Risk Factors Comparison 2024-02-26 to 2023-02-24 Form: 10-K

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The Company is subject to a number of risks that if realized could materially adversely affect its business, results of operations, cash flow, financial condition or prospects. The following is a summary of the principal risk factors facing the Company: • The Company is dependent on its patent rights, and if its patent rights are invalidated or circumvented, its business could be materially adversely affected. • As the Company' s products lose market exclusivity, the Company generally experiences a significant and rapid loss of sales from those products. • Key products generate a significant amount of the Company' s profits and cash flows, and any events that adversely affect the markets for its leading products could have a material adverse effect on the Company' s results of operations and financial condition. ~~The Company expects that sales of Lagevrio, which were $ 5. 7 billion in 2022, will decline significantly to approximately $ 1. 0 billion in 2023.~~ • The Company' s research and development efforts may not succeed in developing commercially successful products and the Company may not be able to acquire commercially successful products in other ways; ~~in consequence~~ **consequently** , the Company may not be able to replace sales of successful products that lose patent protection. • The Company' s success is dependent on the successful development and marketing of new products, which are subject to substantial risks. • The Company faces continued pricing pressure with respect to its products. • Unfavorable or uncertain economic conditions, together with cost- reduction measures being taken by certain governments, could negatively affect the Company' s operating results. • The Company faces intense competition from **both** lower cost generic products **and** ~~. • The Company faces intense competition from~~ competitors' products ~~. • COVID- 19- related disruptions have had an adverse impact on the Company' s business, operations and financial performance. The Company is unable to predict the full extent to which the COVID- 19 pandemic or any future pandemic, epidemic or similar public health threat will adversely impact its business, operations, financial performance, results of operations, and financial condition~~ . • The Company has significant global operations, which expose it to additional risks, and any adverse event could have a material adverse effect on the Company' s results of operations and financial condition. • Climate change or legal, regulatory or market measures to address climate change may negatively affect the Company' s business, results of operations, cash flows and prospects. • Environmental, social and governance (ESG) matters may impact the Company' s business and reputation. • Failure to attract and retain highly qualified personnel could affect the Company' s ability to successfully develop and commercialize products. • The Company may experience difficulties and delays in manufacturing certain of its products, including vaccines. • The Company may not be able to realize the expected benefits of its investments in emerging markets ~~. • The ongoing war between Russia and Ukraine and related global disruptions could adversely affect the Company' s business, results of operations and financial condition~~ . • The Company is exposed to market risk from fluctuations in currency exchange rates and interest rates. • Pharmaceutical products can develop unexpected safety or efficacy concerns. • Reliance on third- party relationships and outsourcing arrangements could materially adversely affect the Company' s business. • Negative events in the animal health industry could have a material adverse effect on future results of operations and financial condition **of the Company or its Animal Health business** . • Biologics and vaccines carry unique risks and uncertainties, which could have a material adverse effect on the Company' s future results of operations and financial condition. • The health care industry in the U. S. has been, and will continue to be, subject to increasing regulation and political action. • The Company' s products, including products in development, cannot be marketed unless the Company obtains and maintains regulatory approval. • Developments following regulatory approval may adversely affect sales of the Company' s products. • The Company is subject to a variety of U. S. and international laws and regulations. • The Company is subject to evolving and complex tax laws, which may result in additional liabilities that may affect results of operations and financial condition. • Adverse outcomes in current or future legal matters could negatively affect Merck' s business. • Product liability insurance for products may be limited, cost prohibitive or unavailable. • The Company is increasingly dependent on sophisticated software applications and computing infrastructure. The Company ~~could~~ **continues to** be a target of ~~future~~ cyber- attacks that could lead to a disruption of its worldwide operations, including manufacturing, research and sales operations. • Social media and mobile messaging platforms present risks and challenges. The above list is not exhaustive, and the Company faces additional challenges and risks. Investors should carefully consider all of the information set forth in this Form 10- K, including the following risk factors, before deciding to invest in any of the Company' s securities. Risk Factors The risks below are not the only ones the Company faces. Additional risks not currently known to the Company or that the Company presently deems immaterial may also impair its business operations. The Company' s business, financial condition, results of operations, cash flow or prospects could be materially adversely affected by any of these risks. This Form 10- K also contains forward- looking statements that involve risks and uncertainties. The Company' s results could materially differ from those anticipated in these forward- looking statements as a result of certain factors, including the risks it faces described below and elsewhere. See " Cautionary Factors that May Affect Future Results " below. Risks Related to the Company' s Business Patent protection is considered, in the aggregate, to be of material importance to the Company' s marketing of human health and animal health products in the U. S. and in most major foreign markets. Patents covering products that it has introduced normally provide market exclusivity, which is important for the successful marketing and sale of its products. The Company seeks patents covering each of its products in each of the markets where it intends to sell the products and where meaningful patent protection is available. Even if the Company succeeds in obtaining patents covering its products, third parties or government authorities may challenge or seek to invalidate or circumvent its patents and patent applications. It is important for the Company' s business to successfully assert and defend the patent rights that provide market exclusivity for its products. The Company is often involved in patent disputes relating to challenges to its

patents or claims by third parties of infringement against the Company. The Company asserts and defends its patents both within and outside the U. S., including by filing claims of infringement against other parties. See Item 8. " Financial Statements and Supplementary Data, " Note 11. " Contingencies and Environmental Liabilities " below. In particular, manufacturers of generic or biosimilar pharmaceutical products from time to time file abbreviated NDAs or BLAs with the FDA seeking to market generic / biosimilar forms of the Company' s products prior to the expiration of relevant patents owned or licensed by the Company. The Company normally responds by asserting one or more of its patents with a lawsuit alleging patent infringement. Patent litigation and other challenges to the Company' s patents are costly and unpredictable and may deprive the Company of market exclusivity for a patented product or, in some cases, third- party patents may prevent the Company from marketing and selling a product in a particular geographic area. Additionally, certain foreign governments have indicated that compulsory licenses to patents may be granted in the case of national emergencies or in other circumstances, which could diminish or eliminate sales and profits from those regions and negatively affect the Company' s results of operations. Further, court decisions relating to other companies' patents, potential legislation in both the U. S. and certain foreign markets relating to patents, as well as regulatory initiatives may result in a more general weakening of intellectual property protection. If one or more important products lose patent protection in profitable markets, sales of those products are likely to decline significantly as a result of generic versions of those products becoming available. The Company' s results of operations may be adversely affected by the lost sales unless and until the Company has launched commercially successful products that replace the lost sales. In addition, if products that were measured at fair value and capitalized in connection with acquisitions experience difficulties in the market that negatively affect product cash flows, the Company may recognize material non- cash impairment charges with respect to the value of those products. A chart listing the **key** patent protection for certain of the Company' s marketed products, and U. S. patent protection for candidates in Phase 3 clinical development is set forth above in Item 1. " Business — Patents, Trademarks and Licenses. " The Company depends upon patents to provide it with exclusive marketing rights for its products for some period of time. Loss of patent protection for one of the Company' s products typically leads to a significant and rapid loss of sales for that product as lower priced generic versions of that drug become available. In the case of products that contribute significantly to the Company' s sales, the loss of market exclusivity can have a material adverse effect on the Company' s business, cash flow, results of operations, financial condition and prospects. **In** ~~While the key U. S. patent for Januvia and Janumet claiming the sitagliptin compound expired in January~~ 2023, ~~as a result of favorable court rulings and settlement agreements related to a later expiring patent directed to the specific sitagliptin salt form of the products, the Company expects that these~~ -- **the** ~~products will not lose market exclusivity in the U. S. until May 2026. However, certain of the rulings are currently being appealed, and an unfavorable court decision would likely cause the products to lose exclusivity in the U. S. toward the end of 2023. The~~ Company lost market exclusivity for ~~Januvia~~ **Bridion** in ~~all of~~ the EU and ~~for Janumet in some European countries in September 2022. Merck expects that exclusivity for Janumet will be lost in other~~ -- **the** ~~European countries~~ **Company has experienced a substantial decline** in **Bridion sales in** ~~April 2023. While the~~ **those** ~~Company~~ **markets. Bridion** lost market exclusivity **in Japan in January 2024 and will lose market exclusivity in the U. S. in 2026 (subject to patent litigation discussed below) and the Company expects that sales in those markets will decline substantially thereafter. In addition, the Company expects to lose market exclusivity in the U. S.** for ~~Januvia~~ **Keytruda** in ~~China in 2022~~ **2028 and** ~~with the approval of a generic equivalent product, the impact on sales in 2023 is expected to be modest. It is anticipated that a generic equivalent of Janumet will be approved in China in the first quarter of 2023, but the impact to sales in 2023 is also expected to be modest. As these products lose exclusivity,~~ the Company anticipates that sales of ~~Januvia and Janumet~~ **Keytruda in the U. S.** will decline substantially **thereafter** . The Company' s ability to generate profits and operating cash flow depends largely upon the continued profitability of the Company' s key products, such as Keytruda, Gardasil / Gardasil 9, Lynparza, Bravecto, and Bridion **. In 2023, the Company' s oncology portfolio, led by Keytruda, and its vaccines portfolio, led by Gardasil / Gardasil 9, represented substantially all of the Company' s revenue growth. In particular, in the aggregate, in 2023, sales of Keytruda and Gardasil / Gardasil 9 represented 56 % of the Company' s total sales** . As a result of the Company' s dependence on key products, any event that adversely affects any of these products or the markets for any of these products could have a significant adverse impact on results of operations and financial condition. These events could include loss of patent protection, increased costs associated with manufacturing, generic or over- the- counter availability of the Company' s product or a competitive product, the discovery of previously unknown side effects, results of post- approval trials, increased competition from the introduction of new, more effective treatments and discontinuation or removal from the market of the product for any reason. Such events could have a material adverse effect on the sales of any such products ~~. In particular, in 2022, sales of Lagevrio, which were $ 5. 7 billion, represented a substantial portion of the Company' s revenue and profit growth. The Company expects that sales of Lagevrio will decline significantly to approximately $ 1. 0 billion in 2023~~ . In order to remain competitive, the Company, like other major pharmaceutical companies, must continue to launch new products. Expected declines in sales of products after the loss of market exclusivity mean that the Company' s future success is dependent on its pipeline of new products, including new products that it may develop through collaborations and joint ventures and products that it is able to obtain through license or acquisition. To accomplish this, the Company commits substantial effort, funds and other resources to research and development, both through its own dedicated resources and through various collaborations with third parties. There is a high rate of failure inherent in the research and development process for new drugs and vaccines. As a result, there is a high risk that funds invested by the Company in research programs will not generate financial returns. This risk profile is compounded by the fact that this research has a long investment cycle. To bring a pharmaceutical compound from the discovery phase to market may take a decade or more and failure can occur at any point in the process, including later in the process after significant funds have been invested. For a description of the research and development process, see Item 1. " Business — Research and Development " above. Each phase of testing is highly regulated and during each phase there is a substantial risk that the Company will encounter serious obstacles

or will not achieve its goals. Therefore, the Company may abandon a product in which it has invested substantial amounts of time and resources. Some of the risks encountered in the research and development process include the following: preclinical testing of a new compound may yield disappointing results; competing products from other manufacturers may reach the market first; clinical trials of a new drug may not be successful; a new drug may not be effective or may have harmful side effects; a new drug may not be approved by the regulators for its intended use; it may not be possible to obtain a patent for a new drug; payers may refuse to cover or reimburse the new product; or sales of a new product may be disappointing. The Company cannot state with certainty when or whether any of its products now under development will be approved or launched; whether it will be able to develop, license or otherwise acquire compounds, product candidates or products; or whether any products, once launched, will be commercially successful. The Company must maintain a continuous flow of successful new products and successful new indications for existing products sufficient both to cover its substantial research and development costs and to replace sales that are lost as profitable products lose market exclusivity or are displaced by competing products or therapies. Failure to do so in the short term or long term would have a material adverse effect on the Company' s business, results of operations, cash flow, financial condition and prospects. Products that appear promising in development may fail to reach the market or fail to succeed for numerous reasons, including the following: • findings of ineffectiveness, superior safety or efficacy of competing products, or harmful side effects in clinical or preclinical testing; • failure to receive the necessary regulatory approvals, including delays in the approval of new products and new indications, or the anticipated labeling, and uncertainties about the time required to obtain regulatory approvals and the benefit / risk standards applied by regulatory agencies in determining whether to grant approvals; • failure in certain markets to obtain reimbursement commensurate with the level of innovation and clinical benefit presented by the product; • lack of economic feasibility due to manufacturing costs or other factors; and • preclusion from commercialization by the proprietary rights of others. In the future, if certain pipeline programs are cancelled or if the Company believes that their commercial prospects have been reduced, the Company may recognize material non- cash impairment charges for those programs that were measured at fair value and capitalized in connection with acquisitions or certain collaborations. Failure to successfully develop and market new products in the short term or long term would have a material adverse effect on the Company' s business, results of operations, cash flow, financial condition and prospects. The Company faces continued pricing pressure globally and, particularly in mature markets, from managed care organizations, government agencies and programs that could negatively affect the Company' s sales and profit margins. In the U. S., these include (i) ~~practices of managed care groups and institutional and governmental purchasers, (ii)~~ U. S. federal laws and regulations related to Medicare and Medicaid, including the Medicare Prescription Drug Improvement and Modernization Act of 2003, the ACA, **and** the ~~Inflation Reduction Act~~ **IRA, (ii) practices of managed care groups and institutional and governmental purchasers** , and (iii) state activities aimed at increasing price transparency, including new laws as noted above in Item 1. " Competition and the Health Care Environment. " Changes to the health care system enacted as part of health care reform in the U. S., as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, could result in further pricing pressures. **As noted in Item 1. " Competition and the Health Care Environment, " in 2023, HHS included Januvia in the first year of the IRA' s price setting program, which absent further legislative or court intervention will result in a government set price becoming effective on January 1, 2026. Furthermore, the Company anticipates that HHS will include Keytruda in a subsequent selection of products to undergo IRA price setting, with such price likely to be effective in early 2028.** In addition, in the U. S., larger customers have received higher rebates on drugs in certain highly competitive categories. The Company must also compete to be placed on formularies of managed care organizations. Exclusion of a product from a formulary can lead to reduced usage in the managed care organization. In order to provide information about the Company' s pricing practices, the Company annually posts on its website its Pricing Transparency Report for the U. S. The report provides the Company' s average annual list price and net price increases across the Company' s U. S. portfolio dating back to 2010. In ~~2022~~ **2023** , the Company' s gross U. S. sales were reduced by **37** ~~39. 7~~ % as a result of rebates, discounts and returns. Outside the U. S., numerous major markets, including the EU, Japan and China have pervasive government involvement in funding health care and, in that regard, fix the pricing and reimbursement of pharmaceutical and vaccine products. Consequently, in those markets, the Company is subject to government decision making and budgetary actions with respect to its products. In Japan, the pharmaceutical industry is subject to government- mandated annual price reductions of pharmaceutical products and certain vaccines. Furthermore, the **Japanese** government can order re- pricing for specific products if it determines that use of such product will exceed certain thresholds defined under applicable re- pricing rules. The Company expects pricing pressures to continue in the future. The Company' s business may be adversely affected by local and global economic conditions, including with respect to inflation, interest rates, and costs of raw materials and packaging. Uncertainty in global economic and geopolitical conditions may result in a slowdown to the global economy that could affect the Company' s business by reducing the prices that drug wholesalers and retailers, hospitals, government agencies and managed health care providers may be able or willing to pay for the Company' s products or by reducing the demand for the Company' s products, which could in turn negatively impact the Company' s sales and result in a material adverse effect on the Company' s business, cash flow, results of operations, financial condition and prospects. As discussed above in **Item 1.** " Competition and the Health Care Environment, " global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. Changes to the U. S. health care system as part of health care reform, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, have contributed to pricing pressure. In several international markets, government- mandated pricing actions have reduced prices of generic and patented drugs. In addition, the Company' s sales performance in ~~2022~~ **2023** was negatively affected by other cost- reduction measures taken by governments and other third parties to lower health care costs. The Company anticipates all of these actions, and additional actions in the future, will negatively affect sales and profits. If credit and economic conditions worsen, the resulting economic and currency impacts in the affected markets and globally

could have a material adverse effect on the Company' s results ~~. As a result of global macroeconomic conditions, the Company is experiencing some minor disruption and volatility in its global supply chain network. These disruptions could increase in the future and cause delays in shipments of raw materials and packaging, as well as related cost inflation. Any such disruptions, delays or costs may result in the Company' s inability to meet demand for the Company' s products~~. In general, the Company faces increasing competition from lower- cost generic products. The patent rights that protect its products are of varying strengths and durations. In addition, in some countries, patent protection is significantly weaker than in the U. S. or in the EU. In the U. S. and the EU, political pressure to reduce spending on prescription drugs has led to legislation and other measures that encourage the use of generic and biosimilar products. Although it is the Company' s policy to actively protect its patent rights, generic challenges to the Company' s products can arise at any time, and the Company' s patents may not prevent the emergence of generic competition for its products. Loss of patent protection for a product typically is followed promptly by generic substitutes, reducing the Company' s sales of that product. Availability of generic substitutes for the Company' s drugs may adversely affect its results of operations and cash flow. In addition, proposals emerge from time to time in the U. S. and other countries for legislation to further encourage the early and rapid approval of generic drugs. Any such proposal that is enacted into law could worsen this substantial negative effect on the Company' s sales, business, cash flow, results of operations, financial condition and prospects. ~~The~~ **Also, the** Company' s products face intense competition from competitors' products. This competition may increase as new products enter the market. In such an event, the competitors' products may be safer or more effective, more convenient to use, have better insurance coverage or reimbursement levels or be more effectively marketed and sold than the Company' s products. Alternatively, in the case of generic competition, including the generic availability of competitors' branded products, they may be equally safe and effective products that are sold at a substantially lower price than the Company' s products. As a result, if the Company fails to maintain its competitive position, this could have a material adverse effect on its business, cash flow, results of operations, financial condition and prospects. In addition, if products that were measured at fair value and capitalized in connection with acquisitions experience difficulties in the market that negatively impact product cash flows, the Company may recognize material non- cash impairment charges with respect to the value of those products ~~. The Company' s business and financial results have been negatively impacted by COVID- 19- related disruptions since the start of the pandemic. Merck believes that global health systems and patients have largely adapted to the impacts of COVID- 19, however, a substantial portion of Merck' s Pharmaceutical segment revenue is comprised of physician- administered products which could be adversely affected by the pandemic if it continues. The continued duration and severity of the COVID- 19 pandemic is uncertain and difficult to predict. The degree to which COVID- 19- related disruptions impact the Company' s results in 2023 will depend on future developments, beyond the Company' s knowledge or control, including governmental and third- party actions taken to contain or prevent the spread and treatment of the virus and mitigate its public health and economic effects. In addition, any future pandemic, epidemic or similar public health threat could present similar risks to the Company' s business, cash flow, results of operations, financial condition and prospects~~. The extent of the Company' s operations outside the U. S. is significant. Risks inherent in conducting a global business include: • changes in medical reimbursement policies and programs and pricing restrictions in key markets; • multiple regulatory requirements that could restrict the Company' s ability to manufacture and sell its products in key markets; • trade protection measures and import or export licensing requirements, including the imposition of trade sanctions or similar restrictions by the U. S. or other governments; • foreign exchange fluctuations; • diminished protection of intellectual property in some countries; and • possible nationalization and expropriation. In addition, there may be changes to the Company' s business ~~and political position~~ if there is instability, disruption or destruction in a significant geographic region, regardless of cause, including war, terrorism, riot, civil insurrection or social unrest; and natural or man- made disasters, including famine, flood, fire, earthquake, storm or disease. Events like these **, such as the ongoing war between Russia and Ukraine, and rising conflict in the Middle East,** could result in material adverse effects on macroeconomic conditions, currency exchange rates and financial markets **, and may adversely affect the Company' s business, results of operations and financial condition** . The Company believes that climate change has the potential to negatively affect its business and results of operations, cash ~~flows~~ **flow** and prospects. The Company is exposed to physical risks (such as extreme weather conditions **, inland flooding** or rising sea levels), risks in transitioning to a low- carbon economy (such as additional legal or regulatory requirements, changes in technology, market risk and reputational risk) and social and human effects (such as population dislocations and harm to health and well- being) associated with climate change. These risks can be either acute (short- term) or chronic (long- term). The adverse impacts of climate change include increased frequency and severity of natural disasters and extreme weather events such as hurricanes, tornados, wildfires (exacerbated by drought), flooding, and extreme heat. Extreme weather **, inland flooding** and sea- level rise pose physical risks to the Company' s facilities as well as those of its suppliers. Such risks include losses incurred as a result of physical damage to facilities, loss or spoilage of inventory, and business interruption caused by such natural disasters and extreme weather events. Other potential physical impacts due to climate change include reduced access to high- quality water in certain regions and the loss of biodiversity, which could impact future product development. These risks could disrupt the Company' s operations and its supply chain, which may result in increased costs. New legal or regulatory requirements may be enacted to prevent, mitigate, or adapt to the implications of a changing climate and its effects on the environment. These regulations, which may differ across jurisdictions, could result in the Company being subject to new or expanded carbon pricing or taxes, increased compliance costs, restrictions on greenhouse gas emissions, investment in new technologies, increased ~~carbon~~ **greenhouse gas emission** disclosure **(including costs resulting from mandatory or voluntary reporting, diligence or disclosure)** and transparency, **recurring** investments in data gathering and reporting systems, upgrades of facilities to meet new building codes, and the redesign of utility systems, which could increase the Company' s operating costs, including the cost of electricity and energy used by the Company. The Company' s supply chain would likely be subject to these same transitional risks and would likely pass along any increased costs to the Company, ~~all of~~ which may affect the Company' s ability to procure

raw materials or other supplies required for the operation of the Company' s business at the quantities and levels ~~we require~~ **required** . Governmental authorities, non- governmental organizations, customers, investors, external stakeholders and employees are increasingly sensitive to ESG concerns, such as diversity and inclusion, climate change, water use, recyclability or recoverability of packaging, and plastic waste. This focus on ESG concerns may lead to new requirements that could result in increased costs associated with developing, manufacturing and distributing the Company' s products **, and related reporting obligations** . The Company' s ability to compete could also be affected by changing customer preferences and requirements, such as growing demand for **validated net zero greenhouse gas emission targets and** more environmentally friendly products, packaging or supplier practices, or by failure to meet such customer expectations or demand. While the Company strives to improve its ESG performance and has set certain ESG goals and initiatives, the Company risks negative ~~stockholder~~ **shareholder** reaction, including from proxy advisory services, as well as damage to its brand and reputation **and inability to attract and retain employee talent** , if the Company fails to meet its goals and initiatives or otherwise does not act responsibly, or if the Company is perceived to not be acting responsibly, in key ESG areas, including equitable access to medicines and vaccines, product quality and safety, diversity and inclusion, environmental stewardship **, reduction of greenhouse gas emissions** , support for local communities, corporate governance and transparency, and addressing human capital factors in the Company' s operations. Responding to these ESG considerations and implementation of the Company' s ESG goals and initiatives involves risks and uncertainties, requires investments, and depends in part on third- party performance or data that is outside of the Company' s control. In addition, some stakeholders may disagree with the Company' s ESG goals and initiatives. If the Company does not meet the evolving and varied ESG expectations of its investors, customers and other stakeholders, the Company could experience reduced demand for its products, loss of customers, and other negative impacts on the Company' s business and results of operations **. In addition, the Company is subject to expanding ESG mandatory and voluntary reporting, diligence and disclosure requirements, including the EU' s Corporate Sustainability Reporting Directive (CSRD) and potentially the SEC' s proposed climate- related reporting requirements, the recently enacted legislation in California requiring reporting of greenhouse gas emissions and climate risk, and similar regulatory requirements in other jurisdictions. These evolving regulatory requirements are likely to result in increased costs and complexities of compliance in order to collect, measure and report on the relevant ESG- related information** . The Company' s success is largely dependent on its continued ability to attract and retain highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical research and development, governmental regulation and commercialization. Competition for qualified personnel in the pharmaceutical industry, both in the U. S. and internationally, is intense. The Company cannot be sure that it will be able to attract and retain quality personnel or that the costs of doing so will not materially increase. Merck has, in the past, experienced difficulties in manufacturing certain of its products, including vaccines. For example, in 2020 the Company issued a product recall for Zerbaxa following the identification of product sterility issues **and in 2023 the Company voluntarily recalled certain batches of Vaxneuvance in the U. S. due to instances of syringe breakage** . The Company may, in the future, experience other difficulties and delays in manufacturing its products, such as (i) failure of the Company or any of its vendors or suppliers to comply with Current Good Manufacturing Practices and other applicable regulations and quality assurance guidelines that could lead to manufacturing shutdowns, product shortages and delays in product manufacturing; (ii) delays related to the construction of new facilities or the expansion of existing facilities, including those intended to support future demand for the Company' s products; and (iii) other manufacturing or distribution problems including supply chain delays, shortages in raw materials, changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements, changes in types of products produced, or physical limitations that could impact continuous supply. As previously disclosed, the Company is working to reduce the level of nitrosamines in its sitagliptin-containing medicines such as Januvia. **The Company has made significant progress in reducing the level of nitrosamines and is now consistently releasing product in major markets that is expected to comply with the health authorities' long-term limit. However,** ~~Difficulties~~ **difficulties** in reducing those levels, or achieving timely regulatory approvals for required changes, could result in product shortages. In addition, the Company could experience difficulties or delays in manufacturing its products caused by natural disasters, such as hurricanes. Manufacturing difficulties can result in product shortages, leading to lost sales and reputational harm to the Company. The Company has been taking steps to increase its sales in emerging markets. However, there is no guarantee that the Company' s efforts to expand sales in these markets will succeed. Some countries within emerging markets may be especially vulnerable to periods of global financial instability or may have very limited resources to spend on health care. In order for the Company to **operate** successfully **in** ~~implement its~~ emerging markets ~~strategy~~ , it must attract and retain qualified personnel. The Company may also be required to increase its reliance on third- party agents within less developed markets, which may affect its ability to realize continued growth and may also increase the Company' s risk exposure. In addition, many of these countries have currencies that fluctuate substantially and, if such currencies devalue and the Company cannot offset the devaluations, the Company' s financial performance within such countries could be adversely affected. The Company' s business in China has grown rapidly in the past few years, and the importance of China to the Company' s overall pharmaceutical and vaccines business outside the U. S. has increased accordingly. In addition to its commercial operations, the Company has significant research and manufacturing operations in China **, including working with Chinese entities such as Wuxi Apptech Co., Ltd** . If geopolitical tensions were to increase and disrupt the Company' s operations in China, such disruption could result in a material adverse effect on the Company' s product development, sales, business, cash flow, results of operations, financial condition and prospects. Also, continued growth of the Company' s business in China is dependent upon ongoing development of a favorable environment for innovative pharmaceutical products and vaccines, sustained access for the Company' s currently marketed products, and the absence of trade impediments or adverse pricing controls. As noted above in **Item 1.** " Competition and the Health Care Environment, " pricing pressure in China has increased as the Chinese government has been taking steps to reduce costs, including implementing health care reform that has

led to the acceleration of generic substitution, where available. While the mechanism for drugs being added to the NRDL evolves, inclusion may require a price negotiation which could impact the outlook in the market for selected brands ~~. In 2021, drugs were added to the NRDL with an average of more than 60 % price reductions~~ . A new NRDL was recently completed in which new entries averaged 60 % price reductions. While pricing pressure has always existed in China, health care reform has increased this pressure in part due to the acceleration of generic substitution through the government' s VBP program. In 2019, the government implemented the VBP program through a tendering process for mature products which have generic substitutes with a Generic Quality Consistency Evaluation approval. Mature products that have entered into the last five rounds of VBP had, on average, a price reduction of more than 50 %. The Company expects VBP to be a semi- annual process that will have a significant impact on mature products moving forward. For all these reasons, sales within emerging markets carry significant risks. However, at the same time, macro **-** economic growth of selected emerging markets is expected to **lead** ~~outpace Europe and even the U. S., leading~~ to significant increased health care spending in those countries and access to innovative medicines for patients. A failure to maintain the Company' s presence in emerging markets could therefore have a material adverse effect on the Company' s business, cash flow, results of operations, financial condition and prospects. The ~~ongoing war between Russia and Ukraine, and the financial and economic sanctions imposed by the U. S., the EU and other countries in response, are having pervasive direct and indirect effects on the global economy, and may adversely affect the Company' s business, results of operations and financial condition. The Company is working cross- functionally across the globe to monitor and mitigate interruptions to business continuity resulting from the war, including its impact on Merck' s supply chain, operations and clinical trials. For humanitarian reasons, the Company is continuing to supply essential medicines and vaccines in Russia while working to maintain compliance with international sanctions. Merck is donating profits resulting from its operations in Russia to humanitarian causes. The Company does not have research or manufacturing facilities in Russia, currently does not plan to make further investments in Russia, and has suspended screening and enrollment in ongoing clinical trials as well as planning for new studies in Russia, although the Company continues to treat patients already enrolled in existing clinical trials and collect data from these studies. The financial impacts of the war between Russia and Ukraine were immaterial to the Company' s consolidated financial statements in 2022. However, the degree to which the war and related disruptions will impact the Company' s results in the future is difficult to predict and will depend on developments outside of the Company' s control, including, but not limited to, the duration and severity of the war, ongoing and additional financial and economic sanctions imposed by governments in response, restrictions on travel, regional instability, geopolitical shifts, and adverse effects on fuel and energy costs, supply chains, macroeconomic conditions, currency exchange rates and financial markets. Such developments may negatively impact the Company directly or indirectly as well as the parties with which the Company conducts business. In addition, the effects of the war between Russia and Ukraine could heighten other risks disclosed herein, which could materially adversely affect the Company' s business, results of operations and financial condition. The~~ Company operates in multiple jurisdictions and virtually all sales are denominated in currencies of the local jurisdiction. Additionally, the Company has entered and will enter into business development transactions, borrowings or other financial transactions that may give rise to currency and interest rate exposure. Since the Company cannot, with certainty, foresee and mitigate against such adverse ~~fluctuations~~ **changes** , fluctuations in currency exchange rates, interest rates and inflation could negatively affect the Company' s business, cash flow, results of operations, financial condition and prospects **. For example, Argentina is currently experiencing hyperinflation, which is affecting the Company' s operations in that market** . In order to mitigate against the adverse impact of these market fluctuations, the Company will from time to time enter into hedging agreements. While hedging agreements, such as currency options and forwards and interest rate swaps, may limit some of the exposure to exchange rate and interest rate fluctuations, such attempts to mitigate these risks may be costly and not always successful. ~~A portion of Merck' s indebtedness bears interest at variable interest rates, primarily based on the London Interbank Offered Rate (LIBOR). LIBOR is the subject of national, international and other regulatory guidance and proposals for reform, which will cause LIBOR to cease to exist entirely in the future. While the Company has begun to implement alternative reference rates as alternatives to LIBOR, the Company cannot predict the consequences and timing of any additional or unexpected developments, which could include an increase in interest expense.~~ Unexpected safety or efficacy concerns can arise with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals, or declining sales, as well as product liability, consumer fraud and / or other claims, including potential civil or criminal governmental actions. The Company depends on third parties, including suppliers **, distributors** , alliances with other pharmaceutical and biotechnology companies, and third- party service providers, for key aspects of its business including development, manufacture and commercialization of its products and support for its information technology (IT) systems. Failure of these third parties to meet their contractual, regulatory and other obligations to the Company or the development of factors that materially disrupt the relationships between the Company and these third parties could have a material adverse effect on the Company' s business. Future sales of key animal health products could be adversely affected by a number of risk factors including certain risks that are specific to the animal health business. For example, the outbreak of disease carried by animals, such as African Swine Fever **or Avian Influenza** , could lead to their widespread death and precautionary destruction as well as the reduced consumption and demand for animals, which could adversely affect the Company' s results of operations. Also, the outbreak of any highly contagious diseases near the Company' s main production sites could require the Company to immediately halt the manufacture of its animal health products at such sites or force the Company to incur substantial expenses in procuring raw materials or products elsewhere. Other risks specific to animal health include epidemics and pandemics **affecting livestock** , government procurement and pricing practices, weather and global agribusiness economic events. In addition, in ~~2022~~ **2023** , sales of Bravecto were $ 1. ~~0~~ **1** billion, which represented ~~approximately~~ 19 % of the Company' s Animal Health segment sales. Any negative event with respect to Bravecto could have a material adverse effect on the Company' s Animal Health sales. If the Animal Health segment of the Company' s business becomes more significant, the impact of any such events on future results of operations could also become more significant. The

successful development, testing, manufacturing and commercialization of biologics and vaccines, particularly human and animal health vaccines, is a long, complex, expensive and uncertain process. There are unique risks and uncertainties related to biologics and vaccines, including: • There may be limited access to, and supply of, normal and diseased tissue samples, cell lines, pathogens, bacteria, viral strains and other biological materials. In addition, government regulations in multiple jurisdictions, such as the U. S. and the EU, could result in restricted access to, or transport or use of, such materials. If the Company loses access to sufficient sources of such materials, or if tighter restrictions are imposed on the use of such materials, the Company may not be able to conduct research activities as planned and may incur additional development costs. • The development, manufacturing and marketing of biologics and vaccines are subject to regulation by the FDA, the EMA and other regulatory bodies. These regulations are often more complex and extensive than the regulations applicable to other pharmaceutical products. For example, in the U. S., a BLA, including both preclinical and clinical trial data and extensive data regarding the manufacturing procedures, is required for human vaccine candidates, and FDA approval is generally required for the release of each manufactured commercial human vaccine lot. • Manufacturing biologics and vaccines, especially in large quantities, is ~~often~~ complex and may require the use of innovative technologies to handle living micro- organisms. Each lot of an approved biologic and vaccine must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, the Company may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the ~~products~~ **biologics and vaccines** before and after such changes. • Biologics and vaccines are ~~frequently~~ costly to manufacture because production ingredients are derived from living animal or plant material, and most biologics and vaccines cannot be made synthetically. In particular, keeping up with the demand for vaccines may be difficult due to the complexity of producing vaccines. • The use of biologically derived ingredients can lead to variability in the manufacturing process and could lead to allegations of harm, including infections or allergic reactions, which allegations would be reviewed through a standard investigation process that could lead to closure of product facilities due to possible contamination. Any of these events could result in substantial costs. Risks Relating to Government Regulation and Legal Proceedings As discussed above in **Item 1.** " Competition and the Health Care Environment, " the Company believes that the health care industry will continue to be subject to increasing regulation as well as political and legal action, as future proposals to reform the health care system are considered by the Executive branch, Congress and state legislatures. In 2022, Congress passed the **IRA** ~~Inflation Reduction Act~~, which makes significant changes to how drugs are covered and paid for under the Medicare program, including the creation of financial penalties for drugs whose prices rise faster than the rate of inflation, redesign of the Medicare Part D program to require manufacturers to bear more of the liability for certain drug benefits, and government price- setting for certain Medicare Part D drugs, starting in 2026, and Medicare Part B drugs starting in 2028. **As noted in Item 1. " Competition and the Health Care Environment, " in 2023, HHS included Januvia in the first year of the IRA' s price setting program, which absent further legislative or court intervention will result in a government set price becoming effective on January 1, 2026. Furthermore, the Company anticipates that HHS will include Keytruda in a subsequent selection of products to undergo IRA price setting, with such price likely to be effective in early 2028.** In addition, in 2021, Congress passed the American Rescue Plan Act, which included a provision that eliminates the statutory cap on rebates drug manufacturers pay to Medicaid beginning in January 2024. These rebates act as a discount off the list price and eliminating the cap means that manufacturer discounts paid to Medicaid can increase. Prior to this change, manufacturers have not been required to pay more than 100 % of the Average Manufacturer Price (AMP) in rebates to state Medicaid programs for Medicaid- covered drugs. As a result of this provision, beginning in 2024, ~~it is possible that~~ manufacturers may have to pay state Medicaid programs more in rebates than they received on sales of particular products. This change ~~could present~~ **presents** a risk to Merck ~~in the future~~ for drugs that have high Medicaid utilization and rebate exposure that is more than 100 % of the AMP. In the U. S., the Biden Administration and Congress continue to discuss legislation designed to control health care costs, including the cost of drugs. The Company cannot predict what additional future changes in the health care industry in general, or the pharmaceutical industry in particular, will occur; however, any changes could have a material adverse effect on the Company' s business, cash flow, results of operations, financial condition and prospects. The Company' s activities, including research, preclinical testing, clinical trials and the manufacturing and marketing of its products, are subject to extensive regulation by numerous federal, state and local governmental authorities in the U. S., including the FDA, and by foreign regulatory authorities, including in the EU, Japan and China. In the U. S., the FDA administers requirements covering the testing, approval, safety, effectiveness, manufacturing, labeling and marketing of prescription pharmaceuticals and vaccines. In some cases, the FDA requirements have increased the amount of time and resources necessary to develop new products and bring them to market in the U. S. Regulation outside the U. S. also is primarily focused on drug safety and effectiveness and, in many cases, reduction in the cost of drugs. The FDA and foreign regulatory authorities, including in the EU, Japan and China, have substantial discretion to require additional testing, to delay or withhold registration and marketing approval and to otherwise preclude distribution and sale of a product. Even if the Company is successful in developing new products, it will not be able to market any of those products unless and until it has obtained all required regulatory approvals **(which in limited circumstances may include authorizations for emergency use)** in each jurisdiction where it proposes to market the new products. Once obtained, the Company must maintain approval as long as it plans to market its new products in each jurisdiction where approval is required. The Company' s failure to obtain approval, significant delays in the approval process, or its failure to maintain approval in any jurisdiction will prevent it from selling the products in that jurisdiction **and** ~~. The Company would not be able to realize~~ **realizing sales** ~~revenues for those new products in any jurisdiction where it does not have approval~~. Even after a product reaches the market, certain developments following

regulatory approval may decrease demand for the Company' s products, including the following: • results in post- approval Phase 4 trials or other studies; • the re- review of products that are already marketed; • the recall or loss of marketing approval of products that are already marketed; • changing government standards or public expectations regarding safety, efficacy, quality or labeling changes; • scrutiny of advertising and promotion; and • the withdrawal of indications granted pursuant to accelerated approvals. In the past, clinical trials and post- marketing surveillance of certain marketed drugs of the Company and of competitors within the industry have raised concerns that have led to recalls, withdrawals or adverse labeling of marketed products. Clinical trials and post- marketing surveillance of certain marketed drugs also have raised concerns among some prescribers and patients relating to the safety or efficacy of pharmaceutical products in general that have negatively affected the sales of such products. In addition, increased scrutiny of the outcomes of clinical trials has led to increased volatility in market reaction. Further, these matters often attract litigation and, even where the basis for the litigation is groundless, considerable resources may be needed to respond. In addition, following in the wake of product withdrawals and other significant safety issues, health authorities such as the FDA, the EMA, Japan' s PMDA and China' s NMPA have increased their focus on safety when assessing the benefit / risk balance of drugs. Some health authorities appear to have become more cautious when making decisions about approvability of new products or indications. If previously unknown side effects are discovered or if there is an increase in negative publicity regarding known side effects of any of the Company' s products, it could significantly reduce demand for the product or require the Company to take actions that could negatively affect sales, including removing the product from the market, restricting its distribution or applying for labeling changes. Further, in the current environment in which all pharmaceutical companies operate, the Company is at risk for product liability and consumer protection claims and civil and criminal governmental actions related to its products, research and / or marketing activities. In addition, dissemination of promotional materials through evolving digital channels serves to increase visibility and scrutiny in the marketplace. The Company is currently subject to a number of government laws and regulations and, in the future, could become subject to new government laws and regulations. The costs of compliance with such laws and regulations, or the negative results of non- compliance, could adversely affect the business, cash flow, results of operations, financial condition and prospects of the Company; these laws and regulations include (i) additional health care reform initiatives in the U. S. or in other countries, including additional mandatory discounts or fees; (ii) the U. S. Foreign Corrupt Practices Act (FCPA) or other anti- bribery and corruption laws; (iii) new laws, regulations and judicial or other governmental decisions affecting pricing, drug reimbursement, and access or marketing within or across jurisdictions; (iv) changes in intellectual property laws; (v) changes in accounting standards; (vi) new and increasing data privacy regulations and enforcement, particularly in the EU, the U. S., and China; (vii) legislative mandates or preferences for local manufacturing of pharmaceutical or vaccine products; (viii) emerging and new global regulatory requirements for reporting payments and other value transfers to health care professionals; (ix) environmental regulations **, such as the EU' s CSRD** ; and (x) the potential impact of importation restrictions, embargoes, trade sanctions and legislative and / or other regulatory changes. The Company is subject to evolving and complex tax laws in the jurisdictions in which it operates. Significant judgment is required for determining the Company' s tax liabilities, and the Company' s tax returns are routinely examined by various tax authorities. In connection with the Organization for Economic Cooperation and Development (OECD) Base Erosion and Profit Shifting project, companies are required to disclose more information to tax authorities on operations around the world, which may lead to greater audit scrutiny of profits earned in other countries. The Company believes that its accrual for tax contingencies is adequate for all open years based on past experience, interpretations of tax law, and judgments about potential actions by tax authorities; however, due to the complexity of tax contingencies, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued. In addition, the Company may be negatively affected by changes in tax laws, or new tax laws, affecting, for example, tax rates, and / or revised tax law interpretations in domestic or foreign jurisdictions, including, among others, any potential changes to the existing U. S. tax law by the current U. S. Presidential administration and Congress, as well as any changes in tax law resulting from the implementation of the OECD' s two- pillar solution to reform the international tax landscape. The Company has taken the position, based on the opinions of tax counsel, that its distribution of Organon common stock in connection with the 2021 Spin- Off qualifies as a transaction that is tax- free for U. S. federal income tax purposes. If any facts, assumptions, representations, and undertakings from the Company and Organon regarding the past and future conduct of their respective businesses and other matters are incorrect or not otherwise satisfied, the Spin- Off may not qualify for tax- free treatment, which could result in significant U. S. federal income tax liabilities for the Company and its shareholders. Current or future litigation, claims, proceedings and government investigations could preclude or delay the commercialization of Merck' s products or could adversely affect Merck' s business, results of operations, cash flow, prospects and financial condition. Such legal matters may include, but are not limited to: (i) intellectual property disputes; (ii) adverse decisions in litigation, including product safety and liability, consumer protection and commercial cases; (iii) anti- bribery regulations, such as the FCPA, including compliance with ongoing reporting obligations to the government resulting from any settlements; (iv) recalls or withdrawals of pharmaceutical products or forced closings of manufacturing plants; (v) product pricing and promotional matters; (vi) lawsuits, claims and administrative proceedings asserting, or investigations into, violations of securities, antitrust, Federal and state pricing, consumer protection, data privacy and other laws and regulations; (vii) environmental, health, safety and sustainability matters, including regulatory actions in response to climate change; and (viii) tax liabilities resulting from assessments from tax authorities. ~~As previously disclosed, Merck, along with certain subsidiaries, are defendants in a number of lawsuits filed starting in 2018 on behalf of direct and indirect purchasers of Zetia (ezetimibe) alleging violations of federal and state antitrust laws, as well as other state statutory and common law causes of action. The lawsuits filed on behalf of twenty- five direct purchasers, eight retailers, and a class of indirect purchasers are scheduled to proceed to trial on April 17, 2023. In these cases, plaintiffs seek up to a maximum of $ 12. 7 billion in damages after trebling.~~ See Item 8. " Financial Statements and Supplementary Data, " Note 11, " Contingencies and Environmental Liabilities " for more information on the Company' s legal matters. As a result of a number of

factors, product liability insurance has become less available while the cost of such insurance has increased significantly. The Company is subject to a substantial number of product liability claims. See Item 8. " Financial Statements and Supplementary Data, " Note 11. " Contingencies and Environmental Liabilities " below for more information on the Company' s current product liability litigation. With respect to product liability, the Company self- insures substantially all of its risk, as the availability of commercial insurance has become more restrictive. The Company has evaluated its risks and has determined that the cost of obtaining product liability insurance outweighs the likely benefits of the coverage that is available and, as such, has no insurance for most product liabilities. The Company will continually assess the most efficient means to address its risk; however, there can be no guarantee that insurance coverage will be obtained or, if obtained, will be sufficient to fully cover product liabilities that may arise. Risks Related to Technology The Company is increasingly dependent on sophisticated software applications, complex information technology systems, computing infrastructure, and cloud service providers (collectively, IT systems) to conduct critical operations **and financial reporting** . Certain of these systems are managed, hosted, provided or used by third parties to assist in conducting the Company' s business. Disruption, degradation, or manipulation of these IT systems through intentional or accidental means by the Company' s employees, third parties with authorized access or unauthorized third parties could adversely affect key business processes. Cyber- attacks against the Company' s IT systems or third- party providers' IT systems, such as cloud- based systems, could result in exposure of confidential information, the modification of critical data, and / or the failure of critical operations. Misuse of any of these IT systems could result in the disclosure of sensitive personal information or the theft of trade secrets, intellectual property, or other confidential business information. The Company continues to leverage new and innovative technologies across the enterprise to replace outmoded technology and improve the efficacy and efficiency of its business processes, including data acquisition; the use of which can create new risks. **In addition, the Company' s Animal Health business sells technology products that, when deployed, could potentially be compromised by a third party and cause disruption both internally and externally.** Although the aggregate impact of cyber- attacks and network disruptions on the Company' s operations and financial condition has not been material to date, the Company continues to be a target of events of this nature and expects them to continue. The Company monitors its data, information technology and personnel usage of Company IT systems **to identify and attempt** to reduce these risks and continues to do so on an ongoing basis for any current or potential threats. There can be no assurance that the Company' s efforts to protect its data and IT systems or the efforts of third- party providers to protect their IT systems will be successful in preventing disruptions to the Company' s operations, including its manufacturing, research **,** and sales operations. Such disruptions have in the past and could in the future result in loss of revenue, or the loss of critical or sensitive information from the Company' s or the Company' s third- party providers' databases or IT systems and have in the past and could in the future also result in financial, legal, business or reputational harm to the Company and substantial remediation costs **. The Company' s growing use of artificial intelligence (AI) systems to automate processes, analyze data, and support decision-making poses inherent risks. Flaws, biases, or malfunctions in these systems could lead to operational disruptions, data loss, or erroneous decision- making, impacting the Company' s business operations, financial condition, and reputation. Ethical and legal challenges may arise, including biases or discrimination in AI outcomes, non- compliance with data protection regulations, and lack of transparency. Furthermore, the deployment of AI systems could expose the Company to increased cybersecurity threats, such as data breaches and unauthorized access leading to financial losses, legal liabilities, and reputational damage. The Company also faces competitive risks if it fails to adopt AI or other machine learning technologies in a timely fashion** . The inappropriate and / or unauthorized use of certain social media and mobile messaging channels could cause brand damage or information leakage or could lead to legal implications, including from the improper collection and / or dissemination of personally identifiable information. In addition, negative or inaccurate posts or comments about the Company or its products on any social networking platforms could damage the Company' s reputation, brand image and goodwill. Further, the disclosure of non- public Company- sensitive information by the Company' s workforce or others through external media channels could lead to information loss. Although there are internal Company Social Media and Mobile Messaging Policies that guide employees on appropriate personal and professional use of these platforms for communication about the Company, the processes in place may not completely secure and protect information. Identifying new points of entry as new communication tools expand also presents new challenges. (Cautionary Statements Under the Private Securities Litigation Reform Act of 1995) This report and other written reports and oral statements made from time to time by the Company may contain so- called " forward- looking statements, " all of which are based on management' s current expectations and are subject to risks and uncertainties which may cause results to differ materially from those set forth in the statements. One can identify these forward- looking statements by their use of words such as " anticipates, " " expects, " " plans, " " will, " " estimates, " " forecasts, " " projects " and other words of similar meaning, or negative variations of any of the foregoing. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address the Company' s growth strategy, financial results, product approvals, product potential, development programs, environmental or other sustainability initiatives ~~, and may include statements related to the expected impact of the COVID- 19 pandemic~~ . One must carefully consider any such statement and should understand that many factors could cause actual results to differ materially from the Company' s forward- looking statements. These factors include inaccurate assumptions and a broad variety of other risks and uncertainties, including some that are known and some that are not. No forward- looking statement can be guaranteed and actual future results may vary materially. The Company does not assume the obligation to update any forward- looking statement. The Company cautions you not to place undue reliance on these forward-looking statements. Although it is not possible to predict or identify all such factors, they may include the following: • Competition from generic and / or biosimilar products as the Company' s products lose patent protection. • Increased " brand " competition in therapeutic areas important to the Company' s long- term business performance. • The difficulties and uncertainties inherent in new product development. The outcome of the lengthy and complex process of new product

development is inherently uncertain. A drug candidate can fail at any stage of the process and one or more late- stage product candidates could fail to receive regulatory approval. New product candidates may appear promising in development but fail to reach the market because of efficacy or safety concerns, the inability to obtain necessary regulatory approvals, the difficulty or excessive cost to manufacture and / or the infringement of patents or intellectual property rights of others. Furthermore, the sales of new products may prove to be disappointing and fail to reach anticipated levels. • Pricing pressures, both in the U. S. and abroad, including rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and health care reform, pharmaceutical reimbursement and pricing in general. • ~~The impact of the global COVID- 19 pandemic and any future pandemic, epidemic, or similar public health threat, on the Company' s business, operations, financial performance and prospects. •~~ Changes in government laws and regulations, including laws governing intellectual property, and the enforcement thereof affecting the Company' s business. • Efficacy or safety concerns with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals or declining sales. • Significant changes in customer relationships or changes in the behavior and spending patterns of purchasers of health care products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing health care insurance coverage. • Legal factors, including product liability claims, antitrust litigation and governmental investigations, including tax disputes, environmental concerns and patent disputes with branded and generic competitors, any of which could preclude commercialization of products or negatively affect the profitability of existing products. • Cyber- attacks on the Company' s or third- party providers' information technology systems, which could disrupt the Company' s operations. • Lost market opportunity resulting from delays and uncertainties in the approval process of the FDA and **/ or** foreign regulatory authorities. • Increased focus on privacy issues in countries around the world, including the U. S., the EU, and China. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect directly the Company' s business, including laws in a majority of states in the U. S. requiring security breach notification. • Changes in tax laws including changes related to the taxation of foreign earnings. • Changes in accounting pronouncements promulgated by standard- setting or regulatory bodies, including the Financial Accounting Standards Board and the SEC, that are adverse to the Company. • Economic factors over which the Company has no control, including changes in inflation, interest rates and foreign currency exchange rates. This list should not be considered an exhaustive statement of all potential risks and uncertainties. See " Risk Factors " above.