

Risk Factors Comparison 2024-02-23 to 2023-02-24 Form: 10-K

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

We operate in a rapidly changing economic and technological environment that presents numerous risks, many of which are driven by factors that we cannot control or predict. Our business, financial condition and results of operations may be impacted by a number of factors. In addition to the factors discussed elsewhere in this report, the following risks and uncertainties could materially harm our business, financial condition or results of operations, including causing our actual results to differ materially from those projected in any forward-looking statements. The following list of **significant material** risk factors is not all-inclusive or necessarily in order of importance. Additional risks and uncertainties not presently known to us, or that we currently deem immaterial, also may materially adversely affect us in future periods. You should carefully consider these risks and uncertainties before investing in our securities. Risks Related to our Business, Operations and Strategy **Business** **Our success depends on our ability to effectively develop and market our products against those of our competitors. We operate in a highly competitive environment. Our present or future products could be rendered obsolete or economic uneconomical conditions by technological advances by one or more of our present or future competitors. To remain competitive, including disruptions related we must continue to identify, prioritize, develop and acquire new products and technologies, as well as identify, prioritize and improve existing products and technologies. We must also obtain and maintain regulatory approvals for such products, accurately forecast demand, manufacture the correct mix of products, distribute products to multiple global markets and market the those COVID-19 pandemic products profitably. For example, we have experienced elevated charges adversely impacted, and may, either alone or for excess in combination with other risks, in the future adversely impact, our business, results of operations and obsolete inventory while also facing increased backorders due to financial condition, the nature and extent of which are uncertain and unpredictable demand fluctuations across.** Our operations expose us to risks from business interruptions that may arise from a variety of sources, including public health crises and outbreaks of diseases, such as the COVID-19 pandemic and its variants, supply chain disruptions, trade and tariff disputes and global conflicts, that can, singly or **our various markets** in combination with other factors, adversely affect our business and financial results. We experienced a sustained decline in elective surgical procedures globally due to the COVID-19 pandemic and its associated effects, including deferrals of elective surgical procedures and staffing shortages at hospitals. Surgical volumes generally recovered over the course of 2022, but may return to lower levels due to future COVID-19 variants and resurgences. We continue to experience risks and uncertainty in several aspects of our business including relating to global, regional and national supply chain disruption; dynamic economic conditions; foreign exchange rate volatility; inflation; workforce availability changes; healthcare staffing challenges and changes in government spending. We expect several of these factors to continue, and there can be no assurance that we **production mix planning or inventory allocation** will **match** successfully manage these risks without adverse impacts..... part, resulted in challenges to meet end market demand in some instances. We expect similar..... technologies and improve existing products and technologies. Competition **within our markets** is primarily on the basis of technology, innovation, quality, reputation, customer service and pricing. In markets outside of the U. S., other factors influence competition as well, including local distribution systems, complex regulatory environments, and differing medical philosophies and product preferences. Our competition may have greater financial, marketing, **technical** and other resources than us; respond more quickly to new or emerging technologies; undertake more extensive marketing campaigns; operate more effective **planning, manufacturing,** sales and distribution channels; adopt more aggressive pricing policies; or be more successful in attracting potential customers, employees and strategic partners. **We also face competition from pharmaceutical and other therapies that may be more attractive than, or have other benefits over, our products, or that could affect the frequency, progressions or symptoms of diseases and conditions that our products treat.** Any of these factors, alone or in combination, could cause us to have difficulty maintaining or increasing sales of our products. **If we fail to retain the employees, independent agents and distributors upon whom we rely heavily to market our or otherwise have an adverse effect on our business and financial results. Our products may become obsolete,** customers may not buy our products, and our revenue and profitability may decline **without.** Our marketing success in the U. S. and abroad depends significantly upon our employees', agents' and distributors' sales and service expertise in the marketplace. Many of these **the timely** agents have developed professional relationships with existing and potential customers because of the agents' detailed knowledge of products and instruments. A loss of a significant number of our agents could have a material adverse effect on our business and results of operations. **If we do not introduce introduction of new products and enhancements in a timely manner, due to changes in markets, our or due to changes in applicable standards of care. Demand for our products may change, in certain cases, in ways we may not anticipate because of evolving customer needs, changing demographics, changing industry growth rates, declines in the musculoskeletal implant market, the introduction of competing products and technologies, the emergence of alternative treatment methods, and evolving surgical philosophies and industry standards. Our products may become obsolete over without the time timely;** customers may not buy our products and our revenue and profitability may decline. Demand for our products may change, in certain cases, in ways we may not anticipate because of evolving customer needs, changing demographics, slowing industry growth rates, declines in the musculoskeletal implant market, the introduction of new products and technologies and evolving surgical philosophies and industry **enhancements, or due to changes in applicable** standards. **Without the timely introduction of care** new products and enhancements, our products may become obsolete over time. If that happens, our revenue and operating results would suffer. The success of our new **and enhanced** product offerings will depend on several factors, including our

ability to properly identify and anticipate customer needs; commercialize new products in a timely manner; manufacture and deliver instruments and products in sufficient volumes on time; differentiate our offerings from competitors' offerings; achieve positive clinical outcomes for new products; satisfy the increased demands by healthcare payors, providers and patients for shorter hospital stays, faster post-operative recovery and lower-cost procedures; innovate and develop new materials, product designs and surgical techniques; and provide adequate medical education relating to new products. In addition, new materials, product designs, **product enhancements** and surgical techniques that we develop may not be accepted quickly, in some or all markets, because of, among other factors, **entrenched patterns of clinical practice**, the need for regulatory clearance, **entrenched patterns of clinical practice** and uncertainty with respect to third-party reimbursement. Moreover, innovations generally require a substantial investment in research and development before we can determine their commercial viability, and we may not have the financial resources necessary to fund the research, development and production. In addition, even if we are able to successfully develop enhancements or new generations of our products, these enhancements or new generations of products may not produce revenue in excess of the costs of development and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features **in some instances. We expect similar challenges in 2023. As a result, we may experience loss of market share, which we may be unable to recapture, and harm to our reputation, which could adversely affect our business, financial condition and results of operations. Disruptions in the supply of the materials and components used in manufacturing our products or the sterilization of our products by third-party suppliers could adversely affect our business, financial condition and results of operations. We purchase many of the materials and components used in manufacturing our products from third-party suppliers, and we outsource some key manufacturing activities. Certain of these materials and components and outsourced activities can only be obtained from a single source** or a limited number of sources due to quality considerations, expertise, costs or constraints resulting from regulatory requirements. In certain cases, we may not be able to establish additional or replacement suppliers for such materials or components or outsourced activities in a timely or cost effective manner, due to market constraints or as a result of FDA ~~or and~~ other worldwide regulations that require validation of materials and components prior to their use in our products and the complex nature of our and many of our suppliers' manufacturing processes and the need for clearance or approval of significant changes by ~~FDA and other~~ worldwide regulatory bodies prior to implementation. A reduction or interruption in the supply of materials or components used in manufacturing our products, such as due to ~~loss of access to one or more suppliers~~ **experiencing reductions in operations and / or worker absences due to a pandemic or otherwise**; an inability to timely develop and validate alternative sources if required; or a significant increase in the price of such materials or components could adversely affect our business, financial condition and results of operations. In addition, many of our products require sterilization prior to sale, and we utilize a mix of internal resources and contract sterilizers to perform this service. ~~We also provide sterilization services to certain of our customers.~~ To the extent we or our contract sterilizers are unable to sterilize our products ~~or provide sterilization services to our customers~~, whether caused by ~~due to~~ capacity, availability of materials for sterilization, and regulatory or other ~~restrictions~~ **constraints, including federal and state regulations** on the use of ethylene oxide, **or reductions in operations and / or worker absences due to the COVID-19 pandemic** or otherwise, we may be unable to transition to other contract sterilizers, sterilizer locations or sterilization methods in a timely or cost effective manner or at all, which could have a material impact on our results of operations and financial condition. Moreover, we are subject to the SEC's rule regarding disclosure of the use of certain minerals, known as "conflict minerals" (tantalum, tin and tungsten (or their ores) and gold), which are mined from the Democratic Republic of the Congo and adjoining countries. This rule could adversely affect the sourcing, availability and pricing of materials used in the manufacture of our products, which could adversely affect our manufacturing operations and our profitability. In addition, we are incurring additional costs to comply with this rule, including costs related to determining the source of any relevant minerals, metals and other materials used in our products. We have a complex supply chain, and we may not be able to sufficiently verify the origins of the minerals and metals used in our products through our due diligence procedures. As a result, we may face reputational challenges with our customers and other stakeholders. We are **increasingly** dependent on sophisticated information technology and if we fail to effectively maintain or protect our information systems ~~and~~ **or** data, including from ~~cybersecurity events~~ **data breaches**, our business could be adversely affected. We are **increasingly** dependent on sophisticated information technology for our products and infrastructure. As a result of technology initiatives, expanding and evolving privacy and cybersecurity laws, changes in our system platforms and ~~the ongoing~~ integration of **new** business acquisitions, we have been consolidating and integrating the number of systems we operate and have upgraded and expanded our information systems ~~and cybersecurity~~ capabilities. In addition, some of our products and services incorporate software or information technology that collects data regarding patients and patient therapy, and some software and other products we provide to customers connect to our ~~and third-party~~ systems for maintenance and other purposes. We also have outsourced elements of our operations to third parties (including ~~and, as a result, we manage a number of third-party~~ suppliers, ~~customers and other business partners~~), and, as a result, we manage a number of third parties who may ~~now or could in the future~~ have access to our confidential information, including, but not limited to, intellectual property, proprietary business information and personal information of patients, ~~employees team members~~ and customers (collectively "Confidential Information"). Our information systems, and those of third ~~parties~~ **party suppliers** with whom we contract, require an ongoing commitment of significant resources to maintain, protect and enhance existing systems and develop new systems to keep pace with continuing changes in information technology, evolving systems and regulatory standards, changing threats and vulnerabilities, and the increasing need to protect ~~data including patient~~ **and** customer ~~and Confidential Information~~ **information**. In addition, given their size and complexity, these systems ~~are could be~~ vulnerable to service interruptions ~~and or~~ to security breaches from inadvertent or intentional actions by our employees, third-party ~~suppliers~~ **vendors** and / or business partners, ~~and or~~ from cyber-attacks by malicious third parties attempting to gain unauthorized access to our products, systems or

Confidential Information. Our use of artificial intelligence and machine learning in our infrastructure and products exposes us to new threats, risks and uncertainties, including with respect to changing laws and regulations regarding the use of such technologies. Like other large multi-national corporations, we regularly have experienced cyber instances of successful phishing attacks, on our email systems and we expect to continue to be subject to such similar attacks in the future. These We also are subject to other cyber-attacks may, include including phishing, state-sponsored cyber-attacks, industrial espionage, insider threats, computer denial-of-service attacks, computer viruses, ransomware and other malware, payment fraud or other cyber incidents. Evolving artificial intelligence and machine learning continue to improve the capabilities of cyber attackers. In addition, as a result of our adoption of remote work arrangements in many positions, a significant number of our employees who are able to work remotely are doing so, and malicious cyber actors may increase efforts malware campaigns and phishing emails targeting remote workers teleworkers, which exposes us to additional cybersecurity risks. Our cybersecurity program, incident response efforts, business continuity procedures and disaster recovery planning may not be sufficient for all eventualities. If we fail to maintain or protect our information systems and data integrity effectively, we could:

- suffer a loss of access to or alteration of all or a portion of our Confidential Information;
- have difficulty meeting our compliance requirements, including with respect to data retention and reporting, QMS, quality reporting or other requirements;
- have difficulty developing new or enhanced products;
- lose existing customers, suppliers vendors and business partners;
- have difficulty attracting new customers;
- have problems in determining product cost estimates and establishing appropriate pricing;
- suffer outages or disruptions in our operations, or supply chain, products and / or services, including our ZBEdge™ ecosystem;
- have difficulty preventing, detecting, and controlling fraud;
- have disputes with customers, physicians, and other healthcare professionals and payors for our products;
- have regulatory sanctions or penalties imposed;
- incur increased operating expenses;
- be subject to issues with product functionality that may result in a loss of data, risk to patient safety, field actions and / or product recalls;
- incur expenses or lose revenues as a result of a data privacy breach; or
- suffer other adverse consequences.

While we have invested heavily in the protection of our data and information technology, there can be no assurance that our activities related to consolidating the number of systems we operate, upgrading and expanding our information systems capabilities, protecting and enhancing our systems and implementing new systems will be successful. We will continue to dedicate significant resources to protect against unauthorized access to our systems and work with government authorities to detect and reduce the risk of future cyber incidents; however, cyber-attacks are becoming more sophisticated, frequent and adaptive. Therefore, despite our efforts, we cannot assure that cybersecurity incidents cyber-attacks or data breaches will not occur or that technology or information system systems issues will not arise in the future. Any significant breakdown, intrusion, breach, interruption, corruption or destruction of these systems could have a material adverse effect on our business and reputation and could materially adversely affect our results of operations and financial condition. Our success depends on Business and economic conditions have adversely impacted, and may, either alone or our ability to effectively develop and market our products against those of our competitors. We operate in combination with a highly competitive environment. Our present or future products could be rendered obsolete or uneconomical by technological advances by one or more of our present or future competitors or by other therapies risks, in the future adversely impact, our business, results of operations and financial condition, the nature and extent of which impacts are uncertain and unpredictable. Our operations expose us to risks from business interruptions that may arise from a variety of sources, including biological therapies public health crises; supply chain disruptions; loss of or limitations on access to certain markets due to trade and tariff disputes and disruptions or national, regional and global conflicts; adverse economic developments; healthcare staffing challenges; government shutdowns; natural disasters; and other events that can, singly or in combination with other factors, adversely affect our business and financial results. To remain competitive There can be no assurance that we will successfully manage risks, such as we must continue to develop and acquire new products and technologies and improve existing products and technologies. If third-party payors decline to reimburse our customers for our products or reduce reimbursement levels, the demand for our products may decline and our ability to sell our products profitably may be harmed. In addition, we are subject to cost containment measures in the United States and other countries, resulting in pricing pressures, which could have a material adverse effect on our business, results of operations, and cash flows. We sell our products and services to hospitals, doctors and other healthcare providers, which receive reimbursement for the healthcare services provided to their patients from third-party payors, such as domestic and international government programs, private insurance plans and managed care programs. These third-party payors may deny reimbursement if they determine that a product or service used in a procedure was not in accordance with cost-effective treatment methods, as determined by the third-party payor, or was used for an unapproved indication. Third-party payors may also decline to reimburse for experimental procedures and products. In addition, third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for medical products and services. If third-party payors deny or decline reimbursement, reduce reimbursement levels or change reimbursement models for our products, demand for our products may decline, or we may experience increased pressure to reduce the prices of our products, which could have a material adverse effect on our sales and results of operations. Many customers for of our products have formed group purchasing organizations in an effort to contain costs. Group purchasing organizations negotiate pricing arrangements with medical supply manufacturers and distributors, and these negotiated prices are made available to a group purchasing organization's affiliated hospitals and other members. If we are not one of the providers selected by a group purchasing organization, affiliated hospitals and other members may be less likely to purchase our products, and, if the group purchasing organization has negotiated a strict compliance contract for another manufacturer's products, we may be precluded from making sales to members of the group purchasing organization for the duration of the contractual arrangement. Our failure to respond to the cost-containment efforts of group purchasing organizations may cause us to lose market share to our competitors and could have a material adverse effect on our sales and results of operations. Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets in which we do business, and

we have experienced downward pressure on product pricing and other effects of healthcare reform in our international markets. 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 (“ VBP ”) process designed to reduce medical spending, which has in the past resulted in, and could in the future result in, reduced margins on covered devices and products, required renegotiation of distributor arrangements, and incurrence of inventory- related charges. In cases where our product is not selected in VBP, sales of that product are substantially impacted. **Similarly, the Italian Public Administration has implemented a Pay Back Law to obtain reimbursement from the medical device industry to contribute to government overspending on medical devices beginning in 2015, which assessments we are challenging. Additional cost reduction and recovery strategies are likely to be proposed in various jurisdictions, the effects of which are difficult to predict, but may have a material adverse effect on our sales and results of operations.** Pricing pressure ~~continues~~ ~~has also increased~~ due to ~~continued~~ consolidation among healthcare providers, trends toward managed care, the shift toward governments becoming the primary payors of healthcare expenses, reductions in reimbursement levels and government laws and regulations relating to reimbursement and pricing generally. If key participants in government healthcare systems reduce the reimbursement levels for our products, including through **regulatory changes, elections and other** political changes ~~or transitions~~, our business, financial condition, results of operations and cash flows may be adversely affected.

Credit and Liquidity Risks We incurred substantial additional indebtedness in connection with previous mergers and acquisitions and may not be able to meet all of our debt obligations, and interest rate risk could adversely affect our indebtedness. We incurred substantial additional indebtedness in connection with previous mergers and acquisitions. At December 31, ~~2022~~ **2023**, our total indebtedness was \$ 5. ~~7~~ **8** billion. As of December 31, ~~2022~~ **2023**, our debt service principal obligations (excluding interest, leases and equipment notes), during the next 12 months are expected to be \$ 0. ~~5~~ **9** billion. As a result of the increase in our debt, demands on our cash resources have increased ; **such demand would further amplify if we fund future mergers and acquisitions using debt financing.** ~~The~~ **Our current and future** increased level of debt could, among other things: • require us to dedicate a large portion of our cash flow from operations to the servicing and repayment of our debt, thereby reducing funds available for working capital, capital expenditures, research and development expenditures and other general corporate requirements; • limit our ability to obtain additional financing to fund future working capital, capital expenditures, research and development expenditures and other general corporate requirements; • limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate; • restrict our ability to make strategic **investments, collaborations,** acquisitions or dispositions or to exploit business opportunities; • place us at a competitive disadvantage compared to our competitors that have less debt; • adversely affect our credit rating, with the result that the cost of servicing our indebtedness might increase and our ability to obtain surety bonds could be impaired; • adversely affect the market price of our common stock; and • limit our ability to apply proceeds from a future offering or asset sale to purposes other than the servicing and repayment of debt. In addition, the interest rates applicable to certain of our debt obligations are based on a fluctuating rate of interest determined by reference to the Secure Overnight Financing Rate (“ SOFR ”) ~~or the other externally- determined rate rates~~ of interest last quoted by The Wall Street Journal. **SOFR and such other rates have increased from recent lows, which** ~~as has increased our cost of borrowing the “ Prime Rate ” in the United States.~~ Any **further** increase in interest rates applicable to our debt obligations would increase our cost of borrowing and could adversely affect our financial position, results of operations or cash flows. ~~We may have additional tax liabilities. We are subject to income taxes in the U. S. and many foreign jurisdictions. Significant judgment is required in determining our worldwide provision for income taxes. In the ordinary course of our business, there are many transactions and calculations where the ultimate tax determination is uncertain. We are regularly under audit by tax authorities. Although we believe our tax estimates are reasonable, the final determination of tax audits and any related litigation could be materially different from our historical income tax provisions and accruals. The results of an audit or litigation could have a material effect on our financial statements in the period or periods for which that determination is made. Proposed changes~~ **Changes** in tax laws in countries in which we do business **are expected** , if enacted, could lead to changes in tax laws that could negatively impact our effective tax rate ; **further changes in tax laws may have a further negative impact** . Changes in the tax laws and regulations of the jurisdictions where we do business, including an increase in tax rates or an adverse change in the treatment of an item of income or expense, could result in a material increase in our tax expense and / or tax payments, could increase tax uncertainty and could have a material adverse impact on our business, financial condition or results of operations. **Tax law** For example, changes in **certain** the tax laws of foreign jurisdictions are expected **in which we operate conforming** to occur as a result of pillar **Pillar two** ~~Two~~ of the base erosion and profit shifting plan (“ Pillar Two ”) undertaken by the Organisation for Economic Co- operation and Development **will take effect in 2024. We expect the implementation and interpretation of Pillar Two across all jurisdictions where we do business will have an adverse effect on our effective tax rate** , which would **results of operations and cash flows. These tax law changes** require profits earned in **such** jurisdictions in which we operate to be subject to a minimum 15 percent income tax rate. **Currently** In December 2022, **uncertainty exists regarding how** the European Union Council established effective dates of January 1, 2024 and January 1, 2025 for different aspects of Pillar Two **rules interact with existing national tax laws and whether such rules pertaining to the Undertaxed Profits Rule that will take effect in 2025 are consistent with existing tax treaty obligations. We may have additional tax liabilities as a result of examinations and audits** . We are ~~continuing~~ **subject** to evaluate income taxes in the U. S. and many foreign jurisdictions. Significant judgment is required in determining our worldwide provision for income taxes. In the ordinary course of our business, ~~the~~ **there** potential impact on future periods of ~~are many transactions and calculations where~~ the Pillar Two, pending legislative adoption ~~ultimate tax determination is uncertain. We are regularly under audit~~ by additional individual countries ~~tax authorities. Although we believe our tax estimates are reasonable~~ , including those ~~the final determination within the European Union. The spinoff of~~ **tax audits** ~~ZimVie Inc. and~~ **any related litigation** the divestiture of our retained

interest in ZimVie Inc. could result in substantial tax liability. We..... reliance on the opinion and rulings may be materially different from jeopardized. If the spinoff, or our historical the subsequent divestiture of our retained interest in ZimVie, does not qualify for tax-free treatment for U. S. federal income tax purposes, the provisions and accruals. The resulting results of tax liability to us, to our stockholders and- an to ZimVie stockholders audit or litigation could be substantial have a material effect on our financial statements in the period or periods for which that determination is made. If our independent agents and distributors are characterized as employees, we would be subject to additional tax and other liabilities. We structure our relationships with independent agents and distributors in a manner that we believe results in an independent contractor relationship, not an employee relationship. Although we believe that our independent agents and distributors are properly characterized as independent contractors, tax, labor or other regulatory authorities may in the future challenge our characterization of these relationships. Further, we have been subject to lawsuits challenging the characterization of these relationships. Changes in classification from independent contractor to employee can result in a change to various requirements associated with the payment of wages, tax withholding, and the provision of unemployment, health, and other traditional employer- employee related benefits. If regulatory authorities or state, federal or foreign courts were to determine our independent agents or distributors are employees, and not independent contractors, we would be required to withhold income taxes, to withhold and pay social security, Medicare and similar taxes and to pay unemployment and other related payroll taxes, as well as provide other employer- employee related benefits. We would also be liable for unpaid past taxes and subject to penalties. As a result, any determination that our independent agents and distributors are our employees could have a material adverse effect on our business, financial condition or results of operations. Future material impairments in the carrying value of our intangible assets, including goodwill, would negatively affect our operating results. Goodwill and intangible assets represent a significant portion of our assets. At December 31, 2022-2023, we had \$ 8. 6-8 billion in goodwill and \$ 5-4. 1-9 billion of intangible assets. The goodwill results from our acquisition activity and represents the excess of the consideration transferred over the fair value of the net assets acquired. We assess at least annually whether events or changes in circumstances indicate that the carrying value of our intangible assets may not be recoverable. As discussed further in Note 11 to our consolidated financial statements, in the fourth quarter of 2022, we recorded goodwill impairment charges of \$ 289. 8 million as a result of, among other factors, changes in foreign currency exchange rates in our European- based currencies, inflation and a higher interest rate environment ; in the first quarter of 2020, we recorded goodwill impairment charges of \$ 470. 0 million as a result of the adverse impacts from the COVID- 19 pandemic and a change in our reportable segments; and in the second quarter of 2022 and 2021, we recorded \$ 3. 0 million and \$ 16. 3 million, respectively, of in- process research and development (“ IPR & D ”) intangible asset impairments on certain IPR & D projects. If There were no impairment charges during the year ended December 31, 2023, but if the operating performance at one or more of our reporting units falls significantly declines below current levels-, including if elective surgical procedures return to lower levels due to a resurgence of the COVID- 19 pandemic or otherwise, if competing or alternative technologies or pharmacological treatments, emerge, if market conditions or future cash flow estimates for one or more of our businesses decline, or as a result of restructuring initiatives pursuant to which we reorganize our reporting units, we could be required to record additional impairment charges. Any write- off of a material portion of our goodwill or unamortized intangible assets would negatively affect our results of operations. result in substantial tax liability. We obtained Internal Revenue Service (“ IRS ”) rulings and an opinion as to the tax- free nature of the spinoff under the U.S. Internal Revenue Code of 1986, as amended. We subsequently obtained supplemental IRS rulings as to the tax- free nature of our divestiture of retained shares of ZimVie common stock following the spinoff, which divestiture completed in February 2023. The IRS rulings and opinion are based, among other things, on various factual assumptions and representations we made. If any of these assumptions or representations are, or become, inaccurate or incomplete, reliance on the opinion and rulings may be jeopardized. Global Operational Risks We conduct a significant amount of our sales and manufacturing activity activities outside of the U. S., which subjects us to additional business risks and may cause our profitability to decline due to increased costs. We sell our products in more than 100 countries and derived approximately 42 percent of our net sales in 2022-2023 from outside the U. S. We intend to continue to pursue growth opportunities in sales internationally, including in emerging markets, which could expose us to additional risks associated with international sales and operations. Our international operations are, and will continue to be, subject to a number of risks and potential costs, including: • changes to trade restrictions and protection measures, new import or export requirements, new or increased tariffs, trade embargoes and sanctions and other trade barriers, which may prevent us from shipping products to or from a particular market, restrict our access to certain sources of raw materials and other inputs, increase our operating costs and disrupt our ability to collect payment for our products and services in particular markets; • changes in foreign medical reimbursement policies and programs; • differences in and changes to foreign regulatory requirements, such as more stringent requirements for regulatory clearance of products; • differing local product preferences and product requirements; • fluctuations in foreign currency exchange rates; • the effects of inflation, including the effects of different rates of inflation in different countries, on our costs and expenses, and the costs of our products; • diminished protection of intellectual property in some countries outside of the U. S. ; • trade protection measures, import or export requirements, new or increased tariffs, trade embargoes and sanctions and other trade barriers, which may prevent us from shipping products to or receiving products from a particular market, restrict our access to certain sources of raw materials and other inputs, increase our operating costs and disrupt our ability to collect payment for our products and services in particular markets; • foreign exchange controls that might prevent us from repatriating cash earned in countries outside the U. S. ; • complex data privacy and cybersecurity requirements and labor relations laws; • extraterritorial effects of U. S. laws such as the FCPA; • effects of foreign anti- corruption laws, such as the UK Bribery Act; • difficulty in staffing and managing foreign operations; • labor force instability; • increased tax liabilities under foreign potentially negative consequences from changes in tax laws or changes thereto; and • political, social and economic instability and uncertainty, including wars, other conflict and sovereign debt issues. Violations of foreign laws or regulations could result

in fines ; criminal sanctions against us, our **directors, officers, or our employees, agents or distributors**; prohibitions on or **restrictions relating to** the conduct of our business ; and damage to our reputation. Wars and other conflicts may increase certain of these risks and may adversely affect our business and financial performance, including by limiting our ability to operate in, or export from, certain markets. Losing access to such markets or **to exports from such markets** may have a material adverse effect on our business, **and may limit our ability to operate, both** in the affected market and **may limit our ability to operate some of our businesses globally**. ~~The~~ We anticipate that the effects of emerging, expanding and new conflicts, such as a possible expansion of the Russian- Ukrainian conflict ~~or,~~ **a possible expansion of conflicts in the Middle East, or a possible conflict involving China and Taiwan, would may** not be limited to the specific markets involved. For example, the U. S. and other countries have imposed sanctions on Russia, certain of its governmental bodies, certain businesses and certain individuals due to the invasion of Ukraine, and additional sanctions may continue to be imposed. Similar sanctions could be expected to emerge from other conflicts. Sanctions, and other civil, political and economic effects of such conflicts ~~may~~ **are likely to** have adverse impacts **upon us. For example, we produced implants and instruments in China that supported a significant portion of our globally global total profit in 2023; if trade restrictions or other barriers arose that limited our ability to export from China and we are unable to fully mitigate the risk or find alternative sources of supply, such trade restrictions could have a material and adverse effect on our sales and results of operations. Additionally, other trade disruptions including include** supply chain continuity disruption; inflationary pressures and increased costs of raw materials and inputs; manufacturing or shipping delays; increased shipping costs ; **inability to ship products to or from certain countries potentially resulting in an and inability transit delays (such as experienced due to sell certain products globally attacks on shipping transiting the Red Sea)** ; and increased disruptions and delays ~~on affecting~~ **our ability to operate in and** to collect payment for our products and services in particular markets ~~. While Russia and Ukraine do not constitute material portions of our business, a significant escalation or expansion of economic disruption or of the conflict's current scope, or the emergence of new conflicts involving other countries, could adversely affect our results of operations.~~ We are subject to risks arising from currency exchange rate fluctuations, which can increase our costs, cause our profitability to decline and expose us to counterparty risks. A substantial portion of our foreign revenues is generated in Europe and Japan. The U. S. Dollar value of our foreign- generated revenues varies with currency exchange rate fluctuations. Significant increases in the value of the U. S. Dollar relative to the Euro, the Japanese Yen, the Swiss Franc or other currencies could have a material adverse effect on our results of operations. Although we address currency risk management through regular operating and financing activities, and, on a limited basis, through the use of derivative financial instruments, those actions may not prove to be fully effective or may create additional financial obligations for us. Further, if the counterparties to the derivative financial instrument transactions fail to honor their obligations due to financial distress or otherwise, we would be exposed to potential losses or the inability to recover anticipated gains from those transactions. Legal, Regulatory and Compliance Risks We are subject to ~~costly and~~ **complex and expensive** laws and governmental regulations relating to the development, design, product standards, packaging, advertising, promotion, ~~post- postmarket~~ **market** surveillance, manufacturing, labeling and marketing of our products, non-compliance with which could adversely affect our business, financial condition and results of operations. Our global regulatory environment is increasingly stringent, unpredictable and complex. The products **and services** we design, develop, manufacture and market are subject to rigorous regulation by the FDA and numerous other supranational, national, federal, regional, state and local governmental authorities. The process of obtaining regulatory approvals and clearances to market these products can be costly and time consuming and approvals might not be granted for future products on a timely basis, if at all. Delays in receipt of, or failure to obtain, approvals for future products **or product enhancements**, or loss of approval for current products, could result in delayed realization of product revenues or in substantial additional costs. **Emerging opportunities, including those presented by the use of machine learning and artificial intelligence in our current and future products, devices and services are expected to present new, complex and potentially inconsistent legal and regulatory requirements across the various jurisdictions in which we operate.** Both before and after a product is commercially released, we have ongoing responsibilities under FDA regulations, **the EU MDR** and other supranational, national, federal, regional, state and local requirements ~~globally~~. These requirements relate to quality systems, recordkeeping, labeling, promotional **and marketing** requirements, adverse event reporting regulations and other matters, which are subject to continual review and are monitored rigorously through periodic inspections by regulators, which may result in observations (such as on FDA Form 483), and in some cases warning letters, that require corrective action ; or other forms of enforcement. ~~Furthermore, regulators strictly regulate the promotional claims that we may make about approved or cleared products. In the EU, for example, the EU MDR became effective in May 2021 and includes significant additional premarket and post- market requirements. Complying with the requirements of this regulation requires us to incur significant expense. Additionally, the availability of recognized- designated European notified body services to certified- certify to compliance with~~ the new EU MDR requirements is limited, which may delay the marketing approval for some of our products under the EU MDR **(and, potentially, the UK MDR). Furthermore, regulators strictly regulate the promotional claims that we may make about approved or cleared products.** If a regulator were to conclude that we are not in compliance with applicable laws or regulations, that any of our products are ineffective or pose an unreasonable health risk, or that we have marketed or promoted a product for use other than as indicated in **the product** labelling approved by the regulator, the regulator ~~could may~~ ban such products; detain or seize adulterated or misbranded products; order a recall, repair, replacement, or refund of payment of such products; refuse to grant pending premarket approval applications; refuse to provide certificates for exports; require us to notify healthcare professionals and others that the products present unreasonable risks of substantial harm to the public health; and subject us to fines, injunctions or other penalties. The regulator may also impose operating restrictions, including a ceasing of operations at one or more facilities, enjoining and restraining certain violations of applicable law pertaining to our products, seizing our products, and / or assessing civil or criminal penalties against our officers, employees or us. Regulators could also issue a corporate warning letter or a recidivist

warning letter or negotiate the entry of a consent decree of permanent injunction with us, and / or recommend prosecution. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively manufacturing, marketing and selling our products and could have a material adverse effect on our business, financial condition and results of operations. ~~In August 2018, we received a warning letter from the FDA related to observed non-conformities with current good manufacturing practice requirements of the QSR at our Warsaw North Campus manufacturing facility. As of February 24, 2023, this warning letter remained pending. Until the violations are corrected, we may become subject to additional regulatory action by the FDA as described above, the FDA may refuse to grant premarket approval applications and / or the FDA may refuse to grant export certificates, any of which could have a material adverse effect on our business, financial condition and results of operations. Additional information regarding these and other FDA regulatory matters can be found in Note 21 to our consolidated financial statements.~~ Our products and operations are also often subject to the rules of industrial standards bodies, such as the International Standards Organization. If we fail to adequately address any of these regulations, our business could be harmed. If we fail to comply with healthcare fraud and abuse laws and regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected. The sales, marketing and pricing of products and relationships that medical products companies have with healthcare providers are under increased scrutiny around the world. Our industry is subject to various laws and regulations pertaining to healthcare fraud and abuse, including the False Claims Act, the Anti-Kickback Statute, the Stark law, the Physician Payments Sunshine Act, the Food, Drug, and Cosmetic Act and similar laws and regulations in the U. S. and around the world. In addition, we are subject to various laws concerning anti-corruption and anti-bribery matters (including the FCPA), sales to countries or persons subject to economic sanctions and other matters affecting our international operations. Violations of these laws are punishable by criminal and / or civil sanctions, including, in some instances, fines, imprisonment and, within the U. S., exclusion from participation in government healthcare programs, including Medicare, Medicaid and Veterans Administration health programs. These laws are administered by, among others, the DOJ, the Office of Inspector General of the Department of Health and Human Services, the SEC, the OFAC, the Bureau of Industry and Security of the U. S. Department of Commerce and state attorneys general. If we fail to comply with data privacy and security laws and regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected. We process personal and personal health data in our business, particularly through our ZBEdge™ ecosystem ~~, our suite of integrated digital and robotic technologies, incorporating data-powered insights across the continuum of care~~. In addition, some of our products and services incorporate software or information technology that processes **patient** health data ~~regarding patients and patient therapy~~ for treatment ~~, health care~~, maintenance and other purposes. Further, we obtain and process personal data related to our employees, individual business partners (such as physicians and consultants), and website visitors located around the world. These data and information-focused activities carry additional risk. We are subject to ~~supranational, national, state and international data privacy and security~~ laws and regulations that govern the collection, use, disclosure, transfer, storage, location, disposal, **processing** and protection of health-related **personal** and other **personal information**. ~~In addition to U. S. federal laws and regulations, a number of U. S. states have also enacted data privacy and security laws and regulations that govern the collection, use, disclosure, transfer, storage, disposal, and protection of personal information, such as social security numbers, medical and financial information, biometric data and other personal information.~~ The FDA has issued guidance to which we ~~are~~ **may be** subject concerning data security for medical devices. **In addition to U. S. federal laws and regulations, a number of U. S. states have also enacted data privacy and security laws and regulations that govern the collection, use, disclosure, transfer, storage, disposal, and protection of personal information, such as social security numbers, medical and financial information, biometric data and other personal information.** These laws and regulations may be more restrictive **than**, and not **be** preempted by, U. S. federal laws. The legislative and regulatory framework for privacy and data protection issues worldwide is rapidly evolving as countries continue to adopt privacy and data security laws that may apply to us, both because our operations are located in those countries and / or because we provide **products and** services to customers in those countries. In addition, certain of our **suppliers, partners,** affiliates and associates are subject to privacy, security and breach notification regulations established under these and other international, national, state and ~~foreign~~ **local** laws. We, and certain of our **suppliers, partners,** affiliates and associates, are also subject to reporting requirements relating to certain data ~~and other~~ **breaches and cybersecurity events**. The interpretation and enforcement of the laws and regulations described above are uncertain and subject to change, and ~~may require~~ **we expect to incur** substantial costs to monitor **for** and **comply** ~~implement compliance with any~~ **changing and** additional requirements. In addition, new and more stringent multinational, national and state privacy legislation and regulations ~~may~~ **are likely to** be adopted ~~in 2023 and beyond~~. We cannot predict all the jurisdictions in which new legislation, regulation or enforcement might arise, the scope of such legislation, regulation and enforcement, or the potential impact to our business and operations of any such changes. Failure to comply with U. S. and international data protection laws and regulations, and the disclosure of any data or related breach, could result in government enforcement actions (which could include substantial civil and / or criminal penalties and injunctive relief), private litigation and / or adverse publicity and could have a material adverse impact on our business, financial condition or results of operations. Pending and future product liability claims and litigation could adversely impact our financial condition and results of operations and impair our reputation. Our business exposes us to potential product liability risks that are inherent in the design, manufacture and marketing of medical devices. In the ordinary course of business, we are the subject of product liability lawsuits alleging that component failures, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition or injury to patients. As discussed further in Note 21 to our consolidated financial statements, we are defending product liability lawsuits relating to the Durom® Acetabular Component (“Durom Cup”), certain products within the M / L Taper and M / L Taper with Kinectiv® Technology hip stems and Versys® Femoral Head implants, and the M2a- Magnum™ hip system. We are also currently defending a number of other product liability lawsuits and claims related to various other products. Any product liability claim brought against us, with

or without merit, can be costly to defend. Product liability lawsuits and claims, safety alerts or product recalls, regardless of their ultimate outcome, could have a material adverse effect on our business and reputation and on our ability to attract and retain customers. We are substantially dependent on patent and other proprietary rights, and failing to protect such rights or to be successful in litigation related to our rights or the rights of others may result in **our the** payment of significant monetary damages and / or royalty payments, negatively impact our ability to sell current or future products, or prohibit us from enforcing our patent and other proprietary rights against others. Claims of intellectual property infringement and litigation regarding patent and other intellectual property rights are commonplace in our industry and are frequently time consuming and costly. At any given time, we may be involved as either plaintiff or defendant in a number of patent infringement actions, the outcomes of which may not be known for prolonged periods of time. While it is not possible to predict the outcome of patent and other intellectual property litigation, such litigation has in the past resulted in, and could in the future result in, our payment of significant monetary damages and / or royalty payments, negatively impact our ability to sell current or future products, or prohibit us from enforcing our patent and other proprietary rights against others, which could have a material adverse effect on our business, **finances** and results of operations. Our success depends in part on our proprietary technology, processes, methodologies and information. We rely on a combination of patent, copyright, trademark, trade secret and other intellectual property laws and nondisclosure, license, assignment and confidentiality arrangements to establish, maintain and protect our proprietary rights, as well as the intellectual property rights of third parties whose assets we license. However, the steps we have taken to protect our intellectual property rights, and the rights of those from whom we license intellectual property, may not be adequate to prevent unauthorized use, misappropriation or theft of our intellectual property. Further, our currently pending or future patent applications may not result in patents being issued to us, patents issued to or licensed by us in the past or in the future may be challenged or circumvented by competitors, and such patents may be found invalid, unenforceable or insufficiently broad to protect our technology or to provide us with any competitive advantage. Third parties could obtain patents that may require us to negotiate licenses to conduct our business, and the required licenses may not be available on reasonable terms or at all. We also cannot be certain that others will not independently develop substantially equivalent proprietary information. In addition, intellectual property laws differ in various jurisdictions in which we operate and are subject to change at any time, which could further restrict our ability to protect our intellectual property and proprietary rights. In particular, a portion of our revenues is derived from jurisdictions where adequately protecting intellectual property rights may prove more challenging or impossible. We may also not be able to detect unauthorized uses or take timely and effective steps to remedy unauthorized conduct. To prevent or respond to unauthorized uses of our intellectual property, we might be required to engage in costly and time-consuming litigation or other proceedings and we may not ultimately prevail. Any failure to establish, maintain or protect our intellectual property or proprietary rights could have a material adverse effect on our business, financial condition, or results of operations. We are involved in legal proceedings that may result in adverse outcomes. In addition to intellectual property and product liability claims and lawsuits, we are involved in various **other commercial and securities** litigation and **claims and other legal** proceedings that arise from time to time **in the ordinary course of our business**. Although we believe there are substantial defenses in these matters, litigation and other claims are subject to inherent uncertainties and management's view of these matters may change in the future. Given the uncertain nature of legal proceedings generally, we are not able in all cases to estimate the amount or range of loss that could result from an unfavorable outcome. We could in the future incur judgments or enter into settlements of claims that could have a material adverse effect on our **financial** results of operations in any particular period. Risks Related to Our Organizational Documents and Jurisdiction of Incorporation Anti-takeover provisions in our organizational documents could delay or prevent a change of control. Certain provisions of our Restated Certificate of Incorporation, our Restated By-Laws and the Delaware General Corporation Law may have an anti-takeover effect and may delay, **complicate**, defer or prevent a merger, acquisition, tender offer, takeover attempt or other change of control transaction, **including those** that a stockholder might consider in its best interest, **including those attempts** that might result in a premium over the market price for the shares held by our stockholders. ~~These provisions provide for~~ **or that**, among other things: ~~the ability of our board of directors to issue one or more series of preferred stock without further stockholder action; advance notice for nominations of directors by stockholders and for stockholders to include matters to be considered at our annual meetings; certain limitations on convening special stockholder meetings; and the prohibition on engaging in a "business combination" with an "interested stockholder" for three years after the time at which a person became an interested stockholder unless certain conditions are met, as set forth in Section 203 of the Delaware General Corporation Law. These anti-takeover provisions could make it more difficult for a third party to acquire us, even if the third party's offer may be considered beneficial by many of our stockholders. As a result, our stockholders may be limited in their ability to obtain a premium for their shares. Our Restated By-Laws designate certain Delaware courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees. Our Restated By-Laws provide that, unless we consent in writing to the selection of an alternative forum, a state court located within the State of Delaware (or, if no state court located in the State of Delaware has jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for any stockholder (including any beneficial owner) to bring **certain** (i) any derivative action **actions** or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim against us or any **on behalf** of our directors, officers or other ~~the Company~~ employees arising pursuant to any provision of the Delaware General Corporation Law or our Restated Certificate of Incorporation or our Restated By-Laws, as either may be amended from time to time, or (iv) any action asserting a claim against us or any of our directors, officers or other employees governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have received notice of and consented to **this** the foregoing provisions **provision**. This choice of forum provision may limit a stockholder's ability to~~

bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find this choice of forum provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations.