

Risk Factors Comparison 2024-02-08 to 2023-02-09 Form: 10-K

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In addition to the other information in this Annual Report on Form 10-K, stockholders or prospective investors should carefully consider the following risk factors **for a description of the principal risks that we face**. If any of the events described below occurs, our business, **results of operations**, financial condition, **cash flows** ~~results of operations~~, future growth prospects and stock price could suffer. **Further, other unknown or unpredictable factors could also have material adverse effects on our future results**. Risk Factors Summary This summary of risks below is intended to provide an overview of the risks we face and should not be considered a substitute for the more detailed risk factors discussed immediately following this summary. **Risks Relating to Our Strategic Risks - Actions** • The proposed spinoff of our **Renal-Kidney Care business and Acute Therapies** ~~product categories~~ may not be completed on the terms, **structure** or timeline ~~currently contemplated~~ **we have announced**, if at all. • We ~~are will be~~ exposed to new risks as a result of the proposed spinoff and other strategic actions we are undertaking. • We may **continue to experience difficulties with our integration of Hillrom or** fail to realize the anticipated benefits of the Hillrom acquisition. • If our business strategy and development activities are unsuccessful, our business, **results of operations**, financial condition and **cash flows** ~~results of operations~~ could be adversely affected. **Risks Related Relating to Our Financial Performance and Our Common Stock** • Global economic conditions, including inflation and supply chain disruptions, have adversely affected, and could continue to adversely affect, our operations. • Our operating results and financial condition **have, and may in the future,** fluctuate. • We may not achieve our financial goals. • We ~~have~~ incurred a substantial amount of debt in connection with the Hillrom acquisition, **which could adversely affect our business, results of operations, financial condition and cash flows**. • Changes in foreign currency exchange rates and interest rates ~~could have a material~~, **and may in the future have, an** adverse effect on our ~~operating results~~ **of operations, financial condition, cash flows** and liquidity. • Our common stock price has fluctuated significantly and may continue to do so. • Future material impairments in the value of our **goodwill, intangible assets and other** long-lived assets, ~~including goodwill, could would~~ negatively affect our operating results. **Other Risks Relating to Our Business** • ~~The effects of the COVID-19 pandemic have had, and we expect will continue to have, a material adverse effect on our business.~~ • If we are unable to successfully introduce **or monetize** new **and existing** products **or services**, or fail to keep pace with changing consumer preferences and needs ~~and or~~ advances in technology, our business, **results of operations**, financial condition and **cash flows** ~~results of operations~~ could be adversely affected. • Issues with product ~~supply or~~ quality could, among other things, have an adverse effect on our business or cause a loss of customer confidence in us or our products. • There is substantial competition in the product markets in which we operate and the risk of declining demand and pricing pressures could adversely affect our ~~operating business,~~ **results of operations, financial condition and cash flows**. • **Pandemics and other public health emergencies, or the fear thereof, have had, and may in the future have, a material adverse effect on our business**. • If we fail to attract ~~and,~~ **develop,** retain **and engage** key employees, our business may suffer. **Risks Related Relating to Our Business Operations** • Segments of our business are significantly dependent on major contracts with GPOs, IDNs, and certain other distributors and purchasers. • We may not be successful in achieving expected operating efficiencies and sustaining or improving operating expense reductions, and might experience business disruptions and adverse tax consequences associated with restructuring, realignment and cost reduction activities. • If we are unable to obtain sufficient components or raw materials on a timely basis or for a cost-effective price or if we experience other manufacturing, sterilization, supply or distribution difficulties, our business ~~and,~~ **results of operations, financial condition and cash flows** may be adversely affected. • Climate change, or legal, regulatory or market measures to address climate change, could adversely affect our business, **results of operations and,** financial condition **and cash flows**. • Breaches and breakdowns affecting our information technology systems or protected information could have a material adverse effect on us. • We are subject to risks associated with doing business globally. • A portion of our workforce is unionized, and we could face labor disruptions that would interfere with our operations. **Risks Related Relating to Legal and Regulatory Matters** • We are subject to a number of laws and regulations, and we are susceptible to a changing regulatory environment. • Increasing regulatory focus on privacy and ~~security~~ **cybersecurity** issues and expanding laws could impact our business and expose us to increased liability. • If reimbursement or other payment for our current or future products is reduced or modified in the United States or in foreign countries or **there are** changes to policies with respect to pricing, taxation or rebates, our business could suffer. • We could be subject to fines or damages and possible exclusion from participation in federal or state healthcare programs if we fail to comply with the laws and regulations applicable to our business. • If we are unable to protect **or enforce** our patents or other proprietary rights, or if we **become subject to claims or litigation alleging** ~~infringe~~ **infringement of** the patents or other proprietary rights of others, our competitiveness and business prospects may be materially damaged. • Changes in tax laws or exposure to additional income tax liabilities may have a negative impact on our operating results. • We are party to a number of pending lawsuits and other disputes which may have an adverse impact on our business, **results of operations or,** financial condition **and cash flows**. ~~We recently~~ • **Our Amended and Restated By-Laws designate certain courts in the State of Delaware or the federal district courts of the United States will be the sole and exclusive forum for substantially all disputes between us and our stockholders. In January 2023, we** announced a series of strategic actions, including, **among other things,** the proposed spinoff of our **Renal-Kidney Care business into and an independent company (the proposed spinoff)** ~~Acute Therapies product categories,~~ a review of strategic alternatives for our BPS product category and plans to implement a simplified operating model and manufacturing footprint. ~~We~~ **While we have completed implementation of the new operating model, we** may encounter challenges to executing the proposed spinoff ~~of our Renal Care and Acute Therapies~~

product categories on the terms, **structure** and within the timeframe we **have** announced, or at all. The **proposed** spinoff will be subject to the satisfaction of a number of customary conditions, including final approval from ~~the Baxter's~~ Board of Directors, ~~the filing and effectiveness of a registration statement on Form 10, receipt of a favorable Internal Revenue Service ruling or tax opinion from counsel with respect to the tax-free nature of the spin, satisfactory completion of financing arrangements and receipt of any necessary regulatory approvals.~~ The failure to satisfy any of the required conditions could delay the completion of the proposed spinoff for a significant period of time or prevent it from occurring at all. Additionally, **it the proposed spinoff** is complex in nature, and unanticipated developments or changes, including disruptions in general market conditions, changes in law ~~or~~, challenges **or complexities** in executing the ~~separation spinoff~~ of the two businesses **or developments of viable medical, pharmacological and technological advances (as further discussed in "Other Risks Relating to Our Business If we are unable to successfully introduce or monetize new and existing products or services, or fail to keep pace with changing consumer preferences and needs or advances in technology, our business, results of operations, financial condition and cash flows could be adversely affected")** may affect our ability to complete the **proposed** spinoff on the terms or on the timeline we **have** announced, or at all. The terms and conditions of the required regulatory authorizations and consents that are granted, if any, may also impose requirements, limitations or costs, or place restrictions on the conduct of the independent companies or impact our ability to complete the **proposed** spinoff on the terms or timeline we **have** announced, or at all. Although we intend for the proposed spinoff to be tax-free to ~~Baxter the company's~~ stockholders for U. S. federal income tax purposes, we **have initiated the preparatory restructuring, which has generated, and we** expect to **incur continue to generate,** non-U. S. cash taxes -- **tax liabilities** on the preparatory restructuring and may also **generate** incur non-cash tax expense including potential impairments of deferred tax assets. Moreover, there can be no assurance that the proposed spinoff will qualify as tax-free for U. S. federal income tax purposes. The IRS ruling ~~or and tax opinion from counsel~~ mentioned above will be based upon various factual representations and assumptions, as well as certain undertakings made by ~~Baxter the Company~~ and the new independent company. If any of these factual representations or assumptions are, or become, untrue or incomplete in any material respect, an undertaking is not complied with, or the facts upon which the opinion or ruling are based are materially different from the actual facts relating to the **proposed** spinoff, reliance on the opinion or ruling may be jeopardized. If the **proposed** spinoff were ultimately determined to be taxable for U. S. federal income tax purposes, we would incur a significant tax liability, while the distributions to ~~Baxter the company's~~ stockholders would become taxable and the new ~~independent~~ company could incur income tax liabilities as well. We ~~are~~ will be exposed to new risks as a result of the proposed spinoff and other strategic actions we are undertaking. Our strategic actions may not achieve their anticipated benefits, or our costs may exceed our estimates. Our businesses **have begun to face, and will continue to face**, material challenges in connection with the proposed spinoff and the other strategic actions we are undertaking (including **the recent a review of strategic alternatives for our BPS product category and plans to implement implementation of a simplified operating model and the ongoing simplification of our** manufacturing footprint). These challenges include, without limitation, the diversion of management's attention from ongoing business concerns; appropriately allocating assets and liabilities among the companies to be separated in the proposed spinoff, particularly given the complex nature of the **proposed** spinoff; attracting, retaining and motivating key management and other employees; retaining existing, or attracting new, business and operational relationships, including with customers, suppliers, employees and other counterparties; maintaining our relationships with regulators; assigning customer contracts and intellectual property to each of the businesses; and potential negative reactions from the financial markets. In particular, in the last few years, ~~we have the company has~~ undertaken other strategic and business transformation actions (including **the recent divestiture of our BPS business,** the acquisition of Hillrom and cost reduction initiatives) that have entailed changes across our organizational structure, senior leadership, culture, functional alignment, outsourcing and other areas. This poses risks in the form of personnel capacity constraints and institutional knowledge loss that has led to, ~~and could in the future lead to,~~ missed performance or financial targets and harm to our reputation, and these risks are heightened with the additional interdependent actions that will be needed to complete the proposed spinoff and other strategic actions we are **currently implementing and pursuing - pursuing or which we may pursue in the future**. We have ~~begun~~ **incurred,** and will continue to incur, significant expenses in connection with the proposed spinoff and other strategic actions we ~~have announced~~ **are undertaking**. These expenses **have been significant, and continue to grow, and be higher than currently anticipated or** may not yield a discernible benefit if the actions are not completed on schedule or at all. In addition, the anticipated benefits of these actions are based on a number of assumptions, some of which may prove incorrect, and we cannot predict with certainty when the expected benefits will occur, or the extent to which they will be achieved. As a result, even if the proposed spinoff or other strategic actions are completed, they may not achieve some or all of the anticipated strategic, financial, operational or other benefits in the expected timeframe, or at all, which could adversely impact our business, results of operations ~~or~~, financial condition **and cash flows**. Further, even if the proposed spinoff is completed, we cannot assure you that each separate company will be successful. Completion of the **proposed** spinoff will result in independent ~~public~~ companies that are smaller, less diversified companies, with more limited businesses concentrated in their respective industries than ~~Baxter is today~~. As a result, each company will be more vulnerable to changing market conditions, which could have a material adverse effect on its business, **results of operations, financial condition conditions and cash flows** results of operations. In addition, the diversification of revenues, costs and cash flows will diminish, such that each company's results of operations, cash flows, working capital, effective tax rate and financing requirements may be subject to increased volatility, and each company's ability to fund capital expenditures and investments, pay dividends and meet debt obligations and other liabilities may be diminished. **Following completion of the proposed spinoff, Each each** company will also incur one-time and ongoing costs, including **the** costs of operating as independent companies, that the separated businesses will no longer be able to share. In addition, until the market has fully analyzed the values of the separate companies, the price of our common stock and common stock of the new company may experience

volatility. Our common stock or the common stock of the new company may not match some holders' investment strategies or meet minimum criteria for inclusion in stock market indices or portfolios, which could cause certain investors to sell their shares, which could in turn lead to declines in the trading price of such stock. As a result of any of the foregoing or other risks, the combined value of the common stock of the two publicly traded companies may be less than what the value of our common stock would have been absent the **proposed** spinoff. During 2021, we completed the acquisition of Hillrom. The success of this acquisition depends on, among other things, our ability to integrate Hillrom in a manner that facilitates growth opportunities, realizes anticipated cost and revenue synergies (some of which are still being identified) and achieves certain previously communicated net leverage targets without adversely affecting current revenues and investments in future growth. If we are not able to successfully achieve these objectives, the anticipated benefits of the Hillrom acquisition may not be realized fully or at all or may take longer to realize than expected. There is a significant degree of difficulty and management distraction inherent in the process of integrating an acquisition. ~~These~~ **The integration of Hillrom into our operations is complex and time-consuming and certain aspects have taken longer than originally anticipated and have required more effort than was originally planned. Challenges associated with our integration efforts are also heightened due to the other strategic actions we are pursuing. This has resulted in, and may continue to result in, additional expenses and other difficulties as we work to complete our ongoing strategic initiatives, include including** challenges consolidating certain operations and functions (including regulatory and other corporate functions), integrating technologies (including differing ~~IT~~ **information technology** systems and processes), organizations, procedures, policies and operations, addressing differences in the business cultures of the two companies, and retaining key personnel. ~~The integration is complex and time consuming and aspects of it may be delayed,~~ **any of which could adversely affect or our ability to achieve the anticipated benefits** additional and unforeseen expenses may result, in light of ~~the acquisition~~ **our recently announced strategic initiatives**. The integration process and other disruptions resulting from the Hillrom acquisition ~~may~~ **and our ongoing strategic initiatives** also disrupt our ongoing businesses ~~or and could~~ cause inconsistencies in standards, controls, procedures and policies that adversely affect our relationships with market participants, employees, regulators and others with whom we have business or other dealings. Any failure to successfully or cost-effectively integrate Hillrom could have a material adverse effect on our business and cause reputational harm. ~~Challenges associated with our integration efforts are heightened due to the other strategic actions we are pursuing.~~ While we remain committed to deleveraging, we expect to engage in significant business development activities over the longer term (once we have satisfied our net leverage targets), including evaluating acquisitions, joint development opportunities, technology licensing arrangements and other opportunities, **such as potential divestitures and targeted market exits as we look to optimize our product portfolio and improve our operating margins**. These activities may result in substantial investment of our resources (including resources currently focused on **our ongoing** ~~the recently announced~~ strategic initiatives ~~discussed above,~~ **such as the proposed spinoff**). Our success developing products ~~or,~~ expanding into new markets **and optimizing our market presence** from such activities will depend on a number of factors, including our ability to find suitable opportunities **or partners** for acquisition, investment ~~or,~~ alliance **or divestiture**; competition from other companies in the industries in which we operate that are seeking similar opportunities; whether we are able to complete an acquisition, investment ~~or,~~ alliance **or divestiture** on terms that are satisfactory to us **or at all**; the strength of the ~~other company's~~ underlying technology, ~~and~~ products **and of any of the other parties involved in a transaction, as well as their** ability to execute ~~its their~~ business strategies; any intellectual property and litigation related to ~~the any~~ **other company party**'s products or technology; and our ability to successfully integrate the acquired company, business, product, technology or research into our existing operations **(or to divest such company, business, product, technology or research from our existing operations)**, including the ability to adequately fund acquired in-process R & D projects and to maintain adequate controls over the combined operations. Certain of these activities are subject to antitrust and competition laws, which ~~laws~~ could impact our ability to pursue strategic transactions and could result in mandated divestitures in the context of proposed acquisitions. **Additionally, certain divestitures could result in negative market or regulatory reactions**. If we are unsuccessful in our business development activities, we may not realize the intended benefits of such activities, including that acquisition and integration **or divestiture** costs may be greater than expected or the possibility that **the** expected return on investment, synergies and accretion will not be realized or will not be realized within the expected timeframes. For more information, see Note 2-3 in Item 8 of this Annual Report **on Form 10-K**. General global economic downturns and macroeconomic trends, including heightened inflation, capital markets volatility, interest rate and currency rate fluctuations, and economic slowdown or recession, have resulted **in,** and may continue to result in, unfavorable conditions that negatively affect demand for our products and exacerbate ~~some of the other risks~~ **described in this "Risk Factors" section** that affect our business, **results of operations,** financial condition and **cash flows** ~~results of operations~~. Both domestic and international markets **have been experienced experiencing** significant inflationary pressures in ~~fiscal~~ **recent year years 2022** and inflation rates in the U. S., as well as in other countries in which we operate, are currently expected to continue at elevated levels for the near ~~term~~. In addition, the Federal Reserve in the U. S. and other central banks in various countries have raised, and may again raise, interest rates in response to concerns about inflation, which, coupled with reduced government spending and volatility in financial markets, has had, and may continue to have, the effect of further increasing economic uncertainty and heightening these risks. Interest rate increases or other government actions taken to reduce inflation have resulted in, **and may continue to result in,** recessionary pressures in many parts of the world. Furthermore, currency exchange rates have been especially volatile in the recent past, and these currency fluctuations have affected, and may continue to affect, the reported value of our assets and liabilities, as well as our cash flows. We have experienced significant challenges to our global supply chain in recent periods, including production delays and interruptions, increased costs and shortages of raw materials and component parts (including resins and electromechanical devices), **heightened inventory levels to reduce the risk of patient supply disruption** and higher transportation and labor costs, resulting from COVID-19 and other exogenous factors including significant weather events,

elevated inflation levels, disruptions to certain ports of call around the world, the war in Ukraine, **the conflict in the Middle East (including recent attacks on merchant ships in the Red Sea), tensions between China and Taiwan** and other geopolitical events. Due to the nature of our products, which include dense consumable medical products such as IV fluids, and the geographic locations of our manufacturing, **storage and distribution** facilities, which often require us to transport our products long distances **and which are being further consolidated in anticipation of the proposed spinoff**, we may be more susceptible to increases in freight costs and other supply chain challenges than certain of our industry peers. We expect to experience some of these and other challenges related to our supply chain in future periods. These challenges, including the unavailability of certain raw materials and component parts, have also had a negative impact on our sales for certain product categories due to our inability to fully satisfy demand and may continue to have a negative impact on our sales in the future. They have also made it increasingly difficult to model accurately our short- term and long- term financial objectives and may continue to do so in the future. Our ability to generate cash flows from operations has been affected, and could continue to be affected, if there is a material decline in the demand for our products or, in the solvency or planned capital expenditures of our customers or suppliers, or if there is deterioration in our key financial ratios or credit ratings. Current or worsening economic conditions may impact the ability of our customers (including governments) to pay for our products and services and the amount spent on healthcare generally, which could result in decreased demand for our products and services, **a declining decline in** cash flows, longer sales cycles, increased inventory levels, slower adoption of new technologies and increased price competition. These conditions may also adversely affect certain of our suppliers, which could disrupt our ability to produce products. We continue to do business with foreign governments in certain countries **that, including Greece and Italy, which** have experienced deterioration in credit and economic conditions. While global economic conditions **to date** have not significantly impacted our ability to collect receivables, liquidity issues in certain countries have resulted, and may continue to result, in delays in the collection of receivables and credit losses, and may also impact the stability of the U. S. **dollar-Dollar**, Euro, **Renminbi** or **Yuan** **other currencies**. Our operating results and financial condition **have, and may in the future,** fluctuate from quarter **to** quarter and year **to** year for a number of reasons. Events, such as changes to our expectations, strategy or forecasts (including as a result of evolving global macroeconomic conditions and updated expectations regarding the timing of new regulatory approvals) or even a relatively small revenue shortfall or increase in supply chain or other costs which we are unable to offset **have, and may in the future,** cause financial results for a period to be below our expectations or projections. As a result, we believe that period- to- period comparisons of our results of operations are not necessarily meaningful, nor should they be relied upon as an indication of future performance. Our operating results and financial condition are also subject to fluctuation from all of the risks described throughout this section. These fluctuations may adversely affect our results of operations and financial condition and our stock price. We continue to evaluate and refine both our short- term and long- term financial objectives, including our stated commitment to achieve certain net leverage targets. Our ability to achieve these targets depends, in part, on our ability to realize the anticipated benefits of the **Hillrom** acquisition (and related cost and revenue synergy targets) while working to execute on our stated portfolio management and other **ongoing** ~~recently announced~~ strategic initiatives **including the proposed spinoff**. We may fail to achieve our targeted financial results if we are unsuccessful in implementing our strategies, our estimates or assumptions change or for any other reason. Our failure to achieve our financial goals could have a material adverse effect on our business, **results of operations,** financial condition and **cash flows** ~~results of operations. We have incurred a substantial amount of debt in connection with the Hillrom acquisition, which could adversely affect our business, financial condition or results of operations.~~ We incurred acquisition- related debt financing of approximately \$ 11. ~~8~~ **80** billion to fund the cash consideration for the Hillrom acquisition, refinance certain indebtedness of Hillrom and pay related fees and expenses. Our substantially increased indebtedness and higher debt- to- equity ratio following the acquisition has the effect, among other things, of reducing our flexibility to respond to changing business and economic conditions and has increased our borrowing costs (including as a result of the **downgrade downgrades** in our senior debt credit ratings **in since** 2021). The increased **levels- level** of indebtedness and our **future** ~~recent projected~~ financial performance could also reduce funds available (under our credit facilities or otherwise) for investments in product development, capital expenditures, dividend payments, acquisitions, share repurchases and other activities and may create competitive disadvantages for us relative to other companies with lower debt levels. In addition, until we achieve our commitment to reduce our indebtedness following the Hillrom acquisition, our capital allocation activities and operational flexibility is limited. There can be no assurance that we will be successful in doing so on a timely basis or at all. We generate the majority of our ~~revenue~~ **net sales** and profit outside the United States. As a result, our ~~financial~~ **results of operations** have been, and may in the future be, adversely affected by fluctuations in foreign currency exchange rates. We cannot predict with any certainty changes in foreign currency exchange rates or our ability to mitigate these risks. We have experienced, and may continue to experience, additional volatility as a result of inflation and other macroeconomic factors, including in emerging market countries. We are also exposed to changes in interest rates, and our ability to access the money markets and capital markets on terms that are favorable to us, or at all, could be impeded if market conditions are not favorable. For more information see “Financial Instrument Market Risk” in Item 7. **Management's Discussion of Analysis and Financial Condition and Results of Operations** of this Annual Report **on Form 10- K**. Our common stock price has fluctuated significantly and may continue to do so in the future. The price of our common stock has fluctuated significantly and may continue to do so in the future for a number of reasons, including, but not limited to: • market perceptions of any strategic actions or other developments related to our business ~~we announce,~~ including, for example, ~~our announcement regarding~~ the proposed spinoff ~~of our Renal Care and Acute Therapies product categories~~; • variations in our net sales, earnings or other financial results from investors’ expectations or our previously issued guidance; • departure of key personnel; • fluctuations in the results of our operations and general conditions in the economy, our market, and the markets served by our customers, **including with respect to technological advances**; and • the operating and stock performance of comparable companies or related industries. In addition, prices in the stock market have generally been volatile **in recent** ~~over~~

the past few years. In certain cases, the fluctuations have been unrelated to the operating performance of the affected companies. As a result, the price of our common stock could also fluctuate in the future without regard to our operating performance. We regularly review **Future material impairments in the value of our goodwill, intangible assets and other** long-lived assets **would negatively affect our operating results. We regularly review our goodwill**, including identifiable intangible assets, goodwill (which results from our acquisition activity) and property, plant and equipment, for **potential** impairment. Goodwill and acquired indefinite-lived intangible assets are subject to impairment **review-reviews** on an annual basis and whenever potential impairment indicators are present. **Intangible** Other long-lived assets **subject to amortization and property, plant and equipment** are reviewed **for potential impairment** when there is an indication that an impairment may have occurred. **Adverse** Changes **changes** in market to macroeconomic conditions or other **our earnings forecasts, as well as** changes in the future outlook of value may **our strategic goals or business direction, could** lead to impairment charges in the future. In addition, we may from time to time **sell-pursue the sale of** assets that we determine are not critical to our strategy, including in connection with strategic exits, **such as the proposed spinoff. Such transactions could result in** Future events or decisions may lead to asset impairments **impairment and/or charges if the estimated fair value of the assets, less costs to sell, is less than their** related **carrying amount** charges. Certain non-cash impairments may result from a change in our strategic goals, business direction or other factors relating to the overall business environment. Material impairment charges **could-would** negatively affect our results of operations. For example, **as described in the third quarter more detail in Note 4 of 2022-Item 8 of this Annual Report**, we recorded a **recognized \$ 510 million of long-lived asset impairment charges related to the HD business within our Kidney Care segment during 2023. Additionally, as described in more detail in Note 5 of Item 8 of this Annual Report, we recognized \$ 2. 8-81 billion of goodwill impairment impairments relating and \$ 332 million of indefinite-lived intangible asset impairments during 2022, both related to assets acquired in connection with our three December 2021 acquisition of Hillrom reporting units due to macroeconomic conditions, including the rising interest rate environment and broad declines in equity valuations, and reduced earnings forecasts for these units, driven primarily by shortages of certain component parts used in our products, raw materials inflation and increased supply chain costs.** Further adverse changes to macroeconomic conditions or our earnings forecasts could lead to additional goodwill or intangible asset impairment charges in future periods and such charges could be material to our results of operations. For more information on the valuation of goodwill and intangible assets, see "Critical Accounting Policies" in Item 7. **Management's Discussion of Analysis and Financial Condition and Results of Operations** of this Annual Report **on Form 10-K.** We need to successfully introduce **or monetize** new **and existing** products **and services** to achieve our strategic business objectives. We can provide no assurances that our new products will achieve commercial acceptance in the marketplace **,or that we will be able to separately bill for new or existing services.** In addition, difficulties in manufacturing or in obtaining regulatory approvals, have delayed, and may in the future delay or prohibit, **the** introduction of new products into the marketplace. We may not be able to obtain patent protection on our new products or be able to defend our intellectual property rights globally. Warranty claims and service costs relating to our new products might be greater than anticipated, and we might be required to devote significant resources to address any quality issues associated with our new products, which could reduce the resources available for further new product development and other matters. In addition, the introduction of new products **and services** might also cause customers to defer purchases of existing products **or services.** Our future financial performance will also depend in part on our ability to influence, anticipate, identify and respond to changing consumer preferences and needs. We might not correctly anticipate or identify trends in customer preferences or needs or might identify **or react to** them later than competitors do. **Failure** **In order to** successfully introduce **or monetize** new **and existing** products **and services, we must commit, and continue to commit, substantial funds, and other resources to R & D. Failure to successfully introduce new products or services** in a cost-effective manner, or delays in customer purchasing decisions related to the evaluation of new products **or services**, could cause us to lose market share and could materially adversely affect our business. Furthermore, product development requires substantial investment and there is inherent risk in the R & D process. A successful product development process further depends on many other factors, including our ability to adapt to new technologies, demonstrate satisfactory clinical results and differentiate our products from those of our competitors. If we cannot successfully introduce new competitive products or adapt to changing technologies, our products may become obsolete and our **revenue-net sales** and profitability could suffer. Issues with product **supply or** quality could have an adverse effect on our business or cause a loss of customer confidence in us or our products, among other negative consequences. **Our success depends upon the availability and quality of our products and the underlying raw materials and component parts. The medical products and pharmaceutical industries are competitive and subject to complex market dynamics and varying demand levels. These levels vary in response to economic conditions, regulatory requirements, seasonality, natural disasters, pandemics, epidemics and other matters. For example, for many of our suppliers, the effects-development of the COVID-19 pandemic new or enhanced products involves a lengthy regulatory process and is capital intensive. As a result, our ability to match our production levels and capacity to market demand is imprecise and may result in a failure to meet market demand or satisfy customer requirements for our products or, alternatively, an oversupply of inventory. Increased costs relating to freight, raw materials or component parts and difficulties hiring and retaining staff have had and may continue to have, a negative impact on product supply. Failure to meet market demand may result in customers transitioning to available competitive products, loss of market share, negative publicity, reputational damage, loss of customer confidence or other negative consequences (including a decline in stock price). Our success also depends on our ability to maintain and routinely improve product quality and our quality management program. Quality management plays and an essential role in meeting customer requirements, preventing defects, improving our products and services and assuring the safety and efficacy of our products. While we routinely improve product quality and our quality management program. Quality management plays an essential role in meeting customer requirements, preventing defects, improving our products and services and assuring the safety and efficacy of our products. While**

we have a quality system that covers the lifecycle of our products, quality and safety issues have occurred, and may in the future occur, with respect to our products. For example, we have experienced certain Class I recalls related to our Novum IQ Syringe and infusion systems, SIGMA Spectrum pump and Life2000 Ventilator. New or unintended uses of our products (for example, in response to changing clinical practice) may also raise quality or safety issues. A quality or safety issue may result in negative publicity, adverse inspection reports, voluntary or official action indicated, warning letters, import bans, product recalls (either voluntary or required by the FDA or similar governmental authorities in other countries), adverse regulatory site inspection reports, voluntary or official action indicated classifications, warning letters, import bans or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions (which may include corporate integrity agreements), costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses. See “— Risks Related to Legal and Regulatory Matters.” An inability to address a quality or safety issue in an effective and timely manner may also cause negative publicity, potentially leading to a loss of customer confidence in us or our current or future products, which may result in the loss of sales and difficulty in successfully launching new products. Additionally, we have made, and continue to make, significant investments in assets, including inventory and property, plant and equipment, which relate to potential new products or modifications to existing products. Product quality or safety issues may restrict us from being able to realize the expected returns from these investments, potentially resulting in asset impairments in the future. Unaffiliated third-party suppliers provide a number of goods and services to our R & D, clinical and manufacturing organizations, many of whom do so on a spot basis and not pursuant to a contractual arrangement. Our ability to receive goods or services at all or on reasonable financial terms from these third parties will be impacted if they are unable or refuse to supply or service us. Moreover, we may have limited or no recourse if the goods or services are not subject to contractual terms. If we are unable to identify or secure regulatory approval for an alternative provider on reasonable terms, our ability to meet our obligations to our customers could be negatively impacted, which could adversely affect our financial results and our reputation. Additionally, third-party suppliers are required to comply with our quality standards (and those of applicable regulatory bodies). Failure of a third-party supplier to provide compliant raw materials, component parts or supplies (and to help us secure all required regulatory approvals for the use of their products or services) has resulted in delays and service interruptions and quality-related issues, and may do so again in the future, and or cause quality-related issues that may negatively impact our business results and results of operations. Although no single company competes with us in all of our businesses, we face substantial competition in all of our markets from international and domestic healthcare medical products and pharmaceutical companies and providers of all sizes, and these competitors often differ across our businesses. Competition is primarily focused on cost-effectiveness, price, service, product performance and technological innovation. Competition may increase further as additional companies begin to enter our markets, launch new products or modify their existing products to compete directly with ours. If our competitors respond more quickly to new or emerging technologies and changes in customer requirements or we do not introduce new versions or upgrades to our product portfolio in response to those requirements, our products may be rendered obsolete or non-competitive. If our competitors develop more effective or affordable products or achieve earlier patent protection or product commercialization than we do, our business, results of operations, financial condition and operations cash flows will likely be negatively affected. For example, new developments such as pharmaceuticals that reduce the progression of chronic kidney disease into ESRD or reduce its incidence (including through weight loss), as well as innovations in technology and care delivery models, could materially adversely affect the demand for and future pricing and sale of our products and services. Furthermore, if we are forced to reduce our prices due to increased competition, our business could become less profitable. In addition, many healthcare industry companies, including healthcare systems, distributors, manufacturers, providers and insurers, are consolidating or have formed strategic alliances. As the healthcare industry consolidates and new entrants emerge, competition to provide goods and services to industry participants will have become, and more intense. Further, this consolidation creates larger enterprises with greater negotiating power, which they can use to negotiate price concessions. If we face an increase in costs or must reduce (or are unable to successfully achieve targeted price increase increases) our prices because of industry consolidation or otherwise, the long-term nature of our customer contracts or for other reasons, or if we lose customers as a result of consolidation, our business, results of operations, financial condition and cash flows results of operations could be adversely affected. Demand for our products and services depends in large part on overall demand in the healthcare market. With the healthcare market’s increased focus on hospital asset and resource efficiency, as well as reimbursement constraints and competitive dynamics, we have seen spending margins for some of our products decline recently and it they may continue to do so over time. Further, the competitive pressures in our industry could cause us to lose market share unless we increase our commercial investments or reduce our prices, which could adversely impact our operating results. These factors, along with possible legislative, regulatory and other developments, might result in significant shifts in market share among the industry’s major participants, which includes us. Accordingly, if we are unable to effectively differentiate ourselves from our competitors in terms of new products and diversification of our product portfolio, then our market share, sales and profitability could be adversely impacted through lower volume or decreased prices. Pandemics and other public health emergencies, or the fear thereof, have had, and may in the future have, a material adverse effect on our business. The nature and extent of future impacts are uncertain and unpredictable. Our global operations expose us to risks

associated with public health ~~crises~~ **emergencies**, including epidemics and pandemics, such as the COVID- 19 pandemic. ~~COVID-19 has had~~ **Pandemics or other public health emergencies have adversely impacted**, and ~~may we expect will~~ continue to ~~have, an adverse~~ **adversely** impact on, our operations, supply chains and distribution systems, and ~~has have~~ increased, and ~~will may~~ continue to increase, our expenses, including due to preventive and precautionary measures that we, other businesses and governments have taken and may continue to take. **A pandemic or other public health emergency has adversely affected, and many continue to adversely affect, our business in many ways, including, but not limited to, the following:** • ~~During the~~ COVID- 19 ~~pandemic~~ **pandemic** has adversely affected and many continue to adversely affect our business in many ways, ~~we~~ including, but not limited to, the following: • We have experienced, and expect to continue to experience, significant and unpredictable reductions ~~or and~~ increases in demand for certain of our products as healthcare customers re-prioritize ~~prioritized~~ the treatment of patients. Some of our products are particularly sensitive to reductions in elective medical procedures. For example, ~~due to the spread of the Omicron variant in 2022~~, many elective procedures were suspended or postponed in our principal markets as hospital systems prioritized treatment of COVID- 19 patients ~~again~~ or otherwise ~~were~~ **required to** comply with changing government guidelines. ~~If~~ ~~Further delays or cancellations may occur in the future. While we have started to see a resurgence in the scheduling of elective procedures in at least some of the markets in which we operate, if patients and hospital systems de-~~ prioritize, delay or cancel elective procedures in the future, our business, financial condition and results of operations may be negatively affected. Additionally, through the pandemic, certain portions of our patient populations (including End Stage Renal Disease patients) have experienced heightened mortality levels. Demand for related products and services may not rebound to pre- pandemic levels in light of these increased mortality rates. • A significant number of our **customers**, suppliers, manufacturers, distributors and vendors ~~were have been~~ adversely affected by the COVID- 19 pandemic, including obstacles relating to their ability to maintain the continuity of their on- site operations, **which impacted demand for certain of our products and services**. These impacts ~~have~~ caused interruptions and delays in our supply chain, and may ~~continue to do so in the future~~, resulting in more expensive alternative sources of labor and materials and heightened supply chain costs. Any delay or shortage in the supply of components or materials or other operational or logistical challenges ~~may impacts-~~ **impact** our ability to satisfy consumer demand for our products in a timely manner or at all, which could harm our reputation, future sales and profitability. For example, we have experienced supply constraints for amino acid raw materials used in our parenteral nutrition products, as such materials are being used to produce COVID- 19 vaccines. These constraints have resulted in certain product backorders and may do so in the future. • We ~~could have experienced, and may continue to~~ experience, a loss of sales ~~and or~~ profitability due to delayed payments, reduced demand or capital constraints of ~~healthcare professionals, hospitals and other customers~~ (including potential insolvency) **of healthcare professionals, hospitals and other customers, as well as** suppliers and vendors facing liquidity or other financial issues. These liquidity ~~or issues, as well as~~ other financial issues, could be exacerbated if prolonged high levels of unemployment or loss of insurance coverage impact patients' ability to access treatments that use our products and services. • COVID- 19 ~~has~~ adversely impacted the continued service and availability of skilled personnel necessary to run our operations (~~For example, we have faced increased absenteeism in connection with the rise of various COVID- 19 variants. Although we have sought to mitigate these staffing challenges through overtime and enlisting contingent labor, staffing shortages have strained our operations and increased our expenses. • We face increased operational challenges as we continue to take measures to support and protect employee health and safety, including through work from home policies. While many of our employees have returned to work, remote or hybrid working arrangements heighten our risks associated with information technology systems and networks, including cyber- attacks, computer viruses, malicious software, security breaches, and telecommunication failures, both for systems and networks we control directly and for those of that employees and third- party developers rely on to work remotely. Any failure to prevent or our customers mitigate security breaches or cyber risks or detect, or respond adequately to, a security breach or cyber risk, or any other disruptions to our information technology systems and networks (as a result of remote working arrangements or otherwise)~~), can have adverse effects on our business and cause reputational and financial harm. Any of these and other impacts of the pandemic ~~have had, and~~ could **in the future** have, a material adverse effect on our business, **results of operations,** financial condition and **cash flows** ~~results of operations~~. ~~The~~ ~~In addition, the~~ scope and duration of any future public health ~~crisis~~ **emergency** will depend on a number of factors, including the potential emergence of **a new pandemic,** new variants **of COVID- 19**, the pace at which government restrictions are imposed and lifted and the extent of such restrictions, the scope of additional actions taken to mitigate the spread of disease, ~~and~~ the availability, ~~and~~ effectiveness and acceptance of vaccines ~~and~~. **The effect of such a health emergency on our business will also vary based on** the speed **with** and extent to which global markets and utilization rates for our products fully recover from the disruptions caused by such a public health ~~crisis~~ **emergency**. The impact of these and other factors on our business, **results of operations,** financial condition and **cash flows** ~~results of operations~~ will depend on future developments that are highly uncertain and cannot be predicted with confidence. Finally, to the extent COVID- 19 or any future public health ~~crisis~~ **emergency** adversely affects our operations and global economic conditions more generally, many of the other risks described in this " Risk Factors " section may be heightened. ~~We need to successfully introduce new products..... through lower volume or decreased prices.~~ Our ability to compete effectively depends on our ability to attract ~~and~~, **develop,** retain ~~and engage~~ key employees, including people in senior management, sales, marketing, information technology and R & D positions ~~and from~~, as well as our ability to transfer the recently acquired Hillrom business **knowledge and expertise of our workforce to new employees as our employees retire or we otherwise experience employee turnover (including in connection with the completion of acquisitions or divestitures or the proposed spinoff)**. Competition for top talent in the healthcare industry can be intense, **especially for experienced management and technical and professional employees, which could increase costs associated with identifying, attracting and retaining such individuals**. Our ability to recruit ~~and~~, **develop,** retain ~~and engage~~ such talent will depend on a number of factors, including hiring practices of our competitors, compensation and benefits (as may be impacted by any financial performance challenges), work location, work environment

(including our competitors' policies regarding remote or hybrid work arrangements), the market's perception of our **ongoing recently announced** strategic initiatives, **including the proposed spinoff**, and industry economic conditions. **Further, a lack of employee engagement could lead to loss of productivity and increased employee burnout, turnover, absenteeism, product quality incidents and decreased customer and patient satisfaction.** If we cannot effectively recruit and, **develop, retain and engage** qualified employees, our business **and results of operations** could **suffer be adversely impacted**. A portion of our U. S. hospital sales and rentals are made pursuant to contracts with hospital GPOs. At any given time, we are typically at various stages of responding to bids, negotiating and renewing expiring GPO agreements. Failure to be **awarded included in** certain of these agreements could have a material adverse effect on our business, including product sales and service and rental revenue. In addition, we have faced and continue to face challenges related to increasing costs associated with these agreements (associated with ongoing supply chain challenges and inflation), which have negatively impacted our revenues and may continue to do so in the future. Our participation in ~~such programs~~ **these agreements** often requires increased discounting or restrictions on our ability to raise prices, and failure to participate or to be **awarded these agreements** ~~selected for participation in such programs~~ might result in a reduction of sales to the member hospitals. In addition, ~~the industry is~~ **in recent years, select market participants have** showing -- **shown** an increased focus on ~~contracting~~ **individual GPO members negotiating** directly with **manufacturers on committed contracts. IDNs and** health systems or IDNs (which typically represent influential members and owners of GPOs). IDNs and health systems ~~often make key purchasing decisions and have influence over the GPO's contract decisions,~~ **and when negotiating directly with manufacturers,** often request additional discounts or other enhancements. Further, certain other distributors and purchasers have similar processes to the GPOs and IDNs and failure to be included in agreements with these other purchasers could have a material adverse effect on our business. Portions of our business have been, and may in the future be, the subject of restructuring, realignment and cost reduction initiatives. For example, we ~~continue to work to successfully integrate Hillrom into our operations and we recently announced divested~~ **our plans to BPS business and have implemented** a simplified operating model and **we continue to work toward simplifying our** manufacturing footprint **and completing the proposed spinoff**. While we ~~initiate~~ **are undertaking** these actions, **as well as any future initiatives,** with the goal of realizing **potential** efficiencies, we may not be successful in achieving ~~the full~~ efficiencies and cost reduction benefits we expect **in full or at all**. Further, such benefits might be realized later than expected, and the ongoing costs of implementing these measures might be greater than anticipated. If these measures are not successful or sustainable, we might undertake additional realignment and cost reduction efforts, which could result in future charges. Moreover, our ability to achieve our other strategic goals and business plans might be adversely affected, and we could experience business disruptions, if our restructuring and realignment efforts and our cost reduction activities prove ineffective. These actions, the resulting costs, and potential delays or potential lower than anticipated benefits might also impact our foreign tax positions and might require us to record tax reserves against certain deferred tax assets in our international business. The manufacture of our products requires, among other things, the timely supply or delivery of sufficient amounts of quality components and **raw** materials. We manufacture our products in approximately 60 principal manufacturing locations. We acquire our components, **raw** materials and other requirements for manufacturing from many suppliers and vendors in various countries, including sometimes from ourselves for self-supplied requirements. We endeavor, either alone or working closely with our suppliers, to ensure the continuity of our inputs and supplies, but we cannot guarantee these efforts will always be successful. Further, while efforts are made to diversify certain of our sources of components and **raw** materials, in certain instances there is only a sole source or supplier with no **acceptable** alternatives yet identified **and, as applicable, qualified**. Additionally, we obtain certain components and materials on a spot basis from third party suppliers with whom we do not have a contractual ~~arrangement~~ **arrangements**. For most of our components and **raw** materials for which a single source or supplier is used, alternative sources or suppliers may exist, but we have made a strategic determination to use the single source or supplier. Although we ~~do~~ carry strategic inventory and maintain insurance to help mitigate the potential risk related to supply disruption, such measures may not be sufficient or effective. A reduction, interruption or suspension in supply, other supply chain issues, including those due to the revocation of distribution facilities' licenses or as a result of our **ongoing recently announced** strategic initiatives, and our inability to quickly develop acceptable alternative sources for such supply could adversely affect our ability to manufacture, distribute and sell our products in a timely or cost-effective manner **and could prevent us from satisfying obligations under one or more of our customer contracts or arrangements, which could result in significant failure to supply penalties**. We have faced, **and may in the future face,** difficulties obtaining supplies of key materials, such as electromechanical components, active ingredients for pharmaceuticals and resins, due to supply chain disruptions and **global the COVID-19 pandemic pandemics**. Moreover, changes in regulation, world trade policies, international taxes and government-to-government relations and issues with export and import activities could negatively impact our ability to distribute products within a country and across countries. See "— ~~Risks Related~~ **Relating to Legal and Regulatory Matters.**" Additionally, ~~volatility in our costs~~ **success depends upon the availability and quality of our products and the underlying energy, transportation / freight, components, raw materials and other supply, manufacturing component parts. The medical products and distribution costs have had pharmaceutical industries are competitive and subject to complex market dynamics and varying demand levels** could in the future adversely affect our results of operations. These **levels vary** prices might continue to fluctuate based on many factors beyond our control, including, but not limited to, changes in general **response to** economic conditions (including inflation), **political unrest regulatory requirements, seasonality labor costs, delivery costs natural disasters, competition wars, acts of terrorism, pandemics, epidemics** and **other matters** currency exchange rates. Significant increases in the cost of raw materials, sub-assemblies or materials used in the production of our products that cannot be recovered through increased prices of our products (or the unavailability of those raw materials, sub-assemblies or production materials) have adversely ~~affect~~ **affected** our **business,** results of operations, **financial condition and cash flows** and may continue to do so in the future. There can be no assurance that the marketplace will support higher prices or that such

prices and productivity gains will fully offset any commodity cost increases in the future. ~~We may from~~ **From** time to time, ~~we~~ **engage in hedging transactions with respect to raw material purchases but do** enter into fixed price supply contracts ~~at times~~ **with respect to raw material purchases**. Future decisions not to ~~enter into fixed price supply contracts may~~ **engage in hedging transactions or ineffective hedging transactions might** result in increased cost volatility, potentially adversely impacting our profitability. **Volatility in the demand for our products or our costs of energy, transportation, freight, raw materials and component parts and other supply, manufacturing, distribution and warehousing or storage costs have adversely affected, and could in the future adversely affect, our business, results of operations, financial condition and cash flows and have prevented, and may continue to prevent, suppliers from providing goods and services to us on reasonable terms or at all. See also “ Risks Relating to Our Financial Performance and Our Common Stock — Global economic conditions, including inflation and supply chain disruptions, have adversely affected, and could continue to adversely affect, our operations. ”** Many of our products are difficult to manufacture. This is due to the complex nature of manufacturing devices and pharmaceuticals, including biologics, as well as the strict regulatory regime governing our manufacturing operations. Variations in the manufacturing process may result in production failures which could lead to launch delays, product shortage, unanticipated costs, lost revenues and damage to our reputation. A failure to identify and address manufacturing problems prior to the release of products to our customers may also result in a quality or safety issue of the type discussed ~~above~~ **in the “ Risk Factors ” section. We rely heavily on a limited number of providers of transport services for reliable and secure point- to- point transport of our products to our customers and patients and for tracking of these shipments, and from time to time we require warehousing for our products. If any of these providers were to encounter delivery performance issues such as loss, damage or destruction of any systems or machines, it would be costly to replace such systems or machines in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our products and increased cost and expense to our business**. Some of our products are manufactured at a single manufacturing facility or stored at a single storage site. Additionally, some of our manufacturing facilities are located in the same geographic area. Loss or damage to, or closure of, a manufacturing facility or storage site due to a natural disaster, such as we experienced as a result of Hurricane Maria, a pandemic, such as COVID- 19, **war or acts of terrorism** or otherwise could adversely affect our ability to manufacture sufficient quantities of key products or deliver products to meet customer demand or contractual requirements, which may result in a loss of revenue and other adverse business consequences ~~(, including those identified in the paragraphs above)~~. We ~~might~~ **may** be unable to transfer manufacturing of the relevant products to another facility or location in a cost- effective or timely manner, if at all. This potential inability to transfer production could occur for several reasons, including ~~,~~ but not limited to ~~,~~ a lack of necessary relevant manufacturing capability at another facility, or the regulatory requirements of ~~the~~ **FDA** or other governmental regulatory bodies. Such an event could materially negatively impact our **business, results of operations,** financial condition ~~,~~ **results of operations** and cash flows. In addition, several of our manufacturing facilities are leased and we may not be able to renew leases on favorable terms or at all. Because of the time required to approve and license a manufacturing facility, a third- party manufacturer may not be available on a timely basis (if at all) to replace production capacity in the event we lose manufacturing capacity or products are otherwise unavailable. Any of the foregoing could adversely affect our business, **results of operations,** financial condition and **cash flows** ~~results of operations~~. Some of our products require sterilization prior to sale or distribution, and we utilize both Baxter- owned and third- party facilities for this process. If an event occurs that results in damage to or closure, whether temporarily or permanent, of one or more of these facilities, we may be unable to manufacture or sterilize the relevant products at prior levels or at all, and a third party may not be available on a timely basis (if at all) to replace sterilization capacity. For example, in 2021, our facility in Mountain Home, Arkansas ~~entered into a Consent Administrative Order with the Arkansas Division of Environmental Quality relating to certain air~~ **emission-emissions** control technology used to reduce ethylene oxide ~~—emissions from sterilization equipment. Although the events giving rise to the Consent Administrative Order only caused a temporary pause in operations, these events or other disruptions of manufacturing or sterilization processes that we or third parties may experience, whether due to~~ **a** lack of capacity, environmental, regulatory or compliance issues **(including evolving regulatory requirements)** or otherwise, could result in product shortage, unanticipated costs, loss of revenues ~~,~~ **operational restrictions, additional capital expenditure requirements**, litigation and damage to our reputation, all of which could have a material adverse effect on our business, **results of operations,** financial condition and **cash flows** ~~results of operations~~. The long- term effects of climate change are difficult to predict and may be widespread. The impacts of climate change may include physical risks (~~e. g.,~~ **such as water scarcity**, rising sea levels or frequency and severity of extreme weather conditions, including natural disasters **such as hurricanes, cyclones and typhoons**), social and human effects (~~such as e. g.,~~ population dislocations or harm to health and well- being), compliance costs and transition risks (~~including due to e. g.,~~ regulatory or technology changes), shifts in market trends (~~for example if e. g.,~~ customers increasingly prioritize purchasing products that are sustainably made **and that can be reused or recycled**) and other adverse effects. Such impacts ~~,~~ **such as damage to manufacturing facilities, local infrastructure and utilities** (including as a result of Hurricane Maria) have disrupted ~~,~~ and may ~~continue to~~ **in the future** disrupt ~~,~~ our supply chain and **manufacturing** operations by adversely affecting our ability to procure goods or services required for the operation of our business at the quantities and levels we require ~~,~~ due to impairment of the availability and **increases in the** cost of certain products, materials, commodities and energy. For example, material or sustained increases in the price of oil have had an adverse impact on the cost of many of the plastic materials or resins we use to make and package our products, as well as our transportation / freight costs. **Further, the impacts of climate change, particularly severe weather events and droughts, have negatively impacted, and may in the future negatively impact, our ability to obtain material energy and water sources and other resources, including employee availability and access to shipping routes. Any of These these** outcomes may ~~,~~ in turn ~~,~~ result in customers transitioning to available competitive products, loss of market share, negative publicity, reputational damage, loss of customer confidence or other negative consequences ~~(including,~~ **such as** a decline in

stock price). Further, any perceived increase in the potential of severe weather events and business interruption may put an upward pressure on the cost of our risk insurance premiums, which could adversely impact our business, results of operations, financial condition and cash flows. In addition, the increasing concern over climate change has resulted in, and may be expected to continue to result in, more local, state, regional, federal and/or global legal and regulatory requirements relating to climate change, including regulating greenhouse gas emissions and related reporting requirements (and the establishment of enhanced internal processes or systems to track them), alternative energy policies and sustainability initiatives. If legislation or regulations have been, and are expected to continue to be, enacted or promulgated in the United States, United Kingdom, EU or in any other jurisdictions in which we do business that impose more stringent restrictions and requirements than our current legal or regulatory obligations (as a result of our publicly disclosed corporate responsibility goals or otherwise), we may experience disruptions in, or increases in the costs associated with research, development, sourcing, manufacturing and distributing our products. Additionally, rising climate change concerns have led to and could continue to lead to additional regulation that could increase our compliance costs. As a result, any such regulatory changes could have a significant adverse effect on our business, financial condition or result of operations and cash flows. Furthermore, companies across all industries are facing increasing scrutiny from investors, regulators, and other stakeholders related to their ESG commitments, performance, and disclosures, including related to climate change, diversity and inclusion, and governance standards. Investor advocacy groups, certain institutional investors, lenders, investment funds, and other influential investors are increasingly focused on companies' ESG commitments (including our corporate responsibility goals), performance, and disclosures, and in recent years have placed increasing importance on social costs and related implications of their investments. Additionally, organizations that provide information to investors on corporate governance and related matters have developed ratings processes for evaluating companies on their respective approaches to ESG matters, which are increasingly being employed by investors, lenders, and customers to inform their investment, financing, or purchasing decisions. A failure to adequately meet stakeholder expectations, which may differ or conflict, may result in the loss of business, reputational impacts, diluted market valuation, an inability to attract customers, and an inability to attract and retain top talent. Breaches and breakdowns affecting our information technology systems or protected information, including from cyber security breaches and data leakage, could have a material adverse effect on our business, results of operations, financial condition, cash flows, reputation and competitive position. We rely upon information technology systems and infrastructure, including services provided by our partners and third parties, to support our business, products and customers. For example, we routinely rely on technology systems and infrastructure in the collection, use, storage and transfer, disclosure and other processing of voluminous amounts of protected information, including personal data, protected health information, and sensitive data (of patients, employees, customers and third parties), as well as confidential, business, financial, personal and other sensitive information (collectively, "Protected Information"). We also rely on systems for manufacturing, customer orders, shipping, regulatory compliance and various other matters. Certain of our products and systems collect Protected Information regarding patients and their therapy and some are internet enabled or connect to our systems for maintenance and other purposes. The acquisition of Hillrom in December 2021 increased the number of these products and systems within our portfolio. Some of our products connect to the, even though not internet enabled nor connected to our systems, connect to hospital networks, electronic medical records, record systems or electronic health records, record systems. Further, we expect that the breadth and complexity of our information and technology systems and infrastructure will increase as we expand our product offerings to utilize and generate data analytics and potentially artificial intelligence (which create emerging enterprise risks, including but not limited to cybersecurity, monitoring, and oversight). The continuing evolution of technology we use, including cloud-based computing and data hosting as well as artificial intelligence, and reliance on third parties, whom may also use cloud-based computing and data hosting or artificial intelligence tools, creates additional opportunities for the unintentional, intentional, unauthorized or unlawful disclosure, exposure, dissemination, loss, alteration, access or destruction of Protected Information stored or processed in our devices, systems, servers, infrastructure and products (collectively, "Technology"). Security threats, including cyber and other attacks, have become very sophisticated, frequent and adaptive. Our Technology is vulnerable to breakdown, interruption, cyber and other security attacks, system malfunction, unauthorized access, inadvertent exposure or disclosure of information, theft and other events. Third-party systems that we rely upon could also become vulnerable to the same risks and may contain defects in design or manufacture or other problems that could result in system disruption or compromise the information security of our own systems. Any such vulnerability could compromise our Technology and could expose Protected Information to unauthorized third parties and / or cause temporary or permanent loss or unavailability of such Protected Information. In addition, our Technology may cause product functionality issues that could result in risk to patient safety, field actions and/or product recalls. We have, like other large multi-national companies, have experienced cyber incidents in the past and may experience them in the future which have exposed and may continue to expose vulnerabilities in our information technology systems. Although the prior incidents have not had a material effect on our business and we have invested and continue to invest in the protection of data and Technology, there can be no assurance that our efforts (i) have prevented or will prevent future breakdowns, attacks, breaches in our Technology, cyber incidents or other incidents or (ii) ensure compliance with all applicable security, cybersecurity and privacy laws, regulations and standards, including with respect to third-party service providers that host or process Protected Information on our behalf. Any failure to protect against such incidents can or non-compliance with applicable security and privacy laws, regulations and standards could lead to substantial and material regulatory fines and penalties, business disruption, reputational harm, financial loss or litigation, as well as other damages. Misappropriation or other loss of our intellectual property from any of the foregoing may have an adverse effect on our competitive position and may cause us to incur substantial litigation costs. See "Risks Related Relating to Legal and Regulatory Matters." As the our customers and FDA and other global regulators, including data

protection authorities, ~~and our~~ **or customers** ~~supervisory bodies~~, become more sensitive to risks related to cybersecurity, our ability to meet certain information technology safety standards could affect our products' marketability and competitiveness. We could also suffer strained relationships with customers, business partners, physicians and other healthcare professionals, increased costs (for security measures, remediation or otherwise), litigation (including class actions and stockholder derivative actions) or other negative consequences (including a decline in stock price) ~~from~~ **as a result of** breaches, cyber and other security attacks, industrial espionage, ransomware, ~~email or~~ phishing scams, malware or other cyber incidents, which ~~may~~ **could** compromise our system infrastructure **and / or** lead to data leakage, **including either internally or** at our third- party providers or other business partners. **Although we maintain insurance related to cybersecurity risks, there can be no assurance that our insurance will cover a particular cyber incident at issue or that such coverage will be sufficient.** In addition, significant implementation issues may arise as we continue to consolidate and outsource certain computer operations and application support activities (~~),~~ including as a result of our ongoing business transformation activities and in connection with the **ongoing** Hillrom integration and our ~~recently announced~~ **other ongoing** strategic initiatives, **including the proposed spinoff**). Further, a number of our employees have **fully remote or** hybrid work arrangements, which (~~),~~ among other things ~~),~~ **exposes-** **expose** us to heightened risks related to our information technology systems and networks, including cyber ~~-~~attacks, computer viruses, malicious software, security breaches ~~and~~ telecommunication failures, both for systems and networks we control directly and for those that employees and third- party developers rely on to work remotely. We also face all of the same risks listed above and other heightened risks when acquiring a company, in particular if we need to transition or implement certain processes or controls with the acquired company. For example, as we continue to integrate Hillrom into our business, we have identified certain potential areas of vulnerability as we transition its information technology systems, products and processes to our processes and controls, including with respect to cybersecurity and privacy matters. While we **are** working to fully address those vulnerabilities (consistent with our processes and controls) we do not believe any of them present any material risks to our business or operations (including with respect to our Technology). Any such vulnerabilities (or any others) if unidentified or unremediated could have a material adverse effect on our business, results of operations ~~or,~~ financial condition **and cash flows** . Our operations are subject to risks inherent in conducting business globally and under the laws, regulations and customs of various jurisdictions and geographies. These risks include changes in exchange controls and other governmental actions, loss of business in government and public tenders that are held annually in many cases, increasingly complex labor environments, availability of raw materials and component parts, changes in taxation, tariffs, export control restrictions, changes in or violations of U. S. or local laws, dependence on a few government entities as customers, pricing restrictions, economic and political instability, monetary or currency volatility or instability (including as it relates to the U. S. ~~dollar~~ **Dollar** , the Euro, the ~~Yuan~~ **Renminbi** and currencies in emerging market countries (~~including the Turkish Lira~~)), disputes between countries, trade relationships and conflicts, diminished or insufficient protection of intellectual property, and disruption or destruction of operations in a significant geographic region regardless of cause, including natural disaster, pandemic, power loss, cyber - attack, data breach, war, terrorism, riot, labor disruption, civil insurrection or social unrest. Failure to comply with, or material changes to, the laws and regulations that affect our global operations could have an adverse effect on our business, **results of operations, financial condition and cash flows** ~~or results of operations~~. The escalating global economic competition and trade tensions ~~between among~~ the **United States U. S.**, China and Russia could have an adverse effect on our business, **results of operations, financial condition and cash flows** ~~or results of operations~~. Although we have been able to mitigate some of the impact from increased duties imposed by these countries (through petitioning the governments for tariff exclusions and other mitigations), the risk remains of additional tariffs and other kinds of restrictions. Tariff exclusions awarded to us by the **United States U. S.** Government require annual renewal, and policies for granting exclusions could shift. The **United States U. S.**, China and Russia could impose other types of restrictions such as limitations on government procurement or technology export restrictions, which could affect our access to the markets. **See also "Risks Relating to Legal and Regulatory Matters — We are subject to a number of laws and regulations, non- compliance with which could adversely affect our business, results of operations, financial condition and cash flows, and we are susceptible to a changing regulatory environment."** More generally, several governments have raised the possibility of policies to induce " re- shoring " of supply chains, less reliance on imported supplies and greater national production. For example, the Chinese government has issued a series of policies in the past several years to promote local medical devices or suggest government procurement budgets for local products. Another example ~~is~~ **would be** the stronger " Buy American " requirements in the U. S. (pursuant to a U. S. executive order ~~by the Administration~~ on January 25, 2021) ~~or the potential U. S. withdrawal from the World Trade Organization Agreement on Government Procurement (GPA)~~. If such steps triggered retaliation in other markets, such as by restricting access to foreign products ~~in purchases by their government- owned healthcare systems~~ the outcomes could have an adverse effect on our business, **results of operations, financial condition and cash flows** ~~or results of operations~~. Some of our employees both in and outside of the United States (~~including contingent workers~~) work under collective bargaining agreements or national trade union agreements or are subject to works councils. Although we have not recently experienced any significant work stoppages as a result of labor disagreements, we cannot ensure that such a stoppage will not occur in the future. ~~Two~~ **For example, a** collective bargaining ~~agreements-~~ **agreement** for one of our U. S. manufacturing facilities ~~are~~ **is** scheduled to expire in **January 2024 and January 2025 , respectively**. Our inability to negotiate satisfactory new agreements or a labor disturbance at any of our manufacturing facilities could have a material adverse effect on our operations. ~~We are subject to a number of laws and regulations, non- compliance with which could adversely affect our business, financial condition and results of operations, and we are susceptible to a changing regulatory environment.~~ As a participant in the healthcare industry, our operations and products, and those of our customers, are regulated by numerous government agencies, both inside and outside the United States. Laws and regulations ~~include,~~ **such as** the Patient Protection and Affordable ~~Health~~ Care Act (H. R. 3590) and the Health Care and Education Reconciliation Act (H. R. 4872) (~~collectively, the Healthcare Reform Act~~), which aim to decrease

costs through comparative effectiveness research and pilot programs to evaluate alternative payment methodologies. Compliance with these and similar regulations could result in pricing pressure or negatively impact the demand for our products. In a number of situations, even though specific laws and regulations may not directly apply to us, our products must be capable of being used by our customers in a manner that complies with those laws and regulations. The manufacture, distribution, marketing and use of our products are subject to extensive regulation and scrutiny by FDA and other regulatory authorities globally. Any new product must undergo lengthy and rigorous testing and other extensive, costly, and time-consuming procedures mandated by FDA and foreign regulatory authorities. The same testing and procedures sometimes apply to ~~current our~~ products that are up for authorization or renewal or are subject to changes in laws or regulations. For example, our medical devices that are ~~being~~ sold or distributed in the ~~EU European Union~~ have to comply with the ~~EU European Union~~ Medical Device Regulation that entered into force in May 2021. This Medical Device Regulation currently provides a ~~staggered~~ phase ~~in period for~~ manufacturers to comply with related regulations through ~~May-December 2024-2028~~. These regulations require companies that wish to manufacture and distribute medical devices in EU member states to meet certain quality system and safety requirements and ongoing product monitoring responsibilities, and obtain a “CE” marking (i. e., a mandatory conformity marking for certain products sold within the European Economic Area) for their products. Various penalties exist for non-compliance with the laws implementing the European Medical Device Regulations which, if incurred, could have a material adverse impact on portions of our business, results of operations, **financial condition** and cash flows. Changes to current products may be subject to vigorous review, including additional FDA 510 (k) and other regulatory submissions, and approvals or the time needed to secure approvals are not certain. **We may not be able to obtain such approvals on the timing or conditions we expect, or at all.** Our facilities must be approved and licensed prior to production and remain subject to inspection from time to time thereafter. Failure to comply with the requirements of FDA or other regulatory authorities, including a failed inspection or a failure in our adverse event reporting system, has resulted **in**, and could **in the future** result in, adverse inspection reports, voluntary or official action indicated, warning letters, import bans, product recalls or seizures, monetary sanctions, reputational damage, injunctions to halt the manufacture and distribution of products, civil or criminal sanctions, refusal of a government to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses. The failure of our suppliers to comply with regulations could also adversely affect segments of our business as regulatory actions taken by FDA against those manufacturers can result in product shortages, recalls or modifications. Any of these actions could cause a loss of customer confidence in us and our products, which could adversely affect our sales. Our business is also subject to risks associated with U. S. and foreign legislation, regulations and trade agreements relating to the materials we import, including quotas, duties, tariffs or taxes, other charges or restrictions on imports and the nature of materials that can be used in our products, which could adversely affect our operations and our ability to import materials used in our products at current or increased levels. We cannot predict whether additional U. S. and foreign customs quotas, duties (including antidumping or countervailing duties), tariffs, taxes or other charges or restrictions, requirements as to where raw materials and component parts must be purchased, additional workplace regulations or other restrictions on our imports will be imposed in the future or adversely modified, or what effect such actions would have on our costs of operations. Future quotas, duties or tariffs may have a material adverse effect on our business, **results of operations, financial condition and** ~~results of operations or~~ cash flows. Future trade agreements could also provide our competitors with an advantage over us, or increase our costs, either of which could have a material adverse effect on our business, **results of operations, financial condition and** ~~results of operations or~~ cash flows. **See also “Risks Relating to Our Business Operations — We are subject to risks associated with doing business globally.”** The sales, marketing and pricing of products and relationships that medical device and pharmaceutical companies have with healthcare providers are under increased scrutiny by federal, state and foreign government agencies. Compliance with the Anti-Kickback Statute, False Claims Act, Food, Drug and Cosmetic Act (including as these laws relate to off-label promotion of products) and other healthcare-related laws, as well as competition and export and import laws, is under increased focus by the agencies charged with overseeing such activities. The **Department of Justice (the “DOJ”)** and the SEC are focused on the enforcement of the U. S. Foreign Corrupt Practices Act (**the “FCPA”**), particularly as it relates to the conduct of medical product and pharmaceutical companies. The FCPA and similar anti-bribery laws generally prohibit companies and their employees, contractors or agents from making improper payments to government officials for the purpose of obtaining or retaining business. Healthcare professionals in many countries are employed by the government and consequently may be considered government officials. Foreign governments are also focused on examining medical product and pharmaceutical companies’ sales and marketing activities and relationships with healthcare providers and competitive practices generally. The laws and standards governing the promotion, pricing, sale and reimbursement of our products and those governing our relationships with healthcare providers and governments, including the Physician Payments Sunshine Act, are complicated, ~~are~~ subject to frequent change and may be violated unknowingly. **Compliance with these and similar laws (or failure to comply with these laws) could have a material adverse effect on our business, results of operations, financial condition and cash flows. Additionally, failure to comply with applicable laws or our internal policies has resulted, and may result in the future, in the departure or termination of key personnel, which has the potential of disrupting our operations or future performance. Furthermore, governments have chosen (as in the case of the Chinese government) or may choose to prioritize anti-corruption efforts in the healthcare sector as part of their law enforcement activities.** We are also subject to environmental laws, which are becoming more stringent throughout the world. For example, the **Environmental Protection Agency (the “EPA”)** regulates the use of ethylene oxide for sterilization of medical devices and is increasingly focused on reducing emissions from the ethylene oxide sterilization process, which has increased our costs of operations and necessitated changes to our manufacturing plants and processes. Additionally, the European Economic Area (**the “EEA”**) **is phasing out** ~~has placed a sunset date for~~ the use of Bis (2-ethylhexyl) phthalate (**DEHP**); **in the immediate packaging of medicinal products and in medical devices,** and the EEA is **also** considering regulations on per- and polyfluoroalkyl substances, ~~(PFAS) and~~ fluorinated gases **and Polyvinyl**

Chloride. Other governments globally have, or are considering, limiting or prohibiting the use of certain chemicals, including Polyvinyl Chloride and Diethyl Phthalate. These regulatory changes could adversely impact on our ability to manufacture or supply certain products in the EEA. Other environmental laws may have similar consequences to for us or our suppliers, or result in liability to us. Additionally, the U. S. Department of the Treasury's Office of Foreign **Assets** Control and the Bureau of Industry and Security at the U. S. Department of Commerce administer laws and regulations that restrict U. S. persons and, in some instances, non- U. S. persons, in conducting activities, transacting business or making investments in certain countries, or with governments, entities and individuals subject to U. S. economic sanctions. From time to time, certain of our subsidiaries have limited business dealings with **and / or provide humanitarian donations to** countries subject to **these comprehensive sanctions and / or embargoes**, including **Iran-Afghanistan, Sudan-Belarus, Cuba, Russia, Syria, Russia and Cuba-Venezuela**. These dealings represent an insignificant amount of our **consolidated revenues combined net sales** and income but expose us to an increased risk of operating in these countries, including foreign exchange risks or restrictions or limitations on our ability to access funds generated in these jurisdictions, or the risk of violating applicable sanctions or regulations, which are complex and subject to frequent change. Our **ethics and** compliance programs, training, monitoring and policies may not always protect us from conduct by individual employees that violate these laws. Violations or allegations of violations of these laws may result in large civil and criminal penalties, debarment or exclusion from participating in government programs, diversion of management time, attention and resources and may otherwise have an adverse effect on our business, **results of operations,** financial condition and **cash flows results of operations**. The laws and regulations discussed above are broad in scope and subject to evolving interpretations and changes, which may be violated unknowingly, could require us to incur substantial costs regarding compliance or to alter our sales and marketing practices and may subject us to enforcement actions or litigation, **and of** which could adversely affect our business, **results of operations,** financial condition and **cash flows results of operations**. We cannot predict with certainty what laws, regulations and healthcare initiatives, if any, will be implemented, or what the ultimate effect of healthcare reform or any future legislation or regulation will have on us. For more information related to ongoing government investigations, see Note 7-8 in Item 8 of this Annual Report **on Form 10- K**. For more information on regulatory matters currently affecting us, including quality- related matters, see " Certain Regulatory Matters " in Item 7. **Management's Discussion and Analysis of Financial Condition and Results of Operations** of this Annual Report **on Form 10- K**. As a global company, we are subject to global data privacy and **security-cybersecurity** laws, regulations and codes of conduct that apply to our businesses. We are required to comply with increasingly complex and changing legal and regulatory requirements **and frameworks in the United States and in other countries** that govern **not only** the collection, use, storage, security, transfer, disclosure and other processing of **protected health information and** personal **and sensitive data in, but also the timely disclosure of cybersecurity incidents. Further, new and emerging digital and technology laws are gradually being implemented globally and have a strong interplay with privacy and cybersecurity rules, which contributes to the complexity of the regulatory landscape. In** the United States **and in, we are subject to** other -- **the countries, including, but not limited to, The Health Insurance Portability and Accountability Act, as amended (HIPAA), The Health Information Technology for Economic and Clinical Health Act, and the California Consumer Privacy Act (the CCPA), and California Privacy Rights Act (CPRA) as well as the other European Union new and emerging state laws. HIPAA imposes stringent data privacy and security requirements, and the regulatory authority has imposed significant fines and penalties on organizations found to be out of compliance. The CCPA provides consumers with a private right of action against companies that have a security breach due to a lack of appropriate security measures. In addition, to the HHS and the Federal Trade Commission's (FTC) enforcement activity has become more intense, with higher fines, in areas related to health data that are out of scope of HIPAA. Further, we are subject to the EU's General Data Protection Regulation (the GDPR) and the newly revised NIS2 Directive, an EU a European Union-wide cybersecurity legislation (, which will be fully in force in 2024). The GDPR imposes stringent EU European Union data protection requirements and provides for significant penalties for noncompliance (, including heightened fines as compared to prior years) . **Governmental bodies are increasingly imposing cyber- incident disclosure** HIPAA also imposes stringent data privacy and security requirements and the regulatory **regulations with differing criteria for what incidents must** authority has imposed significant fines and penalties on organizations found to be **reported as well as the timelines** out of compliance. CCPA provides consumers with a private right of action against companies who have a security breach due to lack of appropriate security measures. More states (including Colorado, Connecticut, Utah and Virginia) plan to introduce similar legislation in 2023 **which to report them**. We or our third- party providers and business partners may also be subjected to audits or investigations by one or more domestic or foreign government agencies relating to compliance with information security and privacy laws and regulations, and noncompliance with **the such** laws and regulations could result in substantial and material fines or class action litigation. If reimbursement or other payment for our current or future products is reduced or modified in the United States or in foreign countries, including through the implementation or repeal of government- sponsored healthcare reform or other similar actions, cost containment measures, or **there are** changes to policies with respect to pricing, taxation or rebates, our business could suffer. Sales of our products depend, in part, on the extent to which the costs of our products are paid by both public and private payers. These payers include Medicare, Medicaid, **and** private healthcare insurers in the United States and foreign governments and third- party payers outside the United States. Our work with government payers carries various risks inherent in working with government entities and agencies, including government reporting and auditing, additional regulatory oversight, mandated contractual terms, failure of government appropriations **or and** other complex procedural requirements. Public and private payers **have challenged, and** are **expected to continue to** **challenging challenge** the, prices charged for medical products and services. **Such** We may continue to experience downward pricing pressures from any or all of these payers **may which could** result in an adverse effect on our business, **results of operations,** financial condition and **operational results cash flows**. Global efforts toward healthcare cost containment continue to exert pressure on product pricing.**

Governments around the world **continue to** use various mechanisms to control healthcare expenditures, such as price controls, the formation of public contracting authorities, product formularies, which are lists of recommended or approved products, and competitive tenders, which require the submission of a bid to sell products. Sales of our products are dependent, in part, on the availability of reimbursement by government agencies and healthcare programs, as well as insurance companies and other private payers. In much of Europe, Latin America, Asia and Australia, ~~the government~~ **governments provide** healthcare at low cost to patients, ~~and controls~~ **control its their** expenditures by **various means, such as** purchasing products through public tenders, collective purchasing, regulating prices, setting reference prices in public tenders ~~or and~~ limiting reimbursement or patient access to certain products. For example, China has been implementing volume-based procurement policies, a series of centralized reforms being instituted in China on both a national and regional basis that has resulted in significant price cuts for pharmaceuticals and medical consumables. Additionally, austerity measures or other reforms by foreign governments may limit, reduce or eliminate payments for our products and adversely affect both pricing flexibility and demand for our products. In addition, **operations within** ~~our recent acquisition of Hillrom has~~ **Healthcare Systems and Technologies segment** ~~increased~~ **increase** our exposure to risks related to reimbursement as certain portions of that business directly bill various government agencies. The Healthcare Reform Act includes several provisions which impact our businesses in the United States, including increased Medicaid rebates and an expansion of the 340B Drug Pricing Program, which provides certain qualified entities with discounts on the purchase of drugs for outpatient use and an excise tax on the sale of certain drugs. The Healthcare Reform Act reduces Medicare and Medicaid payments to hospitals and other providers, which may cause us to experience downward pricing pressure. Certain portions of the Healthcare Reform Act could negatively impact the demand for our products, and therefore our results of operations ~~and~~, financial position **and cash flows**. In 2019, the U. S. Department of Health and Human Services launched a new kidney health initiative. The CMS published the final ~~End-Stage Renal Disease (ESRD) Treatment Choices (ETC) mandatory payment model in 2020. The ETC launched in 30 % of dialysis clinics across the country on January 1, 2021 and creates payment incentives for the greater use of home dialysis and kidney transplants for those new to and already on dialysis. CMS also announced the implementation of four voluntary payment models with the stated goal of helping healthcare providers reduce the cost and improve the quality of care for patients with late-stage chronic kidney disease and ESRD.~~ **In addition, the 2022 Physician Fee Schedule issued by** CMS has ~~stated~~ **extended coverage of certain Medicare telehealth services through December 31, 2023 and these-- the payment models Consolidated Appropriations Act of 2023 further extended such coverage through December 31, 2024. While the availability of telehealth services can improve access to medical care** ~~are care aimed to prevent or delay the need,~~ **increased reliance on, and utilization of, telemedicine for delivery of healthcare services increases** ~~dialysis and encourage kidney transplantation. CMS launched the~~ **risk of privacy and data breaches and cyberattacks** ~~program on January 1, 2022, at which time 85 entities were enrolled as participants.~~ These proposed regulatory changes in kidney health policy and reimbursement may substantially change the U. S. end stage renal disease market and could increase demand for our peritoneal dialysis products, necessitating significant multi-year capital expenditures in order to meet that demand. However, the impact of such changes and related expenses are difficult to estimate in advance. In addition, a substantial portion of our revenues is dependent on federal healthcare program reimbursement, and any disruptions in federal government operations, including a federal government shutdown or failure of the U. S. government to enact annual appropriations, could have a material adverse effect on our business, **results of operations,** financial condition and **cash flows** ~~results of operations~~. Additionally, disruptions in federal government operations may negatively impact regulatory approvals and guidance that are important to our operations and create uncertainty about the pace of upcoming healthcare regulatory developments or approvals. As a result of these and other measures, including future measures or reforms that cannot be predicted, reimbursement may not be available or sufficient to allow us to sell our products on a competitive basis. Legislation and regulations affecting reimbursement for our products may change at any time and in ways that may be adverse to us. We cannot predict the impact of these pressures and initiatives, or any negative effects of any additional regulations that may affect our business. Portions of our business are subject to stringent laws and regulations at the federal or state levels governing the participation of durable medical equipment suppliers and independent diagnostic testing facilities in federal and state healthcare programs. From time to time, the **U. S.** government seeks additional information related to our claims submissions, and in some instances government contractors perform audits of payments made to us under Medicare, Medicaid, and other federal healthcare programs. On occasion, these reviews identify overpayments for which we submit refunds. At other times, our own internal audits identify the need to refund payments. We believe the frequency and intensity of government audits and review processes has grown, and we expect this will continue ~~in the future,~~ due to increased resources allocated to these activities at both the federal and state Medicaid level, and greater sophistication in data review techniques. In addition, our business contracts with foreign and U. S. federal, state and local government entities **are and is** subject to specific rules, regulations and approvals applicable to government contractors. Our failure to comply with these could result in contract terminations, suspension or debarment from contracting with these entities, civil fines and damages, criminal prosecution and possible exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, as well as possible recoupment of any overpayments related to such violations. While we believe that our practices materially comply with applicable state ~~and~~, federal **and foreign** requirements, the requirements might be interpreted in a manner inconsistent with our interpretation. Failure to comply with applicable laws and regulations, even if inadvertent, could have a material adverse impact on our business, **results of operations, financial condition and cash flows**. Patent and other proprietary rights are essential to our business. Our success depends to a significant degree on our ability to obtain and enforce patents and licenses to patent rights, both in the United States and in other countries. We cannot guarantee that **our** pending patent applications, **or any future patent applications,** will result in issued patents, ~~that our~~ patents issued or licensed will not be challenged or circumvented by competitors, ~~that~~ our patents will not be found to be invalid or ~~that~~ the intellectual property rights of others will not prevent us from selling certain products or including key features in our products. The patent position of a healthcare

company is often uncertain and involves complex legal and factual questions. Significant litigation concerning patents and products is pervasive in our industry. Patent claims include challenges to the coverage and validity of our patents on products or processes as well as allegations that our products infringe patents held by competitors or other third parties. An unfavorable litigation outcome in any of these types of cases could result in a loss of patent protection or the ability to market products, which could lead to a significant loss of sales, or otherwise materially affect ~~future~~ **our business, results of operations, financial condition and cash flows**. We also rely on trademarks, copyrights, trade secrets and know-how to develop, maintain and strengthen our competitive positions. Third parties may know, discover or independently develop equivalent proprietary information or techniques, or they may gain access to our trade secrets or **publicly** disclose our trade secrets ~~to the public~~. Although our employees, consultants, parties to collaboration agreements and other business partners are generally subject to confidentiality or similar agreements to protect our confidential and proprietary information, these agreements may be breached, and we may not have adequate remedies for any breach. To the extent that our employees, consultants, parties to collaboration agreements and other business partners use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. Furthermore, our intellectual property, proprietary technology and sensitive company data is potentially vulnerable to loss, damage ~~or and~~ misappropriation from system malfunction, computer viruses and unauthorized access to our data or misappropriation or misuse thereof by those with permitted access and other events. While we have invested to protect our intellectual property, confidential information and other data, and continue to work diligently in this area, there can be no assurance that our precautionary measures have prevented or will prevent future breakdowns, breaches, cyber incidents or other events. ~~Such events~~ **See also “Risks Relating to Our Business Operations — Breaches and breakdowns affecting our information technology systems or protected information, including from cyber security breaches and data leakage, could have a material adverse effect on our reputation, business, results of operations, financial condition, cash flows, reputation and competitive position.” Any of the events referenced above could have a material adverse effect on our reputation, business, results of operations, financial condition and cash flows.** Changes to the tax laws in the United States or other countries in which we operate could have an adverse effect on our operating results. For example, the ~~outcome~~ **Organization of Economic Co-operation and Development (OECD) and the G20 Inclusive Framework on Base Erosion and Profit Shifting (the Inclusive Framework) has put forth two proposals — Pillar One and Pillar Two — that revise the existing profit allocation and nexus rules and ensure a minimal level of taxation, respectively. On December 12, 2022, the EU member states agreed to implement the Inclusive Framework’s global corporate minimum tax rate of 15 %, and various initiatives currently being undertaken countries both within and outside the EU have enacted new laws implementing Pillar Two or have draft legislation proposed for adoption. The OECD continues to release additional guidance on the two-pillar framework, with widespread implementation in 2024. We are continuing to evaluate the potential impact of the Inclusive Framework on future periods, pending legislative adoption by individual countries** ~~the Organization of Economic Cooperation and Development, and the implementation of such initiatives by taxing authorities across the world, could significantly impact how we allocate profits across multiple jurisdictions, which could have an adversely~~ **adverse impact on our global effective tax obligations rate, income tax expense and cash flows.** Taxing authorities audit us from time to time and may disagree with certain positions we have taken in respect of our tax liabilities. Our tax liabilities are affected by many factors, including the amounts we charge in intra-company transactions for inventory, services, licenses, funding and other items, which are subject to the use of assumptions and judgment. Because we operate in multiple income tax jurisdictions both inside and outside the United States, cross border transactions among our affiliates are a significant part of the manner in which we operate. Although we believe that we transact intra-company business in accordance with arm’s-length principles, tax authorities may disagree with our intra-company charges, cross-jurisdictional transfer pricing or other matters, and may assess additional taxes as a result, including in connection with their review of the restated financial statements we have filed as part of our 2019 Annual Report on Form 10-K. We regularly assess the likely outcomes of these audits in order to determine the appropriateness of our tax provision. However, we may not accurately predict the outcome of these audits and, as a result, the actual outcome of these audits may have an adverse impact on our financial results. For more information on ongoing audits, see Note ~~13-14~~ **13-14** in Item 8 of this Annual Report. We are party to a number of pending lawsuits, settlement discussions, mediations, arbitrations and other disputes, ~~many~~ **some** of which are set forth in Note ~~7-8~~ **7-8** in Item 8 of this Annual Report **on Form 10-K**. In addition, in the future we may be party to additional lawsuits, disputes or other matters, including patent, product liability or other lawsuits. These current and future matters may result in a loss of patent protection, reduced ~~revenue~~ **net sales**, incurrence of significant liabilities and diversion of our management’s time, attention and resources. Given the uncertain nature of litigation and other disputes generally, we are not able in all cases to estimate the amount or range of loss that could result from an unfavorable outcome in our current matters. In view of these uncertainties, the outcome of these current matters may result in charges in excess of any established reserves, and, to the extent available, liability insurance. We also continue to be self-insured with respect to product liability claims. The ~~absence~~ **unavailability or inadequacy** of third-party insurance coverage for current or future **liability** claims ~~could increase~~ **increase** our potential exposure to unanticipated claims and adverse decisions. Protracted litigation and other disputes, including any adverse outcomes, may have an adverse impact on our business, **results of operations or, financial condition and cash flows**. Even claims without merit could subject us to adverse publicity and require us to incur significant legal fees. **Our Amended and Restated Bylaws designate certain courts in the State of Delaware or the federal district courts of the United States will be the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees. Our Amended and Restated Bylaws (Bylaws) provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery in 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) is the sole and exclusive forum, to the fullest**

extent permitted by law, to bring (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for or based on a breach of a fiduciary duty owed by any current or former director or officer or other employee of the company to the company or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or our Certificate of Incorporation or these Bylaws, as either may be amended from time to time, or (iv) any action to interpret, apply, enforce or determine the validity of the Certificate of Incorporation or Bylaws or (v) any other action asserting a claim governed by the internal affairs doctrine or that is otherwise an “ internal corporate claim ” as defined in Section 115 of the Delaware General Corporation Law. The exclusive forum provisions of our Bylaws are not a waiver of, and do not relieve person or entity of duties to comply with, federal securities laws including those specifying the exclusive jurisdiction of federal courts under the Exchange Act and concurrent jurisdiction of federal and state courts under the Securities Act of 1933, as amended. 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 the foregoing provisions of our Bylaws described above. The choice of forum provision may result in increased costs for investors to bring a claim. Further, the 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, other employees, or stockholders, which may discourage such lawsuits against us and our directors, officers, other employees, or stockholders. However, the enforceability of similar forum provisions in other companies’ certificates of incorporation or bylaws have been challenged in legal proceedings. If a court were to find the exclusive choice of forum provision contained in our Bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.