

Risk Factors Comparison 2024-02-14 to 2023-02-10 Form: 10-K

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

This report contains statements that are not historical facts and are considered "forward- looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on current projections about operations, industry conditions, financial condition and liquidity. Words that identify forward- looking statements include, without limitation, words such as "may," "could," "will," "should," "possible," "plan," "predict," "forecast," "potential," "anticipate," "estimate," "expect," "project," "intend," "believe," "may impact," "on track," "goal," "strategy" and words and terms of similar substance used in connection with any discussion of future operating or financial performance, an acquisition or our businesses. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances, including any underlying assumptions, are forward- looking statements. Those statements are not guarantees and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, actual results could differ materially and adversely from these forward- looking statements, historical experience or our present expectations. Some important factors that could cause our actual results to differ from our expectations in any forward- looking statements include: • **weakening of economic conditions, or the anticipation thereof, that could adversely affect the level of demand for our products; geopolitical risks discussed below. Our, including from international conflicts and upcoming elections in the United States and other countries, which could, among other things, lead to increased market volatility; pricing pressures generally, including cost- containment measures that could adversely affect the price of or demand for our products; changes in foreign currency exchange markets; legislative and regulatory actions; unanticipated issues arising in connection with clinical studies and otherwise that affect approval of new products by the FDA and foreign regulatory agencies; inflationary pressures; increased interest rates or interest rate volatility; supply chain disruptions; changes in labor markets; changes in reimbursement levels from third- party payors; a significant increase in product liability claims; the ultimate total cost with respect to recall- related and other regulatory and quality matters; the impact of investigative and legal proceedings and compliance risks; resolution of tax audits; changes in tax laws and regulations; the impact of legislation to reform the healthcare system in the United States or other countries; costs to comply with medical device regulations; changes in financial markets; changes in our credit ratings; changes in the competitive environment; our ability to integrate and realize the anticipated benefits of acquisitions in full or at all or within the expected timeframes; our ability to realize anticipated cost savings; potential negative impacts resulting from climate change or other environmental, social and governance and sustainability related matters; the impact on our operations and financial results of any public health emergency and any related policies and actions by governments or other third parties; breaches or failures of our or our vendors' or customers' information technology systems or products, including by cyber- attack, data leakage, unauthorized access or theft; and other risks detailed in our filings with the SEC. While we believe that the assumptions underlying such forward- looking statements are reasonable, there can be no assurance subject to various risks and uncertainties discussed below that future events could materially and adversely affect our- or developments will business, cash flows, financial condition and results of operations. Additional risks and uncertainties not cause such statements currently known to us or that we currently deem not to be material or that could apply to any company may also materially and adversely affect inaccurate. All forward- looking statements Dollar amounts in millions except per share amounts our- or business, cash flows, financial condition or results of operations as otherwise specified. 4 STRYKER CORPORATION 2023 FORM 10- K contained in this report are qualified in their entirety by this cautionary statement.** We expressly disclaim any intention or obligation to publicly update or revise any forward- looking statement to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that affect the likelihood that actual results will differ from those contained in the forward- looking statements. **Our operations and financial results are subject to various risks and uncertainties discussed below that could materially and adversely affect our business, cash flows, financial condition and results of operations. Additional risks and uncertainties not currently known to us or that we currently deem not to be material or that could apply to any company may also materially and adversely affect our business, cash flows, financial condition or results of operations. If any of the risks discussed below or other risks actually occur or continue to occur, our business, financial condition, operating results or cash flows could be materially adversely affected. Accordingly, you should carefully consider the following risk factors, as well as other information contained in or incorporated by reference in this report.** BUSINESS AND OPERATIONAL RISKS **RISKS** We use a variety of raw materials, components, devices and third- party services in our global supply chains, production and distribution processes; significant shortages, price increases or unavailability of third- party services **have in the past increased, and could in the future increase,** our operating costs **and could** require significant capital expenditures **and** or adversely impact the competitive position of our products: Our reliance on certain suppliers to secure raw materials, components and finished devices, and on certain third- party service providers, such as sterilization service providers, exposes us to product shortages and unanticipated increases in prices, whether due to inflationary pressure, regulatory changes, litigation exposure, **geopolitical tensions** or otherwise. For example, **in the past** certain of our products contain electronic components and we have experienced **and could continue to experience,** limited product availability due to **the an** electronic components shortage in certain product lines. If **the a similar** shortage **persists occurs in the future with respect to other raw materials or components**, we may not be able to obtain **them** electronic components from our suppliers on a timely basis, or at all, or identify **any** alternative suppliers to provide the electronic components we need to produce our products. In addition, several

raw materials, components, finished devices and services are procured from a sole source due to the quality considerations, unique intellectual property considerations or constraints associated with regulatory requirements. If sole- source suppliers or service providers are **acquired or were unable or unwilling to deliver these materials or services as a result of financial difficulties, acquisition by a third party, natural disasters or otherwise**, we may not be able to manufacture or have available one or more products during such period of unavailability and our business could suffer. In certain cases, we may not be able to establish additional or replacement suppliers for such materials or service providers for such services in a timely or cost- effective manner, **largely often** as a result of FDA and other regulations that require, among other things, validation of materials, components and services prior to **Dollar amounts in millions except per share amounts or as otherwise specified. 4** **STRYKER CORPORATION 2022 FORM 10-K** their use in or with our products. In **certain instances we have been unable to meet demand due to supply chain challenges, which has led to loss of sales. Although the impacts have not been material to date, an inability to meet demand due to supply chain challenges in the future could materially adversely impact our reputation, the competitive position of our products and our business. Any of the foregoing risks could have a material adverse impact on our profitability and results of operations.** In addition, **during since 2022** the market has experienced increasing inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts following the COVID- 19 pandemic. We expect these inflationary pressures will continue. Inflation in the United States and in many of the countries where we conduct business has resulted in, and may continue to result in, higher interest rates and increased capital, **energy**, shipping and labor costs, weakening **or strengthening** exchange rates against the United States Dollar and other similar effects. We have experienced, and may continue to experience, inflationary increases in manufacturing costs and operating expenses, as well as negative impacts from weakening **or strengthening** exchange rates against the United States Dollar **and**, **Although we have been may not be able to pass these certain cost increases on to our customers in a timely manner, which we have not been able to pass along all cost increases and we cannot guarantee that we will be able to do so in the future. Inflation, higher interest rates or interest rate volatility may also cause our customers to reduce or delay orders for our products and services. Any of the foregoing could have a material adverse impact on our sales, profitability and results of operations. Inflation may also cause our customers to reduce or delay orders for our products and services, which could have a material adverse impact on our sales and results of operations.** We are subject to **pricing pressures as a result of cost containment measures in the United States and other countries and other factors resulting in pricing pressures**: Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets in which we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. For example, China has implemented a volume- based procurement process designed to decrease prices for medical devices and other products. This has already impacted our joint replacement and spine businesses on a national level, and our trauma and certain neurovascular products on a provincial level, and we expect further adoption of volume- based procurement provincially or nationally in China in **2023-2024**. Pricing pressure has also increased due to continued consolidation among healthcare providers, trends toward managed care, the shift toward governments becoming the primary payers of healthcare expenses, reduction in reimbursement levels and medical procedure volumes and government laws and regulations relating to sales and promotion, reimbursement and pricing generally. **We have also reduced prices for certain products due to increased competition and if we further reduce prices, we could become less profitable. In addition, due to healthcare industry consolidation in recent years, competition to provide goods and services to industry participants has become, and may continue to become, more intense, and this consolidation has produced, and may continue to produce, larger enterprises with more bargaining power. Pricing pressures related to any of the foregoing or other factors have impacted and could in the future impact our results of operations and profitability**. We operate in a highly competitive industry in which competition in the development and improvement of new and existing products is significant: The markets in which we compete are highly competitive, **and a significant element of our strategy is to increase revenue growth by focusing on innovation and new product development**. New business models, products and surgical procedures are introduced on an ongoing basis and our present or future products could be rendered obsolete or uneconomical by **internal or external** technological advances **by us**, as we continue to innovate to address physician and patient needs, or by our existing competitors and new market entrants. Our existing competitors and new market entrants may respond more quickly to **or integrate** new or emerging technologies **such as robotics, artificial intelligence and machine learning in their product offerings**, undertake more extensive marketing campaigns, have greater access to clinical information to support ongoing product position in the market, have greater financial, marketing and other resources or be more successful in attracting potential customers, employees and strategic partners. **There can be no assurance that any products now in development, or that we may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch Dollar amounts in millions except per share amounts or as otherwise specified. 5 new products, our ability to maintain or expand our market position in the markets in which we participate may be negatively impacted**. We may be unable to maintain adequate working relationships with healthcare professionals: We seek to maintain close working relationships with respected physicians and medical personnel in healthcare organizations, such as hospitals and universities, who assist in product research and development. We rely on these professionals to assist us in the development and improvement of proprietary products. If we are unable to maintain these relationships due to regulatory restrictions, hospital access restrictions for non- patients or for other reasons, our ability to develop, market and sell new and improved products could be adversely affected. **For example, China's National Health Commission has launched an anti-corruption campaign focused on investigating government officials and individuals employed by state- owned entities and public institutions in the healthcare sector, which has resulted in us seeing some limitations to physician and surgeon access. Although this has not had a material impact on our business, if other jurisdictions were to take this approach, our business could be adversely impacted**. We rely on indirect distribution channels and major distributors that are

independent of Stryker: In many markets we rely on indirect distribution channels to market, distribute and sell our products. These indirect channels often are the main point of contact for the healthcare professionals and healthcare organization customers who buy and use our products. Our ability to continue to market, distribute and sell our products may be at risk if the indirect channels become insolvent, choose to sell competitive products, choose to stop selling medical technology, **fail to adhere to Stryker requirements** or are subject to new or additional government regulation. We are subject to risks associated with our extensive global operations: We develop, manufacture and distribute our products globally. Our global operations are subject to risks and potential costs **related to, including among other things,** changes in reimbursement; changes in regulatory requirements (such as the **implementation timeline staggered phase- in period for manufacturers to comply with the European Union Medical Device Regulation (MDR) through December** enacted by the European Union in May 2017 and **originally effective in May 2021 2028**); differing local product preferences and product requirements; diminished protection of intellectual property in some countries; tariffs and other trade protection measures, **as well as increasing localization and protectionism policies in certain jurisdictions;** international trade disputes and import or export requirements; difficulty in staffing and managing foreign operations; introduction of new internal business structures and programs; political and economic instability; **current or potential geopolitical conflicts**, such as the **United Kingdom's exit from tensions between China and Taiwan and the wars in Ukraine and the Middle East, and related sanctions and the other developments;** **European Union (Brexit), and disruptions of transportation, including port closures, increased border controls or border closures or reduced transportation availability,** due to military conflicts, a global pandemic of contagious diseases like COVID- 19 or otherwise; such as **reduced availability of transportation, port closures, increased energy border controls or closures, increased transportation costs; fluctuations in currency exchange rates and financial markets;** and increased security threats to our supply chain. **Many of these risks are rapidly evolving and subject to an accelerating pace of change**. Our business could be adversely impacted if we are unable to successfully manage these and other risks of global operations in an increasingly volatile environment. **In addition The ongoing war between Russia and Ukraine, in and the global response to it, may many adversely affect countries, the laws and regulations applicable to us our or business our industry are evolving, and results of we have in certain cases become subject to divergent and conflicting laws and regulations across our operations** : The war between Russia and Ukraine has resulted in the implementation of sanctions by the United States and other governments against Russia and has caused significant volatility and disruptions to the global markets. It is not possible to predict the short- and long- term implications of this war, which could include but are not limited to further sanctions, economic and political instability, increases **increase** in inflation rate and energy prices, supply chain challenges and adverse effects on currency exchange rates and financial markets. In addition, the United States government reported that United States sanctions against Russia in response to the conflict could lead to an increased threat of cyberattacks against United States companies. These increased threats could pose risks **risk over time** to the security of our information technology systems, networks and product offerings, as well as the confidentiality, availability and integrity of our data. Further, if the war expands beyond Ukraine or further intensifies, it could have an adverse impact on our operations in Poland or other areas. We are continuing to monitor the situation in Ukraine and globally as well as assess its potential impact on our business. Although Russia does not constitute a material portion of our business, and we do not rely significantly on Russian or Ukrainian sources of supply, a significant escalation or further expansion of the war or related disruptions to the global markets could have a material adverse effect on our results of operations. Dollar amounts in millions except per share amounts or as otherwise specified. 5 We may be unable to capitalize on previous or future acquisitions: In addition to internally developed products, we invest in new products and technologies through acquisitions, including our acquisition of **Voecera Cerus in 2023**. Such investments are inherently risky, and we cannot guarantee that any acquisition will be successful or will not have a material unfavorable impact on us. The risks include the activities required and resources allocated to integrate new businesses, diversion of management time that could adversely affect management's ability to focus on other projects, the inability to realize the expected benefits, savings or synergies from the acquisition, the loss of key personnel, litigation resulting from the acquisition and exposure to unexpected liabilities of acquired companies. **Certain acquisitions are subject to antitrust and competition laws, and antitrust scrutiny by regulatory agencies and changes to the regulatory approval process in the United States and foreign jurisdictions may cause approvals to take longer than anticipated to obtain, not be obtained at all, or contain burdensome conditions, which may jeopardize, delay or reduce the anticipated benefits of acquisitions to us and could impede the execution of our business strategy**. In addition, we cannot be certain that the businesses we acquire will become or remain profitable. We, **our business partners or our third- party vendors** could experience a **material failure or breach** of a key information technology system, **network,** process or site **or a breach of information security, including a cybersecurity breach or failure of one or more key information technology systems, networks, processes, associated sites or service providers**. We rely extensively on information technology (IT) systems to conduct business. In addition, we rely on networks and services, including internet sites, cloud and software- as- a- service solutions, data hosting and processing facilities and tools and other hardware, software (including open- source software) and technical applications and platforms, some of which are managed, hosted, provided and / or used by third parties or their vendors, to assist in conducting our business. Numerous and evolving cybersecurity threats have posed, and will continue to pose, risks to the security of our IT systems, networks and product offerings, as well as the confidentiality, availability and integrity of our data. Some of our products and services, and information technology systems, contain or use open- source software, which poses particular risks, including potential security vulnerabilities, licensing compliance issues and quality issues. **We A security breach, whether of our products, of our customers' network security and systems or of third- party hosting services have experienced and expect to continue to experience, security breaches of, or unauthorized access to, products or systems. While such breaches or unauthorized access have not been material to date, we cannot guarantee that any future breach or unauthorized access will not be material and any breach or unauthorized access** could impact the use of such products **and systems** and the security of information stored

therein. Although we have made investments **and expect to continue to make investments** seeking to address these threats, including monitoring of networks and systems, **use of artificial intelligence**, hiring of experts, employee training and security policies for employees and third- party providers, the techniques used in these attacks change frequently and may be difficult to detect for periods of time and we may face difficulties in anticipating and implementing adequate preventative measures. When cybersecurity incidents occur, we follow our incident response protocols and address them in accordance with applicable governmental regulations and other legal requirements. Our response to these incidents and our investments to protect our **product offerings and** information technology infrastructure and data may not shield us from significant losses and potential liability or prevent any future interruption or breach of our systems. **Moreover, given the increasing complexity and sophistication of the techniques used by threat actors to obtain unauthorized access or disable or degrade systems, a cyberattack could occur and persist for an extended period of time before being detected, and we may not anticipate these acts or mitigate them adequately or timely, which may compound damages before the incident is discovered or remediated. The extent of a particular cyber incident and the steps that we may need to take to investigate the incident may** Dollar amounts in millions except per share amounts or as otherwise specified. **6 not be immediately clear, and it may take a significant amount of time before such investigation can be completed and full and reliable information about the incident is known. New regulations may require us to disclose information about a material cybersecurity incident before it has been resolved or fully investigated. Additionally, as threats continue to evolve and increase, and as the regulatory environment related to information security, data collection and use, and privacy becomes increasingly rigorous, we may be required to devote significant additional resources to modify and enhance our security controls and to identify and remediate any security vulnerabilities, which could adversely impact our net income.** In addition, a **greater significant** number of our employees working remotely has exposed us, and may continue to expose us, to greater risks related to cybersecurity and cyber- liability. If our IT systems are damaged or cease to function properly, the networks or service providers we rely upon fail to function properly, or we or one of our third- party providers suffer a loss or disclosure of our business or stakeholder information due to any number of causes ranging from catastrophic events or power outages to improper data handling or security breaches **or unauthorized access** and our business continuity plans do not effectively address these failures on a timely basis, we may be exposed to reputational, competitive and business harm as well as litigation and regulatory action. An inability to successfully manage the implementation of our new commercial global enterprise resource planning (ERP) system could adversely affect our operations and operating results: We are in the process of implementing a new commercial ~~global~~ ERP system. This system will replace many of our existing operating and financial systems. The implementation is a major undertaking, both financially and from a management and personnel perspective. Any **material** disruptions, delays or deficiencies in the design and implementation of our new ERP system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business. We may be unable to attract **, develop** and retain **executives and** key employees: Our sales, technical and other key personnel play an integral role in the development, marketing and selling of new and existing products. **Our future performance also depends in large part on the continued services of our senior management.** If we are unable to recruit, hire, develop and retain a talented, competitive work force in our highly competitive industry, or if we are unable to plan effective succession for the future, we may not be able to meet our strategic business objectives. **Ongoing inflationary Inflationary** pressures, **labor demand and shortages** and other macroeconomic factors **have increased and** could also **further** increase the cost of labor and **could** harm our ability to recruit, hire and retain talented employees. In addition, **increased unionization could negatively impact our labor costs and ability to create an engaging, connected culture, which could adversely affect our ability to recruit, hire, develop and retain a talented, competitive workforce. Further, if we are unable to maintain competitive and equitable compensation and benefit programs, including incentive programs which reward financial and operational performance, our ability to recruit, hire, engage, motivate and retain talent could be negatively affected. Additionally,** if we are unable to maintain an inclusive culture that aligns our diverse workforce with our mission and values, **this it** could adversely impact our ability to recruit, hire, develop and retain key talent. Further, **the our** remote **or and** hybrid work environment that has become commonplace as a result **practices, ability to provide flexible and alternative work arrangements, and our practices relating to corporate responsibility may not meet the needs or expectations of our employees, including senior management or the other COVID-19 pandemic key employees, which could negatively impact our ability to attract and retain highly skilled employees, or may** harm our culture and / or decrease employee engagement, which could adversely impact our ability to recruit, hire, develop and retain a talented, competitive workforce. **Effective succession planning is also important to our long- term success. Failure to ensure effective transfer of knowledge and smooth transitions involving executives and other key employees could hinder our strategic planning and execution. Changes in our management team may be disruptive to our business, and any failure to successfully integrate key new hires or promoted employees could adversely affect our business and results of operations. The loss of the services of any of our senior management or other key personnel, or our inability to attract highly qualified senior management and other key personnel, could harm our business. Our ability to execute our business strategy could be impaired if we are unable to replace such persons timely. In addition, recent legal and regulatory changes affect our ability to enforce post- termination obligations from certain employees with respect to non- competition, non- solicitation and protection of confidential information. This may negatively impact our ability to retain employees and protect our information and relationships with customers and other third parties.** Interruption of manufacturing operations could adversely affect our business: We and our suppliers have manufacturing and supply sites all over the world. However, the manufacturing of certain of our product lines is concentrated in one or more plants or geographic regions. We have principal manufacturing and distribution facilities in the United States in Arizona, California, Florida, Illinois, Indiana, Michigan, Minnesota, New Jersey, Puerto Rico, Tennessee, Texas, Utah, Virginia and Washington, and outside the United States in China,

France, Germany, Ireland, Mexico, the Netherlands, **Poland**, Switzerland and Turkey. Damage to our facilities, to our suppliers' or service providers' facilities, or to our central distribution centers as a result of natural disasters, fires, explosions or otherwise, as well as issues in our manufacturing arising from a failure to follow specific internal protocols and procedures, compliance concerns relating to the quality systems regulation, equipment breakdown or malfunction, IT system failures or cybersecurity incidents, environmental hazard incidents or changes to environmental regulations or other factors, could adversely affect the availability of our products. In the event of an interruption in manufacturing, we may be unable to move quickly to alternate means of producing **and distributing** affected products to meet customer demand. In the event of a significant interruption, we may experience lengthy delays in resuming production **or distribution** of affected products due to the need for regulatory approvals, and we may experience loss of market share, additional expense and harm to our reputation. Our insurance program may not be adequate to cover future losses: We maintain third- party insurance to cover our exposure to certain property and casualty losses and are self- insured for claims and expenses related to other property and casualty losses, including product liability, intellectual property infringement and enforcement, environmental, and cybersecurity and data privacy losses. We manage a portion of our exposure to **Dollar amounts in millions except per share amounts or as otherwise specified.** **6** self- insured losses through a wholly- owned captive insurance company. Insurance coverage limits provided by third- party insurers and / or our captive insurance company may not be sufficient to fully cover **unanticipated certain** losses **we** ~~-. The COVID-19 pandemic has materially adversely affected, and could continue to materially adversely affect, our operations, supply chain, manufacturing, product distribution, customers and other business activities: The global COVID-19 pandemic led to severe disruptions in the market in the United States and international economies that may continue for a prolonged duration and trigger.....~~ have experienced, and could continue to experience ~~-, delays and shortages in the supply of components or materials and delays in delivering our products that may result in our inability to satisfy consumer demand for our products in a timely manner or at all, which could harm our reputation, future sales and profitability. In addition, the pandemic adversely impacted the ability of certain third- party suppliers, manufacturers, distributors and customers to retain key employees and ensure the continued service and availability of skilled personnel necessary to run their complex operations. To the extent management or other personnel of our third- party suppliers, manufacturers, distributors and customers are impacted again in significant numbers and are not available to perform their job duties, we could experience delays in, or the suspension of, our manufacturing operations, sales activities, research and product development activities, regulatory work streams, clinical development programs and other important commercial and corporate functions. Moreover, we have observed an overall tightening and increasingly competitive labor market due to labor shortages caused in part by the COVID-19 pandemic and responsive measures, which has included increased wages offered by other employers and voluntary attrition of our employees and the employees of our third- party suppliers, manufacturers, distributors and customers. The extent of the pandemic's continuing effect on our business and industry will depend on future developments, including future resurgences and / or the spread of variants, and the successful development, distribution and acceptance of vaccines for those variants, all of which are uncertain and difficult to predict. We are not able at this time to estimate with certainty the effect of these and other unforeseen factors on our business, but the adverse impact on our business, cash flows, financial condition and results of operations has been, and could in the future be, material. A prolonged or reemerging impact of COVID-19 (or other pandemics in the future) also could heighten many of the other risks described in this report.~~ We have experienced, and may continue to experience, a significant and unpredictable need to adjust our operations as market demand for certain of our products has shifted and continues to shift or as may be mandated by governmental authorities: Some of our products are particularly sensitive to reductions in elective medical procedures. Elective medical procedures were suspended or reduced at various times **during** ~~since the beginning of~~ the COVID- 19 pandemic in many of the markets where our products are marketed and sold, which negatively affected **Dollar amounts in millions except per share amounts or as otherwise specified.** **7** our business, cash flows, financial condition and results of operations. It is not possible to predict whether elective medical procedures will again be suspended or reduced in the future and, to the extent individuals and customers are required to delay or cancel elective procedures ~~as a result of a resurgence of the COVID-19 pandemic or otherwise,~~ our business, cash flows, financial condition and results of operations could be negatively affected. **Further, our customers have experienced, and could continue to experience, staffing shortages that may result in decreased demand for our products, which could negatively affect our business and financial results.** In addition, **during the COVID- 19 pandemic** our products in certain divisions, such as Medical, ~~have experienced -, and could continue to experience,~~ higher demand as our customers ~~have were~~ focused on treating COVID- 19 patients and preparing for future public health emergencies. Unpredictable increases in demand for certain of our products have exceeded in the past, and could exceed in the future, our capacity to meet such demand timely, which could adversely affect our customer relationships and result in negative publicity. In this regard, the accelerated development and production of products and services to address medical and other requirements could increase the risk of regulatory enforcement actions, product defects or related claims ~~business activities-~~ **continue for a prolonged duration and trigger a recession or a period of economic slowdown.** In **response** connection with COVID-19-, **various** governmental authorities and private enterprises implemented, and may **continue to** in the future implement ~~in connection with another pandemic or~~ **reimplement** ~~public health emergency (or in response to the fear thereof),~~ **numerous** measures, such as travel bans and restrictions, quarantines, shelter- in- place orders and shutdowns. ~~Our~~ **A significant number of our** customers, global suppliers, distributors and manufacturing facilities **are located in regions that were affected by the pandemic and those operations** ~~have in the past been, and could~~ **continue to** in the future be, materially affected by restrictive measures implemented in response to ~~the pandemic. As a result~~ ~~pandemic or public health emergency,~~ which has in the past caused **some of our customers, distributors** and **indirect sales channels have at times been** ~~could in the future cause them to be unable to hire and retain employees, distribute or use our products or provide required services. We have~~ ~~as a result~~ experienced, and could **continue to** in the future. **LEGAL AND REGULATORY RISK** Current economic and political conditions make tax rules in

jurisdictions subject to significant change: Our future results of operations could be affected by changes in the effective tax rate as a result of changes in tax laws, regulations and judicial rulings. We are continuing to evaluate the impact of tax reform in the countries in which we operate as new guidance **is published** and **new** regulations are **published adopted**. In addition, further changes in the tax laws could arise, including as a result of the base erosion and profit shifting (BEPS) project undertaken by the Organisation for Economic Cooperation and Development (OECD). The OECD, which represents a coalition of member countries, has **issued recommendations put forth two proposed frameworks — Pillar One and Pillar Two — that revise the existing profit allocation and nexus rules and ensure a minimal level of taxation**, **in some cases respectively. On December 12**, **would make substantial** **2022, the European Union member states agreed to implement the Inclusive Framework's global corporate minimum tax rate of 15 %, and various countries (both within and outside the European Union) have enacted new laws implementing Pillar Two or have proposed legislation. The OECD continues to release additional guidance on the two-pillar framework, with widespread implementation anticipated by 2024. These changes**, **to numerous long-standing tax positions and any additional principles. These contemplated changes**, **to the extent adopted by OECD members and / or other countries**, could increase tax **expense** uncertainty and may adversely affect our provision for **income taxes**. We could be negatively impacted by future changes in the allocation of income to each of the income tax jurisdictions in which we operate: We operate in multiple income tax jurisdictions both in the United States and internationally. Accordingly, our management must determine the appropriate allocation of income to each jurisdiction based on current interpretations of complex income tax regulations. Income tax authorities regularly perform audits of our income tax filings. Income tax audits associated with the allocation of income and other complex issues, including inventory transfer pricing and cost sharing, product royalty and foreign branch arrangements, may require an extended period to resolve and may result in significant income tax adjustments. The impact of **United States** healthcare reform legislation on our business remains uncertain: **Several markets where we sell our products** **In 2010 the Patient Protection and Affordable Care Act (ACA) was enacted. While the provisions of the ACA are intended making efforts** to expand access to **health care or** health insurance coverage **while** and improve the quality of healthcare over time, other provisions of the legislation, including Medicare provisions aimed at decreasing costs, comparative effectiveness research, an **Dollar amounts in millions except per share amounts or as otherwise specified. These efforts may have** **7 independent payment advisory board and pilot programs to evaluate alternative payment methodologies, are having a meaningful effect direct or unintended negative impact on access to medical technology** the way healthcare is developed and delivered and could have a significant effect on our business. There have been ongoing litigation and congressional efforts to modify or repeal all or certain provisions of the ACA. We face uncertainties that might result from modification or repeal of any of the provisions of the ACA, including as a result of current and future executive orders and legislative actions. We cannot predict what **other** healthcare programs and regulations **will could** ultimately be implemented at the federal or state level or the effect that any future legislation or regulation in the United States may have on our business. **Similarly, we cannot predict the impact that healthcare reform legislation in other countries where we sell our products may have on our business.** We are subject to extensive governmental regulation relating to the classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products: The classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products are subject to extensive and evolving regulations and rigorous regulatory enforcement by the FDA, state governments, European Union and other governmental authorities in the United States and internationally. **The These governmental authorities may impose additional requirements or limits on the methods, procedures or agents we use to manufacture and sterilize our products, which could have a negative impact on our business. In addition, the** process of obtaining licenses, regulatory clearances and / or approvals to market and sell our products can be costly and time consuming and the clearances and / or approvals might not be granted timely. We have ongoing responsibilities under the laws and regulations applicable to the manufacturing of products within our facilities and those contracted by third parties that are subject to periodic inspections by the FDA, state Boards of Pharmacy and other governmental authorities to determine compliance with the quality system, medical device reporting regulations and other requirements. We incur significant costs to comply with regulations, including the MDR, **the free trade agreement between the United Kingdom and the European Union that became effective January 1, 2021, and the regulatory laws established by the National Medical Products Administration in China**. If we fail to comply with applicable regulatory requirements, we may be subject to a range of sanctions, including substantial fines, warning letters that require corrective action, product seizures, recalls, **import restrictions**, the suspension of product manufacturing **or sales**, revocation of approvals, exclusion from future participation in government healthcare programs, substantial fines and criminal prosecution. **Dollar amounts in millions except per share amounts or as otherwise specified. 8** We are subject to federal, state and foreign healthcare regulations, including anti-bribery, anti-corruption, anti-kickback and false claims laws, globally and could face substantial penalties if we fail to comply with such regulations and laws: The relationships that we, and third parties that market and / or sell our products, have with healthcare professionals, such as physicians, hospitals, healthcare organizations and others, are subject to scrutiny under various state and federal laws often referred to collectively as healthcare fraud and abuse laws. In addition, the United States and foreign government regulators have increased the enforcement of the Foreign Corrupt Practices Act (FCPA) and other anti-bribery and anti-kickback laws. We also must comply with a variety of other laws that impose extensive tracking and reporting related to all transfers of value provided to certain healthcare professionals and others. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to investigate, audit and monitor compliance or to alter our practices. Violations or alleged violations of these laws could result in litigation and we may be subject to criminal or civil penalties and sanctions, including substantial fines, imprisonment of current or former employees and exclusion from participation in governmental healthcare programs. In 2013 and 2018 we settled claims brought by the **United States Securities and Exchange Commission (SEC)** related to the FCPA. Pursuant to these settlements, we paid fines and penalties and retained an independent compliance

consultant. We continue to implement recommendations that resulted from the independent compliance consultant's review of our commercial practices to enhance our commercial business practices. **In addition, we are currently investigating whether certain business activities in certain foreign countries violated provisions of the FCPA and have been contacted by the SEC, United States Department of Justice and certain other regulatory authorities. Although we are currently unable to predict the outcome of the investigations or the potential impact, if any, on our financial statements, the impacts could potentially be significant.** We are subject to privacy, data protection and data security regulations and laws globally, and could face substantial penalties if we fail to comply with such regulations and laws: We are subject to a variety of laws and regulations globally regarding privacy, data protection, and data security, including those related to the collection, storage, handling, use, disclosure, transfer and security of personally identifiable healthcare information. For example, in the United States, privacy and security regulations under the Health Insurance Portability and Accountability Act of 1996, including the expanded requirements under the Health Information Technology for Economic and Clinical Health Act of 2009, establish comprehensive standards with respect to the use and disclosure of protected health information (PHI), by covered entities, in addition to setting standards to protect the confidentiality, integrity and security of PHI. Regulators are also imposing new data privacy and security requirements, including new and greater monetary fines for privacy violations. For example, the European Union's General Data Protection Regulation (GDPR) established rules regarding the handling of personal data. Non-compliance with the GDPR may result in monetary penalties of up to 4 % of total company revenue. **Various U. S. states and other other governmental authorities around the world have imposed or are imposing considering similar types of laws and regulations, data breach reporting and penalties for non-compliance and increasing security requirements. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to monitor compliance or to alter our practices. As new privacy-related laws and regulations are implemented, the time and resources needed for us to comply with such laws and regulations, as well as our potential liability for non-compliance and reporting obligations in the case of data breaches, have increased and may further increase.** We may be adversely affected by product liability claims, unfavorable court decisions or legal settlements: We are exposed to potential product liability risks inherent in the design, manufacture and marketing of medical devices, many of which are implanted in the human body for long periods of time or indefinitely. ~~We may be exposed to additional potential product liability risks related to products designed, manufactured and marketed in response to the COVID-19 pandemic, including discretionary products and products permitted under the Emergency Use Authorization granted by the FDA.~~ We are currently defendants in a number of product liability matters, including those relating to our Rejuvenate and ABGII Modular- Neck hip stems, LFIT Anatomic CoCr V40 Femoral Heads and the product liability lawsuits and claims relating to Wright Medical Group N. V. (Wright) legacy hip products discussed in Note 7 to our Consolidated Financial Statements. These matters are subject to many uncertainties and outcomes are not predictable. Further, ~~in November 2020 the European Parliament voted in favor of the European Representative Actions Directive (the Collective Redress Directive), which became effective in 2023,~~ mandates a class action regime in each EU member state to facilitate domestic and cross-border class actions in a wide range of areas, including product liability claims with medical devices. ~~The Collective Redress Directive will take effect in 2023 after a 24-month implementation period. The Collective Redress Directive, when implemented,~~ could result in additional litigation risks and significant legal expenses for us. In addition, we may incur significant legal expenses **or reputational damage** for product liability claims regardless of whether we are found to be liable. **Intellectual property litigation and infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products: The medical device industry is characterized by extensive intellectual property litigation and, from time to time, we are the subject of claims of infringement or misappropriation. Regardless of the outcome, such claims are expensive to defend and divert management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against us could result in payment of significant monetary damages and / or royalty payments or negatively impact our ability to sell current or future products in the affected category. Dependence on patent and other proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may impact offerings in our product portfolios: Our long-term success largely depends on our ability to market technologically competitive products. If we fail to obtain or maintain adequate intellectual property protection, it could allow others to sell products that directly compete with proprietary features in our product portfolio. Also, our issued patents may be subject to claims challenging their validity and scope and raising other issues. In addition, currently pending or future patent applications may not result in issued patents.** MARKET RISKS We have exposure to exchange rate fluctuations on cross border transactions and translation of local currency results into United States Dollars: We report our financial results in United States Dollars and approximately 25 % of our net sales are denominated in foreign currencies, including the Australian Dollar, British Pound, Canadian Dollar, Euro and Japanese Yen. Cross border transactions with external parties and intercompany relationships result in increased exposure to foreign currency exchange effects. While we use derivative instruments to manage the impact of currency exchange, our hedging strategies may not be successful, and our unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the United States Dollar results in favorable or unfavorable translation effects when the results of our foreign locations are translated into United States Dollars. Additional capital that we may require in the future may not be available to us or may only be available to us on unfavorable terms, which could negatively affect our liquidity: Our future capital requirements will depend on many factors, including operating requirements, current and future

Dollar amounts in millions except per share amounts or as otherwise specified. 8-9