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

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Investing in our common stock involves a high degree of risk. You should consider and carefully read all of the risks and uncertainties described below, as well as other information included in this Annual Report and in our other public filings. The risks described below are not the only ones facing us. The occurrence of any of the following risks or additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could materially and adversely affect our business, financial condition or results of operations. In such case, the trading price of our common stock could decline, and you may lose all or part of your original investment. This Form 10- K also contains forward- looking statements and estimates that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward- looking statements as a result of specific factors, including the risks and uncertainties described below. Our disclosure and analysis in this Form 10- K contains some forward- looking statements that are based on management' s beliefs and assumptions, current expectations, estimates and forecasts. We also provide forward- looking statements in other materials we release to the public as well as oral forward- looking statements. Such statements give our current expectations or forecasts of future events. They do not relate strictly to historical or current facts. We have attempted, wherever possible, to identify forward- looking statements by using words such as " estimate, " " expect, " " intend, " " believe, " " plan, " " anticipate " and other words and phrases of similar meaning. In particular, these include statements relating to future actions, business plans and prospects, new products, future performance or results of current or anticipated products, sales efforts, expenses, interest rates, foreign- exchange rates, economic effects, the outcome of contingencies, such as legal proceedings, and financial results. Many of the factors that will determine our future results are beyond our ability to control or predict. Achievement of future results is subject to known or unknown risks or uncertainties, including, without limitation, the risks set forth below. Therefore, actual results could differ materially from past results and those expressed or implied in any forward- looking statement. You should bear this in mind as you consider forward- looking statements. Unless required by applicable securities law, we undertake no obligation to publicly update forward- looking statements, whether as a result of new information, future events or otherwise. We also refer you to further disclosures we make on related subjects in our Quarterly Reports on Form 10- Q and Current Reports on Form 8- K to the SEC. Global and Economic Risks Global economic conditions, including inflation and supply chain disruptions, could continue to adversely affect our operations. General global economic downturns and macroeconomic trends, including heightened inflation, capital market volatility, interest rate and currency rate fluctuations, and economic slowdown or recession, may result in unfavorable conditions. Those conditions could negatively affect demand for our products due to customers decreasing their inventories in the near- term or long- term, reduction in sales due to raw material shortages, reduction in research and development efforts, our inability to sufficiently hedge our currency and raw material costs, insolvency of suppliers or customers, and exacerbate some of the other risks that affect our business, financial condition and results of operations. Both domestic and international markets experienced ~~significant~~ inflationary pressures in fiscal year ~~2022~~ **2023** and inflation rates in the U. S., as well as in other countries in which we operate, **could** ~~are currently expected to~~ continue at elevated levels for the near- term. In addition, the Federal Reserve in the U. S. and other central banks in various countries have raised, and may again raise, interest rates in response to concerns about inflation, which, coupled with reduced government spending and volatility in financial markets, may have the effect of further increasing economic uncertainty and heightening these risks. Interest rate increases or other government actions taken to reduce inflation could also result in recessionary pressures in many parts of the world ~~. Our results of operations and financial condition may be adversely affected by the ongoing COVID- 19 pandemic and other public health epidemics. Our operations expose us to risks associated with a pandemic, or outbreak of contagious diseases in the human population, including the COVID - 19 pandemic. The COVID- 19 pandemic has negatively impacted the global economy, disrupted consumer spending and global supply chains, disrupted the labor market, created significant volatility and disruption of financial markets and has resulted in governments around the world implementing stringent measures to help control the spread of the virus. We are subject to risks associated with public health crises, such as pandemics and epidemics, including the COVID- 19 pandemic. The nature and extent of future impacts are highly uncertain and unpredictable. While many countries around the world have removed or reduced the restrictions taken in response to the COVID- 19 pandemic, the emergence of new variants of the SARS- CoV- 2 virus may result in new governmental lockdowns, quarantine requirements or other restrictions to slow the spread of the virus. Any such measures could also impact the global economy more broadly, for example by leading to further economic slowdowns. The global outlook remains uncertain as case counts fluctuate and vaccination and booster rates remain relatively low in many parts of the world. The scope and duration of any future public health crisis, including the potential emergence of new variants of the SARS- CoV- 2 virus, the pace at which government restrictions, including, but not limited to, quarantines, " shelter in place " and " stay at home " order, travel restrictions and other similar measures, are imposed and lifted, the scope of additional actions taken to mitigate the spread of disease, global vaccination and booster rates, may significantly impact our production throughout the supply chain and constrict distribution channels. We are unable to predict the potential future impact that these factors will have on our business, financial condition or results of operations~~ . Unauthorized access to our or our customers' information and systems could negatively impact our business. Our systems and networks, as well as those of our customers, suppliers, service providers, and banks, have and may in the future become the target of cyberattacks or information security breaches which, in turn, could result in the unauthorized release and misuse of confidential or proprietary information about our company, our employees or our customers, as well as disrupt our operations or damage our facilities or those of third parties. Additionally, our systems are subject to regulation to

preserve the privacy of certain data held on those systems. We maintain an extensive network of technical security controls, policy enforcement mechanisms and monitoring systems, in order to address these threats. While these measures are designed to prevent, detect and respond to unauthorized activity in our systems, certain types of attacks could result in financial or information losses and / or reputational harm. If we cannot comply with regulations or prevent the unauthorized access, release and / or corruption of our or our customers' confidential, classified or personally identifiable information, our reputation could be damaged, and / or we could face financial losses. We may also be required to incur additional costs to modify or enhance our systems, or to try to prevent or remediate any such attacks. Modifying or enhancing our systems may result in unanticipated or prolonged disruption events, which could have a material adverse effect on our business and / or results of operations. We are a global company with significant revenues and earnings generated internationally, which exposes us to the impact of foreign currency fluctuations, as well as political and economic risks. A significant portion of our net sales and earnings are generated internationally. Sales outside of the U. S. accounted for ~~55~~ **58** . ~~4~~ **0** % of our consolidated net sales in ~~2022~~ **2023** and we anticipate that sales from international operations will continue to represent a significant portion of our net sales in the future. In addition, many of our manufacturing facilities and suppliers are located outside of the U. S. and we intend to continue our expansion into emerging and / or faster- growing international markets. Our foreign operations subject us to certain commercial, political and financial risks. Our business in these foreign markets is subject to general political conditions, including any political instability (such as those resulting from war, terrorism and insurrections) and general economic conditions in these markets, such as inflation, deflation, interest rate volatility and credit availability. Additionally, a number of factors, including U. S. relations with the governments of the foreign countries in which we operate, changes to international trade agreements and treaties, increases in trade protectionism, or the weakening or loss of certain intellectual property protection rights in some countries, may affect our business, financial condition and results of operations. Foreign regulatory requirements, including those related to the testing, authorization, and labeling of products and import or export licensing requirements, could affect the availability of our products in these markets. In addition to risks associated with general political conditions, our international operations are subject to fluctuations in foreign currency exchange rates. The functional currency for most of our foreign operations is the applicable local currency. As a result, fluctuations in foreign currency exchange rates affect the results of our operations and the value of our foreign assets and liabilities, which in turn may adversely affect results of operations and cash flows and the comparability of period- to- period results of operations. Foreign governmental policies and actions regarding currency valuation could result in actions by the United States and other countries to offset the effects of such fluctuations. Given the unpredictability and volatility of foreign currency exchange rates, ongoing or unusual volatility may adversely impact our business and financial conditions. In order to reduce our exposure to fluctuations in foreign currency exchange rates, we have entered, and expect to continue to enter, into hedging arrangements, including the use of financial derivatives. There can be no certainty that we will be able to enter into or maintain hedges of these currency risks, or that our hedges will be effective, which could have a significant effect on our financial condition and operating results. In addition, our international operations are governed by the U. S. Foreign Corrupt Practices Act and similar foreign anti- corruption laws. Global enforcement of anti-corruption laws has increased substantially in recent years, with more enforcement proceedings by U. S. and foreign governmental agencies and the imposition of significant fines and penalties. While we have implemented policies and procedures relating to compliance with these laws, our international operations create the risk that there may be unauthorized payments or offers of payments made by employees, consultants, sales agents or distributors. Any alleged or actual violations of these laws may subject us to government investigations and significant criminal or civil sanctions and other liabilities, and negatively affect our reputation. We are exposed to credit risk on accounts receivable and certain prepayments made in the normal course of business. This risk is heightened during periods when economic conditions worsen. A substantial majority of our outstanding trade receivables are not covered by collateral or credit insurance. In addition, we have made prepayments ~~associated with insurance premiums~~ and other advances in the normal course of business. While we have procedures to monitor and limit exposure to credit risk on trade receivables and other current assets, there can be no assurance such procedures will effectively limit our credit risk and avoid losses, which could have a material adverse effect on our financial condition and operating results **. Unstable market and economic conditions and adverse developments with respect to financial institutions and associated liquidity risk may have serious adverse consequences on our business and financial condition. The recent and potential future disruptions in access to bank deposits or lending commitments due to bank failure could materially and adversely affect our liquidity, our business and financial condition. Even with our continued effort to mitigate counterparty risk by working with highly liquid, well capitalized counterparties, the failure of any bank in which we deposit our funds could reduce the amount of cash we have available for our operations or delay our ability to access such funds. Any such failure may increase the possibility of a sustained deterioration of financial market liquidity, or illiquidity at clearing, cash management and / or custodial financial institutions. In the event we have a commercial relationship with a bank that has failed or is otherwise distressed, we may experience delays or other issues in meeting our financial obligations. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our cash and cash equivalents and investments may be threatened and could have a material adverse effect on our business and financial condition** . Industry Risks Our sales and profitability are largely dependent on the sale of drug products delivered by injection and the packaging of drug products. If the drug products developed by our customers in the future use another delivery system or are reconfigured to require less frequent dosing, our sales and profitability could suffer. Our business depends to a substantial extent on customers' continued sales and development of products that are delivered by injection. If (i) our customers fail to continue to sell, develop and deploy injectable products; (ii) our customers reconfigure their drug product or develop new drug products requiring less frequent dosing; or (iii) we are unable to develop new products that assist in the delivery of drugs by alternative methods, our sales and profitability may suffer. If we are unable to provide comparative value advantages, timely

fulfill customer orders, or resist pricing pressure, we will have to reduce our prices, which may reduce our profit margins. We compete with several companies across our major product lines. Because of the special nature of these products, competition is based primarily on product design and performance, although total cost is becoming increasingly important as pharmaceutical companies continue with aggressive cost- control programs across their operations. Companies often compete on the basis of price. We aim to differentiate ourselves from our competition by being a " full- service, value- added " global supplier that is able to provide pre- sale compatibility studies, engineering support, and other services and sophisticated post- sale technical support on a global basis. However, we face continued pricing pressure from our customers and competitors. If we are unable to resist or offset the effects of continued pricing pressure through our value- added services, improved operating efficiencies and reduced expenditures, or if we have to reduce our prices, our sales and profitability may suffer. Consolidation in the pharmaceutical and healthcare industries could adversely affect our future revenues and operating income. The pharmaceutical and healthcare industries continue to experience a significant amount of consolidation. As a result of this consolidation, competition to provide goods and services to customers has increased. In addition, group purchasing organizations and integrated health delivery networks have served to concentrate purchasing decisions for some customers, which has placed pricing pressure on suppliers. Further consolidation within the industries we serve could exert additional pressure on the prices of our products. The medical technology industry is very competitive and customer demands and / or new products in the marketplace could cause a reduction in demand. The medical technology industry is subject to rapid technological changes, and we face significant competition across our product lines and in each market in which our products are sold. We face this competition from a wide range of companies, including large medical device companies, some of which have greater financial and marketing resources than we do. We also face competition from firms that are more specialized than we are with respect to particular markets. In some instances, competitors, including pharmaceutical companies, also offer, or are attempting to develop, alternative therapies for diseases that may be delivered via their own, or without, a medical device. The development of new or improved products, processes or technologies by other companies (such as needle- free injection technology) may reduce customer demand for our products or render some of our products or proposed products obsolete or less competitive. In addition, any failure or inability to meet increased customer quality expectations could cause a reduction in demand. Business and Operational Risks Disruption in our manufacturing facilities could have a material adverse effect on our ability to make and sell products and have a negative impact on our reputation, performance or financial condition. We have manufacturing sites throughout the world. In some instances, however, the manufacturing of certain product lines is concentrated in one or only a few of our plants. The functioning of our manufacturing and distribution assets and systems could be disrupted for reasons either within or beyond our control, including, without limitation: extreme weather, water scarcity and other longer- term climatic changes; natural or man-made disasters; pandemic; war; accidental damage; disruption to the supply of material or services; product quality and safety issues; systems failure; workforce actions; or environmental matters. There is a risk that incident management systems in place may prove inadequate and that any disruption may materially adversely affect our ability to make and sell products and therefore, materially adversely affect our reputation, performance or financial condition. Our international sales and operations are subject to risks and uncertainties that vary by country and which could have a material adverse effect on our business and / or results of operations. We conduct business in most of the major pharmaceutical markets in the world. Our international operations and our ability to implement our overall business strategy (including our plan to continue expanding into emerging and / or faster- growing markets outside of the U. S.) are subject to risks and uncertainties that can vary by country, and include: transportation delays and interruptions; political and economic instability and disruptions ~~, including the United Kingdom' s withdrawal from the European Union~~ ; imposition of duties and tariffs; import and export controls; the risks of divergent business expectations or cultural incompatibility inherent in establishing and maintaining operations in foreign countries; difficulties in staffing and managing multi- national operations; labor strikes and / or disputes; and potentially adverse tax consequences. Limitations on our ability to enforce legal rights and remedies with third parties or our joint venture partners outside of the U. S. could also create exposure. In addition, we may not be able to operate in compliance with foreign laws and regulations, or comply with applicable customs, currency exchange control regulations, transfer pricing regulations or any other laws or regulations to which we may be subject, in the event that these laws or regulations change. Any of these events could have an adverse effect on our international operations in the future by reducing the demand for our products or decreasing the prices at which we can sell our products, or otherwise have an adverse effect on our financial condition, results of operations and cash flows. Disruptions in the supply of key raw materials could adversely impact our operations. We generally purchase our raw materials and supplies required for the production of our products in the open market. For reasons of quality assurance, sole source availability or cost effectiveness, many components and raw materials are available and / or purchased only from a single supplier. Due to the stringent regulations and requirements of the FDA and other regulatory authorities regarding the manufacture of our products and the availability of such raw materials, we may not be able to quickly establish additional or replacement sources for these components or raw materials or do so without excessive cost. As a result, a reduction or interruption in supply, or an inability to secure alternative sources of raw materials or components, could have a material adverse effect on our business and / or results of operations. Raw material and energy prices have a significant impact on our profitability. If raw material and / or energy prices increase, and we cannot pass those price increases on to our customers, our profitability and financial condition may suffer. We use three basic raw materials in the manufacture of our products: elastomers (which include synthetic and natural material), aluminum and plastic. In addition, our manufacturing facilities consume a wide variety of energy products to fuel, heat and cool our operations. The price and supply of these materials and energy sources are cyclical and volatile ~~,~~ and may be impacted or disrupted for reasons beyond our control, including supplier shutdowns, supplier capacity constraints, transportation delays, inflationary pricing pressures, work stoppages, labor shortages, geopolitical developments and governmental regulatory actions. For example, the prices of certain commodities, particularly petroleum-based raw materials, have in the recent past exhibited rapid changes, affecting the cost of synthetic elastomers and plastic.

While we generally attempt to pass along increased costs to our customers in the form of sales price increases, historically there has been a time delay between raw material and / or energy price increases and our ability to increase the prices of our products. In some circumstances, we may not be able to increase the prices of our products due to competitive pressure and other factors. If we are unable to pass along increased raw material prices and energy costs to our customers, our profitability, and thus our financial condition, may be adversely affected. If we are not timely or successful in new- product innovation or the development and commercialization of proprietary multi- component systems, our future revenues and operating income could be adversely affected. Our growth partly depends on new- product innovation and the development and commercialization of proprietary multi- component systems for injectable drug administration and other healthcare applications. Product development and commercialization is inherently uncertain and is subject to a number of factors outside of our control, including any necessary regulatory approvals and commercial acceptance for the products. The ultimate timing and successful commercialization of new products and systems requires substantial evaluations of the functional, operational, clinical, and economic viability of our products. In addition, the timely and adequate availability of filling capacity is essential to both conducting definitive stability trials and the timing of commercialization of customers' products in Crystal Zenith vials, syringes and cartridges. Delays, interruptions or failures in developing and commercializing new- product innovations or proprietary multi- component systems could adversely affect future revenues and operating income. In addition, adverse conditions may also result in future charges to recognize impairment in the carrying value of our goodwill and other intangible assets, which could have a material adverse effect on our financial results. We may not succeed in finding and completing acquisitions or other strategic transactions, which could have an adverse effect on our business and results of operations. We have historically engaged in acquisition activity, and we may in the future engage in acquisitions or other strategic transactions, such as joint ventures or investments in other entities. We may be unable to identify suitable targets, opportunistic or otherwise, for acquisitions or other strategic transactions in the future. If we identify a suitable candidate, our ability to successfully implement the strategic transaction would depend on a variety of factors, including our ability to obtain financing on acceptable terms and to comply with the restrictions contained in our debt agreements. Strategic transactions involve risks, including those associated with integrating the operations or maintaining the operations as separate (as applicable), financial reporting, disparate technologies, and personnel of acquired companies, joint ventures or related companies; managing geographically dispersed operations or other strategic investments; the diversion of management' s attention from other business concerns; the inherent risks in entering markets or lines of business in which we have either limited or no direct experience; the potential loss of key employees, customers and strategic partners of acquired companies, joint ventures or companies in which we may make strategic investments; and potentially other unknown risks. We may not successfully integrate any businesses or technologies we may acquire or strategically develop in the future and may not achieve anticipated revenue and cost benefits relating to any such strategic transactions. Strategic transactions may be expensive, time consuming and may strain our resources. Strategic transactions may not be accretive to our earnings and may negatively impact our results of operations as a result of, among other things, the incurrence of debt, one- time write- offs of goodwill, additional carrying costs of patent or trademark portfolios, and amortization expenses of other intangible assets. In addition, strategic transactions that we may pursue could result in dilutive issuances of equity securities. Product defects could adversely affect the results of our operations. The design, manufacturing and marketing of pharmaceutical packaging and medical devices involve certain inherent risks. Manufacturing or design defects, unanticipated use of our products, or inadequate disclosure of risks relating to the use of our products can lead to injury or other adverse events. These events could lead to recalls or safety alerts relating to our products (either voluntary or required by the FDA or similar governmental authorities in other countries), and could result, in certain cases, in the removal of a product from the market. A recall could result in significant costs, as well as negative publicity and damage to our reputation that could reduce demand for our products. Personal injuries relating to the use of our products can also result in product liability claims being brought against us. In some circumstances, such adverse events could also cause delays in new product approvals. A loss of key personnel or highly skilled employees could disrupt our operations. Our future success depends, in large part, on our ability to retain key employees, including our executive officers and individuals in technical, marketing, sales, and research positions. Competition for experienced employees, particularly for persons with specialized skills, can be intense ~~and has intensified following the COVID-19 pandemic~~ . Our ability to recruit such talent will depend on a number of factors, including compensation and benefits, work location and work environment. If we cannot effectively recruit and retain qualified executives and employees, our business could be adversely affected. Although we believe that we will be able to attract and retain talented personnel and replace key personnel should the need arise, our inability to do so on a timely basis could disrupt the operations of the unit affected or our overall operations. In addition, because of the complex nature of many of our products and programs, we are generally dependent on an educated and highly skilled engineering staff and workforce. Our operations could be disrupted by a shortage of available skilled employees. We may be unable to increase capacity or efficiency at our own manufacturing facilities, which could adversely affect our business, financial condition, and results of operations. We must adjust our production capacity as customer demand changes and are focused on increasing capacity at various facilities through our capital strategy. If we are unable to increase capacity levels at the rate we expect, or if unforeseen costs or other challenges associated with increasing that capacity arise, we may not be able to achieve our financial targets. Additionally, we are committed to supporting a full portfolio of our products for our customers. That commitment, along with shifts of product mix and complexity, may result in more frequent equipment change- overs and potentially increased costs because of the high fixed cost nature of our business, causing lower gross margins due to under- absorption of those fixed costs. Our results of operations and earnings may not meet guidance or expectations. We provide public guidance on our expected results of operations for future periods. This guidance is comprised of forward- looking statements subject to risks and uncertainties, including the risks and uncertainties described in this Form 10- K and in our other public filings and public statements, and is based on assumptions we make at the time we provide such guidance. Our guidance may not always be accurate. If, in the future, our results of operations for a particular

period do not meet our guidance or the expectations of investment analysts, or if we reduce our guidance for future periods, the market price of our common stock could decline significantly. No assurance can be given that we will continue to pay or declare dividends. We have historically paid dividends. However, there can be no assurance that we will pay or declare dividends in the future. The actual declaration and payment of future dividends, the amount of any such dividends, and the establishment of record and payment dates, if any, are subject to determination by our Board of Directors each quarter after its review of our then-current strategy, applicable debt covenants and financial performance and position, among other things. Our declaration and payment of future dividends is subject to risks and uncertainties, including deterioration of our financial condition or position; inability to declare a dividend in compliance with applicable laws or debt covenants; an increase in our cash needs or decrease in available cash; and the business judgment of the Board of Directors that a declaration of a dividend is not in our best interest. If we fail to comply with our obligations under our distributorship or license agreements with Daikyo or the agreements are terminated early or not renewed, we could lose license rights and access to certain product and technology that are important to our business. Key value- added and proprietary products and processes are licensed from our affiliate, Daikyo, including but not limited to, Crystal Zenith, FluroTec ® and B2- coating technologies. Our rights to these products and processes are licensed pursuant to agreements that expire in 2027. However, if the agreements are terminated early or not renewed, our business could be adversely impacted. Legal and Regulatory Risks We are subject to regulation by governments around the world, and if these regulations are not complied with, existing and future operations may be curtailed, and we could be subject to liability. As a multinational corporation with operations and distribution channels throughout the world, we are subject to and must comply with extensive laws and regulations in the United States and other jurisdictions in which we have operations and distribution channels. For example, the design, development, manufacturing, marketing and labeling of certain of our products and our customers' products that incorporate our products are subject to regulation by governmental authorities in the U. S., Europe and other countries, including the FDA, the European Medicines Agency and the National Medical Products Administration (China). Complying with governmental regulation can be costly and can result in required modification or withdrawal of existing products and a substantial delay in the introduction of new products. Failure to comply with applicable regulatory requirements or failure to obtain regulatory approval for a new product could subject us to fines, sanctions or other penalties that could negatively affect our reputation, business, financial condition, and results of operations. The global nature of our business also means legal and compliance risks, such as anti- bribery, anti- corruption, fraud, trade, environmental, competition, privacy, and other regulatory matters, will continue to exist and additional legal proceedings and other contingencies will arise from time to time, which could adversely affect us. In addition, the adoption of new laws or regulations, or changes in the interpretation of existing laws or regulations, may result in significant unanticipated legal and reputational risks. Any current or future legal or regulatory proceedings could divert management' s attention from our operations and result in substantial legal fees. Products that incorporate our technologies and medical devices that we produce are subject to regulations and extensive approval or clearance processes, which make the timing and success of new- product commercialization difficult to predict. The process of obtaining and maintaining FDA and other required regulatory approvals is expensive and time- consuming. Historically, most medical devices that incorporate our technologies and medical devices that we produce have been subject to the FDA' s 510 (k) marketing approval process, which typically lasts from six to nine months. Supplemental or full pre- market approval reviews require a significantly longer period, delaying commercialization. Changes in regulation on a global scale must be monitored and actions taken to ensure ongoing compliance. Pharmaceutical products that incorporate our technologies and medical devices that we produce are subject to the FDA' s New Drug Application process, which typically takes a number of years to complete. Additionally, biotechnology products that incorporate our technologies and medical devices that we produce are subject to the FDA' s Biologics License Application process, which also typically takes a number of years to complete. Outside of the U. S., sales of medical devices and pharmaceutical or biotechnology products are subject to international regulatory requirements that vary from country to country. The time required to obtain approval for sale internationally may be longer or shorter than that required for FDA approval. There is no certainty that any regulatory approval may be obtained or maintained indefinitely, and our ability to launch products to the market and maintain market presence is not guaranteed. Changes in the regulation of drug products and devices may increase competitive pressure and adversely affect our business. An effect of the governmental regulation of our medical devices and our customers' drug products, devices, and manufacturing processes is that compliance with regulations makes it difficult to change components and devices produced by one supplier with those from another supplier, due to the large amount of data and information that customers must generate to demonstrate that the components and devices are equivalent and pose no additional risk to the patient. The regulation of our medical devices and our customers' products that incorporate our components and devices has increased over time. If the applicable regulations were to be modified in a way that reduced the level of data and information needed to prove equivalency for a change from one supplier' s components or devices to those made by another, it is likely that the competitive pressure would increase and adversely affect our sales and profitability. If we are not successful in protecting our intellectual property rights, our ability to compete may be affected. Our patents, trademarks and other intellectual property are important to our business. We rely on patent, trademark, copyright, trade secret, and other intellectual property laws, as well as nondisclosure and confidentiality agreements and other methods, to protect our proprietary products, information, technologies and processes. We also have obligations with respect to the non- use and non- disclosure of third- party intellectual property. We may need to engage in litigation or similar activities to enforce our intellectual property rights, to protect our trade secrets or to determine the validity and scope of proprietary rights of others. Any such litigation could require us to expend significant resources and divert the efforts and attention of our management and other personnel from our business operations. There can be no assurance that the steps we will take to prevent misappropriation, infringement or other violation of our intellectual property or the intellectual property of others will be successful. In addition, effective patent, trademark, copyright, and trade secret protection may be unavailable or limited for some of our proprietary products in some countries. Failure to protect our intellectual property or successfully invalidate or

defend against intellectual property protections of third parties could harm our business and results of operations. In addition, if relevant and effective patent protection is not available or has expired, we may not be able to prevent competitors from independently developing products and services similar or duplicative to ours. Significant developments in U. S. policies could have a material adverse effect on our business and / or results of operations. We earn a substantial portion of our income in foreign countries and, as such, we are subject to the tax laws in the United States and numerous foreign jurisdictions. Current economic and political conditions make tax laws and regulations, or their interpretation and application, in any jurisdiction subject to significant change. Proposals to reform U. S. and foreign tax laws could significantly impact how U. S. multinational corporations are taxed on foreign earnings and could increase the U. S. corporate tax rate. Although we cannot predict whether or in what form these proposals may pass, several of the proposals considered, if enacted into law, could have an adverse impact on our effective tax rate, income tax expense and cash flows. We utilize tax rulings and other agreements to obtain certainty in treatment of certain tax matters. These rulings and agreements expire from time to time and may be extended when certain conditions are met or terminated if certain conditions are not met. The impact of any changes in conditions would be the loss of certainty in treatment thus potentially impacting our effective income tax rate. We are also subject to the examination of our tax returns by the United States Internal Revenue Service (" IRS ") and other tax authorities. We regularly assess the likelihood of an adverse outcome resulting from these examinations to determine the adequacy of its provision for income taxes. Although we believe our tax provisions are adequate, the final determination of tax audits and any related disputes rapidly change and could be materially different from our historical income tax provisions and accruals. The results of audits or related disputes could have an adverse effect on our financial statements for the period or periods for which the applicable final determinations are made. For example, we and our subsidiaries are also engaged in a number of intercompany transactions across multiple tax jurisdictions. Although we believe we have clearly reflected the economics of these transactions and the proper local transfer pricing documentation is in place, tax authorities may propose and sustain adjustments that could result in changes that may impact our mix of earnings in countries with differing statutory tax rates. We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm and other adverse business consequences. In addition to our own sensitive and proprietary business information, we handle transactional and personal information worldwide. As a result, we must comply with increasingly complex and rigorous, and sometimes conflicting laws, regulatory standards, industry standards, external and internal privacy and security policies, contracts and other obligations that govern the processing of business and personal data by us and on our behalf. For example **and not limited to** , the European Union' s General Data Protection Regulation (the " EU GDPR "), the United Kingdom' s GDPR (the " UK GDPR ") and California' s Consumer Privacy Act of 2018 ~~, as amended~~ (the" CCPA") ~~impose obligations on companies regarding the handling of personal data and provide certain individual privacy rights to persons whose data is stored. In addition~~ , **as expanded by** ~~it is anticipated that~~ the California Privacy Rights Act of 2020 (" CPRA "), **impose obligations on companies regarding** ~~effective January 1, 2023, will expand~~ the ~~CCPA~~ **handling of personal data and provide certain individual privacy rights to persons whose data is stored** . Furthermore, multiple states in the United States have enacted data privacy laws. Additionally, laws in certain jurisdictions require data localization and impose restrictions on the transfer of personal information across border. For example, the EU GDPR generally restricts the transfer of personal information to countries outside of the European Economic Area without appropriate safeguards or other measures. If we cannot implement a valid compliance mechanism for cross- border privacy and security transfers, we may face increased exposure to regulatory actions, substantial fines and injunctions against processing or transferring personal information from Europe or elsewhere. Compliance with existing and forthcoming laws and regulations can be costly and time consuming, and may require changes to our information technologies, systems and practices and to those of any third parties that process personal information on our behalf. If we fail, or are perceived to have failed, to address or comply with obligations related to data privacy and security, we could face significant consequences, including, but not limited to, proceedings against the Company by governmental entities (e. g. investigations, fines, penalties, audits, inspections) or other entities or individuals, additional reporting requirements and / or governmental agency oversight, damage to our reputation and credibility, or inability to process data or operate in certain jurisdictions, any of which could have a negative impact on revenues and profits. Changing climate, global climate change regulations and greenhouse gas effects may adversely affect our operations and financial performance **.** There is continuing concern from members of the scientific community and the general public that emissions of GHG and other activities have or will cause significant changes in weather patterns and increase the frequency or severity of extreme weather events, including droughts, hurricanes, wildfires and flooding. These types of extreme weather events have and may continue to adversely impact us, raw material availability, our suppliers, our customers and their ability to purchase our products and our ability to timely manufacture and transport our products. We believe it is likely that the scientific and political attention to issues concerning the extent and causes of climate change will continue, with new and more restrictive legislation **or** regulations and focus on ESG initiatives that could affect our financial condition, results of operations and cash flows. Foreign, federal, state and local regulatory and legislative bodies, such as the SEC, have proposed various legislative and regulatory measures relating to increased transparency and standardization of reporting related to factors that may include climate change, regulating GHG emissions, energy policies, recycling of plastic materials, waste taxes, and other governmental charges and mandates. If additional legislation or regulations were enacted, we could incur increased energy, environmental, administrative and other costs and capital expenditures to comply with the limitations. Failure to comply with these regulations could result in fines and could affect our business, financial condition, results of operations and cash flows. We could also face increased costs related to defending and resolving legal claims and other litigation related to climate change and any alleged impact of our operations on climate change. We, along with other companies in many business sectors have been implementing and expanding ESG and sustainability strategies, specifically ways to track and reduce GHG emissions. As a result, our customers may request that

changes be made to our products, procedures or facilities, as well as other aspects of our business, that increase costs and may require the investment of capital or reduction in profit margins if not offset by price increases, customer investment or other cost savings. Failure to provide climate- friendly products or demonstrate GHG reductions could potentially result in loss of market share. Additionally, the costs of procuring energy, including renewable energy, or offsetting GHG emissions to meet our goals, satisfy government regulations or meet the requests of our customers may increase. Failure to comply with anti- bribery, anti- corruption and anti- money laundering laws could subject us to penalties and other adverse consequences. We are subject to the Foreign Corrupt Practices Act (the" FCPA"), the U. K. Bribery Act and other anti- bribery, anti- corruption, and anti- money laundering laws in various jurisdictions around the world. The FCPA, the U. K. Bribery Act and similar applicable laws generally prohibit companies, as well as their officers, directors, employees and third- party intermediaries, business partners and agents, from making improper payments or providing other improper things of value to government officials or other persons. We and our third- party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state owned or affiliated entities and other third parties where we may be held liable for corrupt or other illegal activities, even if we do not explicitly authorize them. While we have policies and procedures and internal controls to address compliance with such laws, we cannot provide assurance that all of our employees and third- party intermediaries, business partners and agents will not take actions in violation of such policies and laws, for which we may be ultimately held responsible. To the extent that we learn that any of our employees or third- party intermediaries, business partners or agents do not adhere to our policies, procedures, or internal controls, we are committed to taking appropriate remedial action. In the event that we believe or have reason to believe that our directors, officers, employees or third- party intermediaries, agents or business partners have or may have violated such laws, we may be required to investigate or to have outside counsel investigate the relevant facts and circumstances. Detecting, investigating and resolving actual or alleged violations can be extensive and require a significant diversion of time, resources, and attention from senior management. Any violation of the FCPA, the U. K. Bribery Act or other applicable anti- bribery, anti- corruption and anti- money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, and criminal or civil sanctions, penalties, and fines, any of which may adversely affect our business and financial condition. Our operations must comply with environmental statutes and regulations, and any failure to comply could result in extensive costs which would harm our business. The manufacturing of some of our products has involved, and may continue to involve, the use, transportation, storage, and disposal of hazardous or toxic materials and is subject to various environmental protection and occupational health and safety laws and regulations in the countries in which we operate. This has exposed us in the past, and could expose us in the future, to risks of accidental contamination and events of non- compliance with environmental laws. Any such occurrences could result in regulatory enforcement or personal injury and property damage claims or could lead to a shutdown of some of our operations, which could have an adverse effect on our business and results of operations. We currently incur costs to comply with environmental laws and regulations and these costs may become more significant, especially as the laws become more stringent and our use of materials changes. Changes in reimbursement practices of third- party payers or other cost containment measures **, including changes to applicable laws and regulations,** could affect the demand for our products and the prices at which they are sold. Our sales depend, in part, on the extent to which healthcare providers and facilities are reimbursed by government authorities (including Medicare, Medicaid and comparable foreign programs) and private insurers for the costs of our products. The coverage policies and reimbursement levels of third- party payers, which can vary among public and private sources and by country, may affect which products customers purchase and the prices they are willing to pay for those products in a particular jurisdiction. Reimbursement rates can also affect the market acceptance rate of new technologies and products. Reforms to reimbursement systems in the U. S. or abroad, changes in coverage by private payers, or adverse decisions by payers could significantly reduce reimbursement for procedures using our products, which could adversely affect customer demand or the price customers are willing to pay for such products. Initiatives to limit the growth of healthcare costs in the U. S. and other countries where we do business may also put industry- wide pressure on medical device or clinical diagnostic pricing. In the U. S., these include, among others, value- based purchasing and managed care arrangements. Governments in other countries are also using various mechanisms to control healthcare expenditures, including increased use of competitive bidding and tenders as well as price regulation. General Risk Factor Our share price has been volatile and may fluctuate, and accordingly, the value of an investment in our common stock may also fluctuate. Stock markets in general and our common stock in particular have experienced significant price and trading volume volatility over recent years. The market price and trading volume of our common stock may continue to be subject to significant fluctuations due to factors described under this Item 1A. Risk Factors, as well as economic and geopolitical conditions in general and to variability in the prevailing sentiment regarding our operations or business prospects, as well as, among other things, changing investment priorities of our shareholders. ITEM IB. UNRESOLVED STAFF COMMENTS As of the filing of this Form 10- K, there were no unresolved comments from the Staff of the SEC. **ITEM 1C. CYBERSECURITY Risk Management and Strategy The Company has implemented the Committee of Sponsoring Organizations (“ COSO ”) Enterprise Risk Management (“ ERM ”) Framework, which outlines the process by which an organization can view any risk by way of governance and culture, integration into strategy, risk assessments, reviewing capabilities and practices, and monitoring and reporting. This process would apply to the cybersecurity risk as it would any of the other enterprise risks. We follow the National Institute of Standards and Technology (“ NIST ”) Cybersecurity Framework (“ CSF ”) with layered security controls to help identify, protect against, detect, respond to, and recover from cyber- attacks. To safeguard our information assets, we have put various procedures and technologies in place. For example, our Cybersecurity Incident Response Plan clearly defines roles and responsibilities for the investigation of and response to information security incidents to minimize disruption of critical computing services and operations and prevent the loss or theft of sensitive or mission- critical information. Our plan covers various cyber incidents like ransomware attacks, cyber- intrusions, data loss, denial of service, insider threats,**

malware attacks, and others. In a material cybersecurity incident, our D & T team, inclusive of our Chief Information Officer and VP of Cybersecurity and Infrastructure Support, address the threat via established escalation procedures, roles, responsibilities, and communication. Any cybersecurity incident that is declared as a crisis would follow our global Incident and Crisis Response and Management Procedure, which includes escalation to the West Leadership Team and Board of Directors, as deemed necessary pending the materiality of the incident. We have not encountered cybersecurity challenges that have materially impacted our operations or financial condition. In addition, we retain an external cybersecurity consultant to assist with a cybersecurity event as needed and maintain appropriate cybersecurity liability insurance. The Company also educates and shares best practices globally with its employees to raise awareness of cybersecurity threats. As part of our onboarding process, we train all new employees on cybersecurity and conduct an annual retraining of all employees on cybersecurity standards. Training also includes how to recognize, report and properly respond to phishing and social engineering schemes. Multiple phishing simulation exercises are conducted throughout the year to increase cybersecurity awareness. Our cybersecurity defenses also utilize technologies such as next generation firewalls, Zero Trust architecture, intrusion detection and prevention measures, anti- malware software, advance threat protection, multifactor authentication, network segmentation and encryption to ensure the security of West intellectual properties, customer and vendor data. In addition, we have a dedicated 24- by- 7 Security Operations Center to facilitate the monitoring of the Company' s cybersecurity landscape and associated applications. Governance Our approach to cybersecurity begins with our responsibility for strong governance and controls. Security begins at the top of our organization, where Company leadership consistently communicates the requirements for vigilance and compliance throughout the organization, and then leads by example. Our diligence and assessment extends beyond West, as the Company performs a cybersecurity assessment when third- party vendors and service providers are onboarded. Throughout the year, we monitor the effectiveness of our third- party vendors' and service providers' control environment, assessing any impact to our Company. The cybersecurity program is led by our Chief Information Officer and VP of Cybersecurity and Infrastructure Support, who provide quarterly updates to the Audit Committee of our Board of Directors, annual updates to the Board of Directors, and regular reports to the West Leadership Team about the program, including information about cyber risk management governance and the status of ongoing efforts to strengthen cybersecurity effectiveness. Additionally, our ERM function monitors cybersecurity risk and provides regular updates to the Audit Committee of our Board of Directors, annual updates to the Board of Directors, and regular reporting to the West Leadership Team on risk mitigation and response efforts. Security controls and processes are developed and maintained to protect sensitive and confidential information while ensuring availability and integrity.