

Risk Factors Comparison 2025-02-26 to 2024-02-21 Form: 10-K

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Our business faces many risks and uncertainties. Any of the risks discussed below, as well as factors described in other places in this Annual Report on Form 10-K, or in our other filings with the SEC, could materially adversely affect our business, consolidated financial position, results of operations or cash flows. In addition, these items could cause our future results to differ from our recent results, from our anticipated future results and from those in any of our forward-looking statements. These risks are not the only ones we face. Other risks that we do not presently know about or that we presently believe are not material could also adversely affect us.

Risks Related to our Business and Industry We face strong competition. Our failure to compete effectively could have a material adverse effect on our business. Our industry is highly competitive. We compete with many domestic and foreign companies ranging from small start-up enterprises that might sell only a single or limited number of competitive products or compete only in a specific market segment, to companies that are larger and more established than us, have a broad range of competitive products, participate in numerous markets and have access to significantly greater financial and marketing resources than we do. We are also subject to potential competition from new technologies or new market entrants. Competitive factors include price, alternative clinical practices, innovation, quality and reputation. Our failure to compete effectively could have a material adverse effect on our business, results of operations, financial condition and cash flows. We may not be successful in developing, acquiring or marketing competitive products and technologies. Our industry is characterized by extensive research and development and rapid technological advances. The future success of our business will depend, in part, on our ability to design, acquire and manufacture new competitive products and enhance existing products. Accordingly, we commit substantial time, funds and other resources to new product development, including research and development, acquisitions, licenses, clinical trials and physician education. We make these substantial expenditures without any assurance that our products will obtain regulatory clearance or reimbursement approval, acquire adequate intellectual property protection or receive market acceptance. Development by our competitors of improved products, technologies or enhancements may make our products, or those we develop, license or acquire in the future, obsolete or less competitive, which could negatively impact our net sales. Our failure to successfully develop, acquire or market competitive new products or enhance existing products could have a material adverse effect on our business, results of operations, financial condition and cash flows. We cannot guarantee that any of our strategic acquisitions, investments or alliances will be successful. We intend to supplement our growth through strategic acquisitions of, investments in and alliances with new medical technologies. The success of any acquisition, investment or alliance may be affected by a number of factors, including our ability to identify and then properly assess and value the potential business opportunity or to successfully integrate any business we may acquire into our existing business. These types of transactions may require more resources and investments than originally anticipated, may divert management's attention from our existing business, may result in exposure to unexpected liabilities of the acquired business, and may not result in the expected benefits, savings or synergies. There can be no assurance that we will be able to identify and successfully make strategic acquisitions of, investments in and alliances with new medical technologies or that any past or future acquisition, investment or alliance will be cost-effective, profitable or successful. We may be unable to attract and retain key employees necessary to be competitive. Our ability to compete effectively depends upon our ability to attract and retain executives and other key employees, including people in technical, marketing, sales, and research and development positions. Competition for experienced employees, particularly for persons with specialized skills, can be intense. Our ability to recruit such talent will depend on a number of factors, including compensation and benefits, work location and work environment. If we cannot effectively recruit and retain qualified executives and employees, our business could be materially adversely affected. We rely on the proper function, security and availability of our information technology systems and data, as well as those of third parties, to operate our business, and a breach of our information technology systems, or our failure to effectively integrate AI into our information technology systems and operations, could have a material adverse effect on our business. We rely on information technology systems to process, transmit and store electronic information in our day-to-day operations. Our information technology systems may fail to perform as anticipated, and we may encounter difficulties in implementing new systems, adapting these systems to changing technologies or expanding them to meet the future needs and growth of our business. Our information technology systems require an ongoing commitment of significant resources to maintain, protect, and enhance existing systems and develop new systems. This enables us to keep pace with continuing changes in information processing technology, evolving legal and regulatory standards and changes in the techniques used to prevent unauthorized access to our data and information systems. There can be no assurance that these efforts will be successful or that systems issues will not arise in the future. In addition, the development, adoption and use of generative artificial intelligence, or AI, technology presents opportunities and risks. ~~AI technology is still in an early stage of development, and we are still assessing how to incorporate AI technology into our information technology systems and operations.~~ **We are developing working to expand our use of AI to drive efficiencies and enhance productivity, including in the areas of product design, procurement, marketing and IT support. In early 2025, we plan to introduce secure enterprise versions of Microsoft Co-Pilot and Enterprise ChatGPT within our organization. We are also assessing the use of embedded AI in our suite of enterprise applications. We plan to conduct security assessments and tests to mitigate risk prior to the rollout of these AI tools. In addition, we have developed and published** a policy with guardrails to address **the** AI-related risks associated with data privacy, cybersecurity and copyright and intellectual property protections. **However, there can be no assurance that we will be able to successfully integrate AI into our operations or that usage of AI will enhance our operations or be beneficial to**

our business, including our efficiency or profitability. The development, adoption and use of AI technology is still at an early stage, and ineffective or inadequate AI development or deployment practices by the Company or third- party vendors could result in negative or unintended consequences. In addition, there are technical challenges associated with achieving the desired level of accuracy, efficiency and reliability in AI technology. The algorithms and models utilized in AI systems may have limitations, including biases, errors or an inability to handle certain data types or scenarios. Furthermore, there is a risk of AI- related system failures, disruptions or vulnerabilities that could compromise the integrity, security or privacy of the generated content. These limitations or failures could result in operational inefficiencies, reputational damage and legal liabilities. Additionally, developing, testing and deploying AI systems may require additional investment and increase our costs. Our failure to effectively integrate AI into our information technology systems and operations could ~~therefore~~ have a material adverse effect on our business. Furthermore, from time to time we consummate new business acquisitions. We face risks associated with defects and vulnerabilities in acquired businesses' systems and difficulties or disruptions in connection with the integration of such acquisitions into our own information technology systems. Lastly, our information technology systems may be subjected to damage or interruption from power outages, computer and telecommunication failures, usage errors by our employees, security breaches, computer viruses or other malicious codes, unauthorized access attempts and cyber, phishing- or ransomware attacks **. In addition, AI technology presents new and significant cybersecurity safety risks**. Furthermore, we rely on third- party vendors to support certain aspects of our information technology systems and to store certain information. These third parties could also be subject to these types of attacks. These attacks could result in our intellectual property and other confidential information, including personal health information, being lost or stolen, disruption of our operations, loss of reputation and other negative consequences, such as increased costs for security measures or remediation costs and diversion of management attention. While we will continue to implement additional protective measures to reduce the risk of and detect future cyber incidents, cyber- attacks are becoming more sophisticated and frequent, and the techniques used in such attacks change rapidly. There can be no assurance that our protective measures will prevent future attacks that could have a material adverse effect on our business. We may be unable to protect our intellectual property rights or may infringe the intellectual property rights of others. We rely on patents, trademarks, trade secrets and other intellectual property assets in the operation of our business. Our efforts to protect our intellectual property and proprietary rights may not be sufficient. We cannot be sure that pending patent applications will result in the issuance of patents or that patents issued or licensed to us will remain valid or prevent competitors from introducing similar competing technologies. Our ability to enforce and protect our intellectual property rights may be limited in certain countries outside of the United States in which we operate, which could make it easier for our competitors to develop or distribute similar or superior competing technologies in those jurisdictions. In addition, our competitive position may be adversely affected by expirations of our significant patents, which would allow competitors to freely use our technology to compete with us. We operate in an industry characterized by extensive patent litigation and competitors may claim that our products infringe their intellectual property rights. Resolution of patent litigation or other intellectual property claims is inherently unpredictable, typically time consuming and costly and can result in significant damage awards and injunctions that could prevent the manufacture and sale of the affected products or require us to make significant royalty payments in order to continue selling the affected products. Any one of these could have a material adverse effect on our business, results of operations, financial condition and cash flows. At any given time we are involved as either a plaintiff or a defendant in a number of patent infringement actions, the outcomes of which may not be known for prolonged periods of time. We can expect to face additional claims of patent infringement in the future. Our business and operations are subject to risks related to global climate change. Global climate change presents risks to our business. Shifts in weather patterns caused by climate change are expected to increase the frequency, severity and duration of certain adverse weather conditions and natural disasters, such as hurricanes, tornadoes, wildfires, droughts, extreme temperatures and flooding. Such extreme weather conditions and the other conditions caused by or related to climate change could increase our operational costs; pose physical risks to our facilities and those of our customers and suppliers; and adversely impact various aspects of our business, including our supply chain, our manufacturing and distribution networks, the availability and cost of raw materials and components, the energy supply, transportation, and other inputs necessary for the operation of our business. In addition, more stringent environmental laws and regulations that are designed to mitigate the effects of climate change may result in increased costs to operate our business, increased compliance costs and adverse impacts on raw material sourcing, our manufacturing operations and the distribution of our products. Such developments could have a material adverse effect on our business, results of operations, financial condition and cash flows. Our customers depend on third- party coverage and reimbursements. The failure of healthcare programs to provide coverage and reimbursement, or reductions in levels of reimbursement, could have a material adverse effect on our business. The ability of our customers to obtain coverage and reimbursements for products they purchase from us is important to our business. Demand for many of our existing and new medical products is, and will continue to be, affected by the extent to which government healthcare programs and private health insurers reimburse our customers for patients' medical expenses in the countries where we do business. Any reduction in the amount of reimbursements received by our customers could harm our business by reducing their selection of our products and the prices they are willing to pay. In addition, as a result of their purchasing power, third- party payors are implementing cost-cutting measures such as seeking discounts, price reductions or other incentives from medical products suppliers and imposing limitations on coverage and reimbursements for medical technologies and procedures. These trends could compel us to reduce prices for our existing products and potential new products and could cause a decrease in the size of the market or a potential increase in competition that could have a material adverse effect on our business, results of operations, financial condition and cash flows. A resurgence of the COVID- 19 pandemic could adversely impact our business operations, financial condition, results of operations and cash flows. The COVID- 19 pandemic caused significant volatility in the global financial markets, caused disruption in global supply and distribution channels and caused us to modify certain of our business practices (including

with respect to remote work policies and physical participation in meetings and other events). While the COVID- 19 pandemic has subsided, new mutations to the virus could lead to a resurgence of the pandemic. The impact of such a resurgence would depend on a number of factors which are uncertain and unpredictable, including the severity, extent and duration of the new outbreak and the potential severe adverse financial impact the outbreak could have on our customers. A resurgence of the COVID- 19 pandemic could result in delays in payments on outstanding accounts receivable, manufacturing, distribution and supply chain disruptions, decreased customer demand for our products, and other adverse effects. If we experience any one of these risks or uncertainties, it may have a material adverse impact to our business, financial condition, results of operations and cash flows. Additionally, our business could be severely impacted by widespread regional, national or global health epidemics unrelated to COVID- 19 in the future. An inability to obtain key components, raw materials or manufactured products from third parties may have a material adverse effect on our business. We depend on the availability of various components, raw materials and manufactured products supplied by others for our operations. If the capabilities of our suppliers and third- party manufacturers are limited or stopped, due to quality, regulatory or other reasons, including natural disasters, pandemics or other health emergencies (such as the COVID- 19 pandemic), political instability, government actions, prolonged power or equipment failures or labor dispute, it could negatively impact our ability to manufacture or deliver our products and could expose us to regulatory actions. Further, for quality assurance or cost effectiveness, we purchase from sole suppliers certain components and raw materials. Although there are other sources in the market place for these items, we may not be able to quickly establish additional or replacement sources for certain components or materials due to regulations and requirements of the FDA and other regulatory authorities regarding the manufacture of our products. The loss of any sole supplier or any sustained supply interruption that affects our ability to manufacture or deliver our products in a timely or cost effective manner could have a material adverse effect on our business, results of operations, financial condition and cash flows. An interruption in our ability to manufacture products may have a material adverse effect on our business. Many of our key products are manufactured at single locations, with limited alternate facilities. In addition, the majority of our manufacturing output is concentrated at the two manufacturing facilities that we operate in Mexico. If one or more of these facilities experience damage, or if these manufacturing capabilities are otherwise limited or stopped due to quality, regulatory or other reasons, including natural disasters, pandemics or other health emergencies (such as the COVID- 19 pandemic), political instability, government actions, prolonged power or equipment failures or labor dispute, it may not be possible to timely manufacture the relevant products at previous levels or at all. A reduction or interruption in any of these manufacturing processes could have a material adverse effect on our business, results of operations, financial condition and cash flows. We may not successfully execute on or achieve the expected benefits of our restructuring initiative. In January 2023, we initiated a three- year restructuring initiative pursuant to which we: (i) have combined our Chronic Care and Pain Management franchises into a single commercial organization focused on the Digestive Health and Pain Management and Recovery product categories; (ii) plan to rationalize our product portfolio including certain low- margin, low- growth product categories, through targeted divestitures **(such as the RH Divestiture)**; (iii) have undertaken additional cost management activities to enhance our operating profitability; and (iv) plan to pursue efficient capital allocation strategies, including through acquisitions that meet our strategic and financial criteria. The restructuring initiative is subject to a variety of known and unknown risks and uncertainties, including the potential that we may not be able to: (i) successfully execute on the restructuring initiative or (ii) achieve the anticipated benefits and cost- saving opportunities identified in the restructuring initiative. In addition, the expected benefits and cost- saving opportunities related to the restructuring initiative may take longer to realize than expected. Further, implementation of the restructuring initiative could be disruptive to our operations and result in reduced employee morale. Failure to fully realize or maintain the anticipated benefits of the restructuring initiative could have a material adverse impact on our business, results of operations, financial condition and cash flows. We may not achieve the expected benefits of our divestiture activities. One of the objectives of the Transformation Process is the rationalization of our product portfolio through targeted divestitures such as the RH Divestiture. The RH Divestiture represents a key component of the Transformation Process, and is aimed at accelerating the Company' s efforts to focus its portfolio on markets where it is well positioned to succeed. Any divestiture we undertake is subject to a variety of known and unknown risks and uncertainties, including the potential that we may not be able to achieve the anticipated benefits of such divestiture. In addition, the expected benefits related to any divestiture may take longer to realize than expected. Further, any divestiture could be disruptive to our operations and result in reduced employee morale. Failure to fully realize the anticipated benefits of any divestiture could have a material adverse impact on our business, results of operations, financial condition and cash flows. Ongoing regional conflicts and the related implications could have a material adverse effect on our business and results of operations. We are subject to risks as a result of regional conflicts in different parts of the world, including the conflict between Russia and Ukraine and conflict in the Middle East. As a result of the ongoing military conflict between Russia and Ukraine, the United States and other countries have imposed significant sanctions on Russia and could impose even wider sanctions. Conflict in the Middle East could negatively affect sales of our products in that region and could give rise to embargoes on, or disruptions to, the supply of petroleum. **In addition, actual or threatened military conflict between China and Taiwan could result in significant disruptions to our supply chain.** These military conflicts and related sanctions or embargoes could damage or disrupt international commerce, shipping, supply chains and the global economy. We cannot predict the broader or longer- term consequences of these conflicts, which could include further sanctions and embargoes, regional instability, geopolitical shifts, exchange rate fluctuations, inflation, financial market disruptions and economic recession. Further, these conflicts could exacerbate supply chain challenges, lead to an increase in cyberattacks from Russia and elsewhere, affect the global price and availability of key commodities, reduce our sales and earnings or otherwise have an adverse effect on our business and results of operations. In addition, these regional conflicts may have the effect of heightening other risks disclosed in this Item 1A, any of which could materially and adversely affect our business and results of operations. Such risks include but are not limited to interruptions in the transportation channels for the manufacture and global

distribution of our products, heightened inflation, depressed levels of consumer and commercial spending, disruptions to our global technology infrastructure, adverse changes in international trade policies and relations, and the inability to implement and execute our business strategy. We are currently unable to predict the extent, nature or duration of any of these occurrences. Supply chain disruptions could have a material adverse effect on our business. We rely on a complex global supply chain composed of multiple external suppliers, some of which are single- source suppliers. These suppliers provide raw materials and other inputs for our production processes; supply certain components for our products; and deliver other goods and services used in our business. We cannot be certain that our current suppliers will continue to provide us with the quantities of materials that we require or satisfy our anticipated specifications and quality requirements on a timely basis or at all. In addition, any supply chain disruption in limited or sole sourced raw materials could materially harm our ability to manufacture our products until a new source of supply, if any, could be identified and qualified. In addition, we rely on various transportation channels for global distribution of our products through shipping ports located throughout the world. Labor unrest, political instability, the outbreak of pandemics or other health emergencies (such as the COVID- 19 pandemic), trade restrictions, transport capacity and costs, port security, weather conditions, natural disasters or other events could slow port activities and could adversely affect our business by interrupting product shipments and may increase our transportation costs if we are forced to use more expensive shipping alternatives. From time to time we may be negatively impacted by supply chain disruptions, including **disruptions caused by** the following: • Suppliers extending lead times, experiencing capacity constraints, limiting or canceling supply, allocating supply to other customers (including our competitors), delaying or canceling deliveries, going out of business or increasing prices; • Supplier quality issues; • A resurgence of the COVID- 19 pandemic or other pandemics, epidemics or infectious disease outbreaks; • Cybersecurity events, manmade or natural disasters, operational failures or other events that disrupt us or our suppliers; • **Military conflicts and associated sanctions or embargoes;** • Long lead times to qualify alternate or additional suppliers, or the unavailability of qualified alternate suppliers; and • Other events or occurrences that are beyond our control, including transportation delays, inflationary pricing pressures, work stoppages, labor shortages and governmental regulatory actions. These and other supply chain issues can increase our costs, disrupt or reduce our production, delay our product shipments, prevent us from meeting customer demand and damage our customer relationships. They may keep us from successfully implementing our business strategy and could materially harm our business, results of operations, financial condition and cash flows. Our business, operating results, and cash flows have been affected and may continue to be adversely affected by ~~the rising rate of inflation~~ **inflationary pressures**. Inflationary pressures have increased due to general macroeconomic factors as well as the global supply chain disruptions, labor shortages and other factors. We expect those inflationary trends to continue for the foreseeable future. These inflationary pressures have affected our manufacturing costs, operating expenses (including wages) and other expenses. We may not be able to pass these cost increases on to our customers in a timely manner, which could have an impact on our gross margins and profitability. In addition, inflation has resulted in higher interest rates and could otherwise adversely impact the macroeconomic environment, which in turn could adversely impact our customers and their ability or willingness to purchase our products. Our inability to successfully manage the effects of inflation could have a material adverse effect on our business, results of operations and cash flows. The adoption and interpretation of tax laws may have a material adverse effect on our business. The laws and rules and related interpretations dealing with income taxation are frequently reviewed and amended by governmental bodies, officials and regulatory agencies in the United States and other jurisdictions in which we do business. The governmental bodies may include the U. S. Internal Revenue Service, the U. S. Treasury Department, the U. S. Congress, taxing authorities in countries outside the United States, and various state, provincial, local or municipal regulatory agencies. Our provision for income taxes and results of operations may be adversely affected by changes to our operating structure, changes in the mix of income and expenses in countries with differing tax rates, changes in the valuation of deferred tax assets and liabilities or changes in tax laws, regulations or administrative interpretations thereof. For example, the U. S. federal government could make changes to existing U. S. tax laws, including the Tax Cuts and Jobs Act of 2017 or the Coronavirus Aid, Relief and Economic Security (CARES) Act of 2020, which could include an increase in the corporate tax rate and the tax rate on foreign earnings. It cannot be predicted whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated, issued or amended that could result in a material adverse effect on our financial position, results of operations or cash flows. We face significant uncertainty in the healthcare industry due to government healthcare reform **and legislative changes** in the United States and elsewhere. The U. S. Congress, regulatory agencies and certain state legislatures, as well as international legislators and regulators, periodically review and assess alternative healthcare delivery systems and payment methods with an objective of ultimately reducing healthcare costs and expanding access. We cannot predict with certainty what healthcare initiatives, if any, will be implemented by states or foreign governments or what ultimate effect healthcare reform or any future legislation or regulation may have on our customers' purchasing decisions regarding our products. However, the implementation of new legislation and regulation may lower reimbursements for our products, reduce medical procedure volumes and materially adversely affect **our business, results of operations, financial condition and cash flows. In addition, we could be adversely impacted by legislative or regulatory changes to Medicaid, Medicare or other government healthcare programs, which govern provider reimbursement levels for medical expenses. For example, certain members of the US Congress have proposed significant cuts to Medicaid, which in turn could reduce reimbursement levels for products such as those sold by us. Any reduction in the amount of reimbursements received by our customers under federal and / or state programs such as Medicare or Medicaid could have a material adverse effect on** our business, results of operations, financial condition and cash flows. We are subject to extensive government regulation, which may require us to incur significant expenses to ensure compliance. Many of our products are subject to extensive regulation in the United States by the FDA and other regulatory authorities and by comparable government agencies in other countries concerning the development, design, approval, manufacture, labeling, importing and exporting and sale and marketing of many of our products. Furthermore, our facilities are

subject to periodic inspection by the FDA and other federal, state and foreign government authorities, which require manufacturers of medical devices to adhere to certain regulations, including the FDA's Quality System Regulation, which requires periodic audits, design controls, quality control testing and documentation procedures, as well as complaint evaluations and investigation. Regulations regarding the development, manufacture and sale of medical products are evolving and subject to future change. We cannot predict what impact those regulatory changes may have on our business. Failure to comply with applicable regulations could lead to manufacturing shutdowns, product shortages, delays in product manufacturing, product seizures, recalls, operating restrictions, withdrawal or suspension of required licenses, and prohibitions against exporting of products to, or importing products from, countries outside the United States and may require significant resources to resolve. Any one or more of these events could have a material adverse effect on our business, results of operations, financial condition and cash flows. We are subject to healthcare fraud and abuse laws and regulations that could result in significant liability, require us to change our business practices or restrict our operations in the future. We are subject to various U. S. federal, state and local laws targeting fraud and abuse in the healthcare industry, including the Food Drug and Cosmetic Act and anti-kickback and false claims laws. Violations of these laws are punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in healthcare programs such as Medicare and Medicaid. These laws and regulations are wide ranging and subject to changing interpretation and application, which could restrict our sales or marketing practices. Furthermore, since many of our customers rely on reimbursement from Medicare, Medicaid and other governmental programs to cover a substantial portion of their expenditures, our exclusion from such programs as a result of a violation of these laws could have a material adverse effect on our business, results of operations, financial condition and cash flows. We must obtain clearance or approval from the appropriate regulatory authorities prior to introducing a new product or a modification to an existing product. The regulatory clearance process may result in substantial costs, delays and limitations on the types and uses of products we can bring to market, any of which could have a material adverse effect on our business. In the United States, before we can market a new product, or market a new use of, or claim for, or significant modification to, an existing product, we generally must first receive clearance or approval from the FDA and certain other regulatory authorities. Most major markets for medical devices outside the United States also require clearance, approval or compliance with certain standards before a product can be commercially marketed. The process of obtaining regulatory clearances and approvals to market a medical device can be costly and time consuming, involve rigorous pre-clinical and clinical testing, require changes in products or result in limitations on the indicated uses of products. There can be no assurance that these clearances and approvals will be granted on a timely basis, or at all. In addition, once a medical device has been cleared or approved, a new clearance or approval may be required before the medical device may be modified, its labeling changed or marketed for a different use. Medical devices are cleared or approved for one or more specific intended uses and promoting a device for an off-label use could result in government enforcement action. Furthermore, a product approval or clearance can be withdrawn or limited due to unforeseen problems with the medical device or issues relating to its application. The regulatory clearance and approval process may result in, among other things, the inability to bring a product to market, delayed realization of product net sales, substantial additional costs and limitations on the types of products we may bring to market or their indicated uses, any one of which could have a material adverse effect on our business, results of operations, financial condition and cash flows. We are subject to risks related to our manufacturing operations in Mexico. Our manufacturing facilities in Mexico are authorized to operate as Maquiladoras by the Ministry of Economy of Mexico. Maquiladora status allows us to import certain items from the United States into Mexico duty-free, provided that such items, after processing, are exported from Mexico within a stipulated time frame. Maquiladora status, which is renewed periodically, is subject to various restrictions and requirements, including compliance with the terms of the Maquiladora program and other local regulations. Failure to comply with these regulations, ceasing to qualify for Maquiladora status or other disruptions within the program would cause our manufacturing costs in Mexico to increase and could adversely affect our business, results of operations, financial condition and cash flows. In addition, Mexico periodically experiences heightened civil unrest, and certain areas of the country suffer from persistent criminal activity, both of which could interfere with our manufacturing operations, cause transportation delays or stoppages and otherwise disrupt the supply of products to and from our facilities. Further, we have experienced inflationary pressure on our labor and other costs in Mexico. Continued increases in such costs could adversely affect our business, results of operations, financial condition and cash flows. These pressures may be exacerbated by exchange rate fluctuations in the Mexican peso. **Additionally, considerable uncertainty exists regarding the possible imposition of tariffs on imported goods from Mexico. On February 1, 2025, President Donald Trump announced the imposition of a 25 % tariff on all goods imported from Mexico. Days later, President Trump suspended the imposition of such tariffs for a period of 30 days. As of the date of this Form 10-K, it remains unclear whether new tariffs will be imposed on goods imported from Mexico and, if so, at what level and for how long. Furthermore, President Trump has expressed his desire to renegotiate, or possibly withdraw from, the United States-Mexico-Canada Agreement (USMCA), which overhauled and updated the North American Free Trade Agreement (NAFTA). An amendment to or the United States' withdrawal from the USMCA could result in increased tariffs or other new trade restrictions on imports from Mexico. Increased tariffs on goods imported from Mexico, whether resulting from a Presidential executive order or amendments to the USMCA, may result in significant increases in tariffs on products imported from Mexico, which would increase the cost of such products.** These risks, as well as certain other risks described generally in this Item 1A as they relate specifically to Mexico (including, without limitation, the risk of currency rate fluctuations, the risk of manufacturing interruptions and the risk of doing business outside the United States), could adversely affect our business, results of operations, financial condition and cash flows. We may incur product liability losses, litigation liability, product recalls, safety alerts or regulatory action associated with our products which could be costly and disruptive to our business. The risk of product liability claims is inherent in the design, manufacture and marketing of medical products of the type we produce and sell. A number of factors could result in an unsafe condition or injury to, or death of, a patient with respect

to the products that we manufacture or sell, including the physician's skill, technique and experience in performing the relevant surgical procedure, component failures, manufacturing flaws, design defects or inadequate disclosure of product-related risks or information. In addition to product liability claims and litigation, an unsafe condition or injury to, or death of, a patient associated with our products could lead to a recall of, or issuance of a safety alert relating to, our products, or suspension or delay of regulatory product approvals or clearances, product seizures or detentions, governmental investigations, civil or criminal sanctions or injunctions to halt manufacturing and distribution of our products. Any one of these could result in significant costs and negative publicity resulting in reduced market acceptance and demand for our products and harm our reputation. In addition, a recall or injunction affecting our products could temporarily shut down production lines or place products on a shipping hold. All of the foregoing types of legal proceedings and regulatory actions are inherently unpredictable and, regardless of the outcome, could disrupt our business, result in substantial costs or the diversion of management attention and could have a material adverse effect on our business, results of operations, financial condition and cash flows. Economic conditions have affected and may continue to adversely affect our business, results of operations, financial condition and cash flows. Disruptions in the financial markets, economic recessions and other macro-economic challenges affecting the economy and the economic outlook of the United States, Europe, Japan, China and other parts of the world may have an adverse impact on our results of operations, financial condition and cash flows. Economic conditions and depressed levels of consumer and commercial spending have caused and may continue to cause our customers to reduce, modify, delay or cancel plans to purchase our products, and we have observed certain hospitals delaying and prioritizing purchasing decisions, which has had and may continue to have a material adverse effect on our business, results of operations, financial condition and cash flows. In addition, as a result of economic conditions, our customers inside and outside the United States, including foreign governmental entities or other entities that rely on government healthcare systems or government funding, may be unable to pay their obligations on a timely basis or to make payment in full. If our customers' cash flow or operating and financial performance deteriorate or fail to improve, or if our customers are unable to make scheduled payments or obtain credit, they may not be able to pay, or may delay payment of accounts receivable owed to us. These conditions also may have an adverse effect on certain of our suppliers who may reduce output or change terms of sales, which could cause a disruption in our ability to produce our products. Any inability of current and / or potential customers to pay us for our products or any demands by our suppliers for different payment terms may have a material adverse effect on our business, results of operations, financial condition and cash flows. Currency exchange rate fluctuations could have a material adverse effect on our business and results of operations. Due to our international operations, we transact business in many foreign currencies and are subject to the effects of changes in foreign currency exchange rates, including the Mexican peso, Japanese yen, Australian dollar and the Euro. Our financial statements are reported in U. S. dollars with international transactions being translated into U. S. dollars. If the U. S. dollar strengthens in relation to the currencies of other countries where we sell our products, our U. S. dollar reported net sales and income will decrease. Additionally, we incur significant costs in foreign currencies and a fluctuation in those currencies' value can negatively impact manufacturing and selling costs. ~~We While we have in the past engaged, and may in the future engage, in various~~ hedging transactions in attempts to minimize the effects of foreign currency exchange rate fluctuations ~~, there~~ **There** can be no assurance that these hedging transactions will be effective. Changes in the relative values of currencies occur regularly and could have an adverse effect on our business, results of operations, financial condition and cash flows. Our exposure to currency exchange rate fluctuations is heightened due to the concentration of our manufacturing operations in Mexico. For example, a hypothetical appreciation of 10 % in the value of the Mexican peso in relation to the U. S. dollar would have negatively impacted operating profit for the year ended December 31, ~~2023~~ **2024** by approximately \$ 0. ~~7~~ **2** million. We are exposed to price fluctuations of key commodities, which may negatively impact our results of operations. We rely on product inputs in the manufacture of our products. Prices of oil and gas affect our distribution and transportation costs. Prices of these commodities are volatile and have fluctuated significantly in recent years, which has contributed to, and in the future may continue to contribute to, fluctuations in our results of operations. Our ability to hedge commodity price volatility is limited. Furthermore, due to competitive dynamics, the cost containment efforts of our customers and third- party payors, and contractual limitations, particularly with respect to products we sell under group purchasing agreements, which generally set pricing for a three- year term, we may be unable to pass along commodity- driven cost increases through higher prices. If we cannot fully offset cost increases through other cost reductions, or recover these costs through price increases or surcharges, we could experience lower margins and profitability which could have a material adverse effect on our business, results of operations, financial condition and cash flows. Cost- containment efforts of our customers, healthcare purchasing groups, third- party payors and governmental organizations could adversely affect our sales and profitability. Many of our customers are members of GPOs, or integrated delivery networks (" IDNs "). GPOs and IDNs negotiate pricing arrangements with healthcare product manufacturers and distributors and offer the negotiated prices to affiliated hospitals and other members. Although we are the sole contracted supplier to certain GPOs for certain product categories, members of the GPO are generally free to purchase from other suppliers, and such contract positions can offer no assurance that sales volumes of those products will be maintained. In addition, initiatives sponsored by government agencies and other third- party payors to limit healthcare costs, including price regulation and competitive bidding for the sale of our products, are ongoing in markets where we sell our products. Pricing pressure has also increased in our markets due to consolidation among healthcare providers, trends toward managed care, governments becoming payors of healthcare expenses and regulation relating to reimbursements. The increasing leverage of organized buying groups and consolidated customers and pricing pressure from third- party payors may reduce market prices for our products, thereby reducing our profitability and have a material adverse effect on our business, results of operations, financial condition and cash flows. We are subject to political, economic and regulatory risks associated with doing business outside of the United States. Most of our manufacturing facilities are located outside the United States in Mexico. ~~We also may~~ **In addition, we** use contract manufacturers outside the United States from time to time and may source many of our raw materials and components

from foreign suppliers, **including suppliers in China and Mexico**. We distribute and sell our products globally. In **2023-2024**, approximately **20-21%** of our net sales were generated outside of North America and we expect this percentage will grow over time. Our operations outside of the United States are subject to risks that are inherent in conducting business internationally, including compliance with both United States and foreign laws and regulations that apply to our international operations. These laws and regulations include robust data privacy requirements, labor relations laws that may impede employer flexibility, tax laws, anti-competition regulations, import, customs and trade restrictions, export requirements, economic sanction laws, environmental, health and safety laws, anti-bribery laws such as the U. S. Foreign Corrupt Practices Act and similar anti-bribery laws in other jurisdictions. Given the high level of complexity of these laws, there is a risk that some provisions may be violated inadvertently or through fraudulent or negligent behavior of individual employees, our failure to comply with certain formal documentation requirements or otherwise. In addition, these laws are subject to changes, which may require additional resources or make it more difficult for us to comply with these laws. Violations of the laws and regulations governing our international operations could result in fines or criminal sanctions against us, our officers or our employees, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to manufacture or distribute our products in one or more countries and could have a material adverse effect on our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, our business, results of operations, financial condition and cash flows. Our success depends, in part, on our ability to anticipate and prevent or mitigate these risks and manage difficulties as they arise. We **are subject to tariffs and taxes in the United States and numerous foreign jurisdictions, and we** may be subject to trade protection measures that are being contemplated by the United States and other governments around the world, as well as potential disruptions in trade agreements, such as the exit of the United Kingdom from the EU. ~~These measures and disruptions may result in new or higher tariffs, during 2024 the United States announced import-export restrictions and taxes. Changes in, or revised interpretations of import-export laws or international trade agreements, along with new or increased tariffs, trade restrictions on a Chinese-sourced component of certain of our taxation products. While we have received an extension on income earned or goods manufactured outside the effectiveness of such tariffs, we are exploring options to identify a longer-term solution to such tariffs (although there can be no assurance that we will succeed in such efforts). In addition, changes in the United States government following the 2024 presidential and congressional elections may have a material adverse effect on our business, financial condition, results of operations in significant changes to United States trade policies and cash flows significantly increased tariffs on imported goods, and may cause other countries to react to such changes.~~ In addition to the foregoing, engaging in international business inherently involves a number of other difficulties and risks, including: • different local medical practices, product preferences and product requirements, • price and currency controls and exchange rate fluctuations, • cost and availability of international shipping channels, • longer payment cycles in certain countries other than the United States, • minimal or diminished protection of intellectual property in certain countries, • uncertainties regarding judicial systems, including difficulties in enforcing agreements through certain non- U. S. legal systems, • political instability and actual or anticipated military or political conflicts, expropriation of assets, economic instability and the impact on interest rates, inflation and the credit worthiness of our customers, and • difficulties and costs of staffing and managing non- U. S. operations. These risks and difficulties, individually or in the aggregate, could have a material adverse effect on our business, results of operations, financial condition and cash flows. **New or increased tariffs or other trade restrictions could have a material adverse effect on our business, financial condition, results of operations and cash flows. We are subject to tariffs and taxes in the United States and numerous foreign jurisdictions, and we may be subject to trade protection measures that are being contemplated by the United States and other governments around the world, as well as potential disruptions in trade agreements, such as a possible amendment to or withdrawal from the USMCA and the exit of the United Kingdom from the EU. For example, during 2024 the United States announced increased tariffs on a Chinese-sourced component of certain of our products. While we have received an extension on the effectiveness of such tariffs, we are exploring options to identify a longer-term solution to such tariffs (although there can be no assurance that we will succeed in such efforts). In addition, changes in the United States government following the 2024 presidential and congressional elections may result in significant changes to United States trade policies and significantly increased tariffs on imported goods, and may cause other countries to react to such changes. Considerable uncertainty exists regarding tariff policy towards Mexico, Canada, China and other countries. On February 1, 2025, President Trump announced the imposition of a 25 % tariff on all goods imported from Mexico and Canada. Days later, President Trump suspended the imposition of such tariffs for a period of 30 days. Also in February 2025, President Trump imposed a 10 % tariff on goods imported from China, resulting in retaliatory tariffs imposed on United States exports to China. As of the date of this Form 10- K, it remains unclear whether additional new tariffs will be imposed on imported goods and, if so, at what level and for how long. Furthermore, President Trump has expressed his antipathy towards certain existing international trade agreements and organizations, including the USMCA and the United States' membership in the World Trade Organization (the "WTO"). An amendment to or the United States' withdrawal from the USMCA or the WTO could result in increased tariffs or other new trade restrictions on imports from Mexico, Canada, China and other countries. These developments, measures and disruptions may result in new or higher tariffs, import-export restrictions and taxes. Changes in, or revised interpretations of import-export laws or international trade agreements, along with new or increased tariffs, trade restrictions or taxation on income earned or goods manufactured outside the United States may have a material adverse effect on our business, financial condition, results of operations and cash flows.** We may need additional financing in the future to meet our capital needs or to make acquisitions and such financing may not be available on favorable terms, if at all. We intend to continue our research and development activities and make acquisitions. Accordingly, we may need to seek additional debt or equity financing. We may be unable to obtain any desired additional financing on terms favorable to us, if at all. If

adequate funds are not available on acceptable terms, we may be unable to fund our expansion, successfully develop or enhance products or respond to competitive pressures, any of which could negatively affect our business. Events in the banking industry and the associated macroeconomic impacts may have a material adverse effect on our business operations, financial condition, results of operations and cash flows. Financial conditions affecting the banking system and financial markets and the potential threats to the solvency of commercial banks, investment banks and other financial institutions may have an adverse effect on our operations and the operations of companies with which we do business or in which we hold a minority stake. There can be no assurance that the actions taken by the Federal Reserve, the Treasury Department and the Federal Deposit Insurance Corporation since early 2023 in response to bank solvency concerns will achieve the purpose of stabilizing the financial markets, restoring consumer confidence, or have other intended effects. Concerns about the stability of financial markets and the solvency of lenders may cause further negative effects across the banking system and may cause the costs of obtaining financing from the credit markets to increase, which may limit our ability to secure adequate financing in the future or have other negative effects on our business operations, financial condition, results of operations and cash flows. Any non-cash impairment of our long-lived assets, including intangible assets and goodwill, could have a material adverse impact on our results of operations. We review long-lived assets, such as property, equipment and intangible assets for impairment whenever events or changes in circumstances indicate that their carrying values may not be recoverable. Goodwill is tested for impairment annually and whenever events and circumstances indicate that, more likely than not, impairment may have occurred. **In the fourth quarter of 2024, we revised downward our future projections for certain product lines due to lower net sales and future year margin expectations. This required us to assess the recoverability of a specific asset group during the fourth quarter of 2024, which resulted in an impairment loss of \$ 100. 2 million. Additionally, due to a decrease in our market capitalization, we determined it was more likely than not that the fair value of our medical devices reporting unit may be below its carrying value. Accordingly, we completed an interim goodwill impairment test as of December 1, 2024 and concluded that the fair value of the reporting unit was lower than its carrying value. As a result, during the fourth quarter of 2024, we recorded a \$ 336. 5 million impairment to goodwill.** The evaluation of long-lived assets and goodwill requires us to form estimates and assumptions with respect to a number of factors, including future sales growth, cash flows, our weighted average cost of capital (WACC) and a terminal value. Our evaluation of goodwill also includes consideration of ~~our current market capitalization~~ **approach valuation methodologies**. Unanticipated changes in any of the factors used in our evaluation could result in a non-cash charge for impairment in a future period, which may significantly affect our results of operations in the period of such charge.

Risks Related to Ownership of Avanos Common Stock We cannot guarantee that our stock price will not decline or fluctuate significantly. The price at which Avanos common stock trades has fluctuated and may continue to fluctuate significantly. The market price, or fluctuations in price, for Avanos common stock may be negatively influenced by many factors, including: • actual or unanticipated fluctuations in our quarterly and annual operating results, • the outcome of litigation and enforcement actions, • developments generally affecting the healthcare industry, • changes in market valuations of comparable companies, • the amount of our indebtedness, • general economic, industry and market conditions, • the depth and liquidity of the market for Avanos common stock, • price fluctuations in key commodities, • announcements by us or our competitors regarding performance, strategy, significant acquisitions, divestitures, strategic partnerships, joint ventures or capital commitments, • fluctuations in interest and currency exchange rates, and • perceptions of or speculations by the press or investment community. These and other factors may lower the market price of Avanos common stock, regardless of our actual financial condition or operating performance. We have no present intention to pay dividends on Avanos common stock. We have no present intention to pay dividends on Avanos common stock. Any determination to pay dividends to holders of Avanos common stock will be at the discretion of our Board of Directors and will depend on many factors, including our financial condition, results of operations, projections, liquidity, earnings, legal requirements, restrictions in our debt agreements and other factors that our Board of Directors deems relevant. The percentage of ownership of existing stockholders in Avanos may be diluted in the future. In the future, a stockholder's percentage ownership in Avanos may be diluted because of equity issuances for acquisitions, capital market transactions or otherwise, including equity awards that we may grant to our directors, officers and employees. In addition, our compensation committee has, and we anticipate that they will continue in the future to, grant stock options or other equity based awards to our employees. These awards will have a dilutive effect on existing stockholders and on our earnings per share, which could adversely affect the market price of shares of Avanos common stock. In addition, our certificate of incorporation authorizes us to issue, without the approval of Avanos stockholders, one or more classes or series of preferred stock having such designation, powers, preferences and relative, participating, optional and other special rights, including preferences over Avanos common stock with respect to dividends and distributions, as our Board of Directors generally may determine. If our Board of Directors were to approve the issuance of preferred stock in the future, the terms of one or more classes or series of such preferred stock could dilute the voting power or reduce the value of Avanos common stock. Similarly, the repurchase or redemption rights or liquidation preferences we could assign to Avanos preferred stock could affect the residual value of Avanos common stock. Certain provisions of our certificate of incorporation may make it difficult for stockholders to initiate litigation against us in a favorable forum for disputes with us or our directors or officers. Our amended and restated certificate of incorporation designates the Court of Chancery of the State of Delaware (or if that court does not have jurisdiction, the U. S. District Court for the District of Delaware) as the exclusive forum for certain litigation 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 or officers. Certain provisions of our certificate of incorporation and by-laws and of Delaware law may make it difficult for stockholders to change the composition of our Board of Directors and may discourage hostile takeover attempts which some of our stockholders may consider to be beneficial. Certain provisions contained in our certificate of incorporation and by-laws and those contained in Delaware law may have the effect of delaying or preventing changes in control if our Board of Directors determines that such changes in control are not in the best interests of us and our stockholders.

These provisions include, among other things, the following: • the ability of our Board of Directors to issue shares of preferred stock and to determine the price and other terms, including preferences and voting rights, of those shares without stockholder approval, • the inability of our stockholders to call a special meeting of stockholders, • stockholder action may be taken only at a special or regular meeting of stockholders, • advance notice procedures for nominating candidates to our Board of Directors or presenting matters at stockholder meetings, • stockholder removal of directors only for cause and only by a supermajority vote, • the ability of our Board of Directors, and not our stockholders, to fill vacancies on our Board of Directors, and • supermajority voting requirements to amend our by-laws and certain provisions of our certificate of incorporation and to engage in certain types of business combinations. While these provisions have the effect of encouraging persons seeking to acquire control of our company to negotiate with our Board of Directors, they could enable the Board of Directors to hinder or frustrate a transaction that some, or a majority, of the stockholders might believe to be in their best interests and, in that case, may prevent or discourage attempts to remove and replace incumbent directors. We are also subject to Delaware laws that could have similar effects. One of these laws prohibits us from engaging in a business combination with a significant stockholder unless specific conditions are met.