

Risk Factors Comparison 2025-02-28 to 2024-02-26 Form: 10-K

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You should carefully consider the following risks and other information in this Annual Report on Form 10-K in evaluating us and deciding to invest in our Common Stock. Any of the following risks could materially and adversely affect our results of operations, financial condition and the price of our Common Stock. Summary of Risk Factors The following is a summary of the principal risks that could significantly and negatively affect our business, prospects, financial conditions, or operating results. For a more complete discussion of the material risks facing our business, please see below: Risks Related to Our Business • Key products generate a significant amount of our profits and cash flows, and any events that adversely affect the markets for our leading products could adversely affect our results of operations and financial condition. • We face continued pricing pressure with respect to our products. ~~16~~ We face intense competition from competitors' products. • We have limited in-house discovery and early research capabilities and will continue to rely on future acquisitions, partnerships and collaborations to expand our innovative pipeline and early discovery and research capabilities, which may limit our ability to discover or develop new products or expand our existing products into new markets to replace the sales of products that lose patent protection and therefore we may not be able to maintain our current levels of profitability. • Our growth could be limited by the scope of our intellectual property licenses for certain women's health care products. • We **rely on third parties for activities related to preclinical and clinical testing.** • We may experience difficulties identifying **future** acquisition opportunities or completing such transactions. ~~We or~~ **Even if we complete such transactions, we may have difficulty integrating our or otherwise realizing** partners may fail to demonstrate the **benefits** safety and efficacy of **such acquisitions** any of our product candidates in pre-clinical and clinical trials, which would prevent or delay development, regulatory approval or clearance, and commercialization of our product candidates. • We may be unable to market our pharmaceutical products or medical devices if we do not obtain and maintain required regulatory approvals or marketing authorizations. • **We and / or our partners may fail to demonstrate the safety and efficacy of any of our product candidates in pre-clinical and clinical trials, which would prevent or delay development, regulatory approval or clearance, and commercialization of our product candidates.** • Developments following regulatory approval or marketing authorization may adversely affect sales of our pharmaceutical products or medical devices. • **Disruptions at the FDA, the SEC and other comparable foreign government agencies caused by funding shortages or other events could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions, which could negatively impact our business.** • Issues with product 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. • Certain of our products currently benefit from patent protection and market exclusivity. When the patent protection and market exclusivity periods for such products expire, a significant and rapid loss of sales from those products is generally experienced. Expiry of patent protection and market exclusivity for products that contribute significantly to our sales will adversely affect our business. • We depend on our patent rights for the marketing of certain of our products, and invalidation or circumvention of our patent rights would adversely affect our business. • We have incurred substantial indebtedness, which could adversely affect our financial condition and results of operations. • We are subject to minimum purchase obligations under certain supply agreements, and if we fail to meet those minimum purchase requirements, our financial results may be unfavorably impacted. ~~Risks Related to the Spinoff~~ ~~Merek~~ **The health care industry in the United States has been, and will continue to be, subject to judicial decisions and increasing laws, regulation, executive orders and political action.** • We are subject to a variety of laws and regulations, and we may face serious consequences for violations if we fail to meet the applicable legal and regulatory requirements. • **We or our third-party suppliers, logistics, and manufacturers** may not **comply with ethical business practices** satisfy its obligations under various transition agreements that have been or **with related laws** will be executed as part of the spinoff or we may not have necessary systems and **regulations, including relating to AI use** services in place when certain of the transition agreements expire. • **Our business** Potential indemnification liabilities to Merck pursuant to the Separation and Distribution Agreement could adversely affect us **operations are subject to risks related to climate change and natural disasters.** • There **Our business** could be significant income tax liability to us if **negatively impacted by corporate citizenship and sustainability matters.** ~~18~~ • **Our corporate restructuring and the spinoff or certain related transactions associated headcount reduction may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business** determined to be taxable for U. S. federal income tax purposes. ~~Risks Related to Our Common Stock~~ • The price and trading volume of our Common Stock may be volatile, and stockholders could lose all or part of their investment **in us.** • We cannot guarantee the timing, amount or payment of any dividends on our Common Stock. • Certain provisions in our amended and restated certificate of incorporation and bylaws, and of Delaware law, may prevent or delay an acquisition of ~~Organon us~~, which could decrease the trading price of our Common Stock. • Our amended and restated bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, and the United States federal district courts as the exclusive forum for claims under the Securities Act of 1933, as amended (the "Securities Act"), which could limit our stockholders' ability to obtain what such stockholders believe to be a favorable judicial forum for disputes with us or our directors, officers or employees. ~~17~~ Our ability to generate profits and operating cash flow depends largely upon the continued profitability of our key products, such as Nexplanon, **Arcoxia** ~~Cozaar / Hyzaar~~, Singulair and the ezetimibe family of products. As a result of our dependence on key

products, any event that adversely affects any of these products or the markets for any of these products could adversely affect our sales, results of operations or cash flows. These adverse events could include increased costs associated with manufacturing, product shortages, increased generic or over-the-counter availability of our products or competitive products, 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 these products for any reason. We also expect that competition will continue to adversely affect the sales of these products **(including generic competition as a result of LOE in 2024 for Atozet and, if we are unable to obtain an additional period of market exclusivity for Nexplanon)**. We face continued pricing pressure in the United States and globally and, particularly in the EU, the **UK-United Kingdom**, China and Japan, from managed care organizations, government agencies and programs that could adversely affect our sales and profit margins. We expect pricing pressure to continue in the future. Changes to the health care system **due to enacted as part of** health care reform in the United States, 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. In addition, in the United States, larger customers have received higher rebates on drugs in certain highly competitive categories. We must also compete to be placed on formularies of managed care organizations and other payors. Exclusion of a product from a formulary can lead to reduced usage in the population covered by the managed care organization or other payor. Outside the United States, numerous major markets, **including such as** the EU, the **UK-United Kingdom**, China and Japan, have **pervasive-active** government involvement **including in health care funding and, in that regard,** extensive pricing and reimbursement mechanisms and processes for pharmaceutical products **affecting**. ~~Consequently, in those markets, we are subject to government decision-making and budgetary actions with respect to~~ our products. Cost containment efforts by governments and private organizations are described in greater detail in the Business-Regulatory section above. Our products face intense competition from competitors' **1** products, including **lower-cost** generic versions of our products that have lost market exclusivity. Competitors' **2** products may be equally safe and as effective as our products but sold at a substantially lower price than our products. Alternatively, our competitors' **3** 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 our products. Our efforts to compete with other companies' **4** products or our failure to maintain **our the** competitive position **of our products** could adversely affect our business, cash flow, results of operations, financial condition or prospects. **19-** We have limited in-house discovery and early research capabilities and will continue to rely on future acquisitions, partnerships and collaborations to expand our innovative pipeline and early discovery and research capabilities, which may limit our ability to discover or develop new products or expand our existing products into new markets to replace the sales of products that lose patent protection, and therefore we may not be able to maintain our current levels of profitability. We have limited in-house discovery and early research staff and facilities, and we do not currently intend to extensively hire or acquire such staff or facilities in the near future. Instead, we intend to continue to rely on future acquisitions, partnerships and collaborations with third parties to expand our innovative pipeline, existing portfolio and innovation and early research capabilities. However, we may be unable to establish any agreements with third-party developers or manufacturers or do so on favorable terms. Further, should we be able to enter into such agreements, these agreements may pose risks, including that we would be reliant on and accountable for the third-party **5**'s knowledge and capabilities, data, quality of operations and compliance **to-with** regulations, and other systems to conduct clinical trials, prepare regulatory application submissions and required post-approval reports, manufacture or distribute product, or other activities. ~~18-~~ We intend to grow our business through new indications or formulations of our existing products or expansion of existing products into new markets or new geographies. However, ~~we expect that~~ our ability to do so could be limited by the scope of our limited intellectual property licenses for certain women **6**'s health products. ~~For example, a license from Merck for Nexplanon permits use of the underlying technology solely as a contraceptive implant containing only the active pharmaceutical ingredient currently used in the product. Additionally, in December 2021, we signed a supplemental license with Merck that provides a limited expansion of the fields in which we may use the underlying technology of Nexplanon beyond contraception in exchange for milestone payments.~~ We may not be able to offset any sales losses for products that lose or do not have exclusivity by growing sales in other markets. If we cannot produce sufficient revenues from expansion into new products, new indications or formulations of our existing products or expansion of existing products into new markets or new geographies, then we may not be able to maintain our current levels of profitability, and this could adversely affect our business, cash flow, results of operations, financial condition or prospects. We rely on third parties **for activities related to preclinical and clinical testing.** ~~We rely on third parties~~ to manufacture and **7**, distribute and conduct certain preclinical and clinical testing activities for our products. Oversight of these third parties can require substantial resources and creates potential risks to us, including: we may be unable to establish agreements with third parties, including third party manufacturers, on acceptable terms or even at all; we may not have sufficient quantities of product; third parties may fail to perform delegated responsibilities to an acceptable level of quality, or may fail to comply with regulatory requirements; or third parties may misappropriate or disclose our proprietary information, including trade secrets and know-how. Our reliance on third parties for research and development activities will also reduce our control over these activities but does not relieve us of our responsibilities, including that we must ensure that clinical trials are conducted in accordance with the general investigational plan and protocols for the trial; ensure compliance with regulatory standards like good clinical practices; and register ongoing clinical trials and results to government-sponsored databases. Our failures, or the failure of third parties, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions. Further, issues related to manufacture of product, preclinical testing, and / or clinical testing may affect our ability to obtain or maintain marketing approval for our products in a timely manner, or at all. This may hinder or delay efforts to successfully commercialize our product candidates. ~~We~~ **As part of our business strategy to expand our product offerings and geographic presence, we** intend to continue

pursuing acquisitions of complementary businesses, licensing arrangements and strategic partnerships **such to expand our product offerings and geographic presence as part our acquisition of Dermavant and our agreements with Centergene and Lilly to promote Emgality and Rayvow in Europe. However, we may experience difficulties identifying future acquisition opportunities** our or business strategy. We may not complete **completing these such** transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the expected benefits of any acquisition, license arrangement or strategic partnerships. Such opportunities may relate to products, technologies or operations with which we have limited or no historical experience. Many of our competitors for these opportunities are well established and have extensive experience identifying and effecting these types of strategic acquisitions. Moreover, some of these competitors may possess greater financial, technical, human and other resources than we do. **Further, any future transactions may not be completed in a timely manner, on a cost-effective basis, or at all, and we may not realize the expected benefits of any acquisition, license arrangement or strategic partnerships. For example, there are risks associated with regulatory approval of any product we may acquire, and even if approved, such approvals may not be secured in the timeframes we anticipate. See “ We may be unable to market our pharmaceutical products or medical devices if we do not obtain and maintain required regulatory approvals or marketing authorizations ” below. In addition, such acquisition opportunities may relate to products, technologies or operations with which we have limited or no historical experience.- 20-** Even if we are successful in making acquisitions **or entering into other business development arrangements**, the products and technologies we acquire may not be successful or may require significantly greater resources and investments than we originally ~~anticipated-~~ **anticipate, including due to material issues that we fail to identify in connection with our due diligence of the counterparty and its products or product candidates**. We could experience negative effects on our results of operations and financial condition from acquisition-related charges, amortization of intangible assets and asset impairment charges. ~~We~~ **Integrating acquired businesses could lead us to experience difficulties in integrating- numerous risks related to combining** geographically separated organizations, systems and facilities, and personnel with diverse backgrounds ~~-If, as well as encountering unforeseen cybersecurity risks an and breaches from the businesses acquired business fails to operate as anticipated or cannot be successfully integrated with our- or existing business,~~ **their manufacturers and vendors and unforeseen product liability matters. Any of the foregoing could materially and adversely affect** our business, financial condition, results of operations or cash flows ~~could be materially and adversely affected~~. Our activities, including the manufacturing and marketing of our pharmaceutical products and medical devices, are subject to extensive regulation by numerous federal, state and local ~~provincial state~~ governmental authorities in the United States, including the FDA, and by ~~foreign~~ regulatory authorities ~~;~~ **including** in the EU, the UK, China and Japan. In the United States, the FDA administers requirements covering the laboratory testing, clinical trials, clearance, approval, safety, effectiveness, manufacturing, labeling and marketing of prescription pharmaceuticals and medical devices. Regulation of our pharmaceutical products outside the United States also is primarily focused on ~~drug product~~ safety and effectiveness and, in many cases, reduction in ~~the product~~ cost of drugs. In addition, regulatory authorities ~~in the United States and internationally~~ have increased their focus on safety when assessing the benefit / risk balance of ~~drugs~~ **pharmaceutical products**. These regulatory authorities, including in China and Japan, also have substantial discretion to require additional testing in local populations, to delay or withhold registration and marketing approval ~~- 19-~~ and to otherwise preclude distribution and sale of a product. We ~~currently market one product in the United.....~~ **marketing activities in those countries. We** cannot market **or sell** our pharmaceutical products or medical devices or new indications or modifications to our existing products unless and until we have obtained all required regulatory approvals or marketing authorizations in each relevant jurisdiction. Our applications or submissions for regulatory approval or marketing authorization may be rejected or otherwise delayed by the FDA or other ~~foreign~~ regulatory authorities. ~~For example, It is possible that~~ the FDA ~~may could~~ issue complete response letters indicating that **any of** our applications for our pharmaceutical products are not ready for approval. ~~Once~~ **Even if the requisite approvals are** obtained, we must maintain **such approval approvals** or marketing **authorization authorizations** as long as we plan to market products in each jurisdiction where approval or marketing authorization is required. **For instance, we** currently market one product in the United States regulated as a medical device, Jada ~~(acquired through our acquisition of Alydia Health, as described elsewhere in this report)~~. We currently market Jada outside of the United States in a number of international markets and **it** is subject to the regulatory requirements imposed in those jurisdictions. In the future, we also plan to continue to sell **Jada** ~~our medical devices~~ in additional major international markets and **it** will be subject to the regulatory requirements imposed in those jurisdictions. For example, in order to sell medical devices in **the EU member countries,** we **will need to comply with the EU’s Medical Device Regulation.** The FDA or other regulators may **also** change their policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay regulatory approval or marketing authorization of our future products or impact our ability to modify our currently marketed products on a timely basis. Our failure to obtain approval or marketing authorization, significant delays in the approval or marketing authorization process or our failure to maintain approval or marketing authorization in any jurisdiction will prevent us from selling the products in that jurisdiction. We would not be able to realize revenues for our pharmaceutical products or medical devices in any jurisdiction where we do not have required approval or marketing authorization. We **and /** or our partners may fail to adequately demonstrate the safety and efficacy of any of our pharmaceutical product candidates or medical devices in pre-clinical studies and clinical trials, which would prevent or delay development, regulatory approval or marketing authorization and commercialization of our product candidates. Before obtaining regulatory approval from the FDA or other comparable ~~foreign~~ regulatory authorities **outside the United States** for the sale of our pharmaceutical product candidates, we must demonstrate through pre-clinical studies and clinical trials, that our product candidates are both safe and effective for use in each target indication and population. Obtaining marketing authorization for our devices may also require pre-clinical and clinical trials. Pre-clinical and clinical trials are difficult to design and implement, and can take many years to complete, and their ultimate outcome is uncertain. Failure can occur at any time during the pre-clinical study and clinical trial

processes. Accordingly, there is a high risk of failure, and we may never succeed in obtaining regulatory approval or marketing authorization of our product candidates. **- 21-** We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent receipt of regulatory approval or marketing authorization, or our ability to commercialize our product candidates, including for example, issues with study execution including timely access to study drugs; inability to recruit and enroll study subjects; failure of our product candidates in pre-clinical studies or clinical trials to demonstrate safety and efficacy; receipt of feedback from the FDA or other regulatory authorities that require us to modify the design of our clinical trials; and negative or inconclusive clinical trial results that may require us to conduct additional clinical trials or abandon certain research and / or development programs. We may be required to conduct additional pre-clinical studies, clinical trials or other testing of our product candidates beyond those that we currently contemplate, or we may be unable to successfully complete pre-clinical studies or clinical trials of our product candidates or other testing in a timely manner. If the results of these studies, trials or tests are not positive (or are only modestly positive), or if there are safety concerns, we may incur unplanned costs, as well as delays in our efforts to obtain regulatory approval or marketing authorization. Even if we receive such approval, ~~we it~~ may be more limited or restrictive than anticipated, or be subject to additional post-marketing testing requirements. ~~-20-~~ Even after a pharmaceutical product or medical device reaches the market, we continue to be subject to significant post-marketing regulatory requirements and oversight. The regulatory approvals or marketing authorizations that we may receive for our pharmaceutical products and medical devices will require the submission of reports to regulatory authorities and on-going surveillance to monitor the safety and efficacy of our products, may contain significant limitations related to use restrictions for specified groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. In addition, even after a pharmaceutical product or device has obtained marketing authorization or clearance, the manufacturing processes, labeling, packaging, distribution, adverse event and device malfunction reporting, storage, advertising, promotion, import, export, recalls and recordkeeping for our products will be subject to ongoing regulatory requirements, and we will be subject to periodic inspections. Failure to comply with any of these requirements could subject us to a variety of formal or informal enforcement actions by the FDA or other regulators, result in a recall or market withdrawal of our products, require us to cease manufacturing and distribution of the products, trigger product liability or other litigation, or otherwise impact our ability to realize revenues for our products. ~~As previously disclosed~~ **For example, in January 2023**, we voluntarily initiated market actions, including recalls, in certain markets with respect to our suspension injections Diprosan, Celestone, Chronodose™ 1 (betamethasone), and Celestone Soluspan® (betamethasone) related to a non-conforming component of a manufacturing line at our Heist, Belgium plant. ~~We do not believe this development will materially impact us.~~ **It is possible that future recalls or similar developments could materially and adversely impact our business, result of operations, and financial condition. Although to date, any market actions to which we have been subject have not had a material impact on our business, such actions could in the future have a materially adverse impact on our business, results** of operations, and financial condition. Likewise, if previously unknown side effects, adverse events, malfunctions or other quality or safety concerns are discovered or if there is an increase in negative publicity regarding known side effects of any of our products, it could significantly reduce demand for the product or require us to take actions that could negatively affect sales, including initiating corrections of a marketed product or removing the product from the market, restricting our distribution of the product or applying for marketing authorization for labeling changes. The FDA could also require us to conduct post-marketing studies of our products. Further, we are at risk for product liability and consumer protection claims and civil and criminal governmental actions related to our products, research and marketing activities. In addition, dissemination of promotional materials through evolving digital channels serves to increase visibility and scrutiny in the marketplace. Certain developments may decrease demand for our products, including the following: • scrutiny of advertising and promotion; • negative results in post-approval Phase 4 trials or other studies; • review by regulatory authorities or other expert bodies of our products that are already marketed based on new data or other developments in the field; • the recall, loss or modification of regulatory approval or marketing authorization of products that are already marketed; and • changing government regulations regarding safety, efficacy, quality or labeling. **- 22-** **The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely is subject to the impacts of political events, which are inherently fluid and unpredictable. Disruptions at the FDA and other agencies may increase the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which could adversely affect our business. For example, over the last few years, the U. S. government has faced threats of a prolonged shut down several times and certain regulatory agencies, such as the FDA and the SEC, faced the possibility of furloughing critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA and the SEC to timely review and process our submissions, which could have a material adverse effect on our business. Further, future government shutdowns and agency operational disruptions in comparable foreign governments could impact our ability to continue our operations in other markets.** Our success also depends on our ability to maintain and ~~routinely~~, **when possible**, 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 and may in the future occur with respect to our products. A quality or safety issue may result in adverse inspection reports, voluntary or official action indicated, warning letters, import bans, product recalls (either voluntary or required by FDA or similar governmental authorities in other countries) 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. An inability to address a quality or safety issue in an effective and timely manner may also cause negative publicity or 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. ~~-21-~~ We depend upon patents to provide us with exclusive marketing rights for certain of our products for some period of time. Loss of patent protection typically leads to a significant and rapid loss of sales for that product where lower priced generic versions of that drug or other competitors become available. In the case of ~~current or future~~ products that contribute significantly to our sales, ~~LOE~~ a loss of market exclusivity could materially adversely affect our business, cash flow, results of operations, financial condition or prospects. **In the United States, we expect patent expiry for the Nexplanon implant in 2027 and patent expiry for the Nexplanon applicator in 2030.** We expect market exclusivity for Nexplanon in the United States to expire in 2027, and market exclusivity for the majority of countries where Nexplanon is commercialized outside the United States will expire in 2026. **In addition, in February 2025, we received a Paragraph IV Certification Letter notifying us that Xiromed Pharma Espana, S. L. filed an abbreviated new drug application to the FDA seeking approval to market a generic version of Nexplanon.** See “**Note 18 “ Contingencies — Other Matters ” to the Consolidated Financial Statements in this report for additional information. In the past, our business and results of operations have been adversely impacted by the LOE of our second largest product, Atozet, and if we do not obtain an additional period of new clinical investigation exclusivity for Nexplanon for the proposed five- year indication upon FDA approval of this indication, our business could also suffer negative financial impacts.** See “**Business — Products ” and “ — Intellectual Property ” and “ Management’ s Discussion and Analysis of Financial Condition and Results of Operations — Key Trends Affecting Our Results of Operations ”** for details, including the patent protection for certain of our marketed products. ~~- 23-~~ Patent protections are important to the marketing **and sale** of certain of our products, particularly certain of our women ~~’~~s health products, **as such protection in the United States and in most major non- U. S. markets. Patents covering products that we have introduced normally provide provides** market exclusivity, which is important for the successful marketing and sale of certain of our products. Even if we succeed in obtaining patents covering our products, third parties or government authorities may challenge or seek to invalidate or circumvent our patents and patent applications. It is important for our business to successfully defend the patent rights that provide market exclusivity for our products. We are involved in patent disputes relating to challenges to our patents or claims by third parties of infringement against their patents. We defend our patents both within and outside the United States, including by filing claims of infringement against other parties. In particular, manufacturers of generic pharmaceutical products from time to time file abbreviated new drug applications with the FDA seeking to market generic forms of our products prior to the expiration of relevant patents owned or licensed by it. Patent litigation and other challenges to our patents are costly and unpredictable and may deprive us of market exclusivity for a patented product or, in some cases, third- party patents may prevent us from marketing and selling a product in a particular geographic area, negatively affecting our business and results of operations. 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 our business and results of operations.~~ Further, court decisions relating to other companies ~~’~~ patents, potential legislation in both the United States and certain ~~foreign~~ **other** markets relating to patents, as well as regulatory initiatives, may result in a more general weakening of intellectual property protection. If one or more of our 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. Our results of operations may be adversely affected by the lost sales unless and until we have launched commercially successful products that replace the lost sales. In addition, if products with intangible assets that were measured at fair value and capitalized in connection with acquisitions experience difficulties in the market that negatively affect product cash flows, we may recognize material non- cash impairment charges with respect to the value of those products. ~~At As of~~ December 31, ~~2023~~ **2024**, we had outstanding indebtedness of approximately \$ ~~8. 8~~ **9** billion, as described more fully in the Notes to our financial statements. In addition, we may incur additional debt from time to time to finance acquisitions or for other purposes, subject to the restrictions contained in the documents that govern our indebtedness. Current or future levels of indebtedness may increase the possibility that we will be unable to generate cash sufficient to pay amounts due in respect of such indebtedness. Our ability to issue additional debt or enter into other financing arrangements on acceptable terms could be adversely affected if **our operating results or financial condition decline (which could occur if, among other things,** there is a material decline in the demand for our products, if our customers or suppliers are unable to pay amounts due to us or there are other significantly unfavorable changes in economic conditions. **)** Volatility in the world financial markets could increase borrowing costs or affect our ability to access the capital markets. These conditions may adversely affect our ability to obtain and maintain our credit ratings. ~~-22-~~ We are subject to minimum purchase obligations under certain supply agreements, which requires us to purchase minimum amounts of materials critical to our product manufacturing over specified time periods. If we fail to meet these minimum purchase requirements, we may still be required to pay for the cost of the minimum inventory purchases. If we are unable to offset these payments, it could result in a lower margin. During ~~the year ended December 31, 2022 and 2021,~~ we recognized \$ 5 million ~~and \$ 24 million, respectively,~~ in Cost of Sales pertaining to estimated unavoidable losses associated with a long- term vendor supply contract conveyed as part of the spinoff. We ~~are also~~ **have aware of** a limited number of other arrangements that have similar provisions which could result in these types of payments. We do not currently expect these payments to be material; however, in the aggregate they may become material if additional amounts are identified in the future, and they could have a material adverse effect on our financial condition, results of operations or cash flows. ~~- 24-~~ ~~The health care industry in the United States has been, and will continue to be, subject to increasing regulation and political action.~~ We believe that the health care industry will continue to be ~~subject to~~ **impacted by judicial decisions,** increasing regulation ~~and,~~ political and legal action at both the federal and state **/local** levels in the United States and internationally, and **US executive orders.** While it is

uncertain how **this such developments** will affect our business, **they could, at a minimum, introduce additional uncertainty into the regulatory process, result in legal challenges to actions taken by regulatory agencies, and subject us to additional pricing pressures.** For instance, **Changes changes** to the health care system enacted as part of health care reform in the United States **and**, ~~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 an example, health~~ **Health** care reform has **already** contributed to an increase in the number of patients in the Medicaid program under which sales of pharmaceutical products are subject to substantial rebates. There are pending legal and legislative developments relating to the 340B ~~drug~~ **Drug pricing Pricing program Program**, including ongoing litigation challenging federal enforcement actions against manufacturers and recently introduced and enacted state legislation. We cannot predict the likelihood of additional future changes in the health care industry in general, the pharmaceutical industry in particular, or what impact they may have on our business, cash flow, results of operations, financial condition or prospects. We are ~~subject to a variety of laws and regulations, and we may face serious consequences for violations if we fail to meet the applicable legal and regulatory requirements.~~ We are currently subject to a number of ~~government~~ laws and regulations and, in the future, ~~could~~ **we will likely** 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 our business, cash flow, results of operations, financial condition or prospects. The ~~compliance-related costs of compliance and penalties for non-compliance~~ **compliance-related costs of compliance and related initiatives in the United States or in other countries**, including: additional mandatory discounts or fees; new laws, regulations and judicial ~~or other governmental~~ decisions affecting pricing, reimbursement, and market access or marketing within or across jurisdictions; new and increasing data privacy regulations and enforcement, particularly in the EU, the ~~UK~~ **United Kingdom**, the United States, and China; legislative mandates or preferences for local manufacturing of ~~medical our~~ products; **and** emerging and new global regulatory requirements for reporting payments and other value transfers to health care professionals and health care organizations; **In addition, we are and may in the future become subject to changing environmental regulations (such as the EU's new Urban Wastewater Treatment Directive and other waste and packaging regulations); and emerging and new laws and regulations on addressing human rights and environmental matters in direct operations as well as in the supply chain and in some downstream users; and** importation restrictions, embargoes, ~~and~~ trade sanctions ~~and legislative or~~. **Any of other -- the foregoing may** regulatory changes. We will also be subject to ~~and are monitoring the passage through the legislative process of the proposed draft directive and regulation intending to reform EU pharmaceutical legislation, individually or in~~ (generally known as the **aggregate "EU Pharma Package"**), **have** which is intended to promote innovation and competitiveness through a **material** simplified regulatory framework, provide access to innovative and affordable medicines to patients, recognize innovation with effective incentives, address shortages and supply security, and provide enhanced protection for the environment. We are still evaluating the potential impacts ~~impact~~ of the EU Pharma Package on our business. ~~Because of~~ **Due to** our **global U. S. and international** operations, we are also subject to anti-corruption laws and regulations, in the United States and internationally, including but not limited to U. S. domestic bribery laws, the **US** U. S. Foreign Corrupt Practices Act of 1977, as amended (the **"FCPA"**), the U. K. Bribery Act 2010, and other applicable anti-bribery and corruption laws. ~~Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other third-party collaborators from authorizing, promising, offering, providing, soliciting and / or receiving, directly or indirectly, improper payments or anything else of value to or from foreign officials or other persons in the public or private sector. The FCPA also requires U. S. public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Recent years have seen a substantial increase in the global enforcement of anti-corruption laws. Our operations outside the United States could increase the risk of --23-- such violations. Our business is also heavily regulated and involves significant interaction with foreign officials. In many countries outside excluding the United States U. S., prescribers of our products are employed by government entities, and purchasers are themselves government entities, such as government-affiliated hospitals, universities and other organizations.~~ As such, our interactions with such prescribers and purchasers are subject to regulation under the FCPA, as well as other similar under anti-corruption laws and / or regulations enacted by other countries. The failure to comply with the FCPA and similar such laws could result in **material** civil or criminal sanctions or other adverse consequences. ~~We~~ **In addition to selling our products internationally, we currently engage third parties outside the United States, and may engage additional third parties outside the United States, to sell our products internationally and to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of jurisdictions government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other third-party collaborators-contractors, even if we do not explicitly authorize or have actual knowledge of such activities. Enforcement activities under the laws and regulations described above and any failure (or perceived failure) to comply with such requirements may subject us to administrative and legal proceedings and actions, which could result in substantial civil and criminal fines and penalties, imprisonment of involved persons, the loss of export or import privileges, debarment, tax reassessments, preclusion from participating in public tenders, breach of contract and fraud litigation, reputational harm, and other consequences. - 25-** We have significant global operations, which expose us to additional risks, and any adverse event could adversely affect our results of operations and financial condition. The extent of our operations outside the United States is significant. For example, in ~~2023~~ **2024**, we generated \$ 4. 8 billion in revenues outside the United States, representing approximately ~~76-75~~ % of our total revenues. 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 our ability to manufacture and sell our products in key markets; • multiple, conflicting and changing laws, **executive orders and directives**, and regulations such as privacy regulations, tax laws, tariffs, employment laws, regulatory requirements,

government funding allocation processes, and other governmental approvals, permits and licenses; • trade protection measures and import or export licensing requirements, including the imposition of **tariffs**, trade sanctions or similar restrictions by the United States or other governments; • financial risks, such as foreign currency exchange fluctuations, longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products; • volatility of commodity prices, fuel, shipping rates that impact the costs and / or ability to supply our products; • diminished protection of intellectual property in some countries; and • possible nationalization and expropriation. **Our business, financial condition, results of operations, and reputation could be materially and adversely impacted if we (or third parties upon which we rely) do not comply with applicable requirements and restrictions globally. In addition, our operations depend, in part, on our relationships and business arrangements with third parties that receive government funding. As the U. S. and foreign federal or local governments shift their pharmaceutical approval and regulatory priorities, including funding allocations, we may encounter challenges receiving key regulatory approvals or maintaining business relationships with third parties that depend on government funding, which could materially adversely affect our business, financial condition, results of operations, and reputation.** In addition, there may be changes to our business and strategic position if there is instability, disruption or destruction in a significant geographic region, regardless of cause, including health epidemics or pandemics, riot, civil insurrection or social unrest, and natural or man- made disasters, including famine, flood, fire, earthquake, storm or disease. In addition, our operations and performance may be affected by political or civil unrest or military action. As a result of global economic conditions, some parties may delay or be unable to satisfy their payment or reimbursement obligations. In addition, patients' ability to afford health care may also be affected by job losses or other economic hardships, increased co- pay or deductible obligations, greater cost sensitivity to existing co- pay or deductible obligations, and lost health care insurance coverage. Further, with rising international trade tensions or sanctions, our business may be adversely affected following new or increased tariffs, as well as increased costs of materials, products, and commodities upon which we rely. As a result, changes in international trade policy, changes in trade agreements and the imposition of tariffs or sanctions by the **United States U. S.** or other countries could materially adversely affect our results of operations and financial condition. In February 2022, in response to the armed conflict between Ukraine and Russia, trade sanctions, travel bans and asset / financial freezes were announced by the United States, **European Union the EU** and other countries against Russian entities and designated ~~individual individuals~~ **individuals**. Such restrictions have impacted, and may continue to impact, many global businesses in direct and indirect ways (including, but not limited to, product shipping delays, supply shortages, delays in regulatory approvals and audits and currency exchange rates). Such actions may negatively impact the financial institutions, vendors, manufacturers, suppliers, partners and other third parties with whom we conduct business and therefore may negatively impact us. In addition, although we do not expect the recent Israel- Hamas war **and ongoing conflicts in the Middle East region** to have a direct material impact on our business, the war and escalating tensions in the region may impact global markets or affect our supply chain. ~~-24-~~ We are subject to a significant number of privacy and data protection laws and regulations globally, many of which place restrictions on our ability to transfer, access and use personal data across our business. The legislative and regulatory landscape for privacy ~~and~~ **and artificial intelligence (" AI ")** continues to evolve. The GDPR and related implementing laws in individual EU or the Member States of the European Economic Area ("**the " EEA "**")), **as well as similar legislation in the United Kingdom**, govern the collection and use of personal health data and other personal data in the EU. The GDPR increased responsibility and liability in relation to personal data that we process. It also imposes several obligations and restrictions on the ability to process (which includes collection, storage and access, analysis, and transfer of) personal data, including health data from clinical trials and adverse event reporting. The GDPR also includes requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the ~~- 26-~~ individuals prior to processing their personal data or personal health data, potential notification of personal data breaches to the national data protection authorities, potential consultation obligations to national data protection authorities for certain high- risk data processing, and the security and confidentiality of the personal data. There are also accountability requirements, such as maintaining a record of data processing, conducting data protection impact assessments and appointing data protection officers. Further, the GDPR prohibits the transfer of personal data to countries outside of the EEA that are not considered by the European Commission to provide an adequate level of data protection, including to the United States, except if the data controller meets very specific requirements. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU Member States may result in significant monetary fines and other administrative penalties as well as civil liability claims from individuals whose personal data was processed. Data protection authorities from the different EU Member States may still enforce the GDPR differently, reflecting variations that arise under national- level regulations and guidelines (e. g., labor laws, processing of national identification numbers), which adds to the complexity of processing personal data in the EU. Guidance at both EU level and at the national level in individual EU Member States concerning implementation and compliance practices is often updated or otherwise revised, resulting in a challenging regulatory environment. There is, moreover, a growing trend towards required public disclosure of clinical trial data in the EU, which adds to the complexity of obligations relating to processing health data from clinical trials. Failing to comply with these obligations could lead to government enforcement actions and significant penalties against us, harm to our reputation, and adversely impact our business and operating results. The uncertainty regarding the interplay between different regulatory frameworks further adds to the complexity that we face with regard to data protection regulation. Additional laws and regulations enacted in the United States, **Europe Canada, the United Kingdom, Australia**, Asia and Latin America have increased enforcement and litigation activity in the United States and other developed markets, as well as increased regulatory cooperation among privacy authorities globally. The data protection regulatory environment in China has been evolving quickly, including regulations regarding cross- border transfers of personal data ("**CBDT "**"). These laws, including the PIPPL, regulate the processing of personal information and increase obligations on companies to protect and safeguard **personal** information. These regulations also require

organizations to evaluate **CBDTs** ~~cross-border transfer of personal information~~ and may require localization of certain data if ~~specific~~. **If we fail to effectively adjust to the changing regulatory landscape and comply with applicable laws and regulations in our operating regions, our business, prospects, financial conditions— condition and operating results would be materially and adversely affected. In addition to the foregoing, AI- based solutions, including generative AI, are met increasingly being used in the pharmaceutical industry, including by us, and we expect to use other systems and tools that incorporate AI- based technologies in the future. The use of AI solutions by our employees or third parties on which we rely could lead to the public disclosure of confidential information (including personal data or proprietary information) in contravention of our internal policies, data protection or other applicable laws, or contractual requirements. The misuse of AI solutions could also result in unauthorized access and use of personal data of our employees, clinical trial participants, collaborators, or other third parties. In addition, the legal and regulatory landscape surrounding AI technologies is rapidly evolving and uncertain, including in the areas of intellectual property, cybersecurity, and privacy and data protection. Compliance with these new or changing laws, regulations or industry standards relating to AI may impose significant operational costs or otherwise negatively impact our business.** We have adopted a comprehensive global privacy program to help manage these evolving risks, adjust to the changing regulatory landscape and facilitate ~~CBDTs~~ ~~the transfer of personal information across international borders~~. **Any failure by us, or our third- party vendors, to comply with applicable data privacy and security laws may lead to government enforcement actions and private litigation, which could result in financial, legal, business, and reputational harm to us and could have a material adverse effect on our business, results of operations, and financial condition.- 27-** We depend on sophisticated software applications and computing infrastructure. Cyberattacks affecting our IT systems could result in exposure of confidential information, the modification of critical data or the disruption of our worldwide operations, including manufacturing and sales operations. We depend on sophisticated software applications (including **AI** ~~artificial intelligence~~), complex information technology systems, computing infrastructure and cloud service providers (collectively, **"IT systems"**) to conduct critical operations. Certain of these systems are managed, hosted, provided or used by third parties ~~including Merck pursuant to a transition services agreement (the "Transition Services Agreement" or "TSA")~~, to assist in conducting our business. Disruption, degradation, destruction or manipulation of these IT systems through intentional or accidental means by our employees, third parties with authorized access or cyber threat actors could adversely affect key business processes. The size and complexity of our IT systems, and those of our third- party providers with whom we contract, make such systems potentially vulnerable to service interruptions. In addition, we and our third- party providers have experienced and expect to continue to experience phishing attempts, scanning attempts of our network, and other attempts of unauthorized access to our computer environment. Such attacks are increasingly sophisticated and are made by groups and individuals with a wide range of motives and expertise, including state and quasi- state actors, criminal groups, **"hackers"** and others. These attacks could lead to loss of confidentiality, integrity and / or availability of our data, applications or systems. In the ordinary course of business, we and our third- party providers collect, store and transmit large amounts of confidential information (including trade secrets or other intellectual property, proprietary business information and personal information), and we must do so in a secure manner to maintain the confidentiality and integrity of such confidential information **and safeguard personal data**. The size ~~—25—~~ and complexity of ~~we~~ ~~our~~ and our third- party providers ~~'s~~ systems and the large amounts of confidential information present on them also makes them potentially vulnerable to security breaches from inadvertent or intentional actions by our employees, partners or vendors, or from attacks by malicious third parties. Maintaining **and safeguarding** the confidentiality, **privacy**, integrity, and availability of this confidential information ~~(including trade secrets or other intellectual property, proprietary business information and personal information)~~, is important to our competitive business position ~~—However, such information can be difficult to protect and could be compromised—~~. While we have taken steps to protect such information, and to ensure that the third- party providers on which we rely have taken adequate steps to protect such information, there can be no assurance that our efforts to protect our data and IT systems or the efforts of third- party providers to protect their IT systems will be successful in preventing disruptions. A breach of our IT systems or our third- party providers ~~'s~~ IT systems, such as cloud- based systems, or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, fraud, trickery, other forms of deception, or any other cause, could enable others to produce competing products, use our proprietary technology or information, and / or adversely affect our business position. Further, any such interruption, security breach, or loss, misappropriation, and / or unauthorized access, use or disclosure of confidential information, including personal information regarding our **patients consumers** and employees, or the modification of critical data, could result in financial, legal, business, and reputational harm to us, including loss of revenue, loss of critical or sensitive information from our or our third- party providers ~~'s~~ databases or IT systems ~~—and substantial remediation and recovery costs. We may experience difficulties or delays —or incur unforeseen expenses in connection with the manufacturing certain of our products. We or our suppliers and other manufacturing partners may experience difficulties or delays in connection with manufacturing our products that may lead to increased costs, such as: failure to comply with applicable regulations and quality assurance guidelines; delays related to the construction of new facilities or the expansion of existing facilities; delays related to the supply of key ingredients or other components of our products; increased costs of key materials, packaging —or operational procedures; difficulties obtaining materials of adequate quality and quantity and other manufacturing or distribution problems, including, but not limited to, changes in manufacturing production sites and limits to manufacturing capacity resulting from regulatory requirements and changes in types of products produced and physical limitations that could impact supply. In addition, we could experience difficulties or delays in manufacturing our products caused by natural disasters, such as hurricanes and wildfires, and public health crises and epidemics / pandemics (including those like the recent COVID- 19 global pandemic)~~. Any of the foregoing could result in product shortages, lost sales, government agency actions, and reputational harm to us, which could have a material adverse effect on our business,

results of operations, and financial condition. ~~-28-~~ We may be unable to obtain sufficient components or raw materials on a timely basis or for a cost-effective price, or we may experience other supply difficulties that could adversely affect both our ability to deliver our products and our results of operations and financial condition. We acquire our components, materials and other requirements for manufacturing from many suppliers and vendors in various countries, ~~including sometimes from itself for self-supplied requirements.~~ We endeavor to achieve, either alone or by working closely with our suppliers, 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 materials, in certain instances there is only a sole source or it would require months or years to establish an alternative supplier. For many of our components and 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 carry strategic inventory and maintain insurance to help mitigate the potential risk related to any related supply disruption, we cannot assure investors that such measures will always be sufficient or effective. Further, if we ~~do~~ **choose to** seek recovery or damages from such supplier for any supply shortages or disruptions, such recovery or damages may be limited and not include indirect or consequential losses or any loss of revenue or lost profits. Our ability to achieve continuity of our supply may also be affected by public health crises and epidemics / pandemics. A reduction or interruption in supply and an inability to quickly develop acceptable alternative sources for such supply could adversely affect our ability to **complete clinical trials,** manufacture and distribute our products in a timely or cost-effective manner, negatively impacting our ability to sell our products. We may not realize benefits from our investments in China and emerging markets. We ~~have been taking~~ **continue to take** steps to increase our sales in China and emerging markets; however, our efforts to expand sales in these markets may not succeed. Some countries may be especially vulnerable to periods of global financial instability or may have ~~-26-~~ very limited resources to spend on health care. In order for us to successfully implement our strategy, we must attract and retain qualified personnel. We may also be required to increase our reliance on third-party agents within less developed markets. In addition, many of these countries have currencies that fluctuate substantially and, if such currencies devalue and we cannot offset the devaluations, our financial performance within such countries could be adversely affected. For example, our business in China is growing, and China is now our second largest market, thereby increasing the importance of China to our overall pharmaceutical business. Continued growth of our business in China depends upon ongoing development of a favorable regulatory environment, sustained availability of our currently marketed products within China, and our ability to mitigate the impact of any trade impediments or adverse pricing controls. China has made reduction of costs and provision of affordable ~~drugs~~ **pharmaceutical products** to patients a key priority and has implemented reimbursement and procurement programs to achieve these goals, such as VBP and URPS. ~~These~~ **For example, the VBP programs** ~~regularly reduce~~ **reduces** the ~~price~~ **prices** and / or ~~reimbursement rate~~ **for drugs** ~~affected products~~ by over 50%. These and other such programs could adversely affect our business in China. In addition, we currently rely on a third-party manufacturer to import, repack and then sell a significant portion of our products in China. China's drug regulatory system is regularly changing ~~in response to new policy trends~~. If ~~these trends and the related~~ changes to the requirements for ~~development,~~ importation, registration, distribution, and / or manufacturing of our ~~drugs~~ **products** disrupt our business model that would adversely affect our business in China. Finally, we plan to pivot in China from a primary focus on the public tender market to growth opportunities in the private retail segment, **which is less dependent on public funding**. A failure to make such pivot effectively, or a failure to develop and maintain a presence in China or emerging markets could adversely affect our business, cash flow, results of operations, financial condition or prospects. ~~Current market conditions and recessionary pressures~~ **Adverse developments in the global economy or** in one or more of our **local** markets could impact our ability to grow our business. ~~Over the last few years in the United States and globally, market and economic conditions have been challenging. Non-U. S. countries, particularly in Europe, have experienced recessionary pressures and face continued concerns about the systemic impacts of adverse economic conditions and geopolitical issues. Any negative impact on economic conditions and international markets, continued such as~~ volatility or deterioration in the capital markets, **recession**, inflation, deflation or other adverse economic conditions, **may limit** ~~negatively impact~~ our **ability** ~~business. For instance, we may be unable~~ to replace maturing liabilities and to access the capital markets to meet liquidity needs. **An inflationary environment has led, and may continue to lead, to increased raw material and other costs, negatively impacting our margins and operating results. In addition, ongoing uncertain economic and financial market conditions may also adversely affect the financial condition of our customers, suppliers and other business partners. If our customers' financial conditions are adversely affected, those customers may reduce their purchases of our products or we may not be able to collect accounts receivable, each of which** ~~-29-~~ **could have a material adverse impact on our business operations or financial results, and we may not be able to fully absorb any such additional costs or revenue declines in the prices for our products and services. Any of the foregoing** could have a material adverse effect on our financial condition and results of operations. ~~Ongoing uncertain economic and financial market conditions may also adversely affect the financial condition of our customers, suppliers and other business partners. If our customers' financial conditions are adversely affected, those customers may reduce their purchases of our products or we may not be able to collect accounts receivable, each of which could have a material adverse impact on our business operations or financial results, and we may not be able to fully absorb any such additional costs or revenue declines in the prices for our products and services.~~ Our reputation and promising pipeline render our products prime targets for counterfeiters. Counterfeit **pharmaceutical** products pose a significant risk to patient health and safety because of the conditions under which they are manufactured — often in unregulated, unlicensed, uninspected and unsanitary sites — as well as the lack of regulation of their contents. Failure to mitigate this threat could adversely impact our customers, potentially causing them harm. This, in turn, may result in the loss of confidence in our products ~~and~~ reputation and integrity, and potentially impact our business through lost sales, product recalls, and possible litigation. Inflation could materially adversely affect our business and operations. Our operating results could be materially impacted by changes in the overall macroeconomic environment and other economic factors that impact our cost

structure and revenue results. Changes in economic conditions, supply chain constraints, logistics challenges, labor shortages, the war conflicts in Ukraine, and the Middle East, steps taken by governments and central banks, as well as other stimulus and spending programs, have led to higher inflation, which is likely to lead to an increase in costs and may cause changes in fiscal and monetary policy, including increased interest rates. In a higher inflationary environment, we may be unable to raise the prices of our products and services sufficiently to keep up with the rate of inflation. We are exposed to market risk from fluctuations in currency exchange rates and interest rates. We operate in multiple jurisdictions and virtually all of our sales outside the United States are denominated in currencies other than the US United States-dollar. Additionally, we have historically entered into, and will in the future enter into, business development transactions, borrowings or other financial transactions that may give rise to currency and interest rate exposure. Since we cannot, with certainty, foresee and mitigate against such adverse fluctuations in currency exchange rates, interest rates and inflation could negatively affect our business, cash flow, results of operations, financial condition or prospects. In order to mitigate the adverse impact of these market fluctuations, we enter into hedging agreements from time to time. 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. As a result, currency fluctuations among our reporting currency, the US U.S.-dollar, and other currencies in which we do business will affect our operating results, often in unpredictable ways. Reliance on third- party relationships and outsourcing arrangements could materially adversely affect our business. We depend on third parties, including other suppliers, alliances with other pharmaceutical and biotechnology companies, (including Merck), and third- party service providers, for key aspects of our business, including development, manufacture and commercialization of our products (including supplying our products or key ingredients of our products) and support for our IT systems. Reliance on third parties and their systems poses risks, including that the third parties will not comply with applicable legal or regulatory requirements for activities conducted on our behalf or for our benefit and we may be adversely affected if we have indemnification obligations or tax liabilities to Merck under our Separation and Distribution Agreement. This We could lead be subject to penalties that flow to us, require us to undertake costly corrective measures such as recalling product, interrupt our business plans such as by rendering clinical data not usable for regulatory submissions, or other adverse consequences on our business. We may also learn of certain issues after entering into an agreement that were not identified during diligence and may impact the ability to realize the projected business goals of the agreement. We may enter into agreements with third parties in certain jurisdictions, including China, to continue our business operations in compliance with local regulatory requirements. Failure of these third parties to meet their contractual, regulatory and other obligations to us or the development of factors that materially disrupt the relationships between us and these third parties could adversely affect our business. Please see the risk factor above entitled, "we" "We depend on sophisticated software applications and computing infrastructure. Cyberattacks affecting our IT systems could result in exposure of confidential information, the modification of critical data or the disruption of our worldwide operations, including manufacturing and sales operations," for a description of additional risks relating to our third- party providers that collect, store and transmit large amounts of confidential information.

30- If we or our third- party suppliers, logistics, and manufacturers do not comply with ethical business practices or with related laws and regulations, including relating to AI use, our reputation, business, financial condition, results of operations and prospects could be harmed. Our third- party suppliers use of AI that does not comply with ethical standards, industry recognized AI frameworks or related laws and regulations will expose us to various risks including those relating to privacy, cybersecurity, intellectual property, inaccuracy of data, exposure of our confidential information, producing bias outcomes and overreliance on AI by those third- party suppliers without human oversight. Our reputation and our clients' and customer' willingness to purchase our products depend in part on our and our suppliers', packagers', manufacturers, and formulators' compliance with ethical employment practices, such as with respect to child labor, wages and benefits, forced labor, discrimination, safe and healthy working conditions, and with all legal and regulatory requirements relating to the conduct of their businesses. We do not exercise control over our suppliers, packagers, shippers, manufacturers, and formulators and cannot guarantee their compliance with ethical and lawful business practices. If our suppliers, packagers, shippers, manufacturers, or formulators fail to comply with applicable laws, regulations, safety codes, employment practices, human rights standards, quality standards, environmental standards, production practices, or other obligations, norms, or ethical standards, our reputation and brand image could be harmed, and we could be exposed to litigation, investigations, enforcement actions, monetary liability, and additional costs that would harm our reputation, business, financial condition, results of operations and prospects. The markets for our products, including the women's health market, may not develop as successfully as expected. Our focus on women's health is a key component of our strategy. Our ability to successfully execute our growth strategy in this area is subject to numerous risks, including: • uncertainty of the development of a market for such products; • trends relating to, or the introduction or existence of, competing products, technologies or alternative treatments or therapies that may be more effective, safer or easier to use than our products, technologies, treatments or therapies; • the perception of our products as compared to other products; • recommendation and support for the use of our products or treatments by influential customers, such as obstetricians, gynecologists, reproductive endocrinologists and treatment centers; • changes in judicial decisions, government policy or regulations could impair or repeal contraception coverage mandates under the ACA or patient access to contraception under state laws, which may affect our product sales, payments to us or impose additional coverage limitations or cost- sharing obligations on our patients-consumers; • the availability and extent of data demonstrating the clinical efficacy of our products or treatments; • competition, including the presence of competing products sold by companies with longer operating histories, more recognizable names and more established distribution networks; and • other technological developments. If we are unable to successfully commercialize and create a significant market for our women's health products, our business or prospects could be harmed. Our business and operations are subject to risks related to climate change.

We believe that global climate change will present ~~some~~ a degree of risk to our business. Natural disasters, extreme weather and other conditions caused by or related to climate change could adversely impact our supply chain, including manufacturing and distribution networks, the availability and cost of raw materials and components, energy supply, transportation, or other inputs - 28 - necessary for the operation of our business. Climate change and natural disasters could also result in physical damage to our facilities as well as those of our suppliers, customers, and other business partners, which could cause disruption in our business and operations or increase costs to operate our business. **For instance, California and Florida are two of our top five states in terms of annual U. S. Organon revenues. The geographic location of our healthcare professional and patient customers in these states subjects them to earthquake, drought, wildfire, and hurricane risks, respectively. The recent Hurricanes Milton and Helene and wildfires in California disrupted critical infrastructure and damaged many point-of-care facilities, which displaced or reduced interactions between healthcare professionals and patients that generate demand for our products.** Additionally, increased environmental, social and governance regulations, including to address climate change, may result in increases in our costs to operate our business or restrict certain aspects of our activities. Additional potential effects of climate change to our business could include increased operating costs due to additional regulatory requirements, changes in supply and suppliers due to regulatory requirements, water limitations and disruptions to our supply chain. For example, concern over climate change continues to result in new legal or regulatory requirements designed to ~~mitigate~~ **address** the effects of climate change on the environment, such as the EU's CSRD **and CSDDD**, California's Climate Corporate Data Accountability Act and Climate - 31 - Related Financial Risk Act, and similar regulations **adopted or** under consideration by the **SEC regulators globally**. ~~Some~~ **While certain** potential risks are integrated into our business planning, including investment in reducing energy, water use and greenhouse gas emissions. ~~The,~~ **the** extent and severity of **future natural disasters and / or other** climate change impacts are unknown, and therefore, the scope of potential impact on our business is difficult to predict, and it may be difficult to adequately prepare for such impact. **We are proud of our corporate citizenship and sustainability efforts. We have disclosed a number of initiatives, including initiatives relating to environmental matters, social investments and diversity, equity and inclusion (often referred to as " ESG " initiatives and programs). In recent years, investor advocacy groups and certain institutional investors have placed increasing importance on sustainability, and we may not succeed in our achievement of our initiatives or goals. At the same time, there also exists " anti- ESG " sentiment in certain of our markets, and we may face reduced revenue, reputational harm, market restrictions or legal actions if we are targeted by groups or influential individuals who disagree with our public positions on social or environmental issues. Increasing focus on sustainability matters has resulted in, and is expected to continue to result in, evolving legal and regulatory requirements, including mandatory due diligence, disclosure and reporting requirements, as well as a variety of voluntary disclosure frameworks and standards. We have incurred, and are likely to continue to incur, increased costs complying with such standards and regulations, particularly given the lack of convergence among standards. In addition, our processes and controls may not always comply with evolving standards and regulations for identifying, measuring and reporting sustainability metrics, or our interpretation of reporting standards and regulations may differ from those of others; and such standards and regulations may change over time, any of which could result in significant revisions to our goals or reported progress in achieving such goals. Further, methodologies for reporting our data may be updated and previously reported data may be adjusted to reflect improvement in availability and quality of third- party data, changing assumptions, changes in the nature and scope of our operations (including from acquisitions and divestitures), and other changes in circumstances. Any failure or perceived failure (whether or not valid) to pursue or fulfill our sustainability goals and aspirations or to satisfy various sustainability reporting standards or regulatory requirements within the timelines we announce, or at all, could increase the risk of litigation or result in regulatory actions.** Biosimilars carry unique regulatory risks and uncertainties, which could adversely affect our results of operations and financial condition. There are unique regulatory risks and uncertainties related to biosimilars. The regulation of the testing, approval, safety, effectiveness, manufacturing, labeling and marketing of biosimilars are subject to regulation by the FDA, the EMA and other regulatory bodies. These laws and regulations differ from, and are not as well- established as, those governing pharmaceutical products or the approval of generic pharmaceutical products. In addition, manufacturing biosimilars, especially in large quantities, is often complex and may require the use of innovative technologies to handle living cells and microorganisms. Any changes to the regulatory framework governing biosimilars or in the ability of our partners to manufacture an adequate supply of biosimilars may adversely affect our ability to commercialize the biosimilars in our portfolio. We rely on our collaboration with Samsung Bioepis and Henlius for the successful development and manufacture of our biosimilars products and expect to do so for the foreseeable future. Our current biosimilars portfolio consists primarily of products developed and manufactured by Samsung Bioepis for which we have worldwide commercialization rights, with certain geographic exceptions specified on a product- by- product basis. Our access rights to each product under our agreement with Samsung Bioepis last for 10 years from each such product's launch date on a market- by- market basis. In addition, we are party to a license agreement with Henlius, whereby we have worldwide commercialization rights, in countries except for China (including Hong Kong, Macau, and Taiwan) for biosimilar candidates HLX11 referencing Perjeta, and HLX14, referencing Prolia / Xgeva. See " Business — Third- Party Agreements ". Our ability to successfully commercialize products in our biosimilars portfolio ~~may~~ **will** depend upon maintaining a successful relationship with Samsung Bioepis and Henlius. The success of our commercialization activities may also depend, in part, on the performance, operations and regulatory **and quality** compliance of Samsung Bioepis and Henlius and their suppliers, over which we do not have control. **A failure by Samsung Bioepis, Henlius, and / or their suppliers to fulfill their regulatory or quality obligations could lead to a delay in regulatory approval or commercial marketing of HLX11, HLX14 or any of our other biosimilar products.** If we fail to achieve the benefits of our collaborations, our business, financial condition, and results of operations could be adversely impacted. - 32 - ~~We or our suppliers may not be able to obtain materials or supplies or capacity necessary to conduct~~

clinical trials or to manufacture and sell our products, which could limit our ability to generate revenues. We and our suppliers need access to certain supplies and products and capacity to ensure supply that is used to conduct our clinical trials and to manufacture and sell our products. If we or our suppliers are unable to purchase enough of these materials or find suitable alternative materials in a timely manner, our development efforts for our product candidates may be delayed or our ability to manufacture and sell our products could be limited. We are subject to a number of restrictive covenants under our indebtedness, including customary operating restrictions and financial covenants, which could restrict our ability to pay dividends or adversely affect our financing options and liquidity position. Our current indebtedness contains, and any future indebtedness may contain, customary operating restrictions and financial covenants. This indebtedness may adversely affect our ability to operate or grow our business or could have other material adverse consequences, including by: • limiting our ability to obtain additional financing in the future for working capital, capital expenditures and acquisitions; • limiting our ability to refinance our indebtedness on terms acceptable to us or at all; ~~29~~ • restricting our operations or development plans; • requiring us to dedicate a significant portion of our cash flows from operations to paying amounts due under our indebtedness, thereby reducing funds available for other corporate purposes; • impeding our ability to pay dividends; • making us more vulnerable to economic downturns; or • limiting our ability to withstand competitive pressures. Any of these restrictions on our ability to operate our business in our discretion could adversely affect our business by, among other things, limiting our ability to adapt to changing economic, financial or industry conditions and to take advantage of corporate opportunities, including opportunities to obtain debt financing, repurchase stock, refinance or pay principal on our outstanding debt, dispose of property, complete acquisitions for cash or debt, or make other investments. In addition, events beyond our control, including prevailing economic, financial, and industry conditions, could affect our ability to satisfy applicable financial covenants, and we cannot assure you that we will satisfy them. Any failure to comply with the restrictions of our current indebtedness, or any future financing agreements, including as a result of events beyond our control, may result in an event of default under these agreements, which in turn may result in defaults or acceleration of obligations under these agreements and other agreements, giving our lenders and other debt holders the right to terminate any commitments they may have made to provide us with further funds and to require us to repay all amounts then outstanding. Changes in tax laws or other tax guidance could adversely affect our effective tax rates, financial condition and results of operations. We expect recent changes in tax laws around the world, including as led by the Organization for Economic Cooperation and Development ("~~OECD~~"), such as the adoption by the EU and the enactment by additional countries of a global minimum tax, to negatively impact our effective tax rate and results of operations. Other changes in tax laws or regulations around the world, including in the United States, could negatively impact our cash tax liability, and will likely have a negative impact on our effective tax rate, and results of operations **and lead to greater audit scrutiny**. Social media and mobile messaging platforms present risks and challenges. 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 us or our products on any social networking platforms could damage our reputation, brand image and goodwill. Further, the disclosure of non- public Organon- sensitive information by our workforce or others through external media channels could lead to information loss. Although there are internal Organon policies that guide employees on appropriate personal and professional use of these platforms for communication about us, it may not completely secure and protect information. **Beginning** Identifying new points of entry as new communication tools expand also presents new challenges. Merck may not satisfy its obligations under various transaction agreements that have been or will be executed as part of the spinoff, we may experience delays with approvals relating to the separation from Merck, or we may not have necessary systems and services in **2023** place when certain of the transition agreements expire. In connection with the spinoff, we entered into a Separation and Distribution Agreement with Merck (the "Separation and Distribution Agreement"), the Transition Services Agreement, manufacturing and supply agreements, trademark license agreements, intellectual property license agreements, an employee matters agreement, a tax matters agreement and certain other commercial or operating agreements. These agreements are discussed in greater detail in Note 19 "Third-Party Arrangements and Related Party Disclosures." Certain of these agreements provide for the performance of services by each company for the benefit of the other for a period of time after the distribution. We may rely on Merck to satisfy our performance and payment obligations under these agreements. If Merck is unable to satisfy its obligations under these agreements, including its indemnification obligations, we could experience operational difficulties or losses. In addition, in connection with the spinoff, we have established **implemented restructuring activities related to the ongoing optimization of our internal operations by reducing headcount in most certain markets** ; but is unable **and functions. We expect to import continue these restructuring activities in 2025. We may not realize** , distribute **in full or in part** , the anticipated benefits, savings and improvements in **or our** trade certain products in some markets **cost structure from our restructuring efforts** due to pending licenses **unforeseen difficulties** , **delays or unexpected** permits, and regulatory approvals, among other requirements. Until all required approvals are received, we rely upon Merck to perform certain activities in these markets. We ~~30~~ may incur additional costs during the period of time before all necessary approvals are granted, which may affect our business and result in additional costs in these markets. If we do not have our own systems and services in place, or if we do not have agreements with other providers of these services, when these agreements terminate, we may not be able to operate our business effectively and our profitability may decline. We are **unable** in the process of creating our own, or engaging third parties to **realize** provide, systems and services to replace many of the systems and services Merck is providing, and is expected **operational efficiencies** to provide, during the transition period to us. We may not be successful in effectively or efficiently implementing these systems and **cost savings** services or in transitioning data from **the restructuring**, Merck's systems to our systems. These systems and services may also be more expensive or **our operating results** less efficient than the systems and services Merck is expected to provide during the transition period. The Separation and Distribution Agreement with Merck provides for indemnification obligations designed to make us financially -- **financial**

condition responsible for many liabilities that may exist relating to our business activities, whether incurred prior to or after the distribution, including any pending or future legal matters. These liabilities, which could be material to us **adversely affected**. **Furthermore**, include a general obligation **such restructuring efforts may be disruptive** to indemnify Merck for litigation or **our** governmental proceedings relating to **operations**. For example, **our products headcount reductions could yield- 33- unanticipated consequences, such as increased difficulties in implementing our business strategy**, including **retention**, but not limited to, currently pending litigation relating to Fosamax, Nexplanon, and Propecia / Prosear. More specifically, our obligations to indemnify Merck may in some cases include liability for antitrust litigation; provided, however, that we will not be liable for the results of the antitrust litigation related to Zetia or **our remaining** the product liability litigation in Brazil related to Vioxx² (rofecoxib). For a description of the related legal matters, see Note 20 "Contingencies" to the Financial Statements included in this report. These indemnification liabilities are intended to ensure that, as between Merck and us, we are responsible for all liabilities we assume in connection with the spinoff and that we pay for any liability incurred by Merck (including directors, officers, employees and agents) related to our failure to satisfy such obligations or otherwise in respect of the operation of our business, or any breach by us of the Separation and Distribution Agreement or any ancillary agreement. Our indemnity obligations to Merck as set forth in the Separation and Distribution Agreement may be substantial. There could be significant income tax liability if the spinoff or certain related transactions are determined to be taxable for U. S. federal income tax purposes. Prior to completion of the spinoff, Merck received the tax opinions from its tax advisors that concluded, among other things, that the distribution of all of the outstanding Organon shares to Merck stockholders and certain related transactions qualify as tax-free to Merck and its stockholders under Sections 355 and 368 of the U. S. Internal Revenue Code, except to the extent of any cash received in lieu of fractional shares of our Common Stock. The Tax Opinions are not binding on the Internal Revenue Service ("IRS"). Accordingly, the IRS may reach conclusions with respect to the spinoff that are different from the conclusions reached in the Tax Opinions. The Tax Opinions rely on certain facts, assumptions, representations and undertakings from Merck and Organon regarding the past and future conduct of the companies' respective businesses and other matters, which, if incomplete, incorrect or not satisfied, could alter the conclusions of the party giving such Tax Opinion. If the spinoff is ultimately determined to be taxable, the spinoff could be treated as a taxable dividend to Merck's stockholders for U. S. federal income tax purposes, and Merck's stockholders could incur significant U. S. federal income tax liabilities. In addition, Merck would recognize a taxable gain to the extent that the fair market value of our Common Stock exceeds Merck's tax basis in such stock on the date of the spinoff. Each of Merck and Organon generally will be responsible for any tax-related losses imposed on Merck or Organon, respectively, as a result of the failure of a transaction to qualify for tax-free treatment, to the extent that the failure to so qualify is attributable to actions, events or transactions relating to Merck's or Organon's respective stock, assets or business, or a breach of the relevant covenants made by Merck or Organon in the tax matters agreement. Please also see "Contractual restrictions limit our ability to engage in certain corporate transactions that stockholders may consider favorable" below. Contractual restrictions limit our ability to engage in certain corporate transactions that stockholders may consider favorable. To preserve the tax-free treatment to Merck of the spinoff, we entered into a tax matters agreement (the "Tax Matters Agreement" or "TMA") with Merck, which restricted us from taking any action that would have prevented the distribution and related transactions from being tax-free for U. S. federal income tax purposes. In addition, we are required to indemnify Merck against any tax liabilities as a result of such actions, even if we did not participate in or otherwise facilitate such actions. In the event the spinoff fails to be tax-free as a result of such actions, our indemnity obligation for Merck's tax liability under the tax matters agreement would be substantial and could materially affect our cash flow. In addition, certain provisions of the agreements that we entered into with Merck require Merck's consent to any assignment by us of our rights and obligations- 31- under the agreements. The consent and termination rights set forth in these agreements might discourage, delay or prevent a change of control that stockholders may consider favorable. Certain of our executive officers and directors may have actual or potential conflicts of interest because of their previous positions at Merck. Because of their former positions with Merck, certain of our executive officers and directors own shares of Merck Common Stock and continue to participate in certain Merck benefit programs. Even though our Board of Directors consists of a majority of directors who are independent, and our executive officers who were previously employees of Merck ceased to be employees of Merck in connection with the spinoff, some of our executive officers and directors continue to have financial interests in Merck. Continuing ownership of Merck Common Stock and continued participation in Merck benefit programs could create, or appear to create, potential conflicts of interest if we and Merck pursue the same corporate opportunities or face decisions that could have different implications for us and Merck. The price and trading volume of our Common Stock may be volatile, and stockholders could lose all or part of their investment in us. The trading volume and market price of our Common Stock may be volatile. This volatility could negatively impact our ability to raise additional capital or utilize equity as consideration in any acquisition transactions we may seek to pursue, and could make it more difficult for existing stockholders to sell their shares of our Common Stock at a price they consider acceptable or at all. This volatility is caused by a variety of factors, including, among the other risks described in this report: • our liquidity and ability to obtain additional capital, including the market's reaction to any capital-raising transaction we may pursue; • declining working capital to fund operations, or other signs of financial uncertainty; • any negative decisions by the FDA or comparable regulatory bodies outside the United States regarding our products and product candidates; • market assessments of any strategic transaction or collaboration arrangement we may pursue; • sales of substantial amounts of our Common Stock, or the perception that substantial amounts of our Common Stock may be sold, by stockholders in the public market; • changes in earnings estimated by securities analysts or our ability to meet those estimates; • issuance of new or updated research or reports by securities analysts or changed recommendations for our Common Stock; and • significant advances made by competitors that adversely affect our competitive position. In addition, the stock market in general, and the market for stock of companies in the life sciences and pharmaceutical industries in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of comparable companies. In the past, following periods of

volatility in the overall market and the market price of a particular Company's securities, securities class action litigation has often been instituted against a company. This type of litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources. We currently expect that we will continue to pay quarterly cash dividends **on our common stock**. The timing, declaration, amount and payment of any future dividends to stockholders will fall within the discretion of our Board of Directors, **subject to Delaware law**. The Board of Directors' decisions regarding the payment of dividends will depend on many factors, such as our financial condition, earnings, corporate strategy, capital requirements, debt service obligations, industry practice, legal requirements, regulatory constraints, and other factors that the Board deems relevant. our ability to pay any dividends will depend on our ongoing ability to generate cash from operations and access capital markets.

~~32- Certain provisions in our amended and restated certificate of incorporation and bylaws, and of Delaware law, may prevent or delay an acquisition of us, which could decrease the trading price of our Common Stock.~~ We are a Delaware corporation, and our amended and restated certificate of incorporation, bylaws, and Delaware law each contain provisions that are intended to deter coercive takeover practices and inadequate takeover bids by making such practices or bids unacceptably expensive to the bidder and encouraging prospective acquirors to negotiate with our Board of Directors rather than to attempt a hostile takeover. Specifically, because we have not chosen to be exempt from Section 203 of the Delaware General Corporation Law, this provision could also delay or prevent a change of control that stockholders may favor. Section 203 provides that, subject to limited exceptions, persons that acquire, or are affiliated with a person that acquires, more than 15 % of the outstanding voting stock of a Delaware corporation may not engage in any business combination with that corporation, including by merger, consolidation or acquisitions of additional shares, for a three- year period following the date on which that person or their affiliates becomes the holder of more than 15 % of the corporation's outstanding voting stock. In addition, our amended and restated certificate of incorporation and bylaws include additional provisions that may have anti- takeover effects and may delay, deter or prevent a takeover attempt that our stockholders might consider in their best interests. For example, our amended and restated certificate of incorporation and bylaws: **34-** • permit our Board of Directors to issue one or more series of preferred stock with such powers, rights and preferences as the Board of Directors shall determine ; • ~~subject to a three- year sunset starting with our first annual meeting of stockholders, provide for a classified Board of Directors, with each class serving a staggered three- year term, which could have the effect of making the replacement of incumbent directors more time consuming and difficult;~~ • provide that as long as our Board of Directors is classified, our directors can be removed for cause only; • prohibit stockholder action by written consent; • provide that special meetings of stockholders can be called only by the Board of Directors; • provide that vacancies on the Board of Directors could be filled only by a majority vote of directors then in office, even if less than a quorum, or by a sole remaining director; and • establish advance notice requirements for stockholder proposals and nominations of candidates for election as directors. We believe these provisions will protect our stockholders from coercive or otherwise unfair takeover tactics by requiring potential acquirors to negotiate with our Board of Directors and by providing our Board of Directors with more time to assess any acquisition proposal. These provisions are not intended to make us immune from takeovers. However, these provisions will apply even if the offer may be considered beneficial by some stockholders and could delay or prevent an acquisition that our Board of Directors determines is not in the best interests of us and our stockholders. These provisions may also prevent or discourage attempts to remove and replace incumbent directors. In addition, these limitations may adversely affect the prevailing market price and market for our Common Stock if they are viewed as limiting the liquidity of our stock or discouraging takeover attempts in the future. Our amended and restated bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, and the United States federal district courts as the exclusive forum for claims under the Securities Act, which could limit our stockholders' ability to obtain what such stockholders believe to be a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated bylaws provide that, unless we select or consent to the selection, in writing, of an alternative forum, all internal corporate claims, which include claims in the right of Organon (i) that are based upon a violation of a duty by a current or former director, officer, employee or stockholder in such capacity or (ii) as to which the Delaware General Corporation Law confers jurisdiction upon the Court of Chancery, will, to the fullest extent permitted by law, be exclusively brought in the Court of Chancery of the State of Delaware or, if such court does not have jurisdiction, another state court or a federal court located within the State of Delaware. Furthermore, unless we select or consent to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Our exclusive forum provision does not apply to suits brought to enforce any liability or duty created by the Exchange Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. These exclusive provisions may limit a stockholder's ability to bring a claim in a judicial forum that **they he, she or it** believes to be favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits. It is possible ~~33-~~ that a court could find these exclusive forum provisions inapplicable or unenforceable with respect to one or more of the specified types of actions or proceedings, and we may incur additional costs associated with resolving such matters in other jurisdictions, which could materially adversely affect our business, financial condition and results of operations and result in a diversion of the time and resources of our management and board of directors.