Risk Factors Comparison 2024-02-26 to 2023-02-27 Form: 10-K

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

You should carefully consider the following risks and other information in this Annual Report on Form 10- K in evaluating ~~Organon~~ **us** and deciding to invest in ~~the~~ **our** Common Stock. Any of the following risks could materially and adversely affect **our** ~~Organon' s~~ results of operations, financial condition and the price of ~~the~~ **our** Common Stock. Summary of Risk Factors The following is a summary of the principal risks that could significantly and negatively affect **our** ~~Organon' s~~ business, prospects, financial conditions, or operating results. For a more complete discussion of the material risks facing **our** ~~Organon' s~~ business, please see below: Risks Related to **Our** ~~Organon' s~~ Business ~~• Organon has a limited history of operating as an independent company, and its historical financial results included elsewhere in this report are not necessarily representative of what its actual financial position or results of operations would have been as an independent company and may not be a reliable indicator of its future results.~~ • Key products generate a significant amount of **our** ~~Organon' s~~ profits and cash flows, and any events that adversely affect the markets for **our** ~~Organon' s~~ leading products could adversely affect ~~its~~ **our** results of operations and financial condition. • ~~Organon~~ **We** ~~faces~~ **face** continued pricing pressure with respect to ~~its~~ **our** products. **- 16-** • ~~Organon~~ **We** ~~faces~~ **face** intense competition from competitors' products. • ~~Organon has~~ **We have** limited in- house discovery and early research capabilities and will continue to rely on future acquisitions, partnerships and collaborations to expand ~~its~~ **our** innovative pipeline and early discovery and research capabilities, which may limit ~~its~~ **our** ability to discover or develop new products or expand ~~its~~ **our** existing products into new markets to replace the sales of products that lose patent protection and therefore ~~Organon~~ **we** may not be able to maintain ~~its~~ **our** current levels of profitability. • ~~Organon~~ **Our growth could be limited by the scope of our intellectual property licenses for certain women' s health care products. • We** may experience difficulties identifying acquisition opportunities or completing such transactions. • ~~Organon~~ **We or** ~~or~~ **our** ~~its~~ partners may fail to demonstrate the safety and efficacy of any of ~~its~~ **our** product candidates in pre- clinical and clinical trials, which would prevent or delay development, regulatory approval or clearance, and commercialization of **our** ~~Organon' s~~ product candidates. • ~~Organon~~ **We** may be unable to market ~~its~~ **our** pharmaceutical products or medical devices if ~~it does~~ **we do** not obtain and maintain required regulatory approvals or marketing authorizations. ~~- 28-~~ • Developments following regulatory approval or marketing authorization may adversely affect sales of **our** ~~Organon' s~~ pharmaceutical products or medical devices. • 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** ~~Organon' s~~ 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** ~~Organon' s~~ sales will adversely affect ~~its~~ **our** business. • ~~Organon~~ **We** ~~depends~~ **depend** on ~~its~~ **our** patent rights for the marketing of certain of ~~its~~ **our** products, and invalidation or circumvention of **our** ~~Organon' s~~ patent rights would adversely affect ~~its~~ **our** business. • ~~Organon is~~ **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 ~~Organon~~ **we** ~~fails~~ **fail** to meet those minimum purchase requirements, ~~its~~ **our** financial results may be unfavorably impacted. ~~• Organon has incurred substantial indebtedness, which could adversely affect its financial condition and results of operations. • Organon is subject to a number of restrictive covenants under its indebtedness, including customary operating restrictions and financial covenants, which could restrict Organon' s ability to pay dividends or adversely affect its financing options and liquidity position.~~ Risks Related to the Spinoff ~~• As Organon builds its information technology infrastructure and transitions its data to its own systems, Organon could incur substantial additional costs and experience temporary business interruptions.~~ • Merck may not satisfy its obligations under various transition agreements that have been or will be executed as part of the spinoff or ~~Organon~~ **we** may not have necessary systems and services in place when certain of the transition agreements expire. • Potential indemnification liabilities to Merck pursuant to the Separation and Distribution Agreement could adversely affect ~~Organon~~ **us** . • There could be significant income tax liability **to us** if the spinoff or certain related transactions are determined to be taxable for U. S. federal income tax purposes. ~~• Contractual restrictions limit Organon' s ability to engage in certain corporate transactions.~~ Risks Related to **Our** ~~Organon' s~~ Common Stock • The price and trading volume of **our** ~~Organon' s~~ Common Stock may be volatile, and stockholders could lose all or part of their investment ~~in Organon~~ . • ~~Organon~~ **We** cannot guarantee the timing, amount or payment of any dividends on ~~the~~ **our** Common Stock. • Certain provisions in **our** ~~Organon' s~~ amended and restated certificate of incorporation and bylaws, and of Delaware law, may prevent or delay an acquisition of Organon, which could decrease the trading price of ~~the~~ **our** Common Stock. • **Our** ~~Certain provisions of agreements that Organon entered into with Merck may limit Organon' s ability to operate its business. • Organon' s~~ 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** ~~Organon' s~~ 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** ~~Organon' s~~ stockholders' ability to obtain what such stockholders believe to be a favorable judicial forum for disputes with ~~Organon~~ **us or** ~~or~~ **our** ~~its~~ directors, officers or employees.- ~~29~~ **17** - **Our** ~~Prior to the spinoff, Merck performed various corporate functions for Organon, including information technology services, research and development, distribution, support for operations, legal, payroll, finance, tax and accounting, general administrative services and other support services. Organon' s historical financial results reflect allocations of corporate expenses from Merck for these and similar functions that may be less than the comparable expenses Organon would have incurred had it operated as a separate publicly traded company.~~

~~Prior to the spinoff, Organon shared economies of scope and scale in costs, employees, vendor relationships and relationships with its partners. While Organon has entered into transition agreements that govern certain commercial and other relationships between it and Merck, those arrangements may not capture the benefits to Organon's business that resulted from being integrated with the other affiliates of Merck. Organon's~~ ability to generate profits and operating cash flow depends largely upon the continued profitability of ~~its~~ **our** key products, such as Nexplanon, Cozaar / Hyzaar, Singulair and the ~~Ezetimibe~~ **ezetimibe** family of products. As a result of **our** ~~Organon's~~ 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** ~~Organon's~~ 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** ~~Organon's~~ 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. ~~Organon~~ **We** also ~~expects~~ **expect** that competition will continue to adversely affect the sales of these products. ~~Organon~~ **We** ~~faces~~ **face** continued pricing pressure **in the United States and** globally and, particularly in ~~mature markets~~ **the EU, the UK, China and Japan,** from managed care organizations, government agencies and programs that could adversely affect ~~its~~ **our** sales and profit margins. ~~Organon~~ **We** ~~expects~~ **expect** pricing pressure to continue in the future ~~. For example, in the United States, Organon experiences significant pricing pressure from: managed care groups, institutional and governmental purchasers, U. S. federal laws and regulations related to Medicare and Medicaid (including the Medicare Prescription Drug Improvement and Modernization Act of 2003, the ACA, and the IRA), and state laws aimed at regulating prices, securing higher rebates, and increasing price transparency). Current and past administrations have listed drug pricing as a health care reform priority. For example, former President Trump used several means, including federal budget proposals, executive orders, and policy initiatives, to propose or implement drug pricing reform; on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100 % of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024; and on August 16, 2022, President Biden signed the IRA into law, which sets forth meaningful changes to drug product reimbursement by Medicare. As discussed in the section entitled" Business- Competition and the Health Care Environment", the IRA, among other things, requires manufacturers to pay 10 % of the negotiated price of brands, biologics and biosimilar products, when Medicare Part D beneficiaries are in the initial coverage phase, and 20 % of the negotiated price in the catastrophic phase of Medicare Part D coverage; establishes a" maximum fair price" beginning in 2026 for certain high expenditure pharmaceutical and biological products covered under Medicare Parts B and D; and allows Medicare to, beginning in 2023, penalize drug companies that raise prices for products covered under Medicare Parts B and D faster than inflation through establishing a rebate obligation for those companies~~ . Changes to the health care system 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. ~~Organon~~ **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 the EU, the UK, China and Japan, have pervasive government involvement in health care funding and, in that regard, extensive pricing and reimbursement mechanisms and processes for pharmaceutical products. Consequently, in those markets, ~~Organon is~~ **we are** subject to government decision- making and budgetary actions with respect to ~~its~~ **our** products. **Cost containment efforts by governments and private organizations are described in greater detail in the Business** - **Regulatory** ~~30- For instance, pricing pressure from the Chinese government has recently increased, including through a series of health care reforms to accelerate generic substitution through the government's VBP and GQCE programs. In 2019, the Chinese government implemented the VBP program through a tendering process for mature products that have generic substitutes with a" GQCE" approval process. Mature products that have entered into the first seven rounds of VBP have had, on average, a price reduction~~ -- **section above** ~~of approximately 50 %~~ . **Our** ~~Organon expects VBP to be a semi- annual process that will have a significant impact on mature products moving forward. There are 300 molecules currently included under VBP, and it is expected that an aggregate of 500 molecules will be subject to VBP by 2025. After the expiration of the national VBP period, individual provinces may implement their own provincial- level VBP programs. In addition, the Universal Reimbursement Payment Standard (" URPS") program is currently being piloted in multiple Chinese provinces. Under the URPS, the government will usually determine the reimbursement prices by referring to the prices of the lowest- priced VBP winning products, with any remaining costs are then passed along to the patients in the form of a co- pay, which reduces the affordability of certain products with prices that exceed the lowest- priced VBP- winning products. The URPS policy will create additional pricing and volume pressure for pharmaceutical products that are subject to the program and may adversely affect Organon's business and results of operations. In Japan, the pharmaceutical industry is subject to government- mandated biennial price reductions of pharmaceutical products. Furthermore, the government can order re- pricing for specific products if it determines that use of such product will exceed certain thresholds defined under applicable re- pricing rules. Organon's~~ products face intense competition from competitors' products, including lower cost generic versions of ~~its~~ **our** products that have lost market exclusivity. Competitors' products may be equally safe and as effective as **our** ~~Organon's~~ products but sold at a substantially lower price than **our** ~~Organon's~~ products. Alternatively, **our** ~~Organon's~~ competitors' products may be safer or more effective, more convenient to use, have better insurance coverage or reimbursement levels or be more effectively marketed and sold than **our** ~~Organon's~~ products. **Our** ~~Organon's~~ efforts to compete with other companies or **our** ~~Organon's~~ failure to maintain ~~its~~ **our** competitive position could adversely affect ~~its~~ **our** business, cash flow, results of operations, financial condition or prospects. ~~Organon has~~ **We have** limited in- house discovery and early research capabilities and will continue to rely on future acquisitions, partnerships and collaborations to expand ~~its~~ **our** innovative pipeline and early

discovery and research capabilities, which may limit ~~its~~ **our** ability to discover or develop new products or expand ~~its~~ **our** existing products into new markets to replace the sales of products that lose patent protection, and therefore ~~Organon~~ **we** may not be able to maintain ~~its~~ **our** current levels of profitability. ~~Organon has~~ **We have** limited in- house discovery and early research staff and facilities, and ~~does~~ **we do** not currently intend to extensively hire or acquire such staff or facilities in the near future. Instead, ~~Organon~~ **we** ~~intends~~ **intend** to continue to rely on future acquisitions, partnerships and collaborations with third parties to expand ~~its~~ **our** innovative pipeline, existing portfolio and innovation and early research capabilities. ~~Organon~~ **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' s knowledge and capabilities, data, quality of operations and compliance to 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** ~~intends~~ **intend** to grow ~~its~~ **our** business through new indications or formulations of ~~its~~ **our** existing products or expansion of existing products into new markets or new geographies. However, ~~Organon~~ **we** ~~expects~~ **expect** that ~~its~~ **our** ability to do so could be limited by the scope of ~~its~~ **our** limited intellectual property licenses for certain women' 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, ~~Organon~~ **we** signed a supplemental license with Merck that provides a limited expansion of the fields in which ~~Organon~~ **we** may use the underlying technology of Nexplanon beyond contraception in exchange for milestone payments. ~~Organon~~ **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 ~~Organon~~ **we** cannot produce sufficient revenues from expansion into new products, new indications or formulations of ~~its~~ **our** existing products or expansion of existing products into new markets or new geographies, then ~~Organon~~ **we** may not be able to maintain ~~its~~ **our** current levels of profitability, and this could adversely affect **our** ~~Organon' s~~ business, cash flow, results of operations, financial condition or prospects. ~~Organon relies~~ **We rely** on third parties for activities related to preclinical and clinical testing. ~~Organon relies~~ **We rely** on third parties to manufacture and distribute ~~its products for preclinical~~ and ~~clinical testing and to~~ conduct certain preclinical and clinical testing activities **for our products** . Oversight of these third parties can require substantial resources and creates potential risks to ~~Organon~~ **us** , including: ~~Organon~~ **we** may be unable to establish agreements with third parties, including third party manufacturers, on acceptable terms or even at all; ~~Organon~~ **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** ~~Organon' s~~ reliance on third parties for research and development activities will also reduce **our** ~~Organon' s~~ control over these activities but does not relieve ~~Organon~~ **us** of ~~its~~ **our** responsibilities, including that ~~Organon~~ **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- ~~- 31-~~ sponsored databases. **Our** ~~Organon' s~~ failures, or the failure of third parties, to comply with applicable regulations could result in sanctions being imposed on ~~Organon~~ **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** ~~Organon' s~~ ability to obtain or maintain marketing approval for ~~its~~ **our** products in a timely manner, or at all. This may hinder or delay efforts to successfully commercialize **our** ~~Organon' s~~ product candidates. ~~Organon~~ **We** ~~intends~~ **intend** to continue pursuing acquisitions of complementary businesses, licensing arrangements and strategic partnerships to expand ~~its~~ **our** product offerings and geographic presence as part of ~~its~~ **our** business strategy. ~~Organon~~ **We** may not complete these transactions in a timely manner, on a cost- effective basis, or at all, and ~~Organon~~ **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 ~~Organon has~~ **we have** limited or no historical experience. ~~For example, Organon was not engaged in the medical device business, until its June 2021, acquisition of Alydia Health, a commercial- stage medical device company. In identifying, evaluating and selecting acquisition targets, Organon may encounter intense competition from other companies having a business objective similar to Organon' s.~~ Many of **our competitors for** these ~~companies~~ **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** ~~Organon does. In addition, certain provisions of the tax matters agreement, which are intended to preserve the intended tax treatment of the spinoff and certain related transactions, may discourage, delay or prevent acquisition proposals or otherwise limit Organon' s ability to pursue certain strategic transactions or engage in other transactions, including mergers or consolidations, for a period of time following the spinoff~~ . Even if ~~Organon is~~ **we are** successful in making acquisitions, the products and technologies ~~Organon~~ **we** ~~acquires~~ **acquire** may not be successful or may require significantly greater resources and investments than ~~it~~ **we** originally anticipated. ~~Organon~~ **We** could experience negative effects on ~~its~~ **our** results of operations and financial condition from acquisition- related charges, amortization of intangible assets and asset impairment charges. ~~Organon~~ **We** could experience difficulties in integrating geographically separated organizations, systems and facilities, and personnel with diverse backgrounds. If an acquired business fails to operate as anticipated or cannot be successfully integrated with **our** ~~Organon' s~~ existing business, ~~its~~ **our** business, financial condition, results of operations or cash flows could be materially and adversely affected. **Our** ~~Organon' s~~ activities, including the manufacturing and marketing of ~~its~~ **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** ~~Organon's~~ pharmaceutical products outside the United States also is primarily focused on drug safety and effectiveness and, in many cases, reduction in the cost of drugs. In addition, regulatory authorities **in** ~~such as~~ the **United States** ~~FDA, the EMA, the MHRA, China's NMPA~~ and **internationally** ~~Japan's Ministry of Health, Labour and Welfare~~ have increased their focus on safety when assessing the benefit / risk balance of drugs. 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. ~~Organon~~ **We** currently ~~markets~~ **market** one product in the United States regulated as a medical device, Jada (acquired through **our** ~~Organon's~~ 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 is subject to the regulatory requirements imposed in those jurisdictions.** In the future, ~~Organon~~ **we** also ~~plans~~ **plan to continue** to sell ~~its~~ **our** medical devices in additional major international markets and will be subject to the regulatory requirements imposed in those jurisdictions. For example, in order to sell medical devices in EU member countries, ~~Organon~~ **we** will need to comply with the MDR. Foreign sales outside the EU (including in the UK) are subject to the foreign government regulations of the relevant jurisdiction, and ~~Organon~~ **we** will need to obtain approval or marketing authorization by the appropriate regulatory authorities before ~~it~~ **we** can commence clinical trials or marketing activities in those countries. ~~Organon~~ **We** cannot market ~~its~~ **our** pharmaceutical products or medical devices or new indications or modifications to ~~its~~ **our** existing products unless and until ~~Organon has~~ **we have** obtained all required regulatory approvals or marketing authorizations in each relevant jurisdiction. **Our** ~~Organon's~~ 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, the FDA may issue complete response letters indicating that **our** ~~Organon's~~ applications for ~~its~~ **our** pharmaceutical products are not ready for approval. Once obtained, ~~Organon~~ **we** must maintain approval or marketing authorization as long as ~~it~~ **we** ~~plans~~ **plan** to market products in each jurisdiction where approval or marketing authorization is required. The FDA or other regulators may change their policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay regulatory approval or marketing ~~- 32-~~ authorization of **our** ~~Organon's~~ future products or impact **our** ~~Organon's~~ ability to modify ~~its~~ **our** currently marketed products on a timely basis. **Our** ~~Organon's~~ failure to obtain approval **or marketing authorization** , significant delays in the approval or marketing authorization process or ~~its~~ **our** failure to maintain approval or marketing authorization in any jurisdiction will prevent ~~Organon~~ **us** from selling the products in that jurisdiction. ~~Organon~~ **We** would not be able to realize revenues for ~~its~~ **our** pharmaceutical products or medical devices in any jurisdiction where ~~it does~~ **we do** not have **required** approval or marketing authorization. ~~Organon~~ **We or** ~~or~~ **our** ~~its~~ partners may fail to adequately demonstrate the safety and efficacy of any of **our** ~~Organon's~~ 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** ~~Organon's~~ product candidates. Before obtaining regulatory approval from the FDA or other comparable foreign regulatory authorities for the sale of **our** ~~Organon's~~ pharmaceutical product candidates, ~~Organon~~ **we** must demonstrate through ~~lengthy~~ pre- clinical studies and clinical trials that ~~its~~ **our** product candidates are both safe and effective for use in each target indication **and population** . Obtaining marketing authorization for **our** ~~Organon's~~ 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 ~~Organon~~ **we** may never succeed in obtaining regulatory approval or marketing authorization of ~~its~~ **our** product candidates. ~~Organon~~ **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** ~~Organon's~~ ability to commercialize ~~its~~ **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 ~~its~~ **our** product candidates in pre- clinical studies or clinical trials to demonstrate safety and efficacy; receipt of feedback from the FDA ~~and~~ **or** other regulatory authorities that require ~~Organon~~ **us** to modify the design of ~~its~~ **our** clinical trials; and negative or inconclusive clinical trial results that may require ~~Organon~~ **us** to conduct additional clinical trials or abandon certain research and / or development programs. ~~Organon~~ **We** may be required to conduct additional pre- clinical studies, clinical trials or other testing of ~~its~~ **our** product candidates beyond those that ~~it~~ **we** currently ~~contemplates~~ **contemplate** , or ~~Organon~~ **we** may be unable to successfully complete pre- clinical studies or clinical trials of ~~its~~ **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, ~~Organon~~ **we** may incur unplanned costs, as well as delays in ~~its~~ **our** efforts to obtain regulatory approval or marketing authorization. Even if ~~Organon~~ **we** ~~receives~~ **receive** such approval, ~~it~~ **we** 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, ~~Organon~~ **we** ~~continues~~ **continue** to be subject to significant post- marketing regulatory requirements and oversight. The regulatory approvals or marketing authorizations that ~~Organon~~ **we** may receive for ~~its~~ **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 ~~its~~ **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** ~~Organon's~~ products will be subject to ongoing regulatory requirements, and ~~Organon~~ **we** will be subject to periodic inspections. Failure to comply with any of these requirements could subject ~~Organon~~ **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** ~~Organon's~~ products, require ~~Organon~~ **us** to cease manufacturing and distribution of the products, trigger product liability or other litigation, or otherwise impact **our**

~~Organon' s~~ ability to realize revenues for ~~its~~ **our** products. As previously disclosed, ~~Organon~~ **we** voluntarily initiated market actions, including recalls, in certain markets with respect to **our** ~~the Company' s~~ suspension injections Diprospan, Celestone **,** ~~Chronodose~~ **ChronodoseTM** ~~®~~ **1** (betamethasone), and Celestone Soluspan ® (betamethasone) related to a non- conforming component of a manufacturing line at **our** ~~Organon' s~~ Heist, Belgium plant. ~~Organon does~~ **We do** not believe this development will materially impact **us** ~~the company~~ . It is possible that future recalls or similar developments could materially and adversely impact **our** ~~Organon' s~~ business, result 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** ~~Organon' s~~ products, it could significantly reduce demand for the product or require ~~it~~ **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** ~~Organon' s~~ distribution **of the product** or applying for marketing authorization for labeling changes. The FDA could also require ~~Organon~~ **us** to conduct **post-** ~~postmarketing~~ ---- **marketing** studies of ~~its~~ **our** products. Further, ~~Organon is~~ **we are** at risk for product liability and consumer protection claims and civil and criminal governmental actions ~~- 33 -~~ related to ~~its~~ **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** ~~Organon' s~~ 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** ~~Organon' s~~ 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. Our success also depends on our ability to maintain and routinely improve product quality and our quality management program. Quality management plays an essential role in meeting customer requirements, preventing defects, improving our products and services and assuring the safety and efficacy of our products. While we have a quality system that covers the lifecycle of our products, quality and safety issues have 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** Our reputation and promising pipeline render our....., and possible litigation. Organon depends - **depend** upon patents to provide ~~it~~ **us** with exclusive marketing rights for certain of ~~its~~ **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** ~~Organon' s~~ sales, a loss of market exclusivity could materially adversely affect ~~its~~ **our** business, cash flow, results of operations, financial condition or prospects. **We** ~~For example, the patent that provided United States market exclusivity for NuvaRing expired in April 2018 and generic competition began in December 2019. Organon experienced a rapid and substantial decline in NuvaRing sales in the United States in 2020 as a result of this generic competition. Organon expects~~ - **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 2025. See" Business — Products **and" — Intellectual Property** " for details, including the patent protection for certain of **our** ~~Organon' s~~ marketed products. Patent protections are important to the marketing of certain of **our** ~~Organon' s~~ products, particularly certain of ~~its~~ **our** women' s health products in the United States and in most major ~~foreign~~ **non- U. S.** markets. Patents covering products that ~~Organon has~~ **we have** introduced normally provide market exclusivity, which is important for the successful marketing and sale of certain of ~~its~~ **our** products. ~~- 34 -~~ Even if ~~Organon~~ **we** ~~succeeds~~ - **succeed** in obtaining patents covering ~~its~~ **our** products, third parties or government authorities may challenge or seek to invalidate or circumvent **our** ~~Organon' s~~ patents and patent applications. It is important for **our** ~~Organon' s~~ business to successfully defend the patent rights that provide market exclusivity for ~~its~~ **our** products. ~~Organon is~~ **We are** involved in patent disputes relating to challenges to ~~its~~ **our** patents or claims by third parties of infringement against ~~it~~ **their patents** . ~~Organon~~ **We** ~~defends~~ - **defend** ~~its~~ **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** ~~Organon' s~~ products prior to the expiration of relevant patents owned or licensed by it. Patent litigation and other challenges to **our** ~~Organon' s~~ patents are costly and unpredictable and may deprive ~~it~~ **us** of market exclusivity for a patented product or, in some cases, third- party patents may prevent ~~Organon~~ **us** from marketing and selling a product in a particular geographic area, negatively affecting ~~its~~ **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** ~~Organon' s~~ business and results of operations. Further, court decisions relating to other companies ~~' '~~ patents, potential legislation in both the United States and certain foreign markets relating to patents, as well as regulatory initiatives, may result in a more general weakening of intellectual property protection. If one or more of **our** ~~Organon' s~~ 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** ~~Organon' s~~ results of operations may be adversely affected by the lost sales unless and until ~~it has~~ **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, ~~Organon~~ **we** may recognize material non- cash impairment charges with respect to the value of those

products. ~~Organon .~~ At December 31, ~~2023~~ **2022** , ~~we~~ **Organon** had outstanding indebtedness of approximately $ 8. ~~8~~ **9** billion,as described more fully in the Notes to ~~our~~ **its** financial statements.In addition, ~~we~~ **Organon** 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~~ **its** indebtedness.Current or future levels of indebtedness may increase the possibility that ~~we~~ **Organon** will be unable to generate cash sufficient to pay amounts due in respect of such indebtedness. ~~Our~~ **Organon' s** ability to issue additional debt or enter into other financing arrangements on acceptable terms ~~could be adversely~~ 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 ~~Organon~~ **us** to purchase minimum amounts of materials critical to ~~its~~ **our** product manufacturing over specified time periods. If ~~Organon~~ **we fails** ~~-~~ **fail** to meet these minimum purchase requirements, ~~it~~ **we** may still be required to pay for the cost of the minimum inventory purchases. If ~~Organon is~~ **we are** unable to offset these payments, it could result in a lower margin. During the year ended December 31, 2022 and 2021, ~~Organon~~ **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. ~~Organon is~~ **We are** also aware of a limited number of other arrangements that have similar provisions which could result in these types of payments. ~~Organon does~~ **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** ~~Organon' s~~ financial condition, results of operations or cash flows. The health care industry in the United States has been, and will continue to be, subject to increasing regulation and political action. ~~Organon~~ **We** ~~believes~~ ~~-~~ **believe** that the health care industry will continue to be subject to increasing regulation and political and legal action at both the ~~Federal~~ **federal** and state levels **in** ~~. In 2010,~~ the United States ~~enacted major health care reform legislation in the form of the Patient Protection~~ and **internationally** ~~the ACA. Since enactment of that law~~ ~~-~~, ~~various insurance market reforms have advanced~~ and **it is uncertain how** ~~state and federal insurance exchanges were launched in 2014. The ACA also increased the mandated Medicaid rebate applicable to most branded drugs from 15. 1 % to 23. 1 % of the product' s Average Manufacturer Price, expanded the rebate to Medicaid managed care utilization, and increased the types of entities eligible for the federal 340B drug discount program. The ACA, together with the Bipartisan Budget Act of 2018, also requires pharmaceutical manufacturers to pay 70 % (up from 50 % from the ACA effective 2019) of the negotiated price of the medicine, including biosimilar products, when Medicare Part D beneficiaries are in the Medicare Part D coverage gap (i. e., the so- called" donut hole provision"). Under the IRA,~~ this ~~coverage gap will be eliminated beginning January 1, 2025. The IRA requires pharmaceutical manufacturers to pay 10 % of the negotiated price of brands, biologics and biosimilar products, when Medicare Part D beneficiaries are in the initial coverage phase, and 20 % of the negotiated price during the catastrophic phase of Medicare Part D coverage. Also, certain pharmaceutical manufacturers are required to pay an annual non- tax deductible health care reform fee. The fee is assessed on each company in proportion to its share of prior year branded pharmaceutical sales to certain government programs, such as Medicare and Medicaid.- 35- As discussed in" Business — Competition and the Health Care Environment," there is significant uncertainty about the future of attempts to legislate health care reforms in the United States. For example, efforts to repeal, modify, or invalidate some or all of the provisions of the ACA, some of which have been successful, create considerable uncertainties for Organon' s business and other pharmaceutical manufacturers. There also has been increasing legislative and enforcement interest in the U. S. with respect to drug pricing practices. There have been, for example, several recent U. S. Congressional inquiries, hearings and proposed and enacted federal legislation and rules, as well as executive orders designed to, among other things, reduce or limit the price of drugs. On August 16, 2022, President Biden signed into law the IRA, which, among other reforms, allows Medicare to: beginning in 2023, penalize drug companies that raise prices for products covered under Medicare Parts B and D faster than inflation. Organon cannot predict how these or future federal legislative proposals~~ will affect ~~it, and, beginning in 2026, establish a" maximum fair price" for certain high expenditure pharmaceutical and biological products covered under Medicare Parts B and D. In 2016, the Centers for Medicare & Medicaid Services issued the Medicaid rebate Final Rule that implemented provisions of the ACA effective April 1, 2016. The Final Rule provided comprehensive guidance on the calculation of Average Manufacturer Price and Best Price, which are two metrics that determine the rebates drug manufacturers are required to pay to state Medicaid programs. Under this Final Rule, among other provisions that have the effect of increasing Medicaid rebate liability, CMS requires manufacturers to include sales to the U. S. Territories in the calculation of AMP and Best Price; however, that provision was delayed several times and took effect on January 1, 2023. On December 31, 2020, CMS published a Final Rule on the Medicaid Program, which, among other things, introduced for the first time a regulatory definition of the terms" line extension" and" new formulation." CMS defined" line extension" as" a new formulation of the drug, but does not include an abuse- deterrent formulation of the drug [.]" CMS adopted an expansive definition of" new formulation" to include" a change to the drug, including, but not limited to: an extended release formulation or~~ **our** ~~other change in release mechanism, a change in dosage form, strength, route of administration, or ingredients." This expanded definition may result in certain of Organon' s drugs being subject to a higher Medicaid rebate liability. The new definitions of" line extension" and" new formulation" took effect on January 1, 2022. Finally, the provisions of this December 2020 Final Rule also may affect rebates owed under the Medicaid Drug Rebate Program in certain circumstances where accumulator adjustment or similar programs are applied to Organon' s drugs and the value of its assistance programs, which is intended for patients, is not counted towards the patient' s deductible or other out- of- pocket costs. In 2020, the FDA issued a final rule implementing provisions of Section 804 of the FDCA, which allows the commercial importation of certain prescription drugs from Canada through FDA- authorized, time- limited programs sponsored by states or Indian tribes, and, in certain future circumstances, pharmacists and wholesalers. At that time, the FDA also released final guidance for industry detailing procedures for drug manufacturers to import FDA-~~

~~approved prescription drug, biological, and combination products (approved under a NDA or Biologics License Application (BLA-)) that were manufactured abroad and authorized and originally intended for sale in a foreign country. A trade organization brought suit, which remains pending in federal district court, challenging the commercial importation final rule. These changes could have a material adverse effect on Organon' s~~ business ~~, cash flow, results of operations, financial condition and prospects~~ . Changes to the health care system 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. As an example, health care reform has contributed to an increase in the number of patients in the Medicaid program under which sales of pharmaceutical products are subject to substantial rebates. ~~Various executive~~ **There are pending legal** and legislative **developments relating to the 340B drug pricing program, including ongoing litigation challenging federal enforcement** actions **against manufacturers** ~~in the United States have been proposed, or may in the future be proposed, to mandate reduced drug prices. For example, in November 2020, CMS issued a Final Rule that was intended to be effective January 1, 2021, which would have instituted a new pricing system for certain prescription drugs~~ and **recently introduced** ~~biologic products covered by Medicare Part B, whereby Medicare would reimburse no more than the" most favored nation price." The rule was immediately challenged in at least four federal courts~~ and **enacted state legislation** ~~was rescinded by CMS on December 29, 2021~~ . **We** ~~Additionally, in November 2020, the Department of Health and Human Services, Office of Inspector General (" OIG") issued a Final Rule, effective January 1, 2022, that eliminates the Anti- Kickback Statute safe harbor for rebates paid to Medicare Part D plans or to pharmacy benefit managers on behalf of such plans. The effectiveness of this Final Rule was delayed as part of the IRA, which was signed into law on August 16, 2022 and requires the Secretary of the Department of Health and Human Services not to implement, administer, or enforce the provisions of the Final Rule prior to January 1, 2032. As a result, it remains to be seen whether, and to what extent, the provisions of this Final Rule will take effect. While Organon cannot anticipate the effects of these changes to the way that it currently contracts, the new framework could significantly alter the way it does business with Part D Plan Sponsors and PBMs on behalf of such plans. - 36- Organon~~ 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 ~~its~~ **our** business, cash flow, results of operations, financial condition or prospects. ~~Organon is~~ **We are** subject to a variety of ~~United States, other national and international~~ laws and regulations, and ~~Organon~~ **we** may face serious consequences for violations if ~~it~~ **we** ~~fails~~ **fail** to meet the applicable legal and regulatory requirements. ~~Organon is~~ **We are** currently subject to a number of government laws and regulations and, in the future, could become subject to new government laws and regulations. The costs of compliance with such laws and regulations, or the negative results of non-compliance, could adversely affect **our** ~~Organon' s~~ business, cash flow, results of operations, financial condition or prospects. The costs of compliance and penalties for non- compliance may be particularly significant with respect to health care reform 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, the United States, and China; legislative mandates or preferences for local manufacturing of medical products; emerging and new global regulatory requirements for reporting payments and other value transfers to health care professionals and health care organizations; environmental regulations; and emerging and new regulations on human rights and environmental matters in the supply chain and importation restrictions, embargoes, trade sanctions and legislative or other 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, (generally known as the" EU Pharma Package"), which is intended to promote innovation and competitiveness through a 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 of the EU Pharma Package on our business.** Because of ~~its~~ **our** U. S. and international operations, ~~Organon is~~ **we are** also subject to anti- corruption laws and regulations, in the United States and internationally, including but not limited to ~~the~~ U. S. domestic bribery **laws,** ~~statute contained in~~ the 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 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** ~~Organon' s~~ business is also heavily regulated and involves significant interaction with foreign officials. In many countries outside the U. S., prescribers of ~~Organon~~ **our** products are employed by government entities, and purchasers are themselves government entities. As such, **our** ~~Organon' s~~ 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 civil or criminal sanctions or other adverse consequences.** In addition to selling ~~its~~ **our** products internationally, ~~Organon~~ **we** currently ~~engages~~ **engage** third parties outside the United States, and may engage additional third parties outside the United States, to sell ~~its~~ **our** products internationally and to obtain necessary permits, licenses, patent registrations and other regulatory approvals. ~~Organon has~~ **We have** direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities and other organizations. ~~Organon~~ **We** can be held liable for the corrupt or other illegal activities of ~~its~~ **our** employees, agents, contractors and other third- party collaborators, even if ~~it does~~ **we do** not explicitly authorize or have actual knowledge of such activities. Enforcement activities

under the laws and regulations described above may subject ~~Organon~~ **us** to administrative and legal proceedings and actions, which could result in substantial civil and criminal fines and penalties, imprisonment, 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. ~~Organon has~~ **We have** significant global operations, which expose ~~it~~ **us** to additional risks, and any adverse event could adversely affect **our** ~~Organon's~~ results of operations and financial condition. The extent of **our** ~~Organon's~~ operations outside the United States is significant. For example, in ~~2022~~ **2023**, ~~Organon~~ **we** generated $ 4. ~~7~~ **8** billion in revenues outside the United States, representing approximately ~~77~~ **76** % of ~~its~~ **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** ~~Organon's~~ ability to manufacture and sell ~~its~~ **our** products in key markets; • multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, tariffs, employment laws, regulatory requirements and other governmental approvals, permits and licenses; • trade protection measures and import or export licensing requirements, including the imposition of trade sanctions or similar restrictions by the United States or other governments; ~~- 37 -~~ • 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** ~~Organon's~~ products; • volatility of commodity prices, fuel, shipping rates that impact the costs and / or ability to supply **our** ~~Organon's~~ products; • diminished protection of intellectual property in some countries; and • possible nationalization and expropriation. In addition, there may be changes to **our** ~~Organon's~~ business and strategic position if there is instability, disruption or destruction in a significant geographic region, regardless of cause, including health epidemics or pandemics ~~(including the ongoing COVID- 19 pandemic)~~, riot, civil insurrection or social unrest, and natural or man- made disasters, including famine, flood, fire, earthquake, storm or disease. In addition, **our** ~~Organon's~~ 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. ~~Job~~ **In addition, patients' ability to afford health care may also be affected by job** losses or other economic hardships **,** ~~may also affect patients' ability to afford health care as a result of~~ increased co- pay or deductible obligations, greater cost sensitivity to existing co- pay or deductible obligations, **and** lost health care insurance coverage ~~or for other reasons~~. Further, with rising international trade tensions or sanctions, **our** ~~Organon's~~ business may be adversely affected following new or increased tariffs, as well as ~~the~~ **increased** costs of materials, products, and commodities upon which ~~Organon~~ **we** rely. As a result, changes in international trade policy, changes in trade agreements and the imposition of tariffs or sanctions by the U. S. or other countries could materially adversely affect **our** ~~Organon's~~ results of operations and financial condition. In ~~particular, in~~ February 2022, **in response to** the armed conflict between Ukraine and Russia ~~escalated, which may adversely impact Organon's business. Specifically~~, trade sanctions, travel bans and asset / financial freezes **were** announced by the United States, European Union and other countries against Russian entities and designated individual 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 ~~Organon~~ **we** ~~conducts~~ **conduct** business and therefore may negatively impact ~~Organon~~ **us**. ~~Organon is~~ **In addition, although we do not expect the recent Israel- Hamas war 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** ~~Organon's~~ ability to transfer, access and use personal data across ~~its~~ **our** business. The legislative and regulatory landscape for privacy and data protection continues to evolve. The GDPR and related implementing laws in individual EU or ~~EEA~~ **the** Member States **of the European Economic Area (" EEA")** 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 ~~Organon~~ **we** ~~processes~~ **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 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 ~~new~~ accountability requirements, such as maintaining a record of data processing, ~~potentially~~ 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 ~~Organon~~ **us**, harm to ~~its~~ **our** reputation, and adversely impact ~~its~~ **our** business and operating results. The uncertainty regarding the interplay between different regulatory frameworks further adds to the complexity that ~~Organon~~ **we** ~~faces~~ **face** with regard to data protection regulation. ~~- 38-~~

Additional laws and regulations enacted in the United States ~~(such as the California Consumer Privacy Act)~~ , Europe, 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. ~~Organon~~ **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 PIPL, regulate the processing of personal information and increase obligations on companies to protect and safeguard information. These regulations also require organizations to evaluate cross- border transfer of personal information and may require localization of certain data if specific conditions are met. We have** adopted a comprehensive global privacy program to **help** manage these evolving risks **, adjust to the changing regulatory landscape** and facilitate the transfer of personal information across international borders ~~, which has been certified as compliant with and approved by the Asia Pacific Economic Cooperation Cross- Border Privacy Rules System~~ . ~~Organon~~ **We** ~~depends~~ **depend** on sophisticated software applications and computing infrastructure. Cyberattacks affecting **our** ~~Organon' s~~ IT systems could result in exposure of confidential information, the modification of critical data or the disruption of ~~its~~ **our** worldwide operations, including manufacturing and sales operations. ~~Organon~~ **We** ~~depends~~ **depend** on sophisticated software applications **(including 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** ~~Organon' s~~ business. Disruption, degradation, destruction or manipulation of these IT systems through intentional or accidental means by **our** ~~Organon' s~~ employees, third parties with authorized access or cyber threat actors could adversely affect key business processes. The size and complexity of **our** ~~Organon' s~~ IT systems, and those of **our** ~~Organon' s~~ third- party providers with whom ~~its~~ **we** ~~contracts~~ **contract** , make such systems potentially vulnerable to service interruptions. In addition, ~~Organon~~ **we** and ~~its~~ **our** third- party providers have experienced and expect to continue to experience phishing attempts, scanning attempts of **our** ~~Organon' s~~ network, and other attempts of unauthorized access to ~~its~~ **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** ~~Organon' s~~ data, applications or systems. In the ordinary course of business, ~~Organon~~ **we** and ~~its~~ **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 ~~Organon~~ **we** must do so in a secure manner to maintain the confidentiality and integrity of such confidential information. The size **- 25-** and complexity of ~~Organon~~ **we** and ~~its~~ **our** third- party providers' 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** ~~Organon' s~~ employees, partners or vendors, or from attacks by malicious third parties. Maintaining the confidentiality, integrity, and availability of this confidential information (including trade secrets or other intellectual property, proprietary business information and personal information) is important to **our** ~~Organon' s~~ competitive business position. However, such information can be difficult to protect and could be compromised. While ~~Organon has~~ **we have** taken steps to protect such information, and to ensure that the third- party providers on which ~~it relies~~ **we rely** have taken adequate steps to protect such information, ~~Organon' s~~ **there can be no assurance that our** efforts to protect ~~its~~ **our** data and IT systems or the efforts of third- party providers to protect their IT systems ~~may not succeed~~ **will be successful in preventing disruptions** . A breach of **our** ~~Organon' s~~ IT systems or ~~its~~ **our** third- party providers' 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 ~~or~~ **,** other forms of deception, or ~~for~~ any other cause, could enable others to produce competing products, use **our** ~~Organon' s~~ proprietary technology or information, and / or adversely affect **our** ~~Organon' s~~ 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** ~~Organon' s~~ patients and employees, or the modification of critical data, could result in financial, legal, business, and reputational harm to **us, including** ~~Organon and could result in~~ loss of revenue, ~~or the~~ loss of critical or sensitive information from ~~Organon' s or~~ **our** ~~its~~ **or our** third- party providers' databases or IT systems, ~~or result in financial, legal, business or reputational harm to Organon~~ and substantial remediation and recovery costs. ~~Organon~~ **We** may experience difficulties ~~,~~ **or** delays **,** or **incur unforeseen** expenses in **connection with the** manufacturing certain of ~~its~~ **our** products. ~~Organon~~ **We or** ~~or~~ **our** ~~its~~ suppliers and other manufacturing partners may experience difficulties ~~,~~ **or** delays ~~or expenses~~ in connection with manufacturing **our** ~~Organon' s~~ 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** ~~Organon' s~~ 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, ~~Organon~~ **we** could experience difficulties or delays in manufacturing ~~its~~ **our** products caused by natural disasters, such as hurricanes, and public health crises and epidemics / pandemics ~~, including~~ **. Any of** the ~~ongoing~~ **foregoing could** ~~39- COVID- 19 pandemic. Manufacturing difficulties, delays or shutdowns, as well as difficulties obtaining materials of adequate quality and quantity, can~~ result in product shortages, ~~leading to~~ lost sales ~~, a significant short- or long- term financial impact~~ , government agency actions, and reputational harm to ~~Organon~~ **us** , which **could have a material** ~~are difficult to predict. Ongoing and future epidemics and pandemics, including the ongoing COVID- 19 pandemic, may adversely~~ -- **adverse effect on our** ~~impact Organon' s~~ business ~~, operations, financial performance~~ , results of operations, and financial condition. **We** ~~Organon' s business and financial results were negatively impacted by the outbreak of COVID- 19. During 2022, our product sales in~~

~~China declined by approximately $ 46 million, primarily as a result of lockdowns and clinic closures in selected cities, as well as a decline in patient visits to the remaining in- patient and out- patient clinics. A significant amount of Organon' s revenue is comprised of physician prescribed products, which, despite underlying demand, have been affected by reduced access, fewer medical visits and delays in elective procedures. Additionally, our portfolio in women' s health includes products that are physician administered, which have been affected by reduced access to physicians and health care centers. These impacts, have resulted in reduced prescription of many products within established brands and women' s health, such as Nexplanon, in some countries outside the U. S., as well as our Fertility brands. The extent to which an epidemic and / or pandemic impacts Organon' s business going forward will depend on future developments, which may include the duration of the outbreak, its severity, the actions to contain the virus or mitigate its impact, the economic impacts of the pandemic and its impact on Organon' s customers and suppliers. Organon~~ may be unable to obtain sufficient components or raw materials on a timely basis or for a cost- effective price, or ~~Organon~~ **we** may experience other supply difficulties that could adversely affect both ~~its~~ **our** ability to deliver ~~its~~ **our** products and ~~its~~ **our** results of operations and financial condition. ~~Organon~~ **We** ~~acquires~~ **acquire** ~~its~~ **our** components, materials and other requirements for manufacturing from many suppliers and vendors in various countries, including sometimes from itself for self- supplied requirements. ~~Organon~~ **We** ~~endeavors~~ **endeavor** to achieve, either alone or by working closely with ~~its~~ **our** suppliers, continuity of **our** ~~Organon' s~~ inputs and supplies, but ~~it~~ **we** cannot guarantee these efforts will always be successful. ~~For instance, Follistim AQ and Atozet' have been challenged by intermittent supply disruptions.~~ Further, while efforts are made to diversify certain of **our** ~~Organon' s~~ 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** ~~Organon' s~~ components and materials for which a single source or supplier is used, alternative sources or suppliers may exist, but ~~Organon has~~ **we have** made a strategic determination to use the single source or supplier. Although **we** ~~Organon does~~ carry strategic inventory and maintain insurance to help mitigate the potential risk related to any related supply disruption, ~~it~~ **we** cannot assure investors that such measures will always be sufficient or effective. Further, if ~~Organon does~~ **we do** 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** ~~Organon' s~~ ability to achieve continuity of ~~its~~ **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** ~~Organon' s~~ ability to manufacture and distribute ~~its~~ **our** products in a timely or cost- effective manner, negatively impacting **our** ~~Organon' s~~ ability to sell ~~its~~ **our** products. ~~Organon~~ **We** may not realize benefits from ~~its~~ **our** investments in **China and** emerging markets. ~~Organon has~~ **We have** been taking steps to increase ~~its~~ **our** sales in **China and** emerging markets; however, **our** ~~Organon' s~~ efforts to expand sales in these markets may not succeed. Some countries ~~within emerging markets~~ 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 ~~Organon~~ **us** to successfully implement **our** ~~its emerging markets~~ strategy, ~~Organon~~ **we** must attract and retain qualified personnel. ~~Organon~~ **We** may also be required to increase **our** ~~Organon' s~~ 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 ~~Organon~~ **we** cannot offset the devaluations, ~~its~~ **our** financial performance within such countries could be adversely affected. For example, **our** ~~Organon' s~~ business in China is growing, and China is now **our** ~~Organon' s~~ second largest market, thereby increasing the importance of China to **our** ~~Organon' s~~ overall pharmaceutical business. Continued growth of **our** ~~Organon' s~~ business in China depends upon ongoing development of a favorable regulatory environment, sustained availability of **our** ~~Organon' s~~ currently marketed products within China, and **our** ~~Organon' s~~ ability to mitigate the impact of any trade impediments or adverse pricing controls. ~~Pricing pressure in~~ China has ~~increased~~ **made reduction of costs and provision of affordable drugs to patients a key priority and has implemented reimbursement and procurement programs to achieve these goals, such** as **VBP and URPS. These programs regularly** ~~the Chinese government has been taking steps to~~ reduce ~~costs, including implementing health care reform that has led to~~ the **price** ~~acceleration of generic substitution, where available. While pricing pressure has always existed in China, health care reform has increased this pressure in part due to the acceleration of generic substitution through the government' s VBP~~ and **/ or reimbursement rate** ~~GQCE programs. In 2019, the government implemented the VBP program through a tendering process~~ for **drugs by over** ~~products that have generic substitutes with a GQCE approval. Mature products that have entered into the first seven rounds of VBP have had, on average, a price reduction of approximately~~ 50 %. ~~Organon expects VBP to be a semi- 40- annual process that will have a significant impact on mature products moving forward, which Organon expects to increase pricing pressure on its products in China. There~~ **These** ~~are 300 molecules currently included under VBP, and it is expected that an~~ **and** ~~aggregate of 500 molecules will be subject to VBP by 2025. Furthermore, the~~ **other such** ~~Chinese government has started its efforts to conform the reimbursement price between GQCE- approved generic products and the applicable originator products. The URPS policy will create additional pricing and volume pressure for pharmaceutical products that are subject to the program~~ **programs could** ~~and may~~ adversely affect **our** ~~Organon' s~~ business **in China** ~~and results of operations~~. In addition, ~~Organon~~ **we** currently ~~relies~~ **rely** on a third- party manufacturer to import, repackage and then sell a significant portion of ~~its~~ **our** products in China. China' s **drug** regulatory ~~landscape continues to evolve, including reform of the Market Authorization Holder, or MAH,~~ system **is regularly changing in response to new policy trends. If these trends** and **the related** ~~change~~ **changes to the** ~~of registration and licensing~~ requirements for **development, importation, registration,** ~~imported pharmaceutical products. These regulatory changes may limit the ability for the third- party manufacturer to continue to sell Organon' s products to downstream distributors~~ **distribution** ~~. The regulatory authority has not made it clear in the existing regulatory framework a pathway for selling these repackaged products to public hospitals. If Organon fails to identify a pathway forward~~, ~~its~~ **and manufacturing of our drugs disrupt our** business **model that would adversely affect our business** in China ~~may be adversely affected~~. Finally, ~~Organon~~ **we** ~~plans~~ **plan** to pivot in China from a primary focus on the public tender market to growth opportunities in the private retail segment. 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** ~~Organon's~~ business, cash flow, results of operations, financial condition or prospects. Current market conditions and recessionary pressures in one or more of our markets could impact our ability to grow our business. Over the last few years in the **United States** ~~U. S.~~ 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 volatility or deterioration in the capital markets, inflation, deflation or other adverse economic conditions ~~may adversely affect our liquidity and financial condition. It~~ may limit our ability to replace maturing liabilities and to access the capital markets to meet liquidity needs, which 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 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' 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 in Ukraine, and 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. ~~Organon is~~ **- 27- We are** exposed to market risk from fluctuations in currency exchange rates and interest rates. ~~Organon~~ **We** ~~operates~~ **operate** in multiple jurisdictions and virtually all of ~~its~~ **our** sales outside the United States are denominated in currencies other than the United States dollar. Additionally, ~~Organon has~~ **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 ~~Organon~~ **we** cannot, with certainty, foresee and mitigate against such adverse fluctuations in currency exchange rates, interest rates and inflation could negatively affect **our** ~~Organon's~~ business, cash flow, results of operations, financial condition or prospects. In order to mitigate the adverse impact of these market fluctuations, ~~Organon~~ **we** ~~enters~~ **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** ~~Organon's~~ reporting currency, the U. S. dollar, and other currencies in which ~~Organon does~~ **we do** business will affect ~~its~~ **our** operating results, often in unpredictable ways. ~~- 41 -~~Reliance on third-party relationships and outsourcing arrangements could materially adversely affect **our** ~~Organon's~~ business. ~~Organon~~ **We** ~~depends~~ **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** ~~Organon's~~ business, including development, manufacture and commercialization of ~~its~~ **our** products (including supplying ~~its~~ **our** products or key ingredients of ~~its~~ **our** products) and support for ~~its~~ **our** IT systems. ~~In addition~~ **Reliance on third parties and their systems poses risks** , ~~in connection~~ **including that the third parties will not comply** with ~~the interim operating arrangements Organon~~ **applicable legal or regulatory requirements for activities conducted on our behalf or for our benefit. This could lead to penalties that flow to us, require us to undertake costly corrective measures such** ~~has~~ **as** ~~been establishing following~~ **recalling product, interrupt our business plans such as by rendering clinical data not usable for regulatory submissions, or** ~~the~~ **other** ~~spinoff, Organon~~ **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 ~~its~~ **our** business operations in compliance with local regulatory requirements. Failure of these third parties to meet their contractual, regulatory and other obligations to ~~Organon~~ **us** or the development of factors that materially disrupt the relationships between ~~it~~ **us** and these third parties could adversely affect **our** ~~Organon's~~ business **. Please see the risk factor above entitled," 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** . The markets for **our** ~~Organon's~~ products, including the women' s health market, may not develop as successfully as expected. **Our** ~~Organon's~~ focus on women' s health is a key component of ~~its~~ **our** strategy. **Our** ~~Organon's~~ ability to successfully execute ~~its~~ **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** ~~Organon's~~ products, technologies, treatments or therapies; • the perception of **our** ~~Organon's~~ products as compared to other products; • recommendation and support for the use of **our** ~~Organon's~~ products or treatments by influential customers, such as obstetricians, gynecologists, reproductive endocrinologists and treatment centers; • changes in government policy or regulations could impair or repeal contraception coverage mandates under the ACA or state

laws, which may affect payments to ~~Organon~~ **us** or impose additional coverage limitations or cost- sharing obligations on ~~its~~ **our** patients; • the availability and extent of data demonstrating the clinical efficacy of **our** ~~Organon' s~~ 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 ~~Organon is~~ **we are** unable to successfully commercialize and create a significant market for ~~its~~ **our** women' s health products, **our** ~~Organon' s~~ business or prospects could be harmed. Our business and operations are subject to risks related to climate change. ~~The effects of~~ **We believe that** global climate change **will** present **some degree of** ~~risks~~ **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. Additionally, increased environmental **, social and governance** ~~regulation~~ **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 the effects of climate change on the environment, such as the EU' s CSRD, California' s Climate Corporate Data Accountability Act and Climate Related Financial Risk Act, and similar regulations under consideration by the SEC. Some potential risks are integrated into our business planning, including investment in reducing energy, water use and greenhouse gas emissions** . The extent and severity of 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 ~~predict and it may be difficult to~~ adequately prepare **for such impact** . Biosimilars carry unique regulatory risks and uncertainties, which could adversely affect **our** ~~Organon' s~~ 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** ~~Organon' s~~ partners to manufacture an adequate supply of biosimilars may adversely affect **our** ~~Organon' s~~ ability to commercialize the biosimilars in ~~its~~ **our** portfolio. **We rely** ~~- 42- Organon relies~~ on ~~its~~ **our** collaboration with Samsung Bioepis and Henlius for the successful development and manufacture of **our** ~~Organon' s~~ biosimilars products and ~~expects~~ **expect** to do so for the foreseeable future. **Our** ~~Organon' s~~ current biosimilars portfolio consists primarily of products developed and manufactured by Samsung Bioepis for which ~~it has~~ **we have** worldwide commercialization rights, with certain geographic exceptions specified on a product- by- product basis. **Our** ~~Organon' s~~ access rights to each product under ~~its~~ **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** ~~In addition, Organon is party to a license agreement with Henlius, whereby Organon has exclusive global license to commercialization rights, other than in China (including Hong Kong, Macau, and Taiwan) for biosimilar candidates HLX11 referencing Perjeta², and HLX14, referencing Prolia / Xgeva. Organon' s~~ ability to successfully commercialize products in ~~its~~ **our** biosimilars portfolio may depend upon maintaining a successful relationship with Samsung Bioepis and Henlius. The success of **our** ~~Organon' s~~ commercialization activities may also depend, in part, on the performance, operations and regulatory compliance of Samsung Bioepis and Henlius and their suppliers, over which ~~Organon does~~ **we do** not have control. **If we fail to** ~~Organon cannot assure investors that its collaboration will be successful or that it will~~ achieve the benefits of ~~its~~ **our** collaborations ~~. Organon has incurred substantial indebtedness~~ , **our business,** ~~which could adversely affect Organon' s~~ financial condition **,** and results of operations . At December 31, 2022,..... into other financing arrangements on acceptable terms could be adversely ~~affected if there~~ **impacted. 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 ~~a material decline in the demand for Organon' s~~ **used to conduct our clinical trials and to manufacture and sell our** products **. If we or** ~~, if Organon' s customers 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** ~~amounts due to Organon~~ or ~~there are other significantly unfavorable changes in economic conditions. Volatility in the world financial markets could increase borrowing costs or affect Organon' s ability to access the capital markets. These conditions may~~ adversely affect **our financing options** ~~Organon' s ability to obtain~~ and **liquidity position** ~~maintain its credit ratings~~ . **Our** ~~Organon' s~~ current indebtedness contains, and any future indebtedness may contain, customary operating restrictions and financial covenants. This indebtedness may adversely affect **our** ~~Organon' s~~ ability to operate or grow ~~its~~ **our** business or could have other material adverse consequences, including by: • limiting **our** ~~Organon' s~~ ability to obtain additional financing in the future for working capital, capital expenditures and acquisitions; • limiting **our** ~~Organon' s~~ ability to refinance ~~its~~ **our** indebtedness on terms acceptable to ~~Organon~~ **us** or at all; **- 29-**

• restricting **our** ~~Organon' s~~ operations or development plans; • requiring ~~Organon~~ **us** to dedicate a significant portion of ~~its~~ **our** cash flows from operations to paying amounts due under ~~its~~ **our** indebtedness, thereby reducing funds available for other corporate purposes; • impeding **our** ~~Organon' s~~ ability to pay dividends; • making ~~Organon~~ **us** more vulnerable to economic downturns; or • limiting **our** ~~Organon' s~~ ability to withstand competitive pressures. Any of these restrictions on **our** ~~Organon' s~~ ability to operate ~~its~~ **our** business in ~~its~~ **our** discretion could adversely affect ~~its~~ **our** business by, among other things, limiting **our** ~~Organon' s~~ 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** ~~Organon' s~~ outstanding debt, dispose of property, complete acquisitions for cash or debt, or make other investments. In addition, events beyond **our** ~~Organon' s~~ control, including prevailing economic, financial, and industry conditions, could affect **our** ~~Organon' s~~ ability to satisfy applicable financial covenants, and ~~Organon~~ **we** cannot assure you that ~~it~~ **we** will satisfy them. Any failure to comply with the restrictions of **our** ~~Organon' s~~ current indebtedness, or any future financing agreements, including as a result of events beyond **our** ~~Organon' s~~ control, may result in an event of default under these agreements, which in turn may result ~~- 43-~~ in defaults or acceleration of obligations under these agreements and other agreements, giving **our** ~~Organon' s~~ lenders and other debt holders the right to terminate any commitments they may have made to provide ~~Organon~~ **us** with further funds and to require ~~Organon~~ **us** to repay all amounts then outstanding. **Changes in tax laws or other tax guidance** ~~As Organon builds its information technology infrastructure and transition its data to its own systems, Organon~~ could ~~incur substantial additional costs and experience temporary business interruptions. In connection with the spinoff, Organon installed and implemented information technology infrastructure to support its critical business functions, including accounting and reporting, manufacturing process control, quality and compliance systems, customer service, inventory control and distribution. Organon may incur temporary interruptions in business operations if it cannot transition effectively from Merck' s existing transactional and operational systems, data centers and the transition services that support these functions as Organon replaces these systems. Organon may not be successful in implementing new systems and transitioning its data, and Organon may incur substantially higher costs for implementation than currently anticipated. Potential operational interruptions impacting Organon as it implements the new systems and replaces Merck' s information technology services, or Organon' s failure to implement the new systems and replace Merck' s services successfully, could disrupt Organon' s business or~~ adversely affect ~~its~~ **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. 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, ~~if~~ **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 ~~is unable to replicate~~ **- sensitive information by** ~~or~~ **our** ~~transition certain systems,~~ **workforce or others through external media channels could lead to information loss. Although there are internal** Organon ~~' s ability to~~ **policies that guide employees on appropriate personal and professional use of these platforms for communication about us, it may not** ~~comply~~ **completely** ~~with regulatory requirements could be impaired~~ **secure and protect information. 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, ~~Organon~~ **we** may experience delays with approvals relating to the separation from Merck, or ~~Organon~~ **we** may not have necessary systems and services in place when certain of the transition agreements expire. In connection with the spinoff, **we** ~~Organon and Merck~~ entered into ~~the~~ **a** Separation and Distribution Agreement ~~and various~~ **with Merck (** ~~other~~ **the" Separation and Distribution** ~~agreements~~ **Agreement ")** , **the** ~~including one or more transition~~ **Transition** ~~services~~ **Services** ~~agreements~~ **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** ~~the section entitled~~ " ~~Certain Relationships~~ **Third- Party Arrangements** and Related ~~Transactions~~ **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. ~~Organon~~ **We** may rely on Merck to satisfy ~~its~~ **our** performance and payment obligations under these agreements. If Merck is unable to satisfy its obligations under these agreements, including its indemnification obligations, ~~Organon~~ **we** could experience operational difficulties or losses. In addition, in connection with the spinoff, ~~Organon has~~ **we have** established operations in ~~certain~~ **most** markets, but is unable to import, distribute, or trade certain products in ~~those~~ **some** markets due to pending licenses, permits, and regulatory approvals, among other requirements. Until all required approvals are received, ~~Organon relies~~ **we rely** upon Merck to perform certain activities in these markets. ~~Organon~~ **We- 30-** may incur additional costs during the period of time before all necessary approvals are granted, which may affect **our** ~~Organon' s~~ business and result in additional costs in these markets. If ~~Organon does~~ **we do** not have ~~its~~ **our** own systems and services in place, or if ~~Organon does~~ **we do** not have agreements with other providers of these services, when these agreements terminate, ~~Organon~~ **we** may not be able to operate ~~its~~ **our** business effectively and ~~its~~ **our** profitability may decline. ~~Organon is~~ **We are** in the process of creating ~~its~~ **our** own, or engaging third parties to provide, systems and services to replace many of the systems and services Merck is providing, and is expected to provide, during the transition period to ~~Organon~~ **us** . ~~Organon~~ **We** may not be successful in effectively or efficiently implementing these systems and services or in transitioning data from Merck' s systems to **our** ~~Organon' s~~ systems. These systems and services may also be more expensive or less efficient than the systems and services

Merck is expected to provide during the transition period. ~~- 44 -~~ The Separation and Distribution Agreement with Merck ~~covers, among other things, provisions governing the relationship between Merck and Organon with respect to and resulting from the spinoff. Among other things, the Separation and Distribution Agreement~~ provides for indemnification obligations designed to make ~~Organon~~ **us** financially responsible for many liabilities that may exist relating to ~~its~~ **our** business activities, whether incurred prior to or after the distribution ~~, pursuant to the Separation and Distribution Agreement~~ , including any pending or future legal matters. These liabilities, which could be material to ~~Organon~~ **us** , include a general obligation to indemnify Merck for litigation or governmental proceedings relating to **our** ~~Organon' s~~ products, including, but not limited to, currently pending litigation relating to Fosamax, Nexplanon, and Propecia / Proscar. More specifically, **our** ~~Organon' s~~ obligations to indemnify Merck may in some cases include liability for antitrust litigation; provided, however, that ~~Organon~~ **we** will not be liable for the results of the antitrust litigation related to Zetia or the product liability litigation in Brazil related to Vioxx² (rofecoxib). For a description of the related legal matters, see Note ~~12~~ **20** " Contingencies" to the Financial Statements included in this report. These indemnification liabilities are intended to ensure that, as between Merck and ~~Organon~~ **us** , ~~Organon is~~ **we are** responsible for all liabilities ~~it~~ **we** ~~assumes~~ **assume** in connection with the spinoff and that ~~Organon~~ **we** ~~pays~~ **pay** for any liability incurred by Merck (including directors, officers, employees and agents) related to **our** ~~Organon' s~~ failure to satisfy such obligations or otherwise in respect of the operation of ~~its~~ **our** business, or any breach by ~~Organon~~ **us** of the Separation and Distribution Agreement or any ancillary agreement. **Our** ~~Organon' s~~ 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 ~~Organon~~ **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 ~~Organon~~ **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** ~~restricts~~ **restricted** ~~Organon~~ **us** from taking any action that **would have** ~~prevents~~ **prevented** the distribution and related transactions from being tax- free for U. S. federal income tax purposes. In ~~particular, under the tax matters agreement, for the two- year period following the distribution, Organon is prohibited, except in certain circumstances, from, among other things: • entering into any transaction resulting in the acquisition of above a certain percentage of Organon' s stock or substantially all of its assets, whether by merger or otherwise; • merging, consolidating, or liquidating; • selling or transferring of Organon' s assets beyond certain thresholds; • issuing equity securities beyond certain thresholds; • repurchasing Organon' s capital stock; • amending Organon' s organizational documents in certain respects; • ceasing to actively conduct certain businesses or causing Organon' s applicable affiliates to cease to actively conduct certain of their businesses; and • taking or failing to take any action that prevents the distribution and related transactions from being tax- free.~~ ~~- 45 -~~ ~~These restrictions may limit Organon' s ability to pursue certain strategic transactions or other transactions that Organon may believe to be in the best interests of its stockholders or that might increase the value of Organon' s business. In~~ addition, ~~Organon is~~ **we are** required to indemnify Merck against any tax liabilities as a result of such actions, even if ~~Organon~~ **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** ~~Organon' s~~ indemnity obligation for Merck' s tax liability under the tax matters agreement would be substantial and could materially affect ~~its~~ **our** cash flow. **In addition,** ~~Certain~~ **certain provisions** of ~~Organon~~ **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** ~~Organon' s~~ executive officers and directors own shares of Merck Common Stock and continue to participate in certain Merck benefit programs. Even though **our** ~~Organon' s~~ Board of Directors consists of a majority of directors who are independent, and **our** ~~Organon' s~~ executive officers who were previously employees of Merck ceased to be employees of Merck in connection with the spinoff, some ~~Organon~~ **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 ~~Organon~~ **we** and Merck pursue the same corporate opportunities or face decisions that could have different implications for ~~Organon~~ **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** ~~Organon' s~~ Common Stock may be volatile. This volatility could negatively impact **our** ~~Organon' s~~ ability to raise additional capital or utilize equity as consideration in any acquisition transactions ~~Organon~~ **we** may seek to pursue, and could make it more difficult for existing stockholders to sell their shares of ~~the~~ **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** ~~Organon' s~~ liquidity and ability to obtain additional capital, including the market' s reaction to any capital- raising transaction ~~Organon~~ **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** ~~Organon' s~~ products and product candidates; • market assessments of any strategic transaction or collaboration arrangement ~~Organon~~ **we** may pursue; • sales of substantial amounts of **our** ~~Organon' s~~ Common Stock, or the perception that substantial amounts of **our** ~~Organon' s~~ Common Stock may be sold, by stockholders in the public market; • changes in earnings estimated by securities analysts or **our** ~~Organon' s~~ ability to meet those estimates; • issuance of new or updated research or reports by securities analysts or changed recommendations for **our** ~~Organon' s~~ Common Stock; and • significant advances made by competitors that adversely affect **our** ~~Organon' s~~ 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 ~~Organon~~ **us**, could result in substantial costs and a diversion of ~~its~~ **our** management' s attention and resources. ~~Organon~~ **We** currently ~~expects~~ **expect** that ~~it~~ **we** will continue to pay quarterly cash dividends. The timing, declaration, amount and payment of any future dividends to stockholders will fall within the discretion of **our** ~~Organon' s~~ Board of Directors. The Board of Directors' decisions regarding the payment of dividends will depend on many factors, such as **our** ~~Organon' s~~ 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** ~~Organon' s~~ ability to pay any dividends will depend on ~~its~~ **our** ongoing ability to generate cash from operations and access capital markets.- ~~46~~ **32** - ~~Organon is~~ **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 ~~its~~ **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** ~~Organon' s~~ Board of Directors rather than to attempt a hostile takeover. Specifically, because ~~Organon has~~ **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** ~~Organon' s~~ 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** ~~Organon' s~~ stockholders might consider in their best interests. For example, **our** ~~Organon' s~~ amended and restated certificate of incorporation and bylaws: • permit **our** ~~Organon' s~~ 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** ~~Organon' s~~ 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** ~~Organon' s~~ Board of Directors is classified, **our** ~~Organon' s~~ 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. ~~Organon~~ **We** ~~believes~~ **believe** these provisions will protect ~~its~~ **our** stockholders from coercive or otherwise unfair takeover tactics by requiring potential acquirors to negotiate with **our** ~~Organon' s~~ Board of Directors and by providing ~~its~~ **our** Board of Directors with more time to assess any acquisition proposal. These provisions are not intended to make ~~Organon~~ **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** ~~Organon' s~~ Board of Directors determines is not in the best interests of ~~Organon~~ **us** and ~~its~~ **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** ~~Organon' s~~ Common Stock if they are viewed as limiting the liquidity of ~~its~~ **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~~ **certain types** of ~~the agreements~~ **actions and proceedings** that ~~Organon entered into~~ **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** ~~Merck require Merck' s consent to any assignment by Organon of its rights and obligations under the agreements. The consent and termination rights set forth in these agreements might discourage, delay or~~ **our directors, officers or employees** ~~prevent a change of control that stockholders may consider favorable~~. **Our** ~~Organon' s~~ amended and restated bylaws provide that, unless ~~Organon~~ **we** ~~selects~~ **select** or ~~consents~~ **consent** to the selection, in writing, of an alternative forum, all internal corporate claims, which include claims in the right of Organon ~~company~~ (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. ~~- 47-~~ Furthermore, unless ~~Organon~~ **we** ~~selects~~ **select** or ~~consents~~ **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** ~~Organon' s~~ 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 he, she or it believes to be favorable for disputes with ~~Organon~~ **us or** ~~or~~ **our** ~~its~~ 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 ~~Organon~~ **we** may incur additional costs associated with resolving such matters in other jurisdictions, which could materially adversely affect **our** ~~Organon' s~~ business, financial condition and results of operations and result in a diversion of the time and resources of ~~its~~ **our** management and board of directors.