may not be successful in developing or marketing replacement products. Additionally, new technologies that we develop may not be rapidly accepted because of industry- specific factors, including the need for regulatory clearance, entrenched patterns of clinical practice and uncertainty over third **-** party reimbursement. If any of these events occurs, our business will be harmed and our revenues and operating results will be adversely affected.- ~~19~~ **20** - We may face intense competition that could harm our business, including competitors, in- sourcing and the possibility of dual sourcing; and we may be unable to compete successfully against new entrants and established companies with greater resources. Competition in connection with the manufacturing of our medical products across all of our product lines, which is fragmented and subject to rapid technological change, has intensified in recent years and may continue to intensify in the future. We encounter significant competition across our product lines and in each market in which our medical products are sold from various medical device companies, some of which may have greater financial, operational, personnel, sales, technical and marketing resources than we do and are more well- established. In addition, our medical customers have in the past elected, and may in the future elect, to insource production or implement supplier diversification initiatives. Such actions have in the past resulted in, and may in the future result in, the customer manufacturing or dual ~~-~~sourcing some or all of the components or products that we currently supply to them, which could cause our operating results to suffer. If we do not respond to changes in technology, our products may become obsolete or less competitive and we may experience a loss of customers and lower revenues. We sell our products to customers in several industries that are characterized by extensive research and development, rapid technological changes, new product introductions and evolving industry standards. Without the timely introduction of new products, technologies and enhancements, our products and services will likely become technologically obsolete or less competitive over time and we may lose or see a reduction in business from a significant number of our customers. We dedicate a significant amount of effort and resources to the development of our products, technologies and enhancements. Our product development efforts may be affected by a number of factors, including our ability to anticipate customer needs, develop or acquire new technologies and enhancements, secure intellectual property protection for our products, and manufacture products in a cost effective manner. We would be harmed if we did not meet customer requirements and expectations. Our inability, for technological or other reasons, to successfully develop and introduce new and innovative products, technologies and enhancements could result in a loss of customers and lower revenues. We intend to develop new products and expand into new geographic and product markets, which may not be successful and could harm our operating results. We intend to develop new and modified products using our existing technologies and engineering capabilities and to continue to expand into new geographic and product markets. These efforts have required and will continue to require us to make substantial investments, including significant RD & E expenditures and capital expenditures for new, expanded or improved manufacturing facilities. Additionally, many of the new products we are developing take longer and more resources to develop and commercialize than those products we are currently marketing, including more time and resources required to obtain regulatory approvals. Specific risks in connection with expanding into new products and product markets include: longer product development cycles, the inability to transfer our quality standards and technology into new products, the failure to receive or the delay in receipt of regulatory approval for new products or modifications to existing products ~~,~~ and the failure of our existing customers or the market generally to accept the new or modified products. Our inability to develop new products or expand into new geographic and product markets, as currently intended, could hurt our business, financial condition and results of operations. If we are not successful in making acquisitions to expand and develop our business, our operating results may suffer. One facet of our growth strategy is to make acquisitions that complement our core competencies in technology and manufacturing to enable us to manufacture and sell additional or enhanced products to our existing customers and to expand our business into related markets. Our continued growth ~~may~~ **through acquisitions** ~~depend~~ **depends** on our ability to successfully identify and acquire companies that complement or enhance our existing business on acceptable terms. We may not be able to identify or complete future acquisitions. In addition, we will need to comply with the terms of our Senior Secured Credit Facilities and any future financing that we may incur, to pursue and complete future acquisitions. In connection with pursuing this growth strategy, some of the risks that we may encounter include expenses associated with and difficulties in identifying potential targets, the costs associated with unsuccessful acquisitions, and higher prices for acquired companies because of significant competition for attractive acquisition targets.- ~~20~~ **21** - Successful integration and anticipated benefits of acquisitions cannot be assured and integration matters could divert attention of management away from operations. Part of our business strategy includes acquiring additional businesses and assets, which we have done in each of the last four years. If we do not successfully integrate acquisitions **,** we may not realize anticipated operating advantages and cost savings. Our ability to realize the anticipated benefits from acquisitions will depend, to a large extent, on our ability to integrate these acquired businesses with our legacy businesses. Integrating and coordinating aspects of the operations and personnel of the acquired business with legacy businesses involves complex operational, technological and personnel- related challenges. This process is time- consuming and expensive, disrupts the businesses of both companies and may not result in the achievement of the full benefits expected by us, including cost synergies expected to arise from supply chain efficiencies and overlapping general and administrative functions. The potential difficulties, and resulting costs and delays, include: • managing a larger combined company; • consolidating corporate and administrative infrastructures; • issues in integrating manufacturing, warehouse and distribution facilities, supply chain, RD & E and sales forces; • difficulties attracting and retaining key personnel; • loss of customers and suppliers and inability to attract new customers and suppliers; • unanticipated issues in integrating information technology, communications and other systems; • incompatibility of purchasing, logistics, marketing, administration and other systems and processes; and • unforeseen and unexpected liabilities related to the acquired business **, which may be beyond the scope of any applicable insurance coverage we may have** . Additionally, the integration of our legacy businesses with an acquired company' s operations, products and personnel may place a significant burden on management and other internal resources. The attention of our management may be directed towards integration considerations and may be diverted from our day- to- day business operations, and matters related to the integration may require commitments of time and resources that could otherwise have been devoted to other opportunities that might have been **more** beneficial to us and our business. The diversion of management' s attention, and any difficulties encountered in the transition and integration process, could harm our business, financial condition and operating results. We may not be able to maintain the levels of operating efficiency that acquired companies have achieved or might achieve separately. Successful integration of each acquisition will depend upon our ability to manage those operations and to eliminate redundant and excess costs. Difficulties in integration may be magnified if we make multiple acquisitions over a relatively short period of time. Because of difficulties in combining and expanding operations, we may not be able to achieve the cost savings and other ~~size- related~~ benefits that we hoped to achieve after these acquisitions. Financial **and Indebtedness** Risks Our operating results may fluctuate, which may make it difficult to forecast our future performance and may result in volatility in our **common** stock price. Our operating results have fluctuated in the past and are likely to continue to fluctuate from quarter to quarter, making forecasting future performance difficult and resulting in volatility in our **common** stock price. These fluctuations are due to a variety of factors, including the following: ~~• the impact of the ongoing pandemic and the pace of recovery;~~ • timing of orders placed by our customers; • our customers' approach to inventory management; • changes in the mix of our revenue represented by our various products and customers could result in reductions in our profits if the mix of our revenue represented by lower margin products increases; • a portion of our costs are fixed in nature, which results in our operations being particularly sensitive to fluctuations in production volumes; • increased costs and decreased availability of raw materials or supplies; and • our ability to effectively execute on operational initiatives to drive manufacturing efficiencies.- ~~21~~ **22** - We have significant indebtedness that could **adversely** affect our operations, financial condition, and cash flows if we fail to meet certain financial covenants required by our debt agreements or if our access to capital markets is interrupted. At December 31, ~~2022~~ **2023** , we had $ ~~931~~ **974** million in principal amount of debt outstanding **under the Senior Secured Credit Facilities and the 2. 125 % convertible senior notes due 2028 (the " 2028 Convertible Notes ")** . As of December 31, ~~2022~~ **2023** , our debt service obligations, comprising principal ~~and~~ **,** interest **and commitment fees on the unused portion of our Revolving Credit Facility** , are estimated to be approximately $ ~~78~~ **44** million for ~~2023~~ **2024** . The outstanding indebtedness and the terms and covenants of the agreements under which this debt was incurred, could, among other things: • require us to dedicate a large portion of our cash flow from operations to the servicing and repayment of our outstanding indebtedness, thereby reducing funds available for working capital, capital expenditures, acquisitions, RD & E expenditures and other general corporate requirements; • limit our ability to obtain additional financing to fund future working capital, capital expenditures, RD & E expenditures and other general corporate requirements in the future **; • delay or prevent an otherwise beneficial takeover or takeover attempt of us** ; • limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate; • restrict our ability to make strategic acquisitions or dispositions or to exploit business opportunities; • place us at a competitive disadvantage compared to our competitors that have less outstanding indebtedness; and • adversely affect the market price of our common stock **, including by dilution resulting from the conversion of all or some of our 2028 Convertible Notes**. Additionally, our failure to comply with the covenants contained in ~~our debt~~ **the 2021 Credit** ~~agreements~~ **Agreement governing our Senior Secured Credit Facilities**, if not waived, could cause a default under ~~the applicable debt agreement~~ **our Senior Secured Credit Facilities** that requires repayment in full, or acceleration, of debt payments. If that were to occur, there can be no assurance that we would be able to refinance or obtain a replacement financing on favorable terms or at all. ~~The transition away from LIBOR may adversely affect our borrowing costs. In 2017, the U. K.' s Financial Conduct Authority, which regulates the London Interbank Offered Rate (" LIBOR "), announced its intention to phase out LIBOR by the end of 2021. The deadline has been mostly extended and most U. S. dollar- denominated LIBOR maturity tenors will continue to be published until June 30, 2023. Our Senior Secured Credit Facilities use LIBOR as a benchmark for determining borrowing rates but also provides for the use of the Secured Overnight Finance Rate (" SOFR ") in the event LIBOR is no longer available. The change to SOFR as the benchmark borrowing rate may result in an effective increase in the applicable interest rate, and thus increased borrowing costs under our Senior Secured Credit Facilities agreement, which could impact our financial condition and results of operations.~~ Economic and credit market uncertainty could interrupt our access to capital markets, borrowings, or financial transactions to hedge certain risks, which could adversely affect our business prospects and financial condition. To date, we have been able to access debt and equity financing that has allowed us to complete acquisitions, make investments in growth opportunities and fund working capital requirements. In addition, we enter into financial transactions to hedge certain risks, including foreign exchange and interest rate risk **, as further discussed below**. Our continued access to capital markets, the stability of our lenders under our Senior Secured Credit Facilities and their willingness to support our needs, and the stability of the parties to our financial transactions that hedge risks are essential for us to meet our current and long- term obligations, fund operations, and fund our strategic initiatives. An interruption in our access to external financing or financial transactions to hedge risk could adversely affect our business prospects and financial condition. **In addition, certain of our borrowings are at variable interest rates and therefore we are subject to interest rate risk. Persistent inflation, especially in Europe and the U. S., has led central banks to raise interest rates to dampen inflation. Changes in interest rates directly impact the amount of interest we pay on our variable rate obligations and continued or sustained increases in interest rates could negatively impact our business. The conditional conversion feature of the 2028 Convertible Notes, if triggered, may adversely affect our financial condition and operating results. Under certain circumstances, the holders of our 2028 Convertible Notes may convert their notes at their option prior to the scheduled maturities. If one or more noteholders elect to convert their 2028 Convertible Notes, we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, holders of our 2028 Convertible Notes will have the right to require us to repurchase their notes upon the occurrence of a fundamental change (as defined in the indenture governing the 2028 Convertible Notes), at a repurchase price equal to the principal amount of the 2028 Convertible Notes to be repurchased, plus accrued and unpaid special interest, if any, to but not including, the fundamental change repurchase date. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the 2028 Convertible Notes or pay the cash amounts due upon conversion. In addition, applicable law, regulatory authorities and the agreements governing our other indebtedness may restrict our ability to repurchase the 2028 Convertible Notes or pay the cash amounts due upon conversion. Our failure to repurchase the 2028 Convertible Notes or to pay the cash amounts due upon conversion when required will constitute a default under the indenture governing the 2028 Convertible Notes. A default under the indenture governing the 2028 Convertible Notes or the fundamental change itself could also lead to a default under agreements governing our other indebtedness, including the 2021 Credit Agreement governing the Senior Secured Credit Facilities, which may result in that other indebtedness becoming immediately payable in full. We may not have sufficient funds to satisfy all amounts due under the other indebtedness and the 2028 Convertible Notes.- 23- Even if holders of the 2028 Convertible Notes do not elect to convert their notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the 2028 Convertible Notes as a current rather than long- term liability, which would result in a material reduction of our net working capital. Certain provisions in the 2028 Convertible Notes and the indenture governing the 2028 Convertible Notes could delay or prevent an otherwise beneficial takeover or takeover attempt of us. Certain provisions in the 2028 Convertible Notes and the indenture governing the 2028 Convertible Notes could make it more difficult or more expensive for a third party to acquire us. For example, if a takeover constitutes a fundamental change, holders of the 2028 Convertible Notes will have the right to require us to repurchase their notes in cash. In addition, if a takeover constitutes a make- whole fundamental change (as defined in the indenture governing the 2028 Convertible Notes), we may be required to increase the conversion rate for holders of the 2028 Convertible Notes who convert their notes in connection with such takeover. In either case, and in other cases, our obligations under the 2028 Convertible Notes and the indenture governing the 2028 Convertible Notes could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management, including in a transaction that holders of our common stock may view as favorable. Transactions relating to our 2028 Convertible Notes may affect the market price of our common stock. The conversion of some or all of our 2028 Convertible Notes would dilute the ownership interests of existing stockholders to the extent we satisfy our conversion obligation by delivering shares of our common stock upon any conversion of such 2028 Convertible Notes. Our 2028 Convertible Notes may become convertible in the future at the option of their holders under certain circumstances. If holders of our 2028 Convertible Notes elect to convert their notes, we may settle our conversion obligation by delivering to them a significant number of shares of our common stock, which would cause dilution to our existing stockholders. In connection with the pricing of the 2028**

Convertible Notes, we entered into capped call transactions with the option counterparties. The capped call transactions are expected generally to reduce potential dilution to our common stock upon conversion of any 2028 Convertible Notes and / or offset any cash payments we are required to make in excess of the principal amount of converted 2028 Convertible Notes, as the case may be, with such reduction and / or offset subject to a cap. In addition, the option counterparties and / or their respective affiliates may modify their hedge positions by entering into or unwinding various derivatives with respect to our common stock and / or purchasing or selling our common stock or other securities of ours in secondary market transactions following the pricing of the 2028 Convertible Notes and prior to the maturity of the 2028 Convertible Notes (and are likely to do so on each exercise date for the capped call transactions or following any termination of any portion of the capped call transactions in connection with any repurchase, redemption or early conversion of the 2028 Convertible Notes). This activity could cause or avoid an increase or decrease in the market price of our common stock. In addition, if any such capped call transactions fail to become effective, the option counterparties or their respective affiliates may unwind their hedge positions with respect to our common stock, which could adversely affect the trading price of our common stock.- 24- We are subject to counterparty risk with respect to the capped call transactions. The option counterparties are financial institutions, and we will be subject to the risk that any or all of them might default under the capped call transactions. Our exposure to the credit risk of the option counterparties will not be secured by any collateral. Past global economic conditions have resulted in the actual or perceived failure or financial difficulties of many financial institutions. If an option counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings with a claim equal to our exposure at that time under the capped call transactions with such option counterparty. Our exposure will depend on many factors but, generally, an increase in our exposure will be correlated to an increase in the market price and in the volatility of our common stock. In addition, upon a default by an option counterparty, we may suffer adverse tax consequences and more dilution than we currently anticipate with respect to our common stock. We can provide no assurance as to the financial stability or viability of the option counterparties. Our international sales and operations are subject to a variety of market and financial risks and costs that could **adversely** affect our profitability and operating results. Our sales outside the U. S., which accounted for approximately ~~45~~ **44** % of sales for ~~2022~~ **2023** , and our operations in Europe, Asia ~~, Israel~~ , Mexico, South America and the Caribbean are and will continue to be subject to a number of risks and potential costs, including: • changes in foreign economic conditions or regulatory requirements; • changes in foreign currency exchange rates; • local product preferences and product requirements; • outstanding accounts receivables that take longer to collect than is typical in the U. S.; • difficulties in enforcing agreements through foreign legal systems; • less protection of intellectual property in some countries outside of the U. S.; • trade protection measures and import and export licensing requirements; • work force instability; • **significant natural disasters and other events or factors impact local infrastructure; •** political and economic instability **, including civil or international conflicts, war and terrorism** ; • transportation delays or interruptions; and • complex tax and cash management issues. These risks are also present in connection with our entry into new geographic markets. ~~- 22-~~ Additionally, as a result of our international operations, we are subject to exposure from currency exchange rate fluctuations. We purchase forward currency contracts in certain currencies to reduce our exposure; however, these transactions may not be adequate or effective to protect us from the exposure for which they are purchased. Historically, foreign currency exchange rate fluctuations have not had a material effect on our net financial results. However, fluctuations in foreign currency exchange rates could have a significant impact on our financial results in the future. We have a complex tax profile due to the global nature of our operations and may experience increases and variability in our quarterly and annual effective tax rate due to several factors, including changes in the mix of pre- tax income and the jurisdictions to which it relates, business acquisitions, settlements with taxing authorities ~~,~~ and changes in tax rates. Our global operations encompass multiple taxing jurisdictions. Variability in the mix and profitability of domestic and international activities, identification and resolution of various tax uncertainties, changes in tax laws and rates, and the extent to which we are able to realize net operating loss and other carryforwards included in deferred tax assets and avoid potential adverse outcomes included in deferred tax liabilities, among other matters, may significantly affect our effective income tax rate in the future. Changes in international tax laws or additional changes in U. S. tax laws could materially affect our financial position and results of operations. The EU and many of its member countries, as well as a number of other countries and organizations such as the Organization for Economic Cooperation and Development, are actively considering tax law changes that would negatively impact our effective tax rate. If tax laws and related regulations change, our financial results could be materially impacted. Given the unpredictability of these possible changes and their potential interdependency, it is possible such changes could adversely impact our financial results. **- 25-** Our effective income tax rate is the result of the income tax rates in the various countries in which we do business. Our mix of income and losses in these jurisdictions affects our effective tax rate. For example, relatively more income in higher tax rate jurisdictions would increase our effective tax rate and thus lower our net income. Similarly, if we generate losses in tax jurisdictions for which no benefits are available, our effective income tax rate will increase. Our effective income tax rate may also be impacted by the recognition of discrete income tax items, such as required adjustments to our liabilities for uncertain tax positions or our deferred tax asset valuation allowance. Our effective income tax rate has fluctuated from ~~10. 4 % in 2020, to~~ 8. 0 % in 2021 ~~and~~ **,** to 14. 0 % **in 2022 and to 15. 5 %** for ~~2022~~ **2023** . A significant increase in our effective income tax rate could have a material adverse impact on our earnings. We have recorded deferred tax assets based on our assessment that we will be able to realize the benefits of our net operating losses and other favorable tax attributes. Realization of deferred tax assets involve significant judgments and estimates which are subject to change and ultimately depends on generating sufficient taxable income of the appropriate character during the appropriate periods. Changes in circumstances may affect the likelihood of such realization, which in turn may trigger a write- down of our deferred tax assets, the amount of which would depend on a number of factors. A write- down would reduce our reported net income, which may adversely impact our financial condition or results of operations or cash flows. In addition, we are potentially subject to ongoing and periodic tax examinations and audits in various jurisdictions, including with respect to the amount of our net operating losses and any limitation thereon. An adjustment to such net operating loss carryforwards, including an adjustment from a taxing authority, could result in higher tax costs, penalties and interest, thereby adversely impacting our financial condition, results of operations or cash flows. We may never realize the full value of our intangible assets, which represent a significant portion of our total assets. At December 31, ~~2022~~ **2023** , we had $ 1. 8 billion of goodwill and other intangible assets, representing ~~64~~ **61** % of our total assets. These intangible assets consist primarily of goodwill, trademarks, tradenames, customer lists and patented technology arising from our acquisitions. Goodwill and other intangible assets with indefinite lives are not amortized, but are tested annually or upon the occurrence of certain events that indicate that the assets may be impaired. Definite lived intangible assets are amortized over their estimated useful lives and are tested for impairment upon the occurrence of certain events that indicate that the assets may not be recoverable. We may not receive the recorded value for our intangible assets if we sell or liquidate our business or assets. In addition, our significant amount of intangible assets increases the risk of a large charge to earnings in the event that the recoverability of these intangible assets is impaired. In the event of a significant charge to earnings, the market price of our common stock could be adversely affected. In addition, intangible assets with definite lives, which represent $ ~~729~~ **692** . ~~6~~ **9** million of our net intangible assets at December 31, ~~2022~~ **2023** , will continue to be amortized. These expenses will continue to reduce our future earnings or increase our future losses. The accounting for intangible assets requires reliance on forward **-** looking estimates of sales and / or earnings. ~~Due to the uncertainty surrounding the global pandemic, estimating~~ **Estimating** the future performance of our business is extremely challenging and the range of deviation from internal estimates could be more significant in ~~this~~ **the current market** environment. ~~As of December 31, 2022, the pandemic has not had an impact on the carrying value of our goodwill and other intangible assets. A prolonged pandemic could have adverse changes on the underlying estimates, assumptions or judgments and could have a material adverse impact on the fair value of our goodwill and other indefinite- lived intangible assets.- 23-~~ Legal and Compliance Risks Regulatory issues resulting from product complaints, ~~or~~ recalls ~~,~~ or regulatory audits could harm our ability to produce and supply products or bring new products to market. The products that we design, manufacture and distribute, including our customers' finished medical devices, product components that are incorporated into our customers' finished medical devices, and our own finished medical devices, are designed, manufactured and distributed globally in compliance with applicable regulations and standards. However, a product complaint, recall **(either voluntary or as required by any governmental authority)** or negative regulatory audit may cause our products, including product components and finished medical devices, to be removed from the market and harm our operating results or financial condition. In addition, during the period in which corrective action is being taken by us to remedy a **product** complaint, recall or negative regulatory audit, regulators may not allow our new products or components to be cleared for marketing and sale. **- 26-** If we become subject to product liability claims, our operating results and financial condition could suffer. Our business exposes us to potential product liability claims, which may take the form of a one- off claim from a single claimant or a class action lawsuit covering multiple claimants. Product failures, including those that arise from the failure to meet product specifications, misuse or malfunction, or design flaws, or the use of our products with other components, systems or medical devices not manufactured or sold by us could result in product liability claims or a recall. Many of our products are components that interact with our customers' medical devices. For example, our batteries are produced to meet electrical performance, longevity and other specifications, but the actual performance of those products is dependent on how they are utilized as part of our customers' devices over the lifetime of their products. Product performance and device interaction from time to time have been, and may in the future be, different than expected for a number of reasons. Consequently, it is possible that customers may experience problems with their medical devices that could require device recall or other corrective action, where our batteries **or other products or components** met the specification at delivery, and for reasons that are not related primarily or at all to any failure by our product to perform in accordance with specifications. It is possible that our customers (or end- users) may in the future assert that our products caused or contributed to device failure. Even if these assertions do not lead to product liability or contract claims, they could harm our reputation and our customer relationships. Furthermore, the design and manufacturing of finished medical devices of the types that we also produce entail an inherent risk of product liability claims. Some of the medical devices that we manufacture and sell are designed to be implanted into the human body. A number of factors could result in an unsafe condition or injury to, or death of, a patient with respect to these medical devices. These factors could also result in product liability claims, a recall of one or more of our medical devices or a safety alert relating to one or more of our medical devices. Provisions contained in our agreements with key customers attempting to limit our damages, including provisions to limit damages to liability for negligence, may not be enforceable in all instances or may otherwise fail to adequately protect us from liability for damages. Product liability claims or product recalls, regardless of their ultimate outcome and whether related to a product component or a finished medical device, could require us to spend significant time and money in litigation and require us to pay significant damages and could divert the attention of our management from our business operations. ~~The occurrence of~~ **We may choose to settle** product liability claims **against us regardless of their actual merit, and the occurrence of product liability claims** or product recalls could **adversely** affect our operating results and financial condition. We carry product liability insurance with coverage that is limited in scope and amount. We may not be able to maintain this insurance at a reasonable cost or on reasonable terms, or at all. This insurance may not be adequate to protect us against product liability claims made against us. If we are unable to protect our intellectual property and proprietary rights, our business could be harmed. We rely on a combination of patents, licenses, trade secrets and know- how to establish and protect our rights to our technologies and products. However, these measures afford only limited protection, and our patent rights, whether issued, subject to license or in process, and our other intellectual property protections may be misappropriated, circumvented or invalidated. The laws of some foreign countries do not offer the same level of protection for our intellectual property as the laws of the U. S. Further, no assurances can be given that any patent application we have filed or will file will result in a patent being issued, or that any existing or future patents will afford adequate or meaningful protection against competitors or against similar technologies. In addition, competitors may design around our technology or develop competing technologies that do not infringe our proprietary rights. As patents and other intellectual property protection expire, we may lose our competitive advantage. If third parties infringe or misappropriate our patents or other proprietary rights, our ~~businesses~~ -- **business** could be seriously harmed. ~~- 24 -~~ In addition, we cannot ~~be assured~~ - **assure you** that our existing or planned products do not or will not infringe on the intellectual property rights of others or that others will not claim such infringement. Our industry has experienced extensive ongoing patent litigation which can result in the incurrence of significant legal costs for indeterminate periods of time, injunctions against the manufacture or sale of infringing products and significant royalty payments. At any given time, we may be a plaintiff or defendant in these types of actions. We cannot assure you that we will be able to prevent competitors from challenging our patents or other intellectual property rights or entering markets we currently serve. In addition to seeking formal patent protection whenever possible, we attempt to protect our proprietary rights and trade secrets by entering into confidentiality agreements with employees, consultants and third parties with which we do business. However, these agreements may be breached and, if a breach occurs, there may be no adequate remedies available to us and we may be unable to prevent the unauthorized disclosure or use of our technical knowledge, practices or procedures. If our trade secrets become known, we may lose our competitive advantages. **- 27-** We may be subject to intellectual property claims, which could be costly and time consuming and could divert our management' s attention from our business operations. In producing our products, third parties may claim that we are infringing on their intellectual property rights, and we may be found to have infringed on those intellectual property rights. We may be unaware of the intellectual property rights of others that may be used in our technology and products. In addition, third parties may claim that our patents have been improperly granted and may seek to invalidate our existing or future patents. If any claim for invalidation prevailed, third parties may manufacture and sell products that compete with our products and our revenues from any related license agreements would decrease accordingly. Former employers of our associates may assert claims that these associates have improperly disclosed to us the confidential or proprietary information of those former employers. We also typically do not receive significant indemnification from parties that license technology to us against third **-** party claims of intellectual property infringement. Any litigation or other challenges regarding our patents or other intellectual property, with or without merit, could be costly and time consuming and could divert the attention of our management and key personnel from our business operations. The complexity of the technology involved in producing our products and the uncertainty of intellectual property litigation increases these risks. If we are not successful in defending these claims, we could be required to stop selling, delay shipments of, or redesign our products, discontinue the use of related technologies or designs, pay monetary amounts as damages, and satisfy indemnification obligations that we have with some of our customers. Claims of intellectual property infringement may also require us to enter into costly royalty or license agreements. However, we may not be able to obtain royalty or license agreements on terms acceptable to us, or at all. We also may be made subject to significant damages or injunctions against development and sale of our products. A failure to comply with customer- driven policies and standards and third- party certification requirements or standards could adversely affect our business and reputation. Our customers have in the past, and may in the future, require us to comply with their own or third-party quality standards, business policies, commercial terms, or other policies or standards, which have been, and may continue to be, even more restrictive than current laws and regulations as well as our pre- existing policies or terms with our suppliers, before they commence, or continue, doing business with us. These policies or standards may be customer- driven, established by the market sectors in which we operate or imposed by third **-** party organizations. Our compliance with these heightened or additional policies, standards and third- party certification requirements, and managing a supply chain in accordance with those policies, standards and requirements, could be costly and time consuming, and our failure to comply could adversely affect our operations, customer relationships, reputation and profitability. In addition, our adoption of these standards could adversely affect our cost competitiveness and ability to provide customers with required service levels. In certain circumstances, to meet the requirements or standards of our customers, we may be obligated to select certain suppliers or make other sourcing choices, and we may bear responsibility for adverse outcomes even if these matters are the result of third- party actions or outside of our control. Our failure to obtain licenses from third parties for new technologies or the loss of these licenses could impair our ability to design and manufacture new products and reduce our revenues. We occasionally license technologies from third parties rather than depending exclusively on our own proprietary technology and developments. Our ability to license new technologies from third parties is and will continue to be critical to our ability to offer new and improved products. We may not be able to continue to identify new technologies developed by others and even if we are able to identify new technologies, we may not be able to negotiate licenses on favorable terms, or at all. Additionally, we may lose rights granted under licenses for reasons beyond our control or if the license has a finite term and cannot be renewed on favorable terms or at all. ~~- 25 -~~ Our business is subject to environmental regulations that could be costly to comply with. Federal, state and local regulations impose various environmental controls on the manufacturing, transportation, storage, use and disposal of batteries and hazardous chemicals and other materials used in, and hazardous waste produced by the manufacturing of our products. Conditions relating to our historical operations, including a former manufacturing facility located in South Plainfield, New Jersey previously operated by a subsidiary of Lake Region Medical, may require expenditures for clean- up in the future that could materially adversely affect our financial results. In addition, changes in environmental laws and regulations may impose costly compliance requirements on us or otherwise subject us to future liabilities. Additional or modified regulations relating to the manufacture, transportation, storage, use and disposal of materials used to manufacture our products or restricting disposal or transportation of batteries may be imposed that may result in higher costs or lower operating results. In addition, we cannot predict the effect that additional or modified environmental regulations may have on us or our customers. **- 28-** Our international operations expose us to legal and regulatory risks, which could adversely affect our business. Our profitability and international operations are, and will continue to be, subject to risks relating to changes in foreign legal and regulatory requirements. In addition, our international operations are governed by various U. S. laws and regulations, including the U. S. Foreign Corrupt Practices Act and other similar anti- corruption laws in other countries that prohibit us and our business partners and other intermediaries from making improper payments or offers of payment to foreign governments and their officials and political parties for the purpose of obtaining or retaining business. **In recent years, both the U. S. and non- U. S. regulators have increased regulation, enforcement, inspections, and governmental investigations of the medical device industry, including increased U. S. government oversight and enforcement of the U. S. Foreign Corrupt Practices Act.** Any alleged or actual violations of these regulations may subject us to government scrutiny, severe criminal or civil sanctions and other liabilities and could adversely affect our business, reputation, operating results, and financial condition. The healthcare industry is highly regulated and subject to various political, economic and regulatory changes that could increase our compliance costs and force us to modify how we develop and price our products. The healthcare industry is highly regulated and is influenced by changing political, economic and regulatory factors. Several of our product lines are subject to international, federal, state and local health and safety, packaging and product content regulations, including the European Medical Device Regulation ~~that went into effect in May 2021~~ , which was adopted by the EU as a common legal framework for all EU member states. In addition, medical devices are subject to regulation by the FDA and similar governmental agencies. These regulations cover a wide variety of product activities from design and development to labeling, manufacturing, promotion, sales and distribution. Compliance with these regulations is time consuming, burdensome and expensive and could adversely affect our ability to sell products. This may result in higher than anticipated costs or lower than anticipated revenues. Furthermore, healthcare industry regulations are complex, change frequently and have tended to become more stringent over time. Federal and state legislatures have periodically considered and implemented programs to reform or amend the U. S. healthcare system at both the federal and state levels. In addition, these regulations may contain proposals to increase governmental involvement in healthcare, lower reimbursement rates or otherwise change the environment in which healthcare industry participants operate. We may be required to incur significant expenses to comply with these regulations or remedy past violations of these regulations. Our failure to comply with applicable government regulations could also result in cessation of portions or all of our operations, impositions of fines and restrictions on our ability to carry on or expand our operations. In addition, because many of our products are sold into regulated industries, we must comply with additional regulations in marketing our products. In response to perceived increases in healthcare costs in recent years, there have been and continue to be proposals by the ~~Presidential~~ **presidential** administrations **of both major U. S. political parties** , members of Congress, state governments, regulators and third- party payors to control these costs and, more generally, to reform the U. S. healthcare system, including by amending, repealing or replacing the Patient Protection and Affordable Care Act. It is unclear how such reforms will progress under the **current presidential administration or if a** new presidential administration **is elected in 2024** . Elements of health care reform such as comparative effectiveness research, an independent payment advisory board, payment system reforms including shared savings pilots and other provisions could meaningfully change the way healthcare is developed and delivered, and may materially adversely impact numerous aspects of our business, results of operations and financial condition. Our business is indirectly subject to healthcare industry cost containment measures that could result in reduced sales of our products. Several of our customers rely on third **-** party payors, such as government programs and private health insurance plans, to reimburse some or all of the cost of the procedures in which our products are used. The continuing efforts of governments, insurance companies and other payors of healthcare costs to contain or reduce those costs could lead to patients being unable to obtain approval for payment from these third **-** party payors for procedures in which our products are used. If this occurs, sales of medical devices may decline significantly and our customers may reduce or eliminate purchases of our products, or demand further price reductions. The cost containment measures that healthcare payors are instituting, both in the U. S. and internationally, could reduce our revenues and harm our operating results. ~~- 26-~~