UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2022

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File No. 001-40235

Organon & Co.

(Exact name of registrant as specified in its charter)

Delaware	**46-4838035**
(State or other jurisdiction of incorporation)	(I.R.S. Employer Identification No.)

30 Hudson Street, Floor 33

Jersey City New Jersey 07302

(Address of principal executive offices) (zip code)

(Registrant's telephone number, including area code) **(551) 430-6900**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	*Trading Symbol(s)*	*Name of each exchange on which registered*
Common Stock ($0.01 par value)	OGN	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒
Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒
If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐
Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒
The aggregate market value of the voting common equity held by non-affiliates of the registrant, computed by reference to the closing price at which the Common Stock was sold as of the end of the second fiscal quarter ended June 30, 2022, was $8.6 billion
The number of shares of Common Stock outstanding as of the close of business on February 22, 2023: 254,382,732

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III will be incorporated by reference from the Registrant's definitive proxy statement for its 2023 Annual Meeting of Stockholders (the "2023 Proxy Statement"), which will be filed pursuant to Regulation 14A with the United States Securities and Exchange Commission ("SEC") within 120 days after the end of the fiscal year to which this report relates.

Table of Contents

The following notations in this Annual Report on Form 10-K (this "2022 Form 10-K") have the meanings as set forth below:

[1] Indicates, in this 2022 Form 10-K, brand names of products, which are not available in the United States.

[2] Indicates brand names of products which are trademarks not owned by Organon. Specific trademark ownership information is included in the Exhibit Index at the end of this 2022 Form 10-K.

PART I
Item 1. Business

Overview

Organon & Co. ("Organon" or the "Company") is a global health care company with a focus on improving the health of women throughout their lives. Organon develops and delivers innovative health solutions through a portfolio of prescription therapies and medical devices within women's health, biosimilars and established brands (the "Organon Products"). Organon has a portfolio of more than 60 medicines and products across a range of therapeutic areas. The Company sells these products through various channels including drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. The Company operates six manufacturing facilities, which are located in Belgium, Brazil, Indonesia, Mexico, the Netherlands and the United Kingdom. Unless otherwise indicated, trademarks appearing in italics throughout this document are trademarks of, or are used under license by, the Organon group of companies.

The Company's operations include the following product portfolios:

- *Women's Health*: Organon's women's health products are sold by prescription primarily in two therapeutic areas, contraception, with key brands such as *Nexplanon*® (etonogestrel implant) (sold as Implanon NXT™ [1] in some countries outside the United States) and *NuvaRing*® (estonogestrel/ethinyl estradiol vaginal ring), and fertility, with key brands such as *Follistim® AQ* (follitropin beta injection) and *Elonva™* [1] (corifollitropin alfa). *Nexplanon*, a long-acting reversible contraceptive, which is a class of contraceptives that is recognized as one of the most effective types of hormonal contraception available to patients with a low long-term average cost. The *Jada*® System is intended to provide control and treatment of abnormal postpartum uterine bleeding or hemorrhage when conservative management is warranted. Organon acquired *Jada*® through its acquisition of Alydia Health. *Elonva* is a sustained follicle stimulant for controlled ovarian stimulation in combination with a gonadotropin-releasing hormone ("GnRH") antagonist for the development of multiple follicles in women participating in assisted reproductive technologies. It is not approved or marketed in the United States but is available and marketed in certain European countries. In addition, Organon has a license from Daré Biosciences for the global commercial rights to *Xaciato™* (clindamycin phosphate vaginal gel, 2%), an FDA-approved medication for the treatment of bacterial vaginosis ("BV") in females 12 years of age and older. Organon's mission is to be the world's leading women's health company and to deliver a better and healthier every day for every woman. Organon plans to continue building on its strengths in reproductive health and fertility as it assembles a suite of health options that help address the areas of high unmet needs for women from adolescence to menopause and beyond.

- *Biosimilars*: Organon's current portfolio spans across immunology and oncology treatments. Organon plans to continue evaluating opportunities in other potential therapeutic areas, including ophthalmology, diabetes and neuroscience. Organon's oncology biosimilars have been launched in more than 20 countries and Organon's immunology biosimilars have been launched in five countries. All five biosimilars in Organon's portfolio have launched in Canada, and two biosimilars, *Ontruzant*® (trastuzumab-dttb) and *Renflexis*® (infliximab-abda) have been launched in the United States. Organon expects to grow its existing portfolio through future launches in other therapeutic areas, both through Organon's partnership with its development partners, Samsung Bioepis and Shanghai Henlius Biotech, Inc. ("Henlius"), and other potential partners. Organon's existing biosimilars portfolio positions the Company for success in this attractive and fast-growing area of health care with several major biologics that will lose patent protection in the next decade.

- *Established Brands*: Organon has a portfolio of established brands, which generally are beyond market exclusivity, including leading brands in cardiovascular, respiratory, dermatology and non-opioid pain management. A number of Organon's established brands lost exclusivity years ago and have faced generic competition for some time, yet still contribute meaningful profitability. Organon intends to stimulate the performance of its established brands products through renewed focus and attention on strategic marketing to create a significant source of capital to fuel its growth aspirations. Organon believes its established brands products will, over time, continue to deliver meaningful revenue and operating profit that can be redirected into organic and inorganic growth opportunities in key product areas and geographies. Organon's established brands portfolio is supported by its large commercial and manufacturing capabilities, including a global network that enables Organon to distribute products to patients in more than 140 countries and territories.

Led by the women's health portfolio coupled with an expanding biosimilars business and stable franchise of established medicines, Organon's products produce strong cash flows to support investments in innovation and future growth opportunities

in women's health. In addition, Organon is pursuing opportunities to collaborate with biopharmaceutical innovators looking to commercialize their products by leveraging its scale and presence in fast growing international markets.

Organon has expanded its women's health and biosimiliars portfolio through the following recent acquisitions and licenses:

- In January 2023, entered into a strategic investment with Claria Medical, Inc. ("Claria") a privately-held company developing an investigational medical device being studied for use during minimally invasive laparoscopic hysterectomy.

- In July 2022, entered into a research collaboration and license agreement with Cirqle Biomedical ("Cirqle") for a novel investigational non-hormonal, on-demand contraceptive candidate.

- In June 2022, entered into a licensing agreement with Henlius, for commercialization rights for biosimilar candidates HLX11, referencing *Perjeta²* (pertuzumab), used for the treatment of certain patients with HER2+ breast cancer in combinations with trastuzumab and chemotherapy and HLX14, referencing *Prolia²*/*Xgeva²* (denosumab), used for the treatment of certain patients with osteoporosis with high risk of fracture and for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastasis from solid tumors.

- In March 2022, entered into a licensing agreement with Daré for global commercial rights to *Xaciato*. *Xaciato* is an FDA-approved medication for the treatment of bacterial vaginosis ("BV") in females 12 years of age and older. *Xaciato* received both Qualified Infectious Disease Product ("QIDP") and Fast Track designations from the FDA for the treatment of BV.

Spinoff from Merck

On June 2, 2021, Organon and Merck & Co. ("Merck") entered into a Separation and Distribution Agreement (the "Separation and Distribution Agreement"). Pursuant to the Separation and Distribution Agreement, Merck agreed to spin off the Organon Products into Organon, a new, publicly traded company (the "spinoff"). As a result, Organon became a standalone publicly traded company and on June 3, 2021 regular-way trading of Organon's Common Stock (the "Common Stock") commenced on the New York Stock Exchange under the ticker symbol "OGN."

The spinoff was completed pursuant to the Separation and Distribution Agreement and other agreements with Merck related to the spinoff including, but not limited to, a tax matters agreement (the "Tax Matters Agreement" or "TMA"), an employee matters agreement the ("Employee Matters Agreement") and a transition services agreement (the "Transition Services Agreement" or "TSA"). See Note 1 "Background and Nature of Operations" and Note 18 "Third-Party Arrangements and Related Party Disclosures" to the Consolidated Financial Statements included in this report for additional details.

Products

Organon is engaged in developing and delivering innovative health solutions through a diverse portfolio of products serving patient needs across multiple therapeutic areas and product categories, consisting of women's health, biosimilars and established brands. These portfolios are further described below, together with select details for products within each group. Organon's sales for each of its product groups are as follows:

	Year Ended December 31,		
($ in millions)	**2022**	**2021**	**2020**
Women's Health	$ 1,673	$ 1,612	$ 1,555
Biosimilars	481	424	330
Established Brands	3,874	4,068	4,540

In 2022, Organon recorded revenues of $6.2 billion. Organon operates on a global scale and Organon's global network enables it to distribute products to patients in more than 140 countries and territories, with approximately 77% of 2022 revenues, or $4.7 billion, generated outside the United States.

The following highlights key products in our portfolios:

Women's Health Portfolio

In 2022, Organon's women's health portfolio accounted for $1.7 billion, or approximately 27%, of Organon's revenues, with $774 million, or approximately 46%, generated outside the United States. Organon's women's health products are sold by prescription primarily in two therapeutic areas, contraception, with key brands such as *Nexplanon* and *NuvaRing*®, and fertility, with key brands such as *Follistim AQ* and *Elonva*. Additionally, Organon continues to assess commercialization opportunities in conditions unique to women or disproportionally affecting women, such as *Jada* acquired as a part of the acquisition of Alydia Health and the licensing agreement with Daré for global commercial rights to *Xaciato*. Organon's women's health products are sold in over 90 markets worldwide, including the United States, China, Canada, Australia, Brazil, and Mexico as well as many other countries in the European Union ("EU"), South America, Asia, and Africa.

Contraception

Organon's contraception portfolio currently consists of the following products, which work to prevent pregnancy primarily by suppressing ovulation:

Nexplanon is a prescription medication for the prevention of pregnancy in women lasting up to three years and is reversible upon removal. *Nexplanon* is a small, thin and flexible arm implant that is placed discreetly under the skin of the inner, upper non-dominant arm by a health care provider. It is a progestin-only, radiopaque, removable implant, containing 68 mg of etonogestrel pre-loaded into an applicator and is typically prescribed in women who are not looking to become pregnant in the near future and do not want to take a daily contraceptive.

NuvaRing is a monthly vaginal contraceptive ring with a combination of progestin and estrogen used to prevent pregnancy in women. *NuvaRing* typically is prescribed for women that want a monthly contraceptive option.

Cerazette™ [1] (desogestrel) is a progestin-only, daily pill used to prevent pregnancy in women. Progestin-only products like *Cerazette[1]* are typically used by women wanting hormonal contraception for whom estrogen-containing contraceptives may not be medically appropriate. *Cerazette[1]* is not approved or marketed in the United States but is available in certain countries outside the United States.

Marvelon™ [1] (desogestrel and ethinyl estradiol pill) and *Mercilon™ [1]* (desogestrel and ethinyl estradiol pill) are both combinations of progestin and estrogen used as daily pills to prevent pregnancy. *Marvelon* contains a higher daily dose of estrogen than *Mercilon*. *Marvelon* and *Mercilon* are not approved or marketed in the United States but are available in certain countries outside the United States, including now in China and Vietnam as a result of a recent transaction with Bayer Healthcare where Organon gained rights to *Marvelon* and *Mercilon* in these markets.

Fertility

Organon's fertility brands include the following products, which are primarily used for in vitro fertilization ("IVF") treatment cycles:

Follistim AQ, which is marketed as *Puregon™ [1]* in most countries outside the United States, contains human follicle-stimulating hormone ("FSH") and is used to promote the development of multiple ovarian follicles in assisted reproduction technology procedures, such as IVF, embryo transfer, gamete intrafallopian transfer and intracytoplasmic sperm injection. *Follistim AQ* belongs to the group of gonadotrophic hormones used by women trying to get pregnant using IVF.

Elonva is an ovarian follicle stimulant with the same mechanism of action as recombinant FSH, but characterized by a prolonged duration of FSH activity. Due to its ability to initiate and sustain growth of multiple ovarian follicles for an entire week, a single subcutaneous injection of the recommended dose of *Elonva* may replace the first seven injections of any daily recombinant FSH preparation in an ovarian stimulation treatment cycle. *Elonva* belongs to the group of gonadotrophic hormones used by women trying to get pregnant using IVF.

Ganirelix Acetate Injection (marketed in certain countries outside the United States as *Orgalutran™ [1]*) is an injectable ("GnRH") antagonist. Ganirelix Acetate Injection is used in fertility treatments in combination with FSH.

Postpartum Hemorrhage

Organon's postpartum hemorrhage portfolio currently consists of *Jada*, which Organon acquired as part of Organon's acquisition of Alydia Health in June 2021. *Jada* is intended to provide control and treatment of abnormal postpartum uterine bleeding or hemorrhage when conservative management is warranted. *Jada* uses a low-level vacuum to encourage the physiologic contraction of the uterus to control bleeding.

Jada was first cleared by the FDA for use in the United States in August of 2020. In September 2021, technological updates to *Jada* received clearance in the United States from the U.S. Food and Drug Administration (the "FDA"), and officially launched in February 2022.

Organon is seeking marketing authorization of *Jada* outside the United States with approvals in select markets starting in 2023.

Bacterial Vaginosis

In March 2022, Organon entered into a license with Daré Bioscience for *Xaciato*. *Xaciato* is an FDA-approved medication for the treatment of BV in females 12 years of age and older. *Xaciato* received both QIDP and Fast Track designations from the FDA for the treatment of bacterial vaginosis.

Organon aims to launch *Xaciato* in the United States in the first half of 2023 and plans to assess opportunities and potentially seek further marketing authorizations for countries outside the United States.

Biosimilars Portfolio

In 2022, Organon's biosimilars portfolio accounted for $481 million, or approximately 8%, of revenues, with $237 million, or approximately 49%, generated outside the United States. The assets in Organon's biosimilars portfolio and Organon's commercial experience in biosimilars provides an opportunity to benefit from future growth anticipated in this area.

Organon's Biosimilars Products

Organon's biosimilars portfolio consists of therapies in immunology and oncology for which it has worldwide commercialization rights with certain geographic exceptions specified on a product-by-product basis pursuant to agreements that it entered into with Samsung Bioepis and Henlius. The marketed portfolio consists of three immunology products, *Hadlima*™ (Originator brand name: *Humira*[2]; generic name: adalimumab), *Brenzys*™ [1] (Originator brand name: *Enbrel*[2]; generic name: etanercept), and *Renflexis*® (Originator brand name: *Remicade*[2]; generic name: infliximab) and, two oncology products, *Ontruzant*® (Originator brand name: *Herceptin*[2]; generic name: trastuzumab) and *Aybintio*™ [1] (Originator brand name: *Avastin*[2]; generic name: bevacizumab).

The following table lists Organon's commercialized biosimilars with reference to the biologic product and the launch or anticipated launch date of the biosimilar:

Organon's Biosimilar	Biologic Product	Launch of Organon's Biosimilar
Hadlima	*Humira*	United States—approved as of July 2019 and expected launch in the middle of 2023; Australia—February 2021; and Canada—February 2021.
Brenzys[1]	*Enbrel*	Canada—September 2016; Australia—April 2017; Brazil—September 2019; and Israel—January 2021.
Renflexis	*Remicade*	United States—July 2017; Australia—August 2017; and Canada—August 2018.
Aybintio	*Avastin*	Europe—September 2020; and Canada—July 2022.
Ontruzant	*Herceptin*	Europe—March 2018; Australia—January 2020; United States—April 2020; Brazil—August 2020; and Canada—August 2022.

Hadlima (SB5)

Hadlima (adalimumab-bwwd) is a tumor necrosis factor ("TNF") antagonist biosimilar to AbbVie's *Humira* (adalimumab) product, approved for use in certain patients for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, ulcerative colitis, and plaque psoriasis. Organon's current United States label for *Hadlima* does not include hidradenitis suppurativa and uveitis indications. Organon has worldwide commercialization rights to *Hadlima* in countries outside the EU, Korea, China, Turkey, and Russia. Samsung Bioepis reached a global settlement with AbbVie permitting Organon to launch *Hadlima* in the United States in June 2023 and outside the United States starting in 2021. *Hadlima* is currently approved in the United States, Australia, Canada, Israel, and Saudi Arabia, and was launched in Australia and Canada in 2021. *Hadlima* was approved by the FDA in July 2019 as a low-concentration (50mg/ml) formulation. In August 2022, the FDA approved the citrate-free, high-concentration (100 mg/mL) formulation of *Hadlima*.

Brenzys (SB4)

Brenzys[1] (etanercept) is a TNF antagonist biosimilar to Amgen / Pfizer's Enbrel (etanercept) product, approved for use in certain patients for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and plaque psoriasis. Organon has commercialization rights to *Brenzys* in countries outside the EU, Korea, China, Japan and the United States, and it is currently approved and commercialized in Australia, Canada, Brazil and Israel.

Renflexis (SB2)

Renflexis (infliximab-abda) is a TNF blocker biosimilar to Johnson & Johnson's *Remicade* (infliximab) product, approved for use in certain patients for the treatment of Crohn's disease, pediatric Crohn's disease, ulcerative colitis, pediatric ulcerative colitis, rheumatoid arthritis in combination with methotrexate, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis. Organon has worldwide commercialization rights to *Renflexis* in countries outside the EU, Korea, China, Turkey and Russia, and it is currently approved and commercialized in the United States, Australia and Canada.

Aybintio (SB8)

Aybintio (bevacizumab) is a vascular endothelial growth factor inhibitor biosimilar to Roche's *Avastin* (bevacizumab) product. *Aybintio* is currently approved and commercialized in the EU for use in certain patients with metastatic carcinoma of the colon or rectum, metastatic non-squamous, non-small cell lung cancer, metastatic renal cell carcinoma, metastatic cervical cancer, epithelial ovarian, fallopian tube, or primary peritoneal cancer and metastatic breast cancer. Organon has commercialization rights to *Aybintio* in the United States, Canada, Germany, Italy, France, the UK and Spain. Organon cannot currently predict the timing of any filing, approval or launch of *Aybintio* in the United States nor does it know when such timing would be determined.

Ontruzant (SB3)

Ontruzant (trastuzumab-dttb) is an HER2/ neu receptor antagonist biosimilar to Roche's *Herceptin* (trastuzumab) product. *Ontruzant* was approved by the FDA in January 2019 for the treatment of HER2 overexpressing breast cancer and HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma consistent with *Herceptin,* and by the European Medicines Agency ("EMA") in November 2017 as the first trastuzumab biosimilar approved in Europe. Samsung Bioepis reached a global settlement with Roche in June 2019 allowing for Organon to launch *Ontruzant* worldwide. Organon has worldwide commercialization rights to *Ontruzant* in countries outside of Korea and China.

Established Brands Portfolio

Established brands represents a broad portfolio of mature brands across multiple therapeutic areas and geographies that are generally beyond market exclusivity. Organon's established brands portfolio contributed approximately $3.9 billion of revenues in 2022, of which approximately 92%, or $3.6 billion, generated outside the United States. Generic competition varies significantly across geographies.

Cardiovascular

In 2022, Organon's cardiovascular portfolio accounted for $1.5 billion, or approximately 24%, of revenues, nearly all of which were generated outside the United States.

Organon's cardiovascular portfolio consists of several cholesterol-modifying medicines, including: *Zetia*® (ezetimibe), which is marketed as *Ezetrol*™ [1] in most countries outside the United States; *Vytorin*® (ezetimibe / simvastatin), which is marketed as *Inegy*™ [1] outside the United States; *Atozet*™ [1] (ezetimibe and atorvastatin), which is marketed in certain countries outside the United States; *Rosuzet*™ [1] (ezetimibe and rosuvastatin), which is also marketed in certain countries outside the United States; and *Zocor*™ [1] (simvastatin), which is also available in certain countries outside the United States, including China. Organon's portfolio also includes *Cozaar*® (losartan) and *Hyzaar*® (losartan / hydrochlorothiazide), which are cardiovascular drugs for the treatment of hypertension.

Respiratory

In 2022, Organon's respiratory portfolio accounted for $1.0 billion, or approximately 17% of revenues, with approximately 80%, or $826 million, generated outside the United States.

Organon's respiratory portfolio is comprised of several treatments used to control and prevent symptoms caused by asthma, including: *Singulair*® (montelukast sodium), *Dulera*® (formoterol/fumarate dihydrate), which is also marketed as *Zenhale*™ [1] in certain markets outside the United States, and *Asmanex*® (mometesone furoate).

Organon's portfolio also includes several products that treat seasonal allergic rhinitis, including: *Singulair*, *Nasonex*® (mometasone), and *Clarinex*® [2] (desloratadine), which is marketed as *Aerius*™ [1] outside of the United States. Organon currently owns prescription rights for *Clarinex* in the United States and *Aerius* in markets around the world.

Dermatology, Bone Health and Non-Opioid Pain Management

In 2022, Organon's dermatology, bone health and non-opioid pain management portfolios accounted for $788 million, or approximately 13%, of revenues, nearly all of which were generated outside the United States. Organon's dermatology portfolio consists of two core products, including *Diprosone*™ [1] (betamethasone cream), a corticosteroid approved for treatment in relief of skin conditions, and *Elocon*® (mometasone cream), a topical prescription medicine approved for treatment in relief of

inflammation and other symptoms caused by certain skin conditions. Organon's bone health portfolio includes *Fosamax*® (alendronate sodium), a bisphosphonate medicine used for the treatment and prevention of osteoporosis in postmenopausal women and to increase bone mass in men with osteoporosis. Organon's non-opioid pain management portfolio consists of three core products, including: *Arcoxia*™ [1] (etoricoxib), a selective cyclooxygenase-2 inhibitor used for acute and chronic treatment of conditions such as acute pain, osteoarthritis and rheumatoid arthritis, *Diprospan*™ [1] (betamethasone), an injectable glucocorticoid drug approved for treatment of conditions such as bursitis, dermatological disorders and inflammatory conditions, and *Celestone*® (betamethasone injectable suspension), a sterile aqueous suspension approved for treatment of inflammation and conditions such as endocrine disorders and gastrointestinal diseases.

Other Established Brands

This portfolio covers Organon's other mature products, some of which remain significant to Organon's product portfolio, including products such as *Proscar*® (finasteride) and *Propecia*® (finasteride). *Proscar*, used for the treatment of symptomatic benign prostatic hyperplasia ("BPH") in men with an enlarged prostate, accounted for $101 million of revenues in 2022. In addition, *Propecia*, used for the treatment of male pattern hair loss, accounted for $125 million of revenues in 2022. Nearly all sales of *Proscar* and *Propecia* were generated outside the United States.

Research and Development

Organon's development strategy seeks to achieve business continuity with its brands and unlock value from its existing products. As part of its growth strategy, Organon seeks to continue to identify scientific collaborations and acquisitions to build an industry leading pipeline across Women's Health with both early- and late-stage assets that enables scientific and commercial leadership and help solidify our position as a Women's Health partner of choice. Organon's research and development organization is supporting these products through global registration, pharmacovigilance, medical affairs and health economics and outcomes research activities.

As of December 31, 2022, Organon has licenses to commercialize the following development stage products:

- An investigational non-hormonal, on-demand contraceptive candidate. Organon and Cirqle Biomedical have entered into a research collaboration and exclusive license agreement for this novel investigational candidate. Under the terms of the agreement, Cirqle will be responsible for conducting preclinical studies according to the mutually agreed research plan. Organon will obtain exclusive worldwide rights to develop and commercialize the product.

- HLX14, a biosimilar to Amgen's *Prolia*[2]*/Xgeva*[2] (denosumab) is a recombinant anti-RANKL human monoclonal antibody *Prolia* is indicated for postmenopausal women with osteoporosis at high risk for fracture, and *Xgeva* is indicated for the prevention of fractures in patients with multiple myeloma and in patients with bone metastases from solid tumors. Organon has worldwide commercialization rights to HXL11 in countries except for China including Hong Kong, Macau and Taiwan. Henlius will be responsible for development and, if approved, will supply the products to Organon.

- HLX11, a biosimilar to Roche's *Perjeta*[2] *(pertuzumab)* is an anti-HER2 domain II humanized monoclonal antibody biosimilar. Pertuzumab is used for the treatment of certain patients with HER2+ breast cancer in combinations with trastuzumab and chemotherapy. Organon has worldwide commercialization rights to HXL11 in countries except for China; including Hong Kong, Macau and Taiwan. Henlius will be responsible for development and, if approved, will supply the products to Organon.

- OG-6219 is an investigational agent being evaluated as a potential treatment for endometriosis. Endometriosis-related pain is a common and chronic condition that affects up to one in 10 women of reproductive age, causes abdominal pain and is associated with infertility. Organon acquired OG-6219 through its acquisition of Forendo Pharma.

- OG-7191 is a preclinical program targeting polycystic ovarian syndrome ("PCOS"), one of the most common women's health conditions often associated with metabolic disorders, hyperandrogenism and infertility. As there are currently no approved therapies for PCOS, this represents another priority disease area for Organon. Organon acquired OG-7191 through its acquisition of Forendo Pharma.

- Ebopiprant is an investigational, orally active, selective prostaglandin F2α (PGF2α) receptor antagonist being evaluated as a potential treatment for preterm labor by reducing inflammation and uterine contractions. Organon licensed the global development, manufacturing and commercial rights to ebopiprant from ObsEva. If approved, it has potential to be a first-in-class innovation for this common and serious condition with no approved therapies for acute treatment of preterm labor in the United States.

Organon relies on internal scientific expertise and close collaborations with partners, and expects to advance product development opportunities, data generation, product registration, and licensing on a global scale.

Sales, Marketing and Distribution Capabilities

Sales and Marketing

Organon has approximately 3,850 employees worldwide focused on commercialization activities, such as marketing, direct selling, digital and omni-channel and insight generation, covering data stewardship, data analytics and data science. Organon has experienced marketers, pricing and access professionals, and data scientists across geographies that Organon is implementing localization and execution of its global brand and business strategies. Organon believes its commercialization capabilities allow it to execute customer engagement strategies optimized across preferred channels and aimed at health care providers, patients and payors. Organon's global and local marketing employees focus on building an integrated digital ecosystem that coordinates engagement across all channels. These engagements include direct face–to–face engagement, virtual engagement, email, social media and Organon's websites. In addition, Organon believes it has the knowledge, capabilities, and resources to achieve optimal local market access for its portfolio in a changing external environment.

Organon has a trade channel strategy that provides a robust capability framework for Organon's activities, including in the selection of channel partners, commercial terms and supportive health care services that promote the efficient, safe and cost-effective delivery of Organon's products. Organon has significant insight into the use of newer technologies and the use of valuable patient services such as patient adherence programs that can further drive value in collaboration with Organon's trade partners.

Organon does not have any single customer that, if such customer were lost, would have a material adverse effect on Organon's business.

Distribution

Organon's global network enables it to distribute products directly and indirectly to patients in more than 140 countries and territories, including through Organon's regional distribution centers. Organon sells its pharmaceutical products primarily to drug wholesalers and retailers, hospitals, clinics, government agencies, pharmacies, and managed health care providers, such as health maintenance organizations, pharmacy benefit managers and other institutions. Organon also sells its pharmaceutical products through third-party distributors and agents for smaller markets. Organon's professional representatives communicate the effectiveness, safety and value of Organon's pharmaceutical products to health care professionals in private practice, group practices, hospitals and managed care organizations.

Manufacturing Capabilities and Global Supply Chain

Organon has high quality manufacturing capabilities, including development and improvement of manufacturing processes. Organon's principal manufacturing capabilities include formulation, fill-and-finishing of products, packaging of products, and distribution and supply to patients in more than 140 countries and territories.

Internal Manufacturing Capabilities

Organon owns and operates six manufacturing sites, as shown in the table below, where it manufactures a range of pharmaceutical products, including hormonal products, sterile formulations, certain medical device combination and standalone medical device products.

Site	Predominant Area of Focus
Campinas, Brazil	Women's health, cardiovascular and respiratory
Cramlington, UK	Cardiovascular and respiratory
Heist, Belgium	Respiratory, dermatology and pain
Oss, Netherlands	Women's health
Pandaan, Indonesia	Cardiovascular, respiratory and dermatology
Xochimilco, Mexico	Cardiovascular and respiratory

A majority of Organon's internal manufacturing sites have long-standing, deep technical capabilities across the broad base of manufacturing platforms that are required to support Organon's product portfolio. Organon's specialized manufacturing capabilities include oral solid dosage manufacturing, liquids, ointments and creams manufacturing, aseptic processing of hormonal products, extrusion technology, inhaler and implant medical device combination products, standalone medical device products, and packaging to facilitate speed to market as well as more direct control of quality and compliance. Organon also continues to manufacture a range of Merck products at each of Organon's six manufacturing sites pursuant to agreements with Merck entered into at the time of the spinoff.

Global Supply Chain

Organon manages its global supply chain through a centralized supply planning organization and regional demand management, distribution and logistics teams structured around North America, Europe, Middle East and Africa, Asia-Pacific and Latin America. Organon's global commercial and manufacturing teams collaborate on various operational efficiency initiatives, including yield improvements, procurement savings, site synergies, manufacturing support rationalization and supply chain distribution optimization, each intended to improve Organon's leverage position.

Organon purchases certain raw materials, active pharmaceutical ingredients, components, devices and other supplies necessary for the commercial production of its products from a variety of third-party suppliers. Organon utilizes third-party contract manufacturers for packaging, formulation and fill-and-finish for its products. Organon also utilizes a combination of logistics service providers as part of its global supply chain, primarily for storage and for shipping and delivering raw materials, intermediate goods and finished goods between internal sites and from production sites to customers.

In order to satisfy the manufacturing and regulatory requirements for the breadth of products in Organon's portfolio, a number of Organon's materials and components are sole-sourced. Certain of these sole-sourced materials are critical to Organon's key products, including women's health and legacy brands. Organon sources 100% of its active pharmaceutical ingredients externally and portions of its drug product. While the majority are single sourced, they are from established pharmaceutical suppliers with whom Organon has significant experience. In particular, Organon relies heavily on one supplier for formulation and/or packaging as Organon's gateway to sales in both Japan and China.

To mitigate supply risk, Organon aims to have a conservative inventory posture and to keep an internal function focused on maintaining an external manufacturing network with operational, quality, technology and procurement capabilities. This function is responsible for identifying, developing and assessing the performance of Organon's suppliers such that they meet quality expectations and satisfy their contractual obligations to Organon. In addition, this function provides rapid response support for potential supply issues. Organon also has an established risk management framework, which is intended to assess and mitigate risk elements across Organon's supply chain.

Organon's manufacturing network and supply chains are designed to provide it with a flexible and scalable global platform for continued expansion, including in emerging markets. Organon believes its extensive manufacturing and supply chain expertise and capabilities positions it well to provide critical therapies for distribution worldwide and to meet growing demand over the long-term.

Quality Management

Organon's facilities and supporting functions, along with its external contractors, suppliers, and partners, make up an integrated, interdependent global network that is dedicated to consistently delivering compliant, reliable product supply to health care providers and patients. Organon has one quality management system deployed globally that enables the development, manufacturing, packaging, labeling, handling, and distribution of Organon's products such that they conform to applicable regulatory requirements in every country it serves. Organon's quality management system is designed to promote and facilitate regulatory and operational excellence, anticipate risks, and prepare the network to effectively respond and adapt to emerging trends.

Human Capital

Organon's human resources organization is led by an experienced team that monitors its employee base and sets annual targets for managing its human capital, including employee retention, engagement, and training targets. The Talent Committee of Organon's Board regularly reviews and discusses with management Organon's diversity, inclusion and leadership development initiatives, objectives, and progress.

Organon has established benefit and incentive compensation plans, including comprehensive medical and life insurance coverage, 401(k) matching programs and other incentive compensation programs that Organon believes align employee incentives directly with Organon's future performance.

As of December 31, 2022, Organon had approximately 10,000 employees worldwide with approximately 1,650 (16.5%) employees in the United States (including Puerto Rico). Approximately 86% of Organon's employees work in key functional areas (Commercial, Research & Development, and Manufacturing/Supply) and 14% are in support functions. Organon has approximately 3,850 employees worldwide focused on commercialization activities, such as marketing, direct selling, digital and omni-channel and insight generation, covering data stewardship, data analytics and data science, and approximately 900 employees are focused on clinical development, safety, and medical affairs and product registration.

Organon strives to build a strong culture with inclusion and belonging at its core, believing that this is fundamental to success and future innovation. More than 30% of Organon's U.S. employees identify as part of an underrepresented ethnic group. Organon supports its workforce through innovative talent and performance programs and have additionally founded ten Employee Resource Groups. Organon also regularly assesses its employees' experience, including measures of engagement, well-being, inclusion, and core cultural values through annual surveys and regular check-ins.

Organon's employees are at the core of its mission to improve the health of women and, given Organon's global nature, it has a strong focus on female representation. Globally, over 50% of Organon's employees are female, and women comprise approximately 40% of Organon's senior leadership (nearly 70% of the Board of Directors; 40% Executive Committee).

Intellectual Property

Patents, Trademarks and Licenses

Patent protection is important to the marketing of certain of Organon's products in the United States and in most major foreign markets. Patents may cover products per se, pharmaceutical formulations, processes for, or intermediates useful in, the manufacture of products, devices for delivering products, or the uses of products. Protection for individual products extends for varying periods in accordance with the legal life of patents in the various countries, and may be extended in some jurisdictions based upon the period of time a patented product is under regulatory review by the relevant health authority. The protection afforded, which may also vary from country to country, depends upon the type of patent and its scope of coverage.

In particular, Organon considers the patents that cover the rod technology in *Nexplanon* to be material to Organon's business. Such device patents will expire in 2027 in the United States and in 2025 in other countries around the world. There are currently no contested proceedings or third-party claims that involve these patents. Organon has been granted a license from Merck for *Nexplanon / Implanon NXT* that 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 signed a supplemental license with Merck that provides a limited expansion of the fields in which it may use the underlying technology of *Nexplanon / Implanon NXT* beyond contraception in exchange for milestone payments.

While the expiration of a product patent normally results in a loss of market exclusivity for the covered pharmaceutical product, commercial benefits may continue to be derived from: (i) later-granted patents on processes and intermediates related to the

most economical method of manufacture of the active ingredient of such product; (ii) patents relating to the use or delivery of such product; (iii) patents relating to novel compositions and formulations; and (iv) in the United States and certain other countries, market or data exclusivity that may be available under relevant law. The effect of product patent expiration on pharmaceutical products also depends upon many other factors, such as the nature of the market and the position of the product in it, the growth of the market, the complexities and economics of the process for manufacture of the active ingredient of the product and the requirements of new drug provisions of the Federal Food, Drug and Cosmetic Act or similar laws and regulations in other countries.

Additions to market or data exclusivity are sought in the United States and other countries through all relevant laws, including laws increasing patent life. Some of the benefits of increases in patent life have been partially offset by an increase in the number of incentives for and use of generic products. Additionally, improvements in intellectual property laws are sought in the United States and other countries through reform of patent and other relevant laws and implementation of international treaties. For further information with respect to Organon's patents, see the sections entitled "Risk Factors" and Note 12 "Contingencies —Patent Litigation" to the Financial Statements included in this report.

Worldwide, all of Organon's important products are sold under trademarks that are considered in the aggregate to be of material importance. Trademark protection continues in some countries as long as used; in other countries, as long as registered. Registration is for fixed terms and can be renewed indefinitely.

Royalty income in 2022 on patent and know-how licenses and other rights amounted to $3 million. Organon also incurred royalty expenses totaling $13 million in 2022 under patent and know-how licenses Organon holds.

Privacy and Data Protection

Organon is subject to a significant number of privacy and data protection laws and regulations globally, many of which place restrictions on Organon's ability to transfer, access and use personal data across its business. The legislative and regulatory landscape for privacy and data protection continues to evolve. There are privacy and data protection frameworks in both developed and emerging markets with the potential to directly affect Organon's business. These include, for instance, the EU General Data Protection Regulation ("GDPR"), which went into effect in May 2018 and imposes penalties of up to 4% of global revenue; China's Personal Information Protection Law ("PIPL"), which came into effect November 1, 2021; and U.S. state privacy laws, such as the California Consumer Privacy Act, which became effective January 1, 2020, and has been amended and strengthened by the California Privacy Rights Act, which came into force January 1, 2023. Additional privacy and data protection laws will come into force in upcoming years, for instance, Virginia's Consumer Data Protection Act, Colorado's Privacy Act, and United Arab Emirates' Protection of Personal Data Protection. These changing requirements could cause Organon to incur substantial costs or require it to change its business practices or compliance procedures in a manner adverse to Organon's business.

Competition and the Health Care Environment

Competition

The markets in which Organon conducts its business and the pharmaceutical industry in general are highly competitive and highly regulated. Organon's competitors include other worldwide research-based pharmaceutical companies, smaller research companies with more limited therapeutic focus and generic drug manufacturers. Organon's operations may be adversely affected by generic and biosimilar competition as Organon's products mature, as well as technological advances of competitors, industry consolidation, patents granted to competitors, competitive combination products, new products of competitors, the generic availability of competitors' branded products and new information from clinical trials of marketed products or post-marketing surveillance. In addition, patent rights are increasingly being challenged by competitors and the outcome can be highly uncertain. An adverse result in a patent dispute can preclude commercialization of products or negatively affect sales of existing products and could result in the payment of royalties or in the recognition of an impairment charge with respect to intangible assets associated with certain products. Competitive pressures have intensified as pressures in the industry have grown.

To remain competitive, the additional resources required to meet market challenges include quality control, flexibility to meet buyer specifications, an efficient distribution system and a strong technical information service. Organon plans to acquire and market products through external alliances, such as licensing arrangements and collaborations, and has designed its sales and marketing efforts to address changing industry conditions. However, the introduction of new products and processes by competitors may result in price reductions and product displacements, even for products protected by patents.

Health Care Environment

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access.

Health Care Programs

The United States enacted major health care reform legislation in 2010 in the form of the Affordable Care Act (the "ACA"). The ACA, among other things, increased the mandated Medicaid drug rebate from 15.1% to 23.1%, 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 Inflation Reduction Act of 2022 (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 in the catastrophic phase of Medicare Part D coverage. Organon's cost-sharing responsibility for any approved product covered by Medicare Part D could be significantly greater under the newly designed Part D benefit structure compared to the pre-IRA benefit design. Organon recorded approximately $16 million, $17 million and $24 million as a reduction to revenue in 2022, 2021 and 2020, respectively, related to the coverage gap or "donut hole" provision. Furthermore, the IRA, among other reforms, allows Medicare to, beginning in 2026, establish a "maximum fair price" for certain high expenditure pharmaceutical and biological products covered under Medicare Parts B and D. Organon's products could be selected for negotiation and become subject to prices representing a significant discount from average prices to wholesalers and direct purchasers. The IRA also 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. The IRA also imposes on manufacturers that fail to comply with certain provisions of the IRA penalties, including civil monetary penalties.

In addition, certain pharmaceutical manufacturers are required to pay an annual non-tax deductible branded prescription drug fee. The total annual industry fee was $2.8 billion in the years 2020 through 2022. The fee is assessed on each company in proportion to its share of prior year branded pharmaceutical sales to certain government programs, including Medicare and Medicaid.

Organon recorded approximately $3 million, $10 million and $4 million of costs within selling, general and administrative expenses in 2022, 2021 and 2020, respectively, for the annual health care reform fee. In February 2016, the Centers for Medicare & Medicaid Services issued the Medicaid Drug Rebate Final Rule, which provided comprehensive guidance on the calculation of Average Manufacturer Price ("AMP") and Best Price—two metrics utilized to determine the rebates drug manufacturers are required to pay to state Medicaid programs. Under this Final Rule, 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 Drug Rebate 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 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 Organon's assistance programs, which is intended for patients, is not counted towards the patient's deductible or other out-of-pocket costs.

In addition, other legislative changes include automatic 2% aggregate reductions in Medicare payments to providers, which results in an overall reduction in physician-administered drug reimbursement from 106% of Average Sales Price ("ASP") to approximately 104.3% of ASP. This change is part of the federal budget sequestration under the Budget Control Act of 2011, which went into effect in April 2013. The sequestration was temporarily halted from May 1, 2020 to March 31, 2022 as a result of various legislation, and later reduced to 1% from April 2022 to June 2022. The temporary suspension of the 2% reduction in Medicare payments to providers that was instituted in the wake of the COVID-19 pandemic expired on July 1, 2022, with the 2% reduction set to remain in effect until 2031 unless additional Congressional action is taken. Organon cannot predict how these and future adjustments to sequestration, and the way in which these laws impact physician reimbursement for Organon's products, will affect Organon's profitability.

Drug Pricing

Organon also faces increasing pricing pressure globally from managed care organizations, government agencies and programs that could negatively affect Organon's sales and profit margins, including, in the United States (i) practices of managed care organizations, federal and state exchanges and institutional and governmental purchasers, and (ii) federal laws and regulations related to Medicare and Medicaid, including the Medicare Prescription Drug, Improvement and Modernization Act of 2003 and the ACA. For example, in November 2020, the OIG issued a Final Rule that would have, effective January 1, 2022, eliminated the Anti-Kickback Statute safe harbor for rebates paid to Medicare Part D plans or to pharmacy benefit managers ("PBMs") 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 on the way Organon currently contracts, the new framework could significantly alter the way Organon does business with Part D Plan Sponsors and PBMs on behalf of such plans.

On August 16, 2022, President Biden signed the IRA into law, which sets forth meaningful changes to drug product reimbursements by Medicare, which may reduce the prices Organon can charge and reimbursement Organon can receive for its products, among other effects.

On October 14, 2022, President Biden issued an Executive Order on Lowering Prescription Drug Costs for Americans which instructed the Secretary of the Department of Health and Human Services to consider whether to select for testing by the CMS Innovation Center new health care payment and delivery models that would lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in the Medicare and Medicaid programs. The Executive Order further directed the Secretary of the Department of Health and Human Services to submit, within 90 days after the date of the Executive Order, a report regarding any models that may lead to lower cost-sharing for commonly used drugs and support value-based payment that promotes high-quality care.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing. Specifically, several U.S. states and localities have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports, and/or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Other state laws prohibit certain marketing-related activities including the provision of gifts, meals or other items to certain healthcare providers, and restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs. In addition, several recently passed state laws require disclosures related to state agencies and/or commercial purchasers with respect to certain price increases that exceed a certain level as identified in the relevant statutes. Some of these laws and regulations contain ambiguous requirements that government officials have not yet clarified. Given the lack of clarity in the laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations.

In 2020, the FDA issued a final rule implementing provisions of Section 804 of the Federal Food, Drug, and Cosmetic Act (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 a final guidance for industry detailing procedures for drug manufacturers to import FDA-approved prescription drug, biological, and combination products (approved under a New Drug Application ("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.

In the United States private sector, consolidation and integration among health care providers is a major factor in the competitive marketplace for pharmaceutical products. Health plans and PBMs have been consolidating into fewer, larger entities, thus enhancing their purchasing strength and importance. Private third-party insurers, as well as governments, employ formularies to control costs by negotiating discounted prices in exchange for formulary inclusion. Failure to obtain timely or adequate pricing or formulary placement for Organon's products or obtaining such placement at unfavorable pricing could adversely affect revenue. In addition to formulary tier co-pay or co-insurance differentials, private health insurance companies and self-insured employers have been raising co-payments and co-insurance required from beneficiaries, particularly for branded pharmaceuticals and biotechnology products. Private health insurance companies are also increasingly imposing utilization management tools, such as clinical protocols requiring prior authorization for a branded product if a generic product is available or requiring the patient to first fail on one or more generic products before permitting access to a branded medicine. These same management tools are also used in treatment areas in which the payor has taken the position that multiple branded

products are therapeutically comparable. As the United States payor market concentrates further and as more drugs become available in generic form, pharmaceutical companies may face greater pricing pressure from private third-party payors. In addition, other proposals that allow international reference pricing or, under certain conditions, the importation of medicines from other countries may be considered.

European Union

Pricing and reimbursement of medicinal products is not harmonized at the EU level, but rather controlled by individual EU Member States. In addition, a majority of countries in the EU attempt to contain drug costs by engaging in reference pricing in which authorities examine pre-determined markets for published prices of drugs. Reference pricing may either compare a product's prices in other markets (external reference pricing) or compare a product's price with those of other products in a national class (internal reference pricing). The authorities then use the price data to set new local prices for brand-name drugs, including Organon's. Guidelines for examining reference pricing are usually set in local markets and can be changed pursuant to local regulations. Some EU Member States have established free-pricing systems, but regulate the pricing for drugs through profit control plans. Others seek to negotiate or set prices based on the cost-effectiveness of a product or an assessment of whether it offers a therapeutic benefit over other products in the relevant class. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In some EU Member States, cross-border imports from low-priced markets also exert competitive pressure that may reduce pricing within an EU Member State.

Additionally, EU Member States have the power to restrict the range of pharmaceutical products for which their national health insurance systems provide reimbursement. In the EU, reimbursement plans vary widely from EU Member State to EU Member State. Some EU Member States provide that drug products may be marketed only after agreement on a reimbursement price. Some EU Member States may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to already available therapies, or so-called health technology assessments ("HTA"), to obtain reimbursement or pricing approval. The HTA of pharmaceutical products is becoming an increasingly common part of the pricing and reimbursement procedures in most EU Member States. The HTA process, which is governed by the national laws of these countries, involves the assessment of the cost-effectiveness, public health impact, therapeutic impact and/or the economic and social impact of use of a given pharmaceutical product in the national health care system of the individual country. Ultimately, HTA measures the added value of a new health technology compared to existing ones. The outcome of HTAs regarding specific pharmaceutical products will often influence the pricing and reimbursement status granted to these pharmaceutical products by the regulatory authorities of individual EU Member States. A negative HTA of one of Organon's products may mean that the product is not reimbursable or may force Organon to reduce Organon's reimbursement price or offer discounts or rebates. A negative HTA by a leading and recognized HTA body could also undermine Organon's ability to obtain reimbursement for the relevant product outside a jurisdiction. For example, EU Member States that have not yet developed HTA mechanisms may rely to some extent on the HTA performed in other countries with a developed HTA framework to inform pricing and reimbursement decisions. HTA procedures require additional data, reviews and administrative processes, all of which increase the complexity, timing and costs of obtaining product reimbursement and exert downward pressure on available reimbursement.

To obtain reimbursement or pricing approval in some EU Member States, Organon may be required to conduct studies that compare the cost-effectiveness of Organon's product candidates to other therapies that are considered the local standard of care. There can be no assurance that any EU Member State will allow favorable pricing, reimbursement and market access conditions for any of Organon's products, or that it will be feasible to conduct additional cost-effectiveness studies, if required.

Brexit

In 2016, the UK held a referendum in which voters approved an exit from the EU, commonly referred to as "Brexit." As a result of that referendum and subsequent negotiations, the UK left the EU on January 31, 2020. A transitional period existed until December 31, 2020, and during this period the EU and the UK operated as if the UK was an EU Member State, and the UK continued to participate in the EU Customs Union allowing for the freedom of movement for people and goods. Since January 1, 2021, the UK has been treated as a third country (i.e., not part of the EU single market or Customs Union) and is no longer bound by any EU laws (although the UK retained existing EU legislation in its national legislation). However, the Northern Irish Protocol currently provides that certain EU laws have effect in Northern Ireland and that Northern Ireland is within the EU single market.

On December 24, 2020, the EU and the UK agreed to a Trade and Cooperation Agreement ("TCA"). The TCA sets out the new arrangements for trade of goods, including medicines and vaccines, which allows goods to continue to flow between the EU and the UK. The TCA provisionally applied from January 1, 2021 and was permanently in force from May 1, 2021. As a result of the TCA, Organon believes its operations will not be materially adversely affected by Brexit.

Japan

In Japan, the pharmaceutical industry is subject to government-mandated biennial price reductions of pharmaceutical products. Furthermore, the government can order re-pricings for specific products if it determines that use of such products will exceed certain thresholds defined under applicable re-pricing rules.

China

Organon's business in China has grown rapidly in the past few years, and the importance of China to Organon's overall pharmaceutical business has increased accordingly. Continued growth of Organon's business in China is dependent upon ongoing development of a favorable environment for innovative pharmaceutical products, sustained access for Organon's current in-line products, and the absence of trade impediments or adverse pricing controls. In recent years, the Chinese government has introduced and implemented several structural reforms to accelerate the shift to innovative products and reduce costs. Since 2017, there have been multiple new policies introduced by the Chinese government to improve access to innovation, reduce the complexity of regulatory filings, and accelerate the review and approval process. This has led to a significant increase in the number of new products being approved each year. Additionally, in 2017, the Chinese government updated the National Reimbursement Drug List ("NRDL") for the first time in eight years. Since 2017, NRDL is being executed on an annual basis, which creates an access platform for innovative products. Though at the same time this regular innovative products access has been coupled with significant price reductions to ensure public access to NRDL and periodical-biannual price reviews for NRDL products.

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 volume-based procurement ("VBP"). In 2019, the government implemented the VBP program through a tendering process for mature products that have generic substitutes with a Generic Quality Consistency Evaluation ("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-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 are 300 molecules currently included under VBP, and it is expected that an aggregate of 500 molecules will be subject to VBP by 2025.

Other Markets

Organon's focus on other markets has continued. Governments in many other markets are also focused on constraining health care costs and have enacted price controls and measures impacting intellectual property, including in exceptional cases, threats of compulsory licenses that aim to put pressure on the price of innovative pharmaceuticals or result in constrained market access to innovative medicine. Organon anticipates that pricing pressures and market access challenges will continue in the future to varying degrees in such markets.

Beyond pricing and market access challenges, other conditions in certain countries outside the United States can affect Organon's efforts to continue to grow in these markets, including potential political instability, changes in trade sanctions and embargoes, significant currency fluctuation and controls, financial crises, limited or changing availability of funding for health care, credit worthiness of health care partners such as hospitals due to COVID-19, and other developments that may adversely impact the business environment for Organon. Further, Organon may engage third-party agents to assist in operating in such markets, which may affect Organon's ability to realize continued growth and may also increase Organon's risk exposure.

In addressing cost containment pressures, Organon engages in public policy advocacy with policymakers and continues to work to demonstrate that its medicines provide value to patients and to those who pay for health care. Organon advocates with government policymakers to encourage a long-term approach to sustainable health care financing that ensures access to innovative medicines and does not disproportionately target pharmaceuticals as a source of budget savings. In markets with historically low rates of health care spending, Organon encourages those governments to increase their investments and adopt market reforms to improve their citizens' access to appropriate health care, including medicines.

Regulation of Organon's Products

The pharmaceutical and medical device industries are also subject to regulation by regional, country, state and local agencies around the world, focused on standards and processes for determining drug and device safety and effectiveness, as well as conditions for sale or reimbursement.

Of particular importance is the FDA in the United States, which administers requirements covering the testing, approval, safety, effectiveness, manufacturing, labeling and marketing of prescription pharmaceuticals and medical devices. In some cases, the FDA requirements and practices have increased the amount of time and resources necessary to develop new products and bring them to market in the United States. At the same time, the FDA has committed to expediting the development and review of products bearing the "breakthrough therapy" designation, and established other expedited programs to support the development, review, and approval of medicines where there is unmet medical need in serious and life-threatening conditions. The FDA has also undertaken efforts to bring generic and biosimilar competition to market more efficiently and in a timelier manner.

The EU has adopted directives and other legislation concerning the classification, approval for marketing, labeling, advertising, manufacturing, wholesale distribution, integrity of the supply chain, pharmacovigilance and safety monitoring of medicinal products for human use. These provide mandatory standards throughout the EU, which may be supplemented or implemented with additional regulations by the EU Member States. In particular, EU regulators may approve products subject to several post-authorization conditions. Examples of typical post-authorization commitments include additional pharmacovigilance, the conduct of clinical trials, the establishment of patient registries, physician or patient education and controlled distribution and prescribing arrangements. Non-compliance with post-authorization conditions, pharmacovigilance and other obligations can lead to regulatory action, including the variation, suspension or withdrawal of the marketing authorizations, or other enforcement or regulatory actions, including the imposition of financial penalties. Organon's policies and procedures are already consistent with the substance of these directives; consequently, Organon believes that they will not have any material effect on Organon's business.

Organon believes that it will continue to be able to conduct its operations, including launching new drugs and devices, in this regulatory environment.

FDA Regulation

Drugs and Biologics

Industry practice and government regulations in the United States and most foreign countries provide for the determination of effectiveness and safety of new chemical compounds suitable for pharmaceutical use through pre-clinical tests and controlled clinical evaluation. Before a new drug may be marketed in the United States, recorded data on pre-clinical and clinical investigations are included in the NDA for a drug or the Biologics License Application ("BLA") for a biologic, and submitted to the FDA for the required approval.

Once scientists identify internal technology development opportunities or external technology licensing opportunities to enable improvement of existing products or development of new products, pre-clinical testing with that compound is commenced. Pre-clinical testing includes laboratory testing and safety studies in animals to gather data on chemistry, pharmacology, immunogenicity, and toxicology, and must be conducted in compliance with Good Laboratory Practice regulations. Pending acceptable pre-clinical data, Organon will submit an Investigational New Drug ("IND") application to the FDA through a combination of internal and external resources, which includes the results of pre-clinical testing, information about the drug composition and manufacturing, and Organon's plan for clinical testing on humans. After submission of the IND, Organon must wait 30 days before initiating clinical testing so that the FDA can review the IND and determine that clinical testing will not expose human subjects to unreasonable risk. The FDA may impose a full or partial hold on an IND before or after it goes into effect, requiring that Organon halt clinical testing in accordance with the hold. Once an IND goes into effect, Organon will then initiate clinical testing under the supervision of qualified investigators in accordance with established regulatory requirements, including Good Clinical Practice regulations. The clinical testing typically begins with Phase 1 studies, which are designed to assess safety, tolerability, pharmacokinetics and preliminary pharmacodynamic activity of the compound in humans. If favorable, additional, larger Phase 2 studies are initiated to determine evidence of the efficacy of the compound in the affected population and define appropriate dosing for the compound, as well as identify any adverse effects that could limit the compound's usefulness. In some situations, the clinical program incorporates adaptive design methodology to use accumulating data to decide how to modify aspects of the ongoing clinical study as it continues without undermining the validity and integrity of the trial. One type of adaptive clinical trial is an adaptive Phase 2a / 2b trial design, a two-stage trial design consisting of a Phase 2a proof-of-concept stage and a Phase 2b dose-optimization finding stage. If data from the Phase 2 trials are satisfactory, Organon commences large-scale Phase 3 trials to confirm the compound's efficacy and safety. Another type of adaptive clinical trial is an adaptive Phase 2 / 3 trial design, a study that can include an interim analysis and an adaptation that changes the trial from having features common in a Phase 2 study (such as multiple dose groups) to a design similar to a Phase 3 trial. An adaptive Phase 2 / 3 trial design can reduce timelines by eliminating activities which would be required to start a separate study. Upon completion of Phase 3 trials, if satisfactory, Organon submits regulatory filings with the appropriate regulatory agencies around the world to have the product candidate approved for marketing. There can be no assurance that a compound that is the result of any particular program will obtain the regulatory approvals necessary for it to be marketed. After a product receives

marketing authorization, the FDA may require Organon to perform post-marketing studies, or Phase 4 studies, which may involve additional clinical trials, nonclinical testing and surveillance programs to monitor the safety of approved products or to provide additional information regarding treatment or a drug's risks, benefits, or best use.

In the United States, upon completion of clinical testing, a complete NDA or BLA is submitted to the FDA. Within 60 days after receipt, the FDA determines if the application is sufficiently complete to permit a substantive review, or instead if the FDA will issue a refuse to file determination. The FDA also assesses, at that time, whether the application will be granted a priority review or standard review. Pursuant to the Prescription Drug User Fee Act, the FDA review period target for NDAs or original BLAs is either six months for priority review or 10 months for a standard review from the time the application is deemed sufficiently complete. An additional two months is added to these timelines for new molecular entities. Once the review timelines are determined, the FDA will generally act upon the application within those timelines, unless a major amendment has been submitted (either at Organon's own initiative or the FDA's request) to the pending application. If this occurs, the FDA may extend the review period to allow for review of the new information, but by no more than three months. These timelines are not binding, and the FDA may not meet them in particular cases. The FDA can act on an application either by issuing an approval letter or by issuing a Complete Response Letter ("CRL") stating that the application will not be approved in its present form and describing all deficiencies that the FDA has identified. Should Organon wish to pursue an application after receiving a CRL, absent an appeal, Organon is able to resubmit the application with information that addresses the questions or issues identified by the FDA to support approval. Resubmissions are subject to review period targets, which vary depending on the underlying submission type and the content of the resubmission.

The FDA has four primary program designations—Fast Track, Breakthrough Therapy, Accelerated Approval and Priority Review—to facilitate and expedite development and review of new drugs to address unmet medical need in the treatment of serious or life-threatening conditions. The Fast Track designation provides pharmaceutical manufacturers with opportunities for frequent interactions with FDA reviewers during the product's development and the ability for the manufacturer to do a rolling submission of the NDA/BLA. A rolling submission allows completed portions of the application to be submitted and reviewed by the FDA on an ongoing basis. The Breakthrough Therapy designation provides manufacturers with the same features of the Fast Track designation as well as intensive guidance on implementing an efficient development program for the product and a commitment by the FDA to involve senior managers and experienced staff in the review. The Accelerated Approval designation allows the FDA to approve a product based on an effect on a surrogate or intermediate endpoint that is reasonably likely to predict a product's clinical benefit and generally requires the manufacturer to conduct required post-approval confirmatory trials to verify the clinical benefit. As a condition of approval, the FDA will require a sponsor of a drug receiving accelerated approval to perform Phase 4 or post-marketing studies to verify and describe the predicted clinical benefit, and the drug may be subject to accelerated withdrawal procedures. The Priority Review designation means that the FDA's goal is to take action on the NDA/BLA within six months compared to 10 months under standard review, with two months added to these periods for new molecular entities.

In addition, the Biologics Price Competition and Innovation Act provides for an abbreviated pathway for obtaining FDA approval of biologic drugs that satisfy certain criteria. If a manufacturer can show that its proposed biosimilar product is highly similar to and has no clinically meaningful differences from the FDA-approved reference product, it can rely in part on the FDA's previous determination of safety and effectiveness for the reference product for obtaining approval. This can potentially lead to a faster and less costly approval process for these products because it generally means that the biosimilar manufacturer does not need to conduct as many clinical trials.

After the NDA or BLA has been approved, a drug can be marketed in the United States and remains subject to post-marketing drug safety monitoring requirements. Any significant changes to an approved drug, such as changes in formulation, labeling, dosage strength, or certain manufacturing changes, require approval by the FDA through a supplemental application, and for certain significant categories of changes, prior approval by the FDA. Additionally, further development of an approved drug for a new use, dosage strength, or a new or different form must be conducted under a new IND. Organon's activities after approval are subject to the FDA's requirements governing, among other things, drug establishment registration and listing, labeling and advertising, and current Good Manufacturing Practices ("cGMP") regulations, which set forth minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. Post-approval reports of product quality defects and adverse events are maintained and submitted to the FDA in accordance with its regulations. The FDA conducts routine inspections of drug manufacturing facilities to monitor compliance with these requirements. Non-compliance with cGMP or other regulatory requirements can lead to regulatory action, including issuance of Warning Letters to Organon or issuance of safety alerts, press releases, or other communications containing warnings about the products; suspension or withdrawal of the marketing authorizations; suspension of any ongoing clinical trials; or other enforcement or regulatory actions, including seeking injunction or imposing civil or criminal penalties or monetary fines.

The FDA regulates the advertising and promotion of Organon's products to ensure that the claims Organon makes are consistent with its regulatory approvals, that there are adequate and reasonable data to substantiate the claims, and that Organon's promotional labeling and advertising are neither false nor misleading in any respect.

As a manufacturer and distributor of drug products, Organon's activities are regulated under various federal and state statutes, including the Drug Quality and Security Act of 2013 (the "DQSA") and state manufacturer and wholesaler laws.

Title II of the DQSA, known as the Drug Supply Chain Security Act, calls for the establishment of a nationwide electronic system that tracks certain prescription drugs at each point in the supply chain to prevent the introduction of counterfeit, adulterated, or mislabeled drugs into the market. Implementation began in 2015 and is scheduled to be completed by late 2023. The FDA has issued regulations and guidance implementing the DQSA, which require manufacturers, distributors, and dispensers to comply with various regulatory requirements related to product identification, product tracing, product verification, detection and response, notification, and wholesaler licensing.

Under the Controlled Substances Act (the "CSA"), manufacturers and distributors of controlled substances must maintain registration with the Drug Enforcement Agency ("DEA"), and comply with various regulatory requirements, including maintaining records and inventory, reporting to the DEA, and meeting certain security and operational safeguards. Similar requirements exist in most states.

Medical Devices

The FDA's laws and regulations that govern medical devices include requirements for the design, development, testing, manufacturing, labeling, clinical trials, and pre-market clearance and approval, among other requirements. Medical devices are classified into three classes based on their risk: Class I devices present the least risk; Class II devices present moderate risk; and Class III devices are the highest risk. The regulatory controls and requirements vary by the class of device. All classes of devices are subject to "general controls," which include: establishment registration and device listing, compliance with the design controls and good manufacturing practice requirements of the Quality System Regulation, medical device reporting, reporting of recalls, corrections and removals, and labeling and promotional requirements. Most Class I devices do not require any review by the FDA prior to marketing. Most Class II devices require the submission of a pre-market notification under section 510(k) of the FDCA prior to marketing. Class II devices are also subject to "special controls," which are unique controls the FDA establishes for each device type, typically in the form of a guidance document that specifies requirements such as performance testing and labeling. Class III devices require FDA approval of a pre-market approval application ("PMA") prior to marketing and are subject to conditions of approval (which may include post-market study requirements or restrictions on the sale and distribution of the device). Devices that have not previously been classified are automatically Class III. However, if the device is low- or moderate-risk, the manufacturer can submit a de novo classification request asking the FDA to classify the device into Class I or Class II and authorize the marketing of the device.

A 510(k) pre-market notification must demonstrate that the proposed device is "substantially equivalent" to a predicate device already on the market. Substantial equivalence means that the proposed device: (1) has the same intended use as the predicate device; and (2) either (a) has the same technological characteristics as the predicate device, or (b) has different technological characteristics, but does not raise different questions of safety and effectiveness than the predicate device and data demonstrate the proposed device is as safe and effective as the predicate device. If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is not "substantially equivalent" to a previously cleared device, or if the FDA has not classified the device, the device is automatically a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a classification into Class I or II via a de novo classification request. A de novo classification request must describe the risks and benefits of the device and demonstrate that general controls (for a Class I device) or general and special controls (for a Class II device) provide reasonable assurance of safety and effectiveness. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data.

Clinical trials are almost always required to support PMAs and are sometimes required to support 510(k) pre-market notifications. Such clinical testing must be conducted in compliance with the FDA's investigational device exemption ("IDE") regulations and additional regulations pertaining to human research. If the device is a "significant risk" device, clinical trial sponsors must obtain the FDA's approval of an IDE application prior to commencing the study. IDE approval is not required for non-significant risk device studies. All device clinical trials are subject to additional requirements, including obtaining informed consent from study subjects and approval by institutional review boards, monitoring, record-keeping, reporting and submitting information regarding certain clinical trials to a public database maintained by the National Institutes of Health.

Once a device has obtained FDA clearance or approval, certain modifications will require further pre-market review before they can be implemented. For 510(k)-cleared devices (or Class II devices authorized through the de novo classification pathway), any change that could significantly affect the safety or effectiveness of the device or that involves a major change to the device's intended use requires clearance of a new 510(k) pre-market notification. Manufacturers are responsible for determining whether a modification meets this standard, and for any changes the company determines do not require a 510(k), the rationale and information supporting the determination must be documented. For PMA approved devices, major changes (i.e., those affecting safety or effectiveness) require FDA approval of a PMA supplement. Certain other changes, including some labelling changes and some manufacturing changes, may be implemented with prior notice to the FDA. Other changes may be reported in periodic reports.

Marketed devices are also subject to ongoing FDA regulation. Requirements include those related to establishment registration and device listing, labeling and advertising, unique device identification, and good manufacturing practice and design controls. Device manufacturers are also subject to the FDA's medical device reporting regulations, which require a manufacturer to report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur. Manufacturer's must also comply with FDA's correction and removal reporting regulations, which require that manufacturers report to the FDA corrections or removals undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health. The FDA conducts routine inspections of device manufacturing facilities to monitor compliance with these requirements. Non-compliance can lead to informal or formal enforcement action, including Untitled Letters, Warning Letters, fines, injunctions, consent decrees, civil penalties, recalls, detention or seizure of Organon's products, import refusals, and criminal prosecution.

Although physicians are permitted to use their medical judgment to use medical devices for indications other than those cleared or approved by the FDA, Organon may not promote its products for such "off-label" uses and can only market its products for cleared or approved uses. Both the FDA and the Federal Trade Commission have authority over aspects of medical device promotion and prohibit false or misleading labeling and advertising. Other federal, state or foreign enforcement authorities can also take action under other laws and regulations, such as false claims laws, if they consider Organon's business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, and exclusion from participation in government health care programs.

The Regulatory Approval Process Outside the United States

Before Organon's pharmaceutical products can be marketed outside the United States, they may be subject to regulatory approval similar to that required in the United States. The requirements governing the conduct of clinical trials, including requirements to conduct additional clinical trials, product licensing, safety reporting, post-authorization requirements, marketing and promotion, interactions with health care professionals, pricing and reimbursement, may vary widely from country to country. No action can be taken to market any product in a country until an appropriate approval application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices may not be approved for such product, which would make launch of such products commercially unfeasible in such countries. There are also regulations setting out requirements for medical devices in jurisdictions outside the United States. These regulations set out requirements for placing devices on the market, investigations/ trials, safety reporting, marketing and promotion.

The European Union

The following section sets out an overview of the regulatory framework for medicinal products and medical devices in the EU. These rules also apply in the additional Member States of the European Economic Area ("EEA"), namely Iceland, Norway and Liechtenstein.

Drug and Biologic Development Process

Like the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC ("Clinical Trials Directive") sought to harmonize the EU clinical trials regulatory framework by setting out common rules for the control and authorization of clinical trials in the EU,

EU Member States have transposed and applied the provisions of the Clinical Trials Directive in a manner that is not always uniform. This has led to variations in the rules governing the conduct of clinical trials in the individual EU Member States. Therefore, the EU has adopted Regulation (EU) No 536/2014 ("Clinical Trials Regulation") as of January 31, 2022.

Under this new Clinical Trials Regulation, the approval of clinical trials in the EU has been simplified and streamlined. For example, the sponsor submits a single application for approval of a clinical trial via the clinical trials information system. As part of the application process, the sponsor proposes a reporting EU Member State, which coordinates the validation and evaluation of the application. The reporting EU Member State consults and coordinates with the other concerned EU Member States. If an application is rejected, it can be amended and resubmitted through the EU Portal. If an approval is issued, the sponsor can start the clinical trial in all concerned EU Member States. However, a concerned EU Member State can in limited circumstances declare an "opt-out" from an approval. In such a case, the clinical trial cannot be conducted in that EU Member State. The Clinical Trials Regulation also aims to streamline and simplify the rules on safety reporting, and introduces enhanced transparency requirements such as mandatory submission of a summary of the clinical trial results to the EU Database.

National laws, regulations, and the applicable Good Clinical Practice and Good Laboratory Practice standards must also be respected during the conduct of the trials, including the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use guidelines on Good Clinical Practice ("GCP").

During the development of a pharmaceutical product, the EMA and national regulators within the EU provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Committee for Medicinal Products for Human Use ("CHMP") on the recommendation of the Scientific Advice Working Party. A fee is incurred with each scientific advice procedure. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies, and pharmacovigilance plans and risk-management programs. Advice is not legally binding for any future Marketing Authorization Application ("MAA") of the product concerned. In the EU, the Pediatric Regulation (EC) No 1901/2006 ("Pediatric Regulation") sets out the requirements for testing medicinal products in pediatric populations. In most EU Member States, companies are also required to have an approved Pediatric Investigation Plan before enrolling pediatric patients in a clinical trial.

Drug and Biologic Marketing Authorization Procedures

In the EU, pharmaceutical products may only be placed on the market after obtaining a Marketing Authorization ("MA"). MAs can be obtained through the centralized procedure, the mutual recognition procedure, the decentralized procedure, or a national procedure (the latter is available only for pharmaceutical products sold in a single EU Member State only). The primary method Organon uses to obtain a MA of pharmaceutical products in the EU is through the centralized procedure.

The centralized procedure provides for the grant of a single MA by the European Commission ("EC"), which is valid for all EU Member States (and, after respective national implementing decisions, in the three additional EEA Member States). The centralized procedure is compulsory for certain pharmaceutical products, including pharmaceutical products derived from biotechnological processes, orphan pharmaceutical products, advanced therapy pharmaceutical products and products with a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases.

Under the centralized procedure, the timeframe for the evaluation of an MAA by the EMA's CHMP is, in principle, 210 days from receipt of a valid MAA. However, this timeline excludes clock stops, which occur when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP, so the overall process typically takes a year or more. Applications may be eligible for accelerated assessment if the CHMP decides the product is of major interest for public health and therapeutic innovation. On request, the CHMP can reduce the time frame to 150 days if the applicant provides sufficient justification for an accelerated assessment. The CHMP will provide a positive opinion regarding the application only if it meets certain quality, safety and efficacy requirements. However, the EC has final authority for granting the MA, and it must issue the decision within 67 days after receipt of the CHMP opinion.

Following the UK's exit from the EU on January 1, 2021, the UK Medicines and Healthcare products Regulatory Agency ("MHRA") converted centralized MAs into UK MAs that apply in Great Britain (as under the Northern Irish Protocol the EU centralized MAs continue to apply in Northern Ireland). MA holders of the centralized MAs had the right to opt-out of the conversion until January 21, 2021; however, this would mean that these products would not be licensed to be marketed in Great Britain. For those with converted MAs, the holder of these MAs had to submit baseline data to the MHRA and pay the national

MA fee. For EU MAs that were granted after January 1, 2021, these MAs will not be automatically converted into UK MAs. However, the MHRA offer some streamlined routes for authorization. For example, for three years from January 1, 2021 the MHRA may rely on the decision of the EC on the approval of a new centralized MA when granted an MA that applies in Great Britain.

If the centralized procedure is not used, then applicants can obtain national marketing authorizations. This can be if a pharmaceutical product falls under the optional scope of the centralized procedure and the applicant opts to use a national (decentralized / mutual recognition) procedure or if the centralized procedure would not apply. The purely national marketing authorization procedure permits a company to apply to the competent authority of a single EU Member State and, if successful, to obtain a MA that is valid only in this EU Member State. However, if the applicant wants a MA in several EU Member States it must use the decentralized or mutual recognition procedure (as applicable) to obtain a suite of national MAs.

The decentralized marketing authorization procedure permits companies to file identical applications for an MA to the competent authorities in several EU Member States simultaneously for a pharmaceutical product that has not yet been authorized in any EU Member State. This procedure is available for pharmaceutical products not falling within the mandatory scope of the centralized procedure. The competent authority of a single EU Member State, the reference EU Member State, is appointed to review the application and provide an assessment report. The competent authorities of the other EU Member States, the concerned EU Member States, are subsequently required to grant MA for their territories based on this assessment. The only exception to this is where the competent authority of an EU Member State considers that there are concerns of potential serious risk to public health related to authorization of the product. In these circumstances the matter is submitted to the Coordination Group for Mutual Recognition and Decentralized Procedures - Human for review.

Where a pharmaceutical product has already been authorized for marketing in an EU Member State, this national authorization can be recognized in another EU Member State through the mutual recognition procedure. The EU Member State that has already granted a MA is the reference EU Member State. The holder of the MA then asks the reference EU Member State to either prepare or update an assessment report. As with the decentralized procedure, the assessment report is shared with the concerned EU Member States. These EU Member States must grant the MA unless the exception (on the grounds of potential serious risk to public health) applies.

Similar to accelerated approval regulations in the United States, conditional MAs can be granted in the EU by the EC in exceptional circumstances. A conditional MA can be granted for pharmaceutical products where, although comprehensive clinical data referring to the safety and efficacy of the pharmaceutical product have not been supplied, a number of criteria are fulfilled: (i) the benefit / risk balance of the product is positive, (ii) it is likely that the applicant will be in a position to provide the comprehensive clinical data post-authorization, (iii) an unmet medical need will be fulfilled by the grant of the marketing authorization and (iv) the benefit to public health of the immediate availability on the market of the pharmaceutical product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional MA must be renewed annually until it is eventually converted into a standard MA when the holder fulfills any obligations imposed and the data supports that the benefits outweigh its risks.

Alternatively, where the applicant can show it is unable to provide comprehensive data on the efficacy and safety under normal conditions (because the condition is too rare, it would be impossible given the current state of scientific knowledge and/or it would be contrary to medical ethics), the EC may grant an MA in exceptional circumstances. MAs granted under exceptional circumstances will be reviewed annually to ensure the benefits continue to outweigh the risks. However, they will usually not result in a normal MA as the data to support its granting will never be generated.

All new MAAs must include a Risk Management Plan ("RMP") describing the risk management system that Organon will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. RMPs and Periodic Safety Update Reports ("PSURs") are routinely available to third parties requesting access, subject to limited redactions.

Normal MAs (i.e., not including Conditional MAs and those granted under exceptional circumstances) have an initial duration of five years. After these five years, the authorization may be renewed on the basis of a reevaluation of the risk-benefit balance. Once renewed, the MA is valid for an unlimited period unless the EC or the national competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Applications for renewal must be made to the EMA at least nine months before the five-year period expires.

Data and Market Exclusivity for Drugs and Biologics

As in the United States, it may be possible to obtain a period of market and / or data exclusivity in the EU that would have the effect of postponing the entry into the marketplace of a competitor's generic, hybrid or biosimilar product (in the case of marketing exclusivity, even if the pharmaceutical product has already received an MA) and for data exclusivity, prohibiting another applicant from relying on the MA holder's pharmacological, toxicological and clinical data in support of another MA for the purposes of submitting an application. New medicinal products authorized in the EU on the basis of a standalone application (i.e., on the basis of a dossier containing a complete suite of pre-clinical tests and clinical trials) qualify for eight years of data exclusivity and 10 years of marketing exclusivity. An additional noncumulative one-year period of marketing exclusivity is possible if during the data exclusivity period (the first eight years of the 10-year marketing exclusivity period), the MA holder obtains an authorization for one or more new therapeutic indications that are deemed to bring a significant clinical benefit compared to existing therapies. This product is referred to as the "reference medicinal product."

The data exclusivity period begins on the date of the reference medicinal product's first MA in the EU. After eight years, a generic product application may be submitted and generic companies may rely on the data in the reference medicinal product's dossier. However, a generic product cannot launch until two (or three, if the reference medicinal product was authorized for an additional indication) years later (or a total of 10 or 11 years after the first MA in the EU of the reference medicinal product).

Another noncumulative one-year period of data exclusivity can be obtained where an application is made for a new indication for a well-established substance, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication. One year of data exclusivity is also available for data generated where a change of classification (i.e., from prescription-only to over the counter) of a pharmaceutical product has been authorized on the basis of significant pre-trial tests or clinical trials. However, this data exclusivity only protects the new switch data (i.e., when examining an application by another applicant for or holder of market authorization for a change of classification of the same substance, a competent authority will not refer to the results of those tests or trials for one year).

However, data and market exclusivity are not monopoly rights. Therefore, another company could also market another version of the pharmaceutical product if such company can complete a full MAA with their own complete database of pharmaceutical tests, pre-clinical studies and clinical trials (without relying on the other initial applicant's data) and obtain MA of its product.

Post-Approval Regulation of Drugs and Biologics

Similar to the United States, both MA holders and manufacturers of pharmaceutical products are subject to comprehensive regulatory oversight by the EMA, the EC and / or the national competent authorities of the EU Member States. This oversight applies both before and after grant of manufacturing licenses and marketing authorizations. It includes control of compliance with EU good manufacturing practices rules, manufacturing authorizations, pharmacovigilance rules and requirements governing advertising, promotion, sale, distribution, recordkeeping, importing and exporting of pharmaceutical products.

Failure by Organon or by any of its third-party partners, including suppliers, manufacturers and distributors, to comply with EU laws and the related national laws of individual EU Member States governing the conduct of clinical trials, manufacturing approval, marketing authorization of pharmaceutical products and marketing of such products, both before and after grant of marketing authorization, statutory health insurance, bribery and anti-corruption or other applicable regulatory requirements, may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

The holder of an MA for a pharmaceutical product in the EU must also comply with EU pharmacovigilance legislation and its related regulations and guidelines, which entail many requirements for conducting pharmacovigilance, or the assessment and monitoring of the safety of pharmaceutical products. These pharmacovigilance rules can impose on holders of MAs the obligation to conduct a labor intensive collection of data regarding the risks and benefits of marketed pharmaceutical products and to engage in ongoing assessments of those risks and benefits, including the possible requirement to conduct additional clinical studies or post-authorization safety studies to obtain further information on a medicine's safety, or to measure the effectiveness of risk-management measures, which may be time consuming, expensive and could impact Organon's profitability. MA holders must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. The EMA reviews PSURs for pharmaceutical products authorized through the centralized procedure. If the EMA has concerns that the risk benefit profile of a product has varied, it

can adopt an opinion advising that the existing MA for the product be suspended, withdrawn or varied. The agency can advise that the MA holder be obliged to conduct post-authorization Phase IV safety studies. The EMA opinion is submitted to the EC for its consideration. If the European Commission agrees with the opinion, it can adopt a decision varying the existing MA. Failure by the marketing authorization holder to fulfill the obligations in the EC's decision can undermine the on-going validity of the MA.

More generally, noncompliance with pharmacovigilance obligations can lead to the variation, suspension or withdrawal of the MA for the product or imposition of financial penalties or other enforcement measures.

The manufacturing process for pharmaceutical products in the EU is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. Manufacturing requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance, including Directive 2001/83/EC, Directive (EU) 2017/1572, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice ("GMP"). Organon and its third-party manufacturers are also subject to other good manufacturing practices, which are extensive regulations governing manufacturing processes, stability testing, record keeping and quality standards as defined by the EMA, the EC, the national competent authorities of EU Member States and other regulatory authorities. Companies may be subject to civil, criminal or administrative sanctions if they fail to comply with these practices. These include suspension of manufacturing authorization in case of non-compliance with the EU or EU Member States' requirements governing the manufacturing of pharmaceutical products.

Compliance with EU GMP standards is required when manufacturing pharmaceutical products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside the EU with the intention to import the active pharmaceutical ingredients into the EU. The manufacturer or importer must have a qualified person who is responsible for certifying that each batch of product has been manufactured in accordance with GMP before releasing the product for commercial distribution in the EU or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with GMP. Similarly, the distribution of pharmaceutical products into and within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the EU Member States.

Sales and Marketing Regulation of Drugs and Biologics

The advertising and promotion of Organon's products is also subject to EU laws, national laws of individual EU Member States and industry self-regulatory codes of conduct concerning promotion of pharmaceutical products, interactions with health care providers, misleading and comparative advertising and unfair commercial practices.

While the laws in individual EU Member States might vary somewhat, in all EU Member States these laws require that promotional materials and advertising in relation to pharmaceutical products comply with the product's Summary of Product Characteristics ("SmPC") as approved by the competent regulatory authorities. The SmPC is the document that provides information to health care providers concerning the safe and effective use of the pharmaceutical product. It forms an intrinsic and integral part of the marketing authorization granted for the pharmaceutical product. Promotion of a pharmaceutical product that does not comply with the SmPC is considered to constitute off-label promotion. The off-label promotion of pharmaceutical products is prohibited in the European Union. The applicable laws at the EU level and in the individual EU Member States also prohibit the direct-to-consumer advertising of prescription-only pharmaceutical products. Enforcement is done on a national basis, in accordance with national rules/codes and is largely on the basis of self-regulation. Penalties for violations of the rules governing the promotion of pharmaceutical products vary between EU Member States but could include public censure, administrative measures, fines and imprisonment. These laws/codes may further limit or restrict the advertising and promotion of Organon's products to the general public and may also impose limitations on its promotional activities with health care professionals.

Anti-Corruption Legislation

In the EU, interactions between pharmaceutical companies and health care providers are also governed by strict laws, regulations, industry self-regulation codes of conduct and health care providers' codes of professional conduct both at the EU level and in the individual EU Member States. Across the EU, the provision of benefits or advantages to health care providers to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of pharmaceutical products is prohibited in the European Union. However, the provision of benefits or advantages to health care providers is also

governed by the national anti-bribery laws of the EU Member States. Violation of these laws could result in substantial fines and imprisonment.

While many EU Member States permit companies to make payments to health care providers in some circumstances, e.g., when they are used as consultants, certain EU Member States required that such payments must be publicly disclosed. Moreover, agreements with health care providers must often be the subject of prior notification and approval by the physician's employer, his / her regulatory professional organization, and / or the competent authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct applicable in the individual EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Medical Device Regulation

In the EU, medical devices are regulated by the European Union Medical Devices Regulation (EU) 2017/745 ("MDR"), which became applicable on May 26, 2021. The MDR and its associated guidance document and harmonize standards and govern, among other things, device design and development, pre-clinical and clinical or performance testing, pre-market conformity assessment, registration and listing, manufacturing, labeling, storage, claims, sales and distribution, export and import and post-market surveillance, vigilance, and market surveillance.

Before a device can be placed on the market in the EU, compliance with the MDR requirements must be demonstrated to affix the Conformité Européene mark ("CE Mark") to the product. To demonstrate compliance with these requirements, a conformity assessment procedure is required, conducted either by the manufacturer (for low risk medical devices only, which are known as Class I devices) or by an organization designated by an EU Member State to conduct conformity assessments known as a Notified Body (for higher risk medical devices, including Class I devices that are sterile and/or have a measuring function, Class IIa, Class IIb and Class III devices). The Notified Body issues a certificate of conformity, which entitles the manufacturer to affix the CE Mark to its devices after having prepared and signed a related EU Declaration of Conformity.

Clinical evidence is required for most medium and high risk devices. In some cases, a clinical study may be required to support a CE marking application. A manufacturer that wishes to conduct a clinical study involving the device is subject to the clinical investigation requirements of the MDR, EU Member State requirements, and current good clinical practices defined in harmonized standards and guidance documents.

After a device is placed on the market, it remains subject to significant regulatory requirements. For CE marked devices, certain modifications to the device or quality system depending on the conformity assessment procedure used must be submitted to and approved by the Notified Body before placing the modified device on the market.

Advertising and promotion of devices is governed by the MDR alongside national laws and guidance and is enforced on a country-by-country basis by National Competent Authorities. The MDR provides that devices may be marketed only for the uses and indications for which they are CE marked. National rules and enforcement environments may vary.

Economic Operators, including device manufacturers, must register their establishments and devices in the European data base on medical devices (EUDAMED) database once available. Device manufacturers are also subject to MDR vigilance requirements, which require that a manufacturer report to the relevant Competent Authorities any serious incident involving devices made available on the market and any field safety corrective action in respect of devices made available on the market or undertaken in a third country in relation to a device made available on the market.

Post-Brexit the MDR does not apply in the UK (apart from Northern Ireland, which under the Northern Irish Protocol is bound by certain EU laws). The medical device legislative framework in the UK is set out in the Medical Devices Regulations 2002. The Medical Devices Regulations 2002 replace the CE mark with a UKCA marking (although EU CE marks will be recognized until at least June 30, 2023), require manufacturers outside the UK to appoint a "UK Responsible Person" if they place devices on the Great British market and more wide-ranging device registration requirements.

Other Markets

Outside the United States, the EU, the EEA and other European Jurisdictions, Organon submits marketing applications to national regulatory authorities. Examples of such include the National Medical Products Administration ("NMPA") in China, the Ministry of Health, Labour and Welfare in Japan, Health Canada, Agência Nacional de Vigilância Sanitária in Brazil, Korea

Food and Drug Administration in South Korea and Therapeutic Goods Administration in Australia. Each country has a separate and independent review process and timeline. In many markets, approval times can be longer as the regulatory authority requires approval in a major market, such as the United States or the EU and issuance of a Certificate of Pharmaceutical Product from that market before initiating their local review process.

Climate and Environmental Matters

Organon believes that climate change could present risks to its business. Some of the potential effects of climate change to Organon's business could include increased operating costs due to additional regulatory requirements, changes in supply due to regulatory requirements, physical risks to Organon's facilities, water limitations and disruptions to Organon's supply chain. Some potential risks are integrated into Organon's business planning, including investment in reducing energy, water use and greenhouse gas emissions. Organon does not believe these potential risks are material to its business at this time.

Organon is not aware of any compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on Organon's business. Expenditures for remediation and environmental liabilities are estimated to be approximately $16 million in the aggregate for the years 2023 through 2027. For additional information, please see "Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Estimates" and Note 12 "Contingencies —Environmental Matters" to the Financial Statements included in this report.

Third-Party Agreements

Samsung Bioepis Development and Commercialization Agreement

On February 18, 2013, Merck entered into a development and commercialization agreement with Samsung Bioepis (as subsequently amended, the "Samsung Bioepis Agreement"). All of the rights and obligations of Merck under the Samsung Bioepis Agreement were transferred to Organon in connection with the spinoff. The Samsung Bioepis Agreement grants Organon an exclusive license to commercialize the following pre-specified biosimilars products (with reference products in parenthesis) developed by Samsung Bioepis: adalimumab *(Humira)*, bevacizumab *(Avastin)*, infliximab *(Remicade)*, trastuzumab *(Herceptin)* and etanercept *(Enbrel)*. See "Business—Organon's Biosimilars Products" for a description of each product and the geographic areas in which Organon has an exclusive license for commercialization activities.

Under the Samsung Bioepis Agreement, Samsung Bioepis is responsible for pre-clinical and clinical development, process development and manufacturing, clinical trials and registration of product candidates. Organon's access rights to each product under the Samsung Bioepis Agreement last for ten years from each such product's launch date on a market-by-market basis. Unless the parties agree to extend the term, the agreement expires upon the expiration of the last such ten-year period. Organon may terminate the agreement with respect to a particular region or product if a product fails to meet certain milestones in such region. Organon may terminate the agreement upon 60 days' written notice to Samsung Bioepis for a particular presentation of a product in a region if Samsung Bioepis's revenue share for such product presentation in such region exceeds a certain contractual threshold. Organon may also terminate the agreement upon 60 days' written notice in the event of a third-party infringement claim that Samsung Bioepis decides to litigate despite Organon's opposition to such litigation.

The Samsung Bioepis Agreement may be terminated by either party on 30 days' written notice for a particular product or region if the parties fail to agree upon a strategy regarding third-party patents within six months following written notice by either party of the existence of such patents. The agreement may also be terminated by either party upon written notice if the other party commits a material breach of its obligations by specified actions within its reasonable control and has not cured such breach within 90 calendar days after notice requesting cure of the breach.

The Samsung Bioepis Agreement provides that gross profits are shared equally in all markets except for certain markets in Brazil where gross profits are shared 65% to Samsung Bioepis and 35% to Organon. The Samsung Bioepis Agreement also provides for payment of certain milestone license fees associated with pre-specified clinical and regulatory milestones to Samsung Bioepis, payment of the supply price for each product to Samsung Bioepis, and an upfront payment to Samsung Bioepis that was completed by Merck at the commencement of the agreement. As of December 31, 2022, there were $25 million in potential future regulatory milestone payments remaining under the agreement. For further information related to the Samsung Bioepis collaboration, see Note 4 "Samsung Collaboration" to the Consolidated Financial Statements included in this report and the Samsung Bioepis Agreement, which is filed as an exhibit to this report.

Shanghai Henlius Biotech, Inc. ("Henlius")

In June 2022, Organon and Henlius, a global biopharmaceutical company, entered into a definitive agreement whereby Organon is licensing commercialization rights for biosimilar candidates HLX11, referencing *Perjeta*, used for the treatment of certain patients with HER2+ breast cancer in combinations with trastuzumab and chemotherapy and HLX14, referencing *Prolia*/*Xgeva*, used for the treatment of certain patients with osteoporosis with high risk of fracture and for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastasis from solid tumors. Organon obtained exclusive global commercialization rights except for China; including Hong Kong, Macau and Taiwan. The agreement includes an option to negotiate an exclusive license for global commercialization rights for biosimilar candidate HLX13, referencing *Yervoy*® (ipilimumab). Ipilimumab is used for the treatment of certain patients with unresectable or metastatic melanoma, as adjuvant treatment of certain patients with cutaneous melanoma, certain patients with renal cell carcinoma, colorectal cancer, hepatocellular carcinoma, non-small cell lung cancer, malignant pleural mesothelioma and esophageal cancer.

Additional Information

Organon is a Delaware corporation incorporated on March 11, 2020. Organon's corporate offices are located at 30 Hudson Street, 33rd Floor, Jersey City, New Jersey 07302.

Organon files Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, amendments to those reports, proxy statements and other information with the SEC. Organon maintains an investor relations page on its website (*www.organon.com*) where such filings made pursuant to Section 13(a) or 15(d) of the Exchange Act may be accessed free of charge as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. We intend to use our Investor Relations website and our corporate website located at www.organon.com as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. Organon's website address is not intended to function as a hyperlink and the information contained on its website is not, and should not be considered part of, and is not incorporated by reference into, this Annual Report on Form 10-K.

Item 1A. Risk Factors

You should carefully consider the following risks and other information in this Annual Report on Form 10-K in evaluating Organon and deciding to invest in the Common Stock. Any of the following risks could materially and adversely affect Organon's results of operations, financial condition and the price of the Common Stock.

Summary of Risk Factors

The following is a summary of the principal risks that could significantly and negatively affect Organon's business, prospects, financial conditions, or operating results. For a more complete discussion of the material risks facing Organon's business, please see below:

Risks Related to 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 Organon's profits and cash flows, and any events that adversely affect the markets for Organon's leading products could adversely affect its results of operations and financial condition.
- Organon faces continued pricing pressure with respect to its products.
- Organon faces intense competition from competitors' products.
- Organon has limited in-house discovery and early research capabilities and will continue to rely on future acquisitions, partnerships and collaborations to expand its innovative pipeline and early discovery and research capabilities, which may limit its ability to discover or develop new products or expand its existing products into new markets to replace the sales of products that lose patent protection and therefore Organon may not be able to maintain its current levels of profitability.
- Organon may experience difficulties identifying acquisition opportunities or completing such transactions.
- Organon or its partners may fail to demonstrate the safety and efficacy of any of its product candidates in pre-clinical and clinical trials, which would prevent or delay development, regulatory approval or clearance, and commercialization of Organon's product candidates.
- Organon may be unable to market its pharmaceutical products or medical devices if it does not obtain and maintain required regulatory approvals or marketing authorizations.

- Developments following regulatory approval or marketing authorization may adversely affect sales of 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 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 Organon's sales will adversely affect its business.
- Organon depends on its patent rights for the marketing of certain of its products, and invalidation or circumvention of Organon's patent rights would adversely affect its business.
- Organon is subject to minimum purchase obligations under certain supply agreements, and if Organon fails to meet those minimum purchase requirements, its 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 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.
- 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.
- Contractual restrictions limit Organon's ability to engage in certain corporate transactions.

Risks Related to Organon's Common Stock

- The price and trading volume of Organon's Common Stock may be volatile, and stockholders could lose all or part of their investment in Organon.
- Organon cannot guarantee the timing, amount or payment of any dividends on the Common Stock.
- Certain provisions in 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 Common Stock.
- 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 Organon's stockholders, and the United States federal district courts as the exclusive forum for claims under the Securities Act, which could limit Organon's stockholders' ability to obtain what such stockholders believe to be a favorable judicial forum for disputes with Organon or its directors, officers or employees.

Risks Related to 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.

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.

Key products generate a significant amount of Organon's profits and cash flows, and any events that adversely affect the markets for Organon's leading products could adversely affect its results of operations and financial condition.

Organon's ability to generate profits and operating cash flow depends largely upon the continued profitability of its key products, such as *Nexplanon*, *Cozaar*/*Hyzaar*, *Singulair* and the Ezetimibe family of products. As a result of 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 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 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 also expects that competition will continue to adversely affect the sales of these products.

Organon faces continued pricing pressure with respect to its products.

Organon faces continued pricing pressure globally and, particularly in mature markets from managed care organizations, government agencies and programs that could adversely affect its sales and profit margins. Organon expects 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 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 subject to government decision-making and budgetary actions with respect to its products.

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 of approximately 50%. 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 faces intense competition from competitors' products.

Organon's products face intense competition from competitors' products, including lower cost generic versions of its products that have lost market exclusivity. Competitors' products may be equally safe and as effective as Organon's products but sold at a substantially lower price than Organon's products. Alternatively, 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 Organon's products. Organon's efforts to compete with other companies or Organon's failure to maintain its competitive position could adversely affect its business, cash flow, results of operations, financial condition or prospects.

Organon has limited in-house discovery and early research capabilities and will continue to rely on future acquisitions, partnerships and collaborations to expand its innovative pipeline and early discovery and research capabilities, which may limit its ability to discover or develop new products or expand its existing products into new markets to replace the sales of products that lose patent protection, and therefore Organon may not be able to maintain its current levels of profitability.

Organon has limited in-house discovery and early research staff and facilities, and does not currently intend to extensively hire or acquire such staff or facilities in the near future. Instead, Organon intends to continue to rely on future acquisitions, partnerships and collaborations with third parties to expand its innovative pipeline, existing portfolio and innovation and early research capabilities. Organon intends to grow its business through new indications or formulations of its existing products or expansion of existing products into new markets or new geographies. However, Organon expects that its ability to do so could be limited by the scope of its 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 signed a supplemental license with Merck that provides a limited expansion of the fields in which Organon may use the underlying technology of *Nexplanon* beyond contraception in exchange for milestone payments. Organon 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 cannot produce sufficient revenues from expansion into new products, new indications or formulations of its existing products or expansion of existing products into new markets or new geographies, then Organon may not be able to maintain its current levels of profitability, and this could adversely affect Organon's business, cash flow, results of operations, financial condition or prospects.

Organon relies on third parties for activities related to preclinical and clinical testing.

Organon relies on third parties to manufacture and distribute its products for preclinical and clinical testing and to conduct certain preclinical and clinical testing activities. Oversight of these third parties can require substantial resources and creates potential risks to Organon, including: Organon may be unable to establish agreements with third parties, including third party manufacturers, on acceptable terms or even at all; Organon may not have sufficient quantities of product; third parties may fail to comply with regulatory requirements; or third parties may misappropriate or disclose our proprietary information, including trade secrets and know-how. Organon's reliance on third parties for research and development activities will also reduce Organon's control over these activities but does not relieve Organon of its responsibilities, including that Organon must ensure that clinical trials are conducted in accordance with the general investigational plan and protocols for the trial; ensure compliance with regulatory standards like good clinical practices; and register ongoing clinical trials and results to government-

sponsored databases. Organon's failures, or the failure of third parties, to comply with applicable regulations could result in sanctions being imposed on Organon, 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 Organon's ability to obtain or maintain marketing approval for its products in a timely manner, or at all. This may hinder or delay efforts to successfully commercialize Organon's product candidates.

Organon may experience difficulties identifying acquisition opportunities or completing such transactions.

Organon intends to continue pursuing acquisitions of complementary businesses, licensing arrangements and strategic partnerships to expand its product offerings and geographic presence as part of its business strategy. Organon may not complete these transactions in a timely manner, on a cost-effective basis, or at all, and Organon 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 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 these companies 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 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 successful in making acquisitions, the products and technologies Organon acquires may not be successful or may require significantly greater resources and investments than it originally anticipated. Organon could experience negative effects on its results of operations and financial condition from acquisition-related charges, amortization of intangible assets and asset impairment charges. Organon 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 Organon's existing business, its business, financial condition, results of operations or cash flows could be materially and adversely affected.

Organon may be unable to market its pharmaceutical products or medical devices if it does not obtain and maintain required regulatory approvals or marketing authorizations.

Organon's activities, including the manufacturing and marketing of its pharmaceutical products and medical devices, are subject to extensive regulation by numerous federal and 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, approval, safety, effectiveness, manufacturing, labeling and marketing of prescription pharmaceuticals and medical devices. Regulation of 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 such as the FDA, the EMA, the MHRA, China's NMPA and 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, to delay or withhold registration and marketing approval and to otherwise preclude distribution and sale of a product. Organon currently markets one product in the United States regulated as a medical device, *Jada* (acquired through Organon's acquisition of Alydia Health, as described elsewhere in this report). In the future, Organon also plans to sell its 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 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 will need to obtain approval or marketing authorization by the appropriate regulatory authorities before it can commence clinical trials or marketing activities in those countries.

Organon cannot market its pharmaceutical products or medical devices or new indications or modifications to its existing products unless and until Organon has obtained all required regulatory approvals or marketing authorizations in each relevant jurisdiction. 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 Organon's applications for its pharmaceutical products are not ready for approval. Once obtained, Organon must maintain approval or marketing authorization as long as it plans 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

authorization of Organon's future products or impact Organon's ability to modify its currently marketed products on a timely basis. Organon's failure to obtain approval, significant delays in the approval or marketing authorization process or its failure to maintain approval or marketing authorization in any jurisdiction will prevent Organon from selling the products in that jurisdiction. Organon would not be able to realize revenues for its pharmaceutical products or medical devices in any jurisdiction where it does not have approval or marketing authorization.

Organon or its partners may fail to adequately demonstrate the safety and efficacy of any of 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 Organon's product candidates.

Before obtaining regulatory approval from the FDA or other comparable foreign regulatory authorities for the sale of Organon's pharmaceutical product candidates, Organon must demonstrate through lengthy pre-clinical studies and clinical trials that its product candidates are both safe and effective for use in each target indication. Obtaining marketing authorization for 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 may never succeed in obtaining regulatory approval or marketing authorization of its product candidates.

Organon 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 Organon's ability to commercialize its product candidates, including for example, inability to recruit and enroll study subjects; failure of its product candidates in pre-clinical studies or clinical trials to demonstrate safety and efficacy; receipt of feedback from the FDA and other regulatory authorities that require Organon to modify the design of its clinical trials; and negative or inconclusive clinical trial results that may require Organon to conduct additional clinical trials or abandon certain research and/or development programs.

Organon may be required to conduct additional pre-clinical studies, clinical trials or other testing of its product candidates beyond those that it currently contemplates, or Organon may be unable to successfully complete pre-clinical studies or clinical trials of its 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 may incur unplanned costs, as well as delays in its efforts to obtain regulatory approval or marketing authorization. Even if Organon receives such approval, it may be more limited or restrictive than anticipated, or be subject to additional post-marketing testing requirements.

Developments following regulatory approval or marketing authorization may adversely affect sales of Organon's pharmaceutical products or medical devices.

Even after a pharmaceutical product or medical device reaches the market, Organon continues to be subject to significant post-marketing regulatory requirements and oversight. The regulatory approvals or marketing authorizations that Organon may receive for its 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 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, the manufacturing processes, labeling, packaging, distribution, adverse event and device malfunction reporting, storage, advertising, promotion, import, export, recalls and recordkeeping for Organon's products will be subject to ongoing regulatory requirements, and Organon will be subject to periodic inspections. Failure to comply with any of these requirements could subject Organon to a variety of formal or informal enforcement actions by the FDA or other regulators, result in a recall or market withdrawal of Organon's products, require Organon to cease manufacturing and distribution of the products, trigger product liability or other litigation, or otherwise impact Organon's ability to realize revenues for its products. As previously disclosed, Organon voluntarily initiated market actions, including recalls, in certain markets with respect to the Company's suspension injections *Diprospan*, *Celestone Chronodose*® (betamethasone), and *Celestone Soluspan*® (betamethasone) related to a non-conforming component of a manufacturing line at Organon's Heist, Belgium plant. Organon does not believe this development will materially impact the company. It is possible that future recalls or similar developments could materially and adversely impact 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 Organon's products, it could significantly reduce demand for the product or require it to take actions that could negatively affect sales, including initiating corrections of a marketed product or removing the product from the market, restricting Organon's distribution or applying for marketing authorization for labeling changes. The FDA could also require Organon to conduct postmarketing studies of its products. Further, Organon is at risk for product liability and consumer protection claims and civil and criminal governmental actions

related to its 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 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 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.

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.

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, 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.

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.

Certain of 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 Organon's sales will adversely affect its business.

Organon depends upon patents to provide it with exclusive marketing rights for certain of its 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 become available. In the case of current or future products that contribute significantly to Organon's sales, a loss of market exclusivity could materially adversely affect its business, cash flow, results of operations, financial condition or prospects. 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 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" for details, including the patent protection for certain of Organon's marketed products.

Organon depends on its patent rights for the marketing of certain of its products, and invalidation or circumvention of Organon's patent rights would adversely affect its business.

Patent protections are important to the marketing of certain of Organon's products, particularly certain of its women's health products in the United States and in most major foreign markets. Patents covering products that Organon has introduced normally provide market exclusivity, which is important for the successful marketing and sale of certain of its products.

Even if Organon succeeds in obtaining patents covering its products, third parties or government authorities may challenge or seek to invalidate or circumvent Organon's patents and patent applications. It is important for Organon's business to successfully defend the patent rights that provide market exclusivity for its products. Organon is involved in patent disputes relating to challenges to its patents or claims by third parties of infringement against it. Organon defends its 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 Organon's products prior to the expiration of relevant patents owned or licensed by it. Patent litigation and other challenges to Organon's patents are costly and unpredictable and may deprive it of market exclusivity for a patented product or, in some cases, third-party patents may prevent Organon from marketing and selling a product in a particular geographic area, negatively affecting its 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 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 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. Organon's results of operations may be adversely affected by the lost sales unless and until it has 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 may recognize material non-cash impairment charges with respect to the value of those products.

Organon is subject to minimum purchase obligations under certain supply agreements, and if Organon fails to meet those minimum purchase requirements, its financial results may be unfavorably impacted.

Organon is subject to minimum purchase obligations under certain supply agreements, which requires Organon to purchase minimum amounts of materials critical to its product manufacturing over specified time periods. If Organon fails to meet these minimum purchase requirements, it may still be required to pay for the cost of the minimum inventory purchases. If Organon is unable to offset these payments, it could result in a lower margin. During the year ended December 31, 2022 and 2021, Organon 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 also aware of a limited number of other arrangements that have similar provisions which could result in these types of payments. Organon does 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 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 believes that the health care industry will continue to be subject to increasing regulation and political and legal action at both the Federal and state levels.

In 2010, the United States enacted major health care reform legislation in the form of the Patient Protection and the ACA. Since enactment of that law, various insurance market reforms have advanced and 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.

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 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 and legislative actions 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 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 was rescinded by CMS on December 29, 2021.

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.

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 business, cash flow, results of operations, financial condition or prospects.

Organon is subject to a variety of United States, other national and international laws and regulations, and Organon may face serious consequences for violations if it fails to meet the applicable legal and regulatory requirements.

Organon is currently subject to a number of government laws and regulations and, in the future, could become subject to new government laws and regulations. The costs of compliance with such laws and regulations, or the negative results of non-compliance, could adversely affect 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.

Because of its U.S. and international operations, Organon is also subject to anti-corruption laws and regulations, in the United States and internationally, including but not limited to the U.S. domestic bribery statute contained in the U.S. Foreign Corrupt Practices Act (the "FCPA"), the U.K. Bribery Act 2010 and other 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 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 such violations. Organon's business is also heavily regulated and involves significant interaction with foreign officials. In many countries outside the U.S., prescribers of Organon products are employed by government entities, and purchasers are themselves government entities. As such, Organon's interactions with such prescribers and purchasers are subject to regulation under the FCPA, as well as other similar anti-corruption laws and/or regulations enacted by other countries.

In addition to selling its products internationally, Organon currently engages third parties outside the United States, and may engage additional third parties outside the United States, to sell its products internationally and to obtain necessary permits, licenses, patent registrations and other regulatory approvals. Organon has direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. Organon can be held liable for the corrupt or other illegal activities of its employees, agents, contractors and other third-party collaborators, even if it does not explicitly authorize or have actual knowledge of such activities.

Enforcement activities under the laws and regulations described above may subject Organon 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 significant global operations, which expose it to additional risks, and any adverse event could adversely affect Organon's results of operations and financial condition.

The extent of Organon's operations outside the United States is significant. For example, in 2022, Organon generated $4.7 billion in revenues outside the United States, representing approximately 77% of its 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 Organon's ability to manufacture and sell its 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;

- 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 Organon's products;
- volatility of commodity prices, fuel, shipping rates that impact the costs and/or ability to supply Organon's products;
- diminished protection of intellectual property in some countries; and
- possible nationalization and expropriation.

In addition, there may be changes to 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, 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 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, lost health care insurance coverage or for other reasons. Further, with rising international trade tensions or sanctions, Organon's business may be adversely affected following new or increased tariffs, as well as the costs of materials, products, and commodities upon which Organon 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 Organon's results of operations and financial condition.

In particular, in February 2022, the armed conflict between Ukraine and Russia escalated, which may adversely impact Organon's business. Specifically, trade sanctions, travel bans and asset/financial freezes 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 conducts business and therefore may negatively impact Organon.

Organon is subject to a significant number of privacy and data protection laws and regulations globally, many of which place restrictions on Organon's ability to transfer, access and use personal data across its 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 Member States 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 processes. 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, harm to its reputation, and adversely impact its business and operating results. The uncertainty regarding the interplay between different regulatory frameworks further adds to the complexity that Organon faces with regard to data protection regulation.

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 has adopted a comprehensive global privacy program to manage these evolving risks 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 depends on sophisticated software applications and computing infrastructure. Cyberattacks affecting Organon's IT systems could result in exposure of confidential information, the modification of critical data or the disruption of its worldwide operations, including manufacturing and sales operations.

Organon depends on sophisticated software applications, 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, to assist in conducting Organon's business. Disruption, degradation, destruction or manipulation of these IT systems through intentional or accidental means by Organon's employees, third parties with authorized access or cyber threat actors could adversely affect key business processes. The size and complexity of Organon's IT systems, and those of Organon's third-party providers with whom its contracts, make such systems potentially vulnerable to service interruptions. In addition, Organon and its third-party providers have experienced and expect to continue to experience phishing attempts, scanning attempts of Organon's network, and other attempts of unauthorized access to its 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 Organon's data, applications or systems.

In the ordinary course of business, Organon and its 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 must do so in a secure manner to maintain the confidentiality and integrity of such confidential information. The size and complexity of Organon and its 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 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 Organon's competitive business position. However, such information can be difficult to protect and could be compromised.

While Organon has taken steps to protect such information, and to ensure that the third-party providers on which it relies have taken adequate steps to protect such information, Organon's efforts to protect its data and IT systems or the efforts of third-party providers to protect their IT systems may not succeed. A breach of Organon's IT systems or its 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 Organon's proprietary technology or information, and/or adversely affect 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 Organon's patients and employees, or the modification of critical data, could result in financial, legal, business, and reputational harm to Organon and could result in loss of revenue, or the loss of critical or sensitive information from Organon's or its 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 may experience difficulties, delays or expenses in manufacturing certain of its products.

Organon or its suppliers and other manufacturing partners may experience difficulties, delays or expenses in connection with manufacturing Organon's products, 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 Organon's products; increased costs of key materials, packaging, or operational procedures; 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, changes in types of products produced and physical limitations that could impact supply. In addition, Organon could experience difficulties or delays in manufacturing its products caused by natural disasters, such as hurricanes, and public health crises and epidemics/pandemics, including the ongoing

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, which are difficult to predict.

Ongoing and future epidemics and pandemics, including the ongoing COVID-19 pandemic, may adversely impact Organon's business, operations, financial performance, results of operations, and financial condition.

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 may experience other supply difficulties that could adversely affect both its ability to deliver its products and its results of operations and financial condition.

Organon acquires its components, materials and other requirements for manufacturing from many suppliers and vendors in various countries, including sometimes from itself for self-supplied requirements. Organon endeavors to achieve, either alone or by working closely with its suppliers, continuity of Organon's inputs and supplies, but it cannot guarantee these efforts will always be successful. For instance, *Follistim AQ* and *Atozet*[1] have been challenged by intermittent supply disruptions. Further, while efforts are made to diversify certain of 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 Organon's components and materials for which a single source or supplier is used, alternative sources or suppliers may exist, but Organon has made a strategic determination to use the single source or supplier. Although Organon does carry strategic inventory and maintain insurance to help mitigate the potential risk related to any related supply disruption, it cannot assure investors that such measures will always be sufficient or effective. Further, if Organon does 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. Organon's ability to achieve continuity of its 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 Organon's ability to manufacture and distribute its products in a timely or cost-effective manner, negatively impacting Organon's ability to sell its products.

Organon may not realize benefits from its investments in emerging markets.

Organon has been taking steps to increase its sales in emerging markets; however, 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 very limited resources to spend on health care. In order for Organon to successfully implement its emerging markets strategy, Organon must attract and retain qualified personnel. Organon may also be required to increase 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 cannot offset the devaluations, its financial performance within such countries could be adversely affected.

For example, Organon's business in China is growing, and China is now Organon's second largest market, thereby increasing the importance of China to Organon's overall pharmaceutical business. Continued growth of Organon's business in China depends upon ongoing development of a favorable regulatory environment, sustained availability of Organon's currently marketed products within China, and Organon's ability to mitigate the impact of any trade impediments or adverse pricing controls. Pricing pressure in China has increased as the Chinese government has been taking steps to reduce costs, including implementing health care reform that has led to the acceleration of generic substitution, where available. While 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 GQCE programs. In 2019, the government implemented the VBP program through a tendering process for 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-

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 are 300 molecules currently included under VBP, and it is expected that an aggregate of 500 molecules will be subject to VBP by 2025.

Furthermore, the 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 and may adversely affect Organon's business and results of operations.

In addition, Organon currently relies on a third-party manufacturer to import, repackage and then sell a significant portion of its products in China. China's regulatory landscape continues to evolve, including reform of the Market Authorization Holder, or MAH, system and change of registration and licensing requirements for 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. 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 business in China may be adversely affected.

Finally, Organon plans 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 emerging markets could adversely affect 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 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.

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 exposed to market risk from fluctuations in currency exchange rates and interest rates.

Organon operates in multiple jurisdictions and virtually all of its sales outside the United States are denominated in currencies other than the United States dollar. Additionally, Organon has 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 cannot, with certainty, foresee and mitigate against such adverse fluctuations in currency exchange rates, interest rates and inflation could negatively affect Organon's business, cash flow, results of operations, financial condition or prospects.

In order to mitigate the adverse impact of these market fluctuations, Organon enters 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 Organon's reporting currency, the U.S. dollar, and other currencies in which Organon does business will affect its operating results, often in unpredictable ways.

Reliance on third-party relationships and outsourcing arrangements could materially adversely affect Organon's business.

Organon depends on third parties, including other suppliers, alliances with other pharmaceutical and biotechnology companies, and third-party service providers, for key aspects of Organon's business, including development, manufacture and commercialization of its products (including supplying its products or key ingredients of its products) and support for its IT systems. In addition, in connection with the interim operating arrangements Organon has been establishing following the spinoff, Organon may enter into agreements with third-parties in certain jurisdictions, including China, to continue its business operations in compliance with local regulatory requirements. Failure of these third parties to meet their contractual, regulatory and other obligations to Organon or the development of factors that materially disrupt the relationships between it and these third parties could adversely affect Organon's business.

The markets for Organon's products, including the women's health market, may not develop as successfully as expected.

Organon's focus on women's health is a key component of its strategy. Organon's ability to successfully execute its 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 Organon's products, technologies, treatments or therapies;
- the perception of Organon's products as compared to other products;
- recommendation and support for the use of 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 or impose additional coverage limitations or cost-sharing obligations on its patients;
- the availability and extent of data demonstrating the clinical efficacy of 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 unable to successfully commercialize and create a significant market for its women's health products, Organon's business or prospects could be harmed.

Our business and operations are subject to risks related to climate change.

The effects of global climate change present risks 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 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 regulation, including to address climate change, may result in increases in our costs to operate our business or restrict certain aspects of our activities. The extent and severity of climate change impacts are unknown, and therefore, the scope of potential impact on our business may be difficult to predict and it may be difficult to adequately prepare.

Biosimilars carry unique regulatory risks and uncertainties, which could adversely affect 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 Organon's partners to manufacture an adequate supply of biosimilars may adversely affect Organon's ability to commercialize the biosimilars in its portfolio.

Organon relies on its collaboration with Samsung Bioepis and Henlius for the successful development and manufacture of Organon's biosimilars products and expects to do so for the foreseeable future.

Organon's current biosimilars portfolio consists primarily of products developed and manufactured by Samsung Bioepis for which it has worldwide commercialization rights, with certain geographic exceptions specified on a product-by-product basis. Organon's access rights to each product under its agreement with Samsung Bioepis last for 10 years from each such product's launch date on a market-by-market basis. See "Business—Third-Party Agreements". 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 *Perjeta*®, and HLX14, referencing *Prolia*/*Xgeva*. Organon's ability to successfully commercialize products in its biosimilars portfolio may depend upon maintaining a successful relationship with Samsung Bioepis and Henlius. The success of 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 not have control. Organon cannot assure investors that its collaboration will be successful or that it will achieve the benefits of its collaborations.

Organon has incurred substantial indebtedness, which could adversely affect Organon's financial condition and results of operations.

At December 31, 2022, Organon had outstanding indebtedness of approximately $8.9 billion, as described more fully in the Notes to its financial statements. In addition, 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 its indebtedness. Current or future levels of indebtedness may increase the possibility that Organon will be unable to generate cash sufficient to pay amounts due in respect of such indebtedness.

Organon's ability to issue additional debt or enter into other financing arrangements on acceptable terms could be adversely affected if there is a material decline in the demand for Organon's products, if Organon's customers or suppliers are unable to pay 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 Organon's ability to obtain and maintain its credit ratings.

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.

Organon's current indebtedness contains, and any future indebtedness may contain, customary operating restrictions and financial covenants. This indebtedness may adversely affect Organon's ability to operate or grow its business or could have other material adverse consequences, including by:

- limiting Organon's ability to obtain additional financing in the future for working capital, capital expenditures and acquisitions;
- limiting Organon's ability to refinance its indebtedness on terms acceptable to Organon or at all;
- restricting Organon's operations or development plans;
- requiring Organon to dedicate a significant portion of its cash flows from operations to paying amounts due under its indebtedness, thereby reducing funds available for other corporate purposes;
- impeding Organon's ability to pay dividends;
- making Organon more vulnerable to economic downturns; or
- limiting Organon's ability to withstand competitive pressures.

Any of these restrictions on Organon's ability to operate its business in its discretion could adversely affect its business by, among other things, limiting 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 Organon's outstanding debt, dispose of property, complete acquisitions for cash or debt, or make other investments. In addition, events beyond Organon's control, including prevailing economic, financial, and industry conditions, could affect Organon's ability to satisfy applicable financial covenants, and Organon cannot assure you that it will satisfy them.

Any failure to comply with the restrictions of Organon's current indebtedness, or any future financing agreements, including as a result of events beyond Organon's control, may result in an event of default under these agreements, which in turn may result

in defaults or acceleration of obligations under these agreements and other agreements, giving Organon's lenders and other debt holders the right to terminate any commitments they may have made to provide Organon with further funds and to require Organon to repay all amounts then outstanding.

Risks Related to the Spinoff

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 results of operations. In addition, if Organon is unable to replicate or transition certain systems, Organon's ability to comply with regulatory requirements could be impaired.

Merck may not satisfy its obligations under various transaction agreements that have been or will be executed as part of the spinoff, Organon may experience delays with approvals relating to the separation from Merck, or Organon may not have necessary systems and services in place when certain of the transition agreements expire.

In connection with the spinoff, Organon and Merck entered into the Separation and Distribution Agreement and various other agreements, including one or more transition services agreements, 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 the section entitled "Certain Relationships and Related Transactions." 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 may rely on Merck to satisfy its performance and payment obligations under these agreements. If Merck is unable to satisfy its obligations under these agreements, including its indemnification obligations, Organon could experience operational difficulties or losses.

In addition, in connection with the spinoff, Organon has established operations in certain markets, but is unable to import, distribute, or trade certain products in those markets due to pending licenses, permits, and regulatory approvals, among other requirements. Until all required approvals are received, Organon relies upon Merck to perform certain activities in these markets. Organon may incur additional costs during the period of time before all necessary approvals are granted, which may affect Organon's business and result in additional costs in these markets.

If Organon does not have its own systems and services in place, or if Organon does not have agreements with other providers of these services, when these agreements terminate, Organon may not be able to operate its business effectively and its profitability may decline. Organon is in the process of creating its 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. Organon may not be successful in effectively or efficiently implementing these systems and services or in transitioning data from Merck's systems to 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.

Potential indemnification liabilities to Merck pursuant to the Separation and Distribution Agreement could adversely affect Organon.

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 financially responsible for many liabilities that may exist relating to its 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, include a general obligation to indemnify Merck for litigation or governmental proceedings relating to Organon's products, including, but not limited to, currently pending litigation relating to *Fosamax*, *Nexplanon*, and *Propecia* / *Proscar*. More specifically, Organon's obligations to indemnify Merck may in some cases include liability for antitrust litigation; provided, however, that Organon 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 "Contingencies" to the Financial Statements included in this report. These indemnification liabilities are intended to ensure that, as between Merck and Organon, Organon is responsible for all liabilities it assumes in connection with the spinoff and that Organon pays for any liability incurred by Merck (including directors, officers, employees and agents) related to Organon's failure to satisfy such obligations or otherwise in respect of the operation of its business, or any breach by Organon of the Separation and Distribution Agreement or any ancillary agreement. 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 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 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 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.

Contractual restrictions limit Organon's ability to engage in certain corporate transactions.

To preserve the tax-free treatment to Merck of the spinoff, the Tax Matters Agreement restricts Organon from taking any action that prevents 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.

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 required to indemnify Merck against any tax liabilities as a result of such actions, even if Organon 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, Organon's indemnity obligation for Merck's tax liability under the tax matters agreement would be substantial and could materially affect its cash flow.

Certain of Organon's 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 Organon's executive officers and directors own shares of Merck Common Stock and continue to participate in certain Merck benefit programs. Even though Organon's Board of Directors consists of a majority of directors who are independent, and Organon's executive officers who were previously employees of Merck ceased to be employees of Merck in connection with the spinoff, some Organon 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 and Merck pursue the same corporate opportunities or face decisions that could have different implications for Organon and Merck.

Risks Related to Organon's Common Stock

The price and trading volume of Organon's Common Stock may be volatile, and stockholders could lose all or part of their investment in Organon.

The trading volume and market price of Organon's Common Stock may be volatile. This volatility could negatively impact Organon's ability to raise additional capital or utilize equity as consideration in any acquisition transactions Organon may seek to pursue, and could make it more difficult for existing stockholders to sell their shares of the 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:

- Organon's liquidity and ability to obtain additional capital, including the market's reaction to any capital-raising transaction Organon 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 Organon's products and product candidates;
- market assessments of any strategic transaction or collaboration arrangement Organon may pursue;
- sales of substantial amounts of Organon's Common Stock, or the perception that substantial amounts of Organon's Common Stock may be sold, by stockholders in the public market;
- changes in earnings estimated by securities analysts or Organon's ability to meet those estimates;
- issuance of new or updated research or reports by securities analysts or changed recommendations for Organon's Common Stock; and
- significant advances made by competitors that adversely affect 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, could result in substantial costs and a diversion of its management's attention and resources.

Organon cannot guarantee the timing, amount or payment of any dividends on the Common Stock.

Organon currently expects that it 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 Organon's Board of Directors. The Board of Directors' decisions regarding the payment of dividends will depend on many factors, such as 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. Organon's ability to pay any dividends will depend on its ongoing ability to generate cash from operations and access capital markets.

Certain provisions in 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 Common Stock.

Organon is a Delaware corporation, and its 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 Organon's Board of Directors rather than to attempt a hostile takeover. Specifically, because Organon has 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, 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 Organon's stockholders might consider in their best interests. For example, Organon's amended and restated certificate of incorporation and bylaws:

- permit 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 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 Organon's Board of Directors is classified, 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 believes these provisions will protect its stockholders from coercive or otherwise unfair takeover tactics by requiring potential acquirors to negotiate with Organon's Board of Directors and by providing its Board of Directors with more time to assess any acquisition proposal. These provisions are not intended to make Organon 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 Organon's Board of Directors determines is not in the best interests of Organon and its 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 Organon's Common Stock if they are viewed as limiting the liquidity of its stock or discouraging takeover attempts in the future.

Certain provisions of agreements that Organon entered into with Merck may limit Organon's ability to operate its business.

Certain of the agreements that Organon entered into with 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 prevent a change of control that stockholders may consider favorable.

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 Organon's stockholders, and the United States federal district courts as the exclusive forum for claims under the Securities Act, which could limit Organon's stockholders' ability to obtain what such stockholders believe to be a favorable judicial forum for disputes with Organon or its directors, officers or employees.

Organon's amended and restated bylaws provide that, unless Organon selects or consents 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.

Furthermore, unless Organon selects or consents 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. 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 or its directors, officers or other employees, which may discourage such lawsuits. It is possible 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 may incur additional costs associated with resolving such matters in other jurisdictions, which could materially adversely affect Organon's business, financial condition and results of operations and result in a diversion of the time and resources of its management and board of directors.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Organon's corporate headquarters is located in Jersey City, New Jersey. Organon also maintains operational headquarters in Pennsylvania. Organon owns and operates six manufacturing facilities in Campinas, Brazil, Cramlington, United Kingdom, Heist, Belgium, Oss, Netherlands, Panaan, Indonesia and Xochimilco, Mexico.

Item 3. Legal Proceedings

We are from time to time subject to claims and litigation arising in the ordinary course of business. These claims and litigation may include, among other things, claims or litigation relating to intellectual property, product liability, securities law, breach of contract and tort, or allegations of violation of United States and foreign competition law, labor laws, consumer protection laws and environmental laws and related regulations. We operate in multiple jurisdictions and, as a result, claims in one jurisdiction may lead to claims or regulatory penalties in other jurisdictions. There can be no assurance as to the ultimate outcome of a legal proceeding; however, we intend to defend vigorously against any pending or future claims and litigation, other than matters deemed appropriate for settlement. We accrue a liability for legal claims when payments associated with the claims become probable and the costs can be reasonably estimated. The actual costs of resolving legal claims may be substantially higher or lower than the amounts accrued for those claims. For a discussion of legal matters as of December 31, 2022, please See Note 12 "Contingencies" to our financial statements included in this report, which is incorporated into this item by reference.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Organon's Common Stock is listed on the New York Stock Exchange under the symbol "OGN." As of February 22, 2023, there were 74,829 holders of record of Organon's Common Stock. This number does not include persons who hold Organon's Common Stock in nominee or "street name" accounts through brokers or banks.

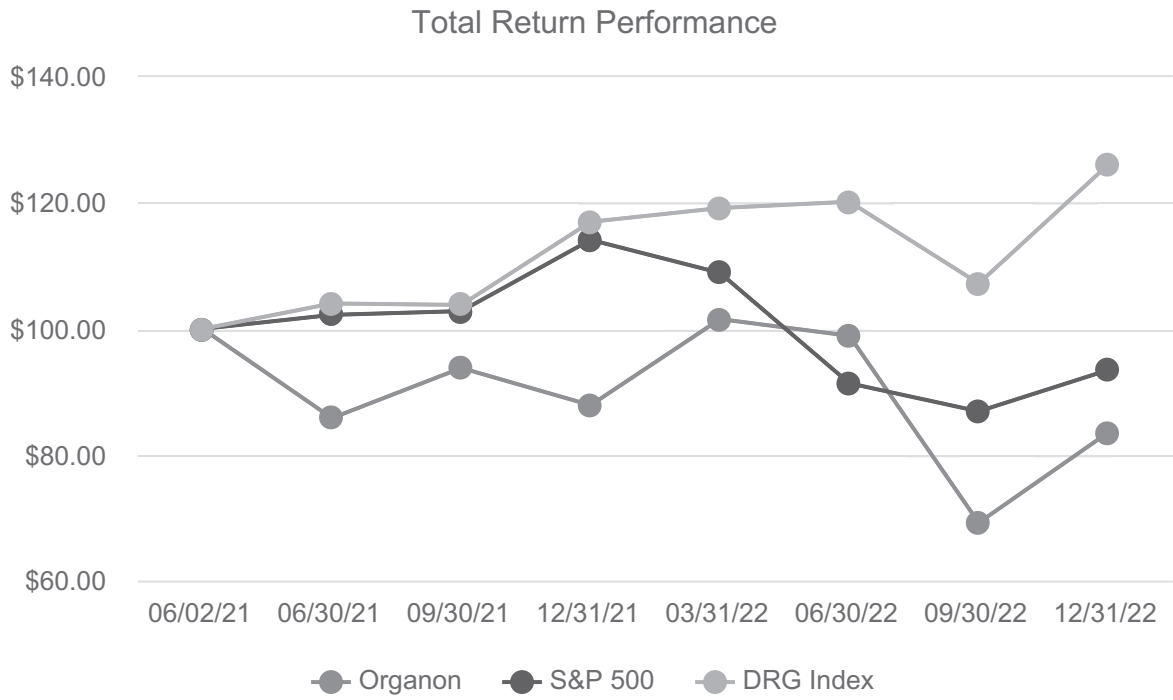
Dividends

During the fourth quarter of 2022, Organon paid cash dividends of $0.28 per share. On February 16, 2023, the Board of Directors declared a quarterly dividend of $0.28 for each issued and outstanding share of the Company's Common Stock. The dividend is payable on March 16, 2023 to stockholders of record at the close of business on February 27, 2023.

The declaration of dividends is subject to the discretion of Organon's Board. The Board is committed to continuing to pay regular cash dividends; however, there can be no assurance as to future dividends. The Board will consider factors such as financial results, capital requirements, financial condition and any other factors it deems relevant. For additional information, see "Risk Factors—Organon cannot guarantee the timing, amount or payment of any dividends on the Common Stock".

Performance Graph

The following graph compares the cumulative total stockholder returns for the period from June 2, 2021 (the effective date of Organon's Separation from Merck) to December 31, 2022 for (i) Organon's Common Stock; (ii) the S&P 500 Index; and (iii) the NYSE Arca Pharmaceutical Index ("DRG"). The graph assumes an investment of $100 on June 2, 2021 through the last trading day of 2022. The calculation of cumulative stockholder return on the S&P 500 Index and the NYSE Arca Pharmaceutical Index include reinvestment of dividend. The performance shown is not necessarily indicative of future performance.



Equity Compensation Plan Information

See Part III, Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters."

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

Organon makes statements in this Annual Report on Form 10-K, and Organon may from time to time make other written reports and oral statements, regarding its outlook or expectations for financial, business or strategic matters regarding or affecting Organon that are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, all of which are based on management's current expectations and are subject to risks and uncertainties which change over time and may cause results to differ materially from those set forth in the statements. One can identify these forward-looking statements by their use of words such as "anticipates," "expects," "plans," "will," "estimates," "forecasts," "projects" and other words of similar meaning, or negative variations of any of the foregoing. One can also identify them by the fact that they do not relate strictly to historical or current facts. Such forward-looking statements include, but are not limited to, statements relating to Organon's growth and acquisition strategies, financial results, product development, product approvals, product potential and development programs. One must carefully consider any such statement and should understand that many factors could cause actual results to differ materially from Organon's forward-looking statements. These factors may be based on inaccurate assumptions and are subject to a broad variety of other risks and uncertainties. No forward-looking statement can be guaranteed and actual future results may vary materially. The factors described in Part I. Item 1A. Risk Factors of this report or otherwise described in Organon's filings with the SEC, provide examples of risks, uncertainties and events that may cause Organon's actual results to differ materially from the expectations expressed in its forward-looking statements, including, but not limited to:

- expanded brand and class competition in the markets in which Organon operates;
- difficulties with performance of third parties Organon relies on for its business growth;
- the failure of any supplier to provide substances, materials, or services as agreed;
- the increased cost of supply, manufacturing, packaging, and operations;
- difficulties developing and sustaining relationships with commercial counterparties;
- competition from generic products as Organon's products lose patent protection;
- difficulties and uncertainties inherent in the implementation of Organon's acquisition strategy or failure to recognize the benefits of such acquisitions;
- pricing pressures globally, including rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and health care reform, pharmaceutical reimbursement and pricing in general;
- the impact of the global COVID-19 pandemic and any future pandemic, epidemic, or similar public health threat on Organon's business, operations and financial performance;
- changes in government laws and regulations in the United States and other jurisdictions, including laws and regulations governing the research, development, approval, clearance, manufacturing, supply, distribution, and/or marketing of Organon's products and related intellectual property, environmental regulations, and the enforcement thereof affecting Organon's business;
- efficacy, safety or other quality concerns with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals or declining sales;
- delays or failures to demonstrate adequate efficacy and safety of Organon's product candidates in pre-clinical and clinical trials, which may prevent or delay the development, approval, clearance, or commercialization of Organon's product candidates;
- future actions of third-parties, including significant changes in customer relationships or changes in the behavior and spending patterns of purchasers of health care products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and forgoing health care insurance coverage;
- legal factors, including product liability claims, antitrust litigation and governmental investigations, including tax disputes, environmental claims and patent disputes with branded and generic competitors, any of which could preclude commercialization of products or negatively affect the profitability of existing products;
- lost market opportunity resulting from delays and uncertainties in clinical trials and the approval or clearance process of the U.S. FDA and other regulatory authorities;
- cyberattacks on, or other failures, accidents, or security breaches of, Organon's or third-party providers' information technology systems, which could disrupt Organon's operations;
- increased focus on privacy issues in countries around the world, including the United States, the European Union, and China, and a more difficult legislative and regulatory landscape for privacy and data protection that continues to evolve with the potential to directly affect Organon's business, including recently enacted laws in a majority of states in the United States requiring security breach notification;
- changes in tax laws including changes related to the taxation of foreign earnings;
- loss of key employees or inability to identify and recruit new employees;

- changes in accounting pronouncements promulgated by standard-setting or regulatory bodies, including the Financial Accounting Standards Board and the SEC, that are adverse to Organon; and
- economic factors over which Organon has no control, including changes in inflation, interest rates, recessionary pressures, and foreign currency exchange rates.

It is not possible to predict or identify all such factors. Consequently, one should not consider the above list or any other such list to be a complete statement of all potential risks or uncertainties. Further, any forward-looking statement speaks only as of the date on which it is made, and Organon undertakes no obligation to update or revise any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events, except as otherwise may be required by law.

General

The following Management's Discussion and Analysis of Financial Condition and Results of Operations is intended to assist the reader in understanding the Company's financial condition and results of operations and should be read in connection with Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2021. This section generally discusses our financial condition and results of operations for the years ended December 31, 2022 and 2021 and should be read in conjunction with the Company's Consolidated Financial Statements included in Part II, Item 8 of this Annual Report on Form 10-K to enhance the understanding of our results of operations, financial condition and cash flows. For a discussion regarding our financial condition and results of operations for the years ended December 31, 2021 and 2020, please refer to Part II — Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2021, which is available on the SEC's website at www.sec.gov.

Organon & Co. ("Organon" or the "Company") is a global health care company with a focus on improving the health of women throughout their lives. Organon develops and delivers innovative health solutions through a portfolio of prescription therapies within women's health, biosimilars and established brands (the "Organon Products"). Organon has a portfolio of more than 60 medicines and products across a range of therapeutic areas. The Company sells these products through various channels including drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. The Company operates six manufacturing facilities, which are located in Belgium, Brazil, Indonesia, Mexico, the Netherlands and the United Kingdom. Unless otherwise indicated, trademarks appearing in italics throughout this document are trademarks of, or are used under license by, the Organon group of companies.

Separation from Merck

On June 2, 2021, Organon and Merck & Co. ("Merck") entered into a Separation and Distribution Agreement (the "Separation and Distribution Agreement"). Pursuant to the Separation and Distribution Agreement, Merck agreed to spin off the Organon Products into Organon, a new, publicly traded company (the "Separation"). The Separation from Merck was completed on June 2, 2021, in which Organon's Common Stock was distributed to all holders of outstanding shares of Merck Common Stock as of the close of business on May 17, 2021 (the "Record Date"). For each share of Merck Common Stock held, such holder received one tenth of one share of Common Stock, and holders received cash in lieu of any fractional share of Common Stock they otherwise would have been entitled to receive in connection with the Distribution. As a result, Organon became a standalone publicly traded company and on June 3, 2021 regular-way trading of the Common Stock commenced on the New York Stock Exchange ("NYSE") under the symbol "OGN." Until the Separation on June 2, 2021, Organon's historical combined financial statements were prepared on a standalone basis and were derived from Merck's consolidated financial statements and accounting records.

For the period subsequent to June 2, 2021, as a standalone publicly traded company, Organon presents its financial statements on a consolidated basis. The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America.

The Separation was completed pursuant to the Separation and Distribution Agreement and other agreements with Merck related to the Separation, including, but not limited to, a tax matters agreement, an employee matters agreement and a transition services agreement. See Part II, Item 8. Note 1 "Background and Nature of Operations" and Note 18 "Third-Party Arrangements and Related Party Disclosures" to the Consolidated Financial Statements included in this report for additional details.

Key Trends Affecting Our Results of Operations

- *Generic Competition*: The majority of our established brands products are beyond market exclusivity. However, these products continue to represent a valuable opportunity arising from long-term sustainable revenue streams and well-established supply chains that together generate significant operating profit relative to low promotional and development expenses.
- *Historical Shift Towards Long-Acting Reversible Contraceptives:* Daily contraceptive pills are by far the largest contraception market segment, with almost half of all women choosing a hormonal contraceptive choosing this particular method. However, the Long-Acting Reversible Contraceptives ("LARC") market segment, which includes Nexplanon, has experienced significant growth in the decade from 2010 through to 2019, driven by a significant shift away from daily oral contraception to LARC. This was driven by payors, providers and patients looking for options beyond commonly used daily contraceptive pills. The COVID-19 pandemic negatively affected the LARC segment during 2021 and 2020 due to clinic closures and the postponement of non-essential medical procedures during country lockdowns. The LARC segment growth did begin to rebound in 2022 during months when clinic restrictions were removed. The LARC market is expected to continue to be an important and large segment of the overall contraception market as payors, providers and patients consider the benefits of long acting and highly effective options including Nexplanon.
- *Increased Access to Fertility Solutions*: We believe governments and payors are implementing favorable policies across major markets that, in turn, drive growth in the market for women's health therapies. For example, in the United States, there has been an increase in fertility insurance mandates and employer coverage, albeit subject to certain exemptions.
- *Growing Acceptance of Biosimilars*: Biologics continue to experience strong growth trends. Given the high cost of many of these biologics treatments, biosimilars are a more affordable alternative and represent a significant opportunity for patients, providers, and payors once a biologics product loses patent protection. Moreover, a significant number of biologics are expected to lose exclusivity over the next decade, representing a large opportunity for more biosimilar approvals.
- *Increased Competitive Pressures*: The markets in which we conduct our business and the pharmaceutical industry in general are highly competitive and highly regulated. Our competitors include other worldwide research-based pharmaceutical companies, smaller research companies with more limited therapeutic focus and generic drug manufacturers.

Recent Developments

Business Development

Claria Medical, Inc. ("Claria")

In January 2023, the Company made a strategic investment in Claria, a privately-held company developing an investigational medical device being studied for use during minimally invasive laparoscopic hysterectomy. Under the terms of the agreement, Organon paid $8 million upfront and has the option to acquire Claria for pre-defined terms at a later date. The upfront payment will be expensed as *Acquired in-process research and development and milestones* in our statement of income in the first quarter of 2023.

Cirqle Biomedical ("Cirqle")

In July 2022, the Company entered into a research collaboration and license agreement with Cirqle for a novel investigational non-hormonal, on-demand contraceptive candidate. Under the terms of the agreement, Cirqle is responsible for conducting preclinical studies according to the mutually agreed research plan. Organon obtained exclusive worldwide rights to develop and commercialize the asset.

Under the terms of the research collaboration and license agreement, Organon recorded a $10 million upfront payment during 2022 as *Acquired in-process research and development and milestones*. Cirqle is eligible to receive potential regulatory and commercial milestone payments of up to $360 million and tiered royalties based on net sales. The remaining potential milestone payments will be recognized by Organon when achievement of the contractual milestones is probable.

Shanghai Henlius Biotech, Inc. ("Henlius")

In June 2022, Organon and Henlius, a global biopharmaceutical company, entered into a definitive agreement whereby Organon is licensing commercialization rights for biosimilar candidates HLX11, referencing *Perjeta*, used for the treatment of certain patients with HER2+ breast cancer in combinations with trastuzumab and chemotherapy and HLX14, referencing *Prolia*/*Xgeva*, used for the treatment of certain patients with osteoporosis with high risk of fracture and for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastasis from solid tumors. Organon obtained exclusive global commercialization rights except for China; including Hong Kong, Macau and Taiwan. The agreement includes an option to negotiate an exclusive license for global commercialization rights for biosimilar candidate HLX13, referencing *Yervoy* used for the treatment of certain patients with unresectable or metastatic melanoma, as adjuvant treatment of certain patients with cutaneous melanoma, certain patients with renal cell carcinoma, colorectal cancer, hepatocellular carcinoma, non-small cell lung cancer, malignant pleural mesothelioma and esophageal cancer.

Under the terms of the license agreement, Organon paid a $73 million upfront payment during 2022, of which $3 million was reflected in *Other current assets* and the remainder was recognized as *Acquired in-process research and development and milestones*. Henlius is eligible to receive potential developmental, regulatory and commercial milestone payments of up to $468 million. During the year ended December 31, 2022, the Company paid an additional $27 million related to certain development milestones which were recognized as *Acquired in-process research and development and milestones.* The remaining potential milestone payments will be recognized by Organon when achievement of the contractual milestones is probable. Henlius will be responsible for development and, if approved, will supply the products to Organon.

Daré Bioscience, Inc. ("Daré")

In March 2022, Organon and Daré, a leader in women's health innovation, entered into an agreement whereby Organon licensed the global commercial rights to *Xaciato*. *Xaciato* is an FDA-approved medication for the treatment of bacterial vaginosis ("BV") in females 12 years of age and older. *Xaciato* received both Qualified Infectious Disease Product ("QIDP") and Fast Track designations from the FDA for the treatment of bacterial vaginosis.

Under the terms of the license agreement, Organon paid a $10 million upfront payment during 2022. Daré is eligible to receive potential regulatory and commercial milestone payments of up to $182.5 million and tiered double-digit royalties based on net sales. *Xaciato* is expected to be available commercially in the U.S. in the first half of 2023. During the year ended December 31, 2022 management determined that the first commercial milestone was deemed probable of occurring, and recognized an intangible asset of $12.5 million reflecting the $10 million upfront payment and $2.5 million commercial milestone. The intangible asset will be amortized over its useful life of 12 years. The remaining potential milestone payments will be recognized by Organon when achievement of the contractual milestones is probable.

Bayer AG

In February 2022, Organon acquired the product rights and related inventory from Bayer AG to *Marvelon* and *Mercilon*, combined oral hormonal daily contraceptive pills, in China, including Hong Kong and Macau, and entered into an agreement to acquire the rights to these products in Vietnam. *Marvelon* and *Mercilon* are already owned, manufactured, and marketed by Organon as prescription oral contraceptives in 20 other markets. The transaction was accounted for as an asset acquisition. In 2022, Organon paid $95 million to acquire the product rights and inventory in China and Vietnam. This resulted in Organon recognizing an intangible asset of $72 million in total related to the product rights with the remainder of the consideration recorded to *Inventories* for the fair value of acquired inventory during 2022. The intangible assets related to currently marketed products will be amortized over their estimated useful lives of 10 years.

COVID-19 Update

Organon remains focused on protecting the safety of its employees and supporting Organon's communities in response to the COVID-19 pandemic. COVID-19-related disruptions, including patients' inability to access health care providers, prioritization of COVID-19 patients, as well as social distancing measures have negatively affected our results during 2021 and 2022.

Our product portfolio is comprised of physician prescribed products, mainly in established brands, which have been affected by social distancing measures and fewer medical visits. 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, as well as the prioritization of COVID-19 patients at health care providers, resulted in reduced administration of certain products within established brands particularly for respiratory and cardiovascular products and women's health products such as *Nexplanon*, as well as our fertility brands. During 2022, our business was impacted by lockdowns in selective cities across

China, which have slowed down with recent policies in China to ease the zero COVID strategy.

We believe that global health systems and patients continue to adapt to the evolving impacts of the COVID-19 pandemic. Due to the significant uncertainty that exists relative to the duration and overall impact of the COVID-19 pandemic resulting from resurgences in COVID-19 infections or new strains of the virus, our future operating performance, particularly in the short-term, may be subject to volatility.

Operating Results

Sales Overview

	Year Ended December 31,			% Change	% Change Excluding Foreign Exchange	% Change	% Change Excluding Foreign Exchange
($ in millions)	2022	2021	2020	2022 vs. 2021		2021 vs. 2020	
United States	$ 1,437	$ 1,383	$ 1,408	4 %	4 %	(2)%	(2)%
International	4,737	4,921	5,124	(4)	4	(4)	(8)
Total	$ 6,174	$ 6,304	$ 6,532	(2)%	4 %	(3)%	(6)%

U.S. plus international may not equal total due to rounding.

Worldwide sales were $6.2 billion for the year ended December 31, 2022, a decrease of 2% compared with 2021. Worldwide sales were negatively impacted by approximately 6%, or $383 million, due to unfavorable foreign exchange. Excluding foreign exchange, sales increases primarily reflect strong performance of *Nexplanon* due to favorable pricing and demand uptake in the United States as well as volume growth across Brazil, Latin America and the institutional business in Africa and strong volume growth for products within the established brands business, particularly for respiratory products *Nasonex* and *Singulair* primarily in Japan and China. Worldwide sales also reflected strong performance in biosimilar products mainly in the United States, resulting from the continued uptake of *Renflexis* in the United States and the strong performance of cardiovascular products, primarily *Atozet,* due to increased demand in France and Spain. This performance was partially offset by declines due to the generic competition for women's health product *NuvaRing* and the authorized generic etonogestrel/ethinyl estradiol vaginal ring in the United States and unfavorable discount rates and lower volume growth in the United States related to *Dulera.*

The loss of exclusivity ("LOE") negatively impacted sales by approximately $30 million during the year ended December 31, 2022, compared to the year ended December 31, 2021, based on the decrease in volume period over period, mainly impacting *NuvaRing* in the United States. Volume-based procurement ("VBP") in China had a $20 million negative impact on sales during the year ended December 31, 2022, compared to the year ended December 31, 2021. Organon expects VBP to impact the Company's established brands product portfolio for the next several quarters.

Organon's operations include a portfolio of products. Highlights of the sales of Organon's products for the year ended December 31, 2022 and 2021 are provided below. See Note 17 "Product and Geographic Information" to the Consolidated Financial Statements for further details on sales of our products.

Women's Health

($ in millions)	Year Ended December 31, 2022	2021	2020	% Change 2022 vs. 2021	% Change Excluding Foreign Exchange 2022 vs. 2021	% Change 2021 vs. 2020	% Change Excluding Foreign Exchange 2021 vs. 2020
Nexplanon/Implanon NXT	$ 834	$ 769	$ 680	8 %	11 %	13 %	12 %
NuvaRing	173	191	236	(9)	(6)	(19)	(21)
Marvelon/Mercilon	110	98	95	12	20	3	2
Follistim AQ	229	237	193	(3)	—	23	19
Ganirelix Acetate Injection	123	111	81	11	18	37	32

Contraception

Worldwide sales of *Nexplanon*, a single-rod subdermal contraceptive implant, increased 8% for the year ended December 31, 2022 compared to 2021, primarily due to the impact of favorable pricing and demand uptake in the United States, the favorable impact from the timing of tenders in Brazil and Latin America and volume growth from the institutional business in Africa.

Worldwide sales of *NuvaRing*, a vaginal contraceptive product, declined 9% for the year ended December 31, 2022, compared to 2021, due to ongoing generic competition in the United States. We expect a continued decline in *NuvaRing* sales as a result of generic competition. In addition to sales of branded *NuvaRing*, we have an agreement with a generic manufacturer that authorizes the sale of a generic etonogestrel/ethinyl estradiol vaginal ring in the United States. Under the terms of the agreement, we are reimbursed on a cost-plus basis by the generic manufacturer for supplying finished goods and receive a share of the net profits recorded by the generic manufacturer. Under the terms of the agreement, our share in the profits declines over time as new participants enter the market. Revenues from this arrangement were $46 million and $73 million for the year ended December 31, 2022 and 2021, respectively. The decline in revenue for the year ended December 31, 2022, is due to the entry of a new market participant.

Worldwide sales of *Marvelon* and *Mercilon*, combined oral hormonal daily contraceptive pills not approved or marketed in the United States but available in certain countries outside the United States, increased 12% for the year ended December 31, 2022, compared to 2021 as a result of the recent transaction with Bayer Healthcare where Organon gained full rights in the China and Vietnam markets.

Fertility

Worldwide sales of *Follistim AQ*® (marketed in most countries outside the United States as *Puregon*), a fertility treatment, declined 3% for the year ended December 31, 2022 compared to 2021, as continuous demand growth in the United States and China was offset by the unfavorable impact of foreign exchange and the negative impact of COVID in China.

Worldwide sales of Ganirelix Acetate Injection (marketed in certain countries outside the United States as *Orgalutran*), a fertility treatment, increased 11% for the year ended December 31, 2022, compared to 2021, driven by demand uptake in the international markets.

Biosimilars

($ in millions)	Year Ended December 31, 2022	2021	2020	% Change 2022 vs. 2021	% Change Excluding Foreign Exchange 2022 vs. 2021	% Change 2021 vs. 2020	% Change Excluding Foreign Exchange 2021 vs. 2020
Renflexis	$ 226	$ 186	$ 135	21 %	22 %	37 %	36 %
Ontruzant	122	126	115	(4)	—	10	7
Brenzys	75	63	74	19	24	(15)	(20)
Hadlima	19	13	—	51	57	—	—

Renflexis is a biosimilar to *Remicade* for the treatment of certain inflammatory diseases. Sales growth of 21% for the year ended December 31, 2022, was driven primarily by continued demand growth, favorable channel mix and favorable discount rates in the United States. We have commercialization rights to *Renflexis* in countries outside Europe, Korea, China, Turkey and Russia.

Ontruzant is a biosimilar to *Herceptin* for the treatment of HER2-overexpressing breast cancer and HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. Sales in the year ended December 31, 2022 declined 4%, driven by the competitive pressures in Europe and the unfavorable impact of foreign exchange offset by the continued uptake in the United States since its launch in July 2020. We have commercialization rights to *Ontruzant* in countries outside of Korea and China.

Brenzys is a biosimilar to *Enbrel* for the treatment of certain inflammatory diseases. Sales in the year ended December 31, 2022 increased 19%, primarily driven by volume growth in Canada. We have commercialization rights to *Brenzys* in countries outside of the United States, Europe, Korea, China and Japan.

Hadlima is a biosimilar to *Humira* for the treatment of certain inflammatory diseases. We have worldwide commercialization rights to *Hadlima* in countries outside of the EU, Korea, China, Turkey and Russia. Samsung Bioepis reached a global settlement with AbbVie permitting us to launch *Hadlima* outside of the United States starting in 2021 and in the United States in June 2023. *Hadlima* is currently approved in the United States, Australia, Canada, and Israel. *Hadlima* was launched in Australia and Canada in February 2021. In August 2022, the U.S. Food and Drug Administration approved the citrate-free, high-concentration (100 mg/mL) formulation of *Hadlima*. We recorded sales of $19 million during the year ended December 31, 2022, reflecting an increase of 51% from modest sales during the year ended December 31, 2021 in markets outside of the US.

Established Brands

Established brands represents a broad portfolio of well-known brands, which generally are beyond market exclusivity, including leading brands in cardiovascular, respiratory, dermatology and non-opioid pain management, for which generic competition varies by market.

Cardiovascular

($ in millions)	Year Ended December 31, 2022	2021	2020	% Change 2022 vs. 2021	% Change Excluding Foreign Exchange 2022 vs. 2021	% Change 2021 vs. 2020	% Change Excluding Foreign Exchange 2021 vs. 2020
Zetia/Vytorin	$ 488	$ 542	$ 664	(10)%	(3)%	(18)%	(22)%
Atozet	457	458	453	—	11	1	(3)
Rosuzet	71	68	130	5	23	(48)	(47)
Cozaar/Hyzaar	323	357	386	(10)	(3)	(7)	(11)

Combined global sales of *Zetia* (marketed in most countries outside of the United States as *Ezetrol*) and *Vytorin* (marketed outside of the United States as *Inegy*), medicines for lowering LDL cholesterol, declined 10% for the year ended December 31, 2022, compared to 2021, primarily driven by increased competition, lower performance in Europe, the impact of VBP in China and the unfavorable impact of foreign exchange offset by increased demand resulting from competitors' supply disruptions in Japan and growing demand in China across retail and public sectors.

Sales of *Atozet*, a medicine for lowering LDL cholesterol, remained consistent for the year ended December 31, 2022, compared to 2021, primarily due to increased demand in France and Spain offset by the unfavorable impact of foreign exchange.

Sales of *Rosuzet*, a medicine for lowering LDL cholesterol, increased 5% for the year ended December 31, 2022, compared to 2021, primarily due to higher demand in Japan partially offset by the impact of foreign exchange.

Combined global sales of *Cozaar*, and *Hyzaar* (a combination of losartan potassium and hydrochlorothiazide that is marketed in Japan as *Preminent*™[1]), a medicine for the treatment of hypertension, declined 10% for the year ended December 31, 2022, compared to 2021, primarily due to lower volume growth in Japan and China and the unfavorable impact of foreign exchange.

Respiratory

	Year Ended December 31,			% Change	% Change Excluding Foreign Exchange	% Change	% Change Excluding Foreign Exchange
($ in millions)	2022	2021	2020	2022 vs. 2021		2021 vs. 2020	
Singulair	$ 411	$ 413	$ 462	(1)%	9 %	(11)%	(13)%
Nasonex	238	206	218	16	22	(6)	(9)
Dulera	180	190	222	(5)	(5)	(15)	(16)

Worldwide sales of *Singulair*, a once-a-day oral medicine for the chronic treatment of asthma and for the relief of symptoms of allergic rhinitis, declined 1% for the year ended December 31, 2022, compared to 2021, primarily attributable the unfavorable impact of foreign exchange offset by volume recovery from the COVID-19 pandemic and demand resulting from competitors' supply disruptions in Japan.

Global sales of *Nasonex*, an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, increased 16% during the year ended December 31, 2022, primarily driven by higher demand resulting from competitors' supply disruptions in Japan and increased demand across several markets, partially offset by the unfavorable impact of foreign exchange. In addition, sales during the year ended December 31, 2022 included a $10 million milestone payment related to a regulatory approval in the United States.

Global sales of *Dulera*, a combination medicine for the treatment of asthma, declined 5% for the year ended December 31, 2022, compared to 2021, primarily due to lower volume growth in the United States.

Non-Opioid Pain, Bone and Dermatology

	Year Ended December 31,			% Change	% Change Excluding Foreign Exchange	% Change	% Change Excluding Foreign Exchange
($ in millions)	2022	2021	2020	2022 vs. 2021		2021 vs. 2020	
Arcoxia[1]	$ 241	$ 244	$ 258	(1)%	4 %	(5)%	(8)%

Sales of *Arcoxia*, a medicine for the treatment of arthritis and pain, declined 1% during the year ended December 31, 2022 compared to 2021, primarily due to the unfavorable impact of foreign exchange offset by higher demand in China and the South East Asia region.

Other

($ in millions)	Year Ended December 31, 2022	2021	2020	% Change 2022 vs. 2021	% Change Excluding Foreign Exchange	% Change 2021 vs. 2020	% Change Excluding Foreign Exchange
Proscar	$ 101	$ 117	$ 176	(14)%	(9)%	(33)%	(37)%

Worldwide sales of *Proscar*, a medicine for the treatment of symptomatic benign prostate enlargement, declined 14% for the year ended December 31, 2022, compared to 2021, primarily due to lower demand in China and the unfavorable impact of foreign exchange.

Costs, Expenses and Other

($ in millions)	Year Ended December 31, 2022	2021	2020	% Change 2022 vs. 2021	% Change 2021 vs. 2020
Cost of sales	$ 2,294	$ 2,382	$ 2,119	(4)%	12 %
Selling, general and administrative	1,704	1,668	1,356	2	23
Research and development	471	339	210	39	61
Acquired in-process research and development and milestones	107	104	—	3	*
Restructuring costs	28	3	60	*	(95)
Interest expense	422	258	—	64	*
Exchange losses	11	4	44	*	(91)
Other expense (income), net	15	17	(9)	(12)	*
	$ 5,052	$ 4,775	$ 3,780	6 %	26 %

** Calculation not meaningful.*

Cost of Sales

Cost of sales decreased 4% compared to the same period in 2021, primarily due to the impact of lower supply sales compared to the prior year, pre-spin allocated costs related to the Separation in the prior year and a $24 million charge pertaining to unavoidable losses associated with a long-term vendor supply contract incurred during the prior year, offset by inventory charges of $36 million relating to a regulatory inspection finding at the Heist manufacturing location which impacts selected injectable steroids brands. During the year ended December 31, 2022 and 2021, the Company recorded impairment charges of $9 million and $7 million, respectively, related to a product right for a biosimilar product. Cost of sales includes amortization of intangible assets which totaled $116 million in 2022, $103 million in 2021 and $86 million in 2020.

Selling, General and Administrative

Selling, general and administrative expenses increased 2% for the year ended December 31, 2022 due to selling and promotional costs related to our women's health portfolio, including costs related to our recent acquisitions, partially offset by pre-spin allocated costs related to the Separation during the prior year which were not incurred during the year ended December 31, 2022.

Research and Development

Research and development expenses increased 39% for the year ended December 31, 2022, primarily due to higher costs associated with the Company's recent acquisitions of clinical stage assets, increased clinical study activity and higher employee-related costs.

Acquired In-Process Research and Development and Milestones

For the year ended December 31, 2022 acquired in-process research and development and milestones of $107 million represent the upfront and development milestones related to the Cirqle and Henlius transactions. Acquired in-process research and development and milestones for the year ended December 31, 2021 of $104 million represents the upfront milestones related to

the licensing agreement for the global development, manufacturing and commercial rights to ebopiprant (OBE022) (the "ebopiprant license") and the acquisition of Forendo Pharma.

Restructuring Costs

During the year end December 31, 2022, the Company initiated restructuring activities to optimize its internal operations. The restructuring charges primarily relate to targeted reduction in headcount in selective territories outside of the U.S. in our commercial organizations. For the year ended December 31, 2022, the Company incurred $28 million related to headcount related restructuring activities.

Interest Expense

For the year ended December 31, 2022, interest expense increased, due to the $9.5 billion of debt, which was incurred by the Company during the second quarter of 2021, increased interest rates and the impact of exchange rates.

Exchange Losses (Gains)

For the year ended December 31, 2022, the change in exchanges losses (gains) was driven by the exchange rate impact on the portion of Euro-denominated debt not designated as a net investment hedge and the fluctuations in foreign exchange.

Other expense (income), net

For the year ended December 31, 2022, other expense, net, remained relatively consistent with the prior year.

Taxes on Income

The effective income tax rates were 18.3% and 11.7% for the year ended December 31, 2022 and 2021, respectively. These effective income tax rates reflect the beneficial impact of foreign earnings, offset by the impact of U.S. inclusions under the Global Intangible Low-Taxed Income regime. The effective income tax rate for the year ended 2021 also reflected a $75 million tax benefit relating to a portion of the non-U.S. step-up of tax basis, as well as the income tax benefit recognized in connection with the conclusion of the Internal Revenue Service ("IRS") examination of Merck's 2015-2016 U.S. federal income tax returns. As a result of that examination conclusion, we reflected an allocation from Merck of $18 million in the Consolidated Financial Statements representing our portion of the payment made to the IRS. Our portion of reserves for unrecognized tax benefits for the years under examination exceeded the allocated adjustments relating to this examination period. Therefore, for the year ended December 31, 2021, we reflected a $29 million net tax benefit. This net benefit reflects reductions in reserves for unrecognized tax benefits and other related liabilities for tax positions relating to the years that were under examination.

On August 16, 2022, the U.S. enacted the Inflation Reduction Act of 2022. Provisions of the bill that relate to tax include the minimum tax on book income, a 1% excise tax on stock buybacks and certain tax incentives to promote clean energy. There are no impacts of the legislation to the 2022 results. The Company is currently assessing future impacts of this recently enacted legislation.

Income/Loss from Discontinued Operations

The historical results of certain Merck non-U.S. legal entities that were contributed to Organon in connection with the Separation included operations related to other Merck products that were retained by Merck. The Merck Retained Products business of the Transferred Entities were contributed by Organon to Merck and its affiliates. Accordingly, the historical results of operations of the Merck Retained Products have been reflected as discontinued operations in the Consolidated Financial Statements for the years ended December 31, 2021 and 2020.

Analysis of Liquidity and Capital Resources

Liquidity and Capital Resources

As of December 31, 2022, Organon had cash and cash equivalents of $706 million. On June 6, 2022, the Company made a discretionary prepayment of $100 million on the U.S. Dollar-denominated term loan. The Company has historically generated and expects to continue to generate positive cash flow from operations. We plan to continue to fund our ongoing operating, investing and financing requirements mainly through cash flows from operations, available liquidity through cash on hand, available capacity under our Revolving Credit Facility and access to capital markets.

Working capital was $1.4 billion as of December 31, 2022 and $1.2 billion as of December 31, 2021. The increase in working capital of continuing operations was primarily driven by a decrease in trade accounts payable.

Net cash provided by operating activities was $858 million for the year ended December 31, 2022 compared to $2.2 billion for the same period in the prior year. The decrease in cash provided by operating activities in 2022 was primarily attributable to the decrease in trade payables, including balances with Merck.

Net cash used in investing activities was $420 million for the year ended December 31, 2022 compared to $481 million for the same period in the prior year, primarily reflecting the asset acquisition of *Marvelon* and *Mercilon* and licensing agreements with Daré, Henlius and Cirqle in the year ended December 31, 2022 and the asset acquisitions of Alydia Health and Forendo Pharma and the ebopiprant license in the year ended December 31, 2021.

Net cash used in financing activities was $433 million for the year ended December 31, 2022 compared to $977 million for the same period in the prior year. The change in cash used in financing activities reflects the settlement of the transactions with Merck in connection with the Separation in 2021 and the prior year issuance of long term debt, partially offset by the payment of dividends in the current year.

Our ability to fund our operations and anticipated capital needs is reliant upon the generation of cash from operations, supplemented as necessary by periodic utilization of our Revolving Credit Facility. Our principal uses of cash in the future will be primarily to fund our operations, working capital needs, capital expenditures, repayment of borrowings, payment of dividends and strategic business development transactions.

Capital expenditures were $196 million and $192 million for the years ended December 31, 2022 and 2021, respectively. Capital expenditures in 2022 and 2021 reflect investments in new capital projects focused primarily on establishing Organon as an independent Company. We estimate that we will continue to invest in new capital projects in 2023, for ongoing projects to stand up Organon, principally related to investments in information technology.

In 2022, the armed conflict between Ukraine and Russia escalated, which may adversely impact Organon's business. Specifically, trade sanctions, travel bans and asset and financial freezes announced by the United States, European Union and other countries against Russian entities and designated individuals, as well as counter-measures announced by Russia, 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, constraints in energy supply, currency exchange rates and exchange controls). Such actions may negatively impact the financial institutions, vendors, manufacturers, suppliers, partners and other third parties with whom Organon conducts business. Organon will continue to monitor the impacts of the conflict, which may negatively impact Organon's operations, financial position or cash flows. For the year ended December 31, 2022 and 2021, Organon's combined revenues from Ukraine and Russia were approximately 2% of total revenues. As of December 31, 2022, the Company's assets in Ukraine and Russia are not material.

Contractual Obligations

Our contractual obligations as of December 31, 2022, which require material cash requirements in the future, consist of contractual milestones, purchase obligations, lease obligations and the settlement of certain tax matters.

Contractual milestones are potential payments based upon the achievement of specified milestones associated with business development transactions. Such milestone payments will only be payable in the event that the Company achieves contractually defined, success-based milestones, such as the advancement of the specified research and development programs; the receipt of regulatory approval for the specified compounds or products; and/or reaching a sales threshold of the specified compounds or products. The timing of the payments of the contractual milestones cannot be estimated and the likelihood of achieving the

milestones cannot be determined. As of December 31, 2022, total potential payments due for contractual milestones are $2.4 billion. Amounts due within the next twelve months are $38 million.

Purchase obligations are enforceable and legally binding obligations for purchases of goods and services which include inventory purchase commitments. As of December 31, 2022, total payments due for purchase obligations are $1.2 billion and extend through 2030. Amounts due within the next twelve months are $343 million.

Lease obligations exclude reasonably certain lease renewals that have not yet been executed. As of December 31, 2022, total payments due for lease obligations are $220 million and extend through 2041. Amounts due within the next twelve months are $56 million.

Organon is responsible for settlement of certain tax matters, of which the Company expects to pay approximately $19 million within the next year.

During 2022, Organon paid cash dividends of $1.12 per share. On February 16, 2023, the Board of Directors declared a quarterly dividend of $0.28 for each issued and outstanding share of the Company's common stock. The dividend is payable on March 16, 2023 to stockholders of record at the close of business on February 27, 2023.

We believe that our financing arrangements, future cash from operations, and access to capital markets will provide adequate resources to fund our future cash flow needs.

The economy of Turkey was deemed hyperinflationary during the second quarter of 2022. Consequently, in accordance with U.S. GAAP, the Company began remeasuring its monetary assets and liabilities for those operations in earnings beginning in the second quarter of 2022. The impact to the Company's financial condition and results is immaterial.

Critical Accounting Estimates

The audited annual consolidated financial statements are prepared in conformity with U.S. GAAP and, accordingly, include certain amounts that are based on management's best estimates and judgments. A discussion of accounting estimates considered critical because of the potential for a significant impact on the financial statements due to the inherent uncertainty in such estimates are disclosed below. Because of the uncertainty inherent in such estimates, actual results may differ from these estimates.

Revenue Recognition

Our accounting policy for revenue recognition has a substantial impact on reported results and relies on certain estimates. Revenue is recognized following a five-step model: (i) identify the customer contract; (ii) identify the contract's performance obligation; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation; and (v) recognize revenue when or as a performance obligation is satisfied. Revenue is reduced for gross-to-net sales adjustments discussed below, all of which involve significant estimates and judgment after considering applicable laws and regulations and definitive contractual agreements with private sector and public sector benefit providers. These types of variable consideration are estimated at the time of sale generally using the expected value method, although the most likely amount method is used for prompt pay discounts. In addition, revenues are recorded net of time value of money discounts if collection of accounts receivable is expected to be in excess of one year. Estimates are assessed each period and adjusted as required to revise information or actual experience.

In the United States, revenue is reduced by sales discounts issued to customers at the point-of-sale, through an intermediary wholesaler (known as chargebacks), or in the form of rebate amounts owed based upon definitive contractual agreements or legal requirements with private sector (Managed Care) and public sector (Medicaid and Medicare Part D customers). Additionally, sales are generally made with a limited right of return under certain conditions.

The provision for aggregate customer discounts in the United States covers chargebacks and rebates. We determine the provision for chargebacks based on expected sell-through levels by our wholesale customers to contracted customers, as well as estimated wholesaler inventory levels. The provision for rebates is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. We use historical customer segment utilization mix, sales, changes to product mix and price, inventory levels in the distribution channel, government pricing calculations and prior payment history in order to estimate the expected provision. Amounts accrued for aggregate customer discounts are evaluated on a quarterly basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers, federal and state agencies, and other customers to the amounts accrued.

We continually monitor our provision for aggregate customer discounts. There were no material adjustments to estimates associated with the aggregate customer discount provision in 2022, 2021, or 2020.

Summarized information about changes in the aggregate customer discount accrual related to sales in the United States is as follows:

	Year Ended December 31,		
($ in millions)	2022	2021	2020
Balance January 1	$ 329	$ 343	$ 365
Provision	2,221	2,000	1,770
Payments[(1)]	(2,165)	(2,014)	(1,792)
Balance December 31	$ 385	$ 329	$ 343

[(1)] Includes 2021 payments made by Merck on behalf of Organon for the period prior to the Separation date.

Accruals for chargebacks are reflected as a direct reduction to accounts receivable and accruals for rebates as current liabilities. The accrued balances relative to these provisions included in accounts receivable and accrued and other current liabilities were $78 million and $307 million, respectively, at December 31, 2022, $54 million and $275 million, respectively, at December 31, 2021 and $41 million and $302 million, respectively, at December 31, 2020.

Outside of the United States, variable consideration in the form of discounts and rebates are a combination of commercially-driven discounts in highly competitive product classes, discounts required to gain or maintain reimbursement, or legislatively mandated rebates. In certain European countries, legislatively mandated rebates are calculated based on an estimate of the government's total unbudgeted spending and our specific payback obligation. Rebates may also be required based on specific product sales thresholds. We apply an estimated factor against our actual invoiced sales to represent the expected level of future discount or rebate obligations associated with the sale.

We maintain a returns policy that allows our customers in certain countries to return product within a specified period prior to and subsequent to the expiration date (generally, three to six months before and 12 months after product expiration). The estimate of the provision for returns is based upon historical experience with actual returns. Additionally, we consider factors such as levels of inventory in the distribution channel, product dating and expiration period, whether products have been discontinued, entrance in the market of generic competition, changes in formularies or launch of over-the-counter products, among others.

See Note 3 "Summary of Accounting Policies" to the Consolidated Financial Statements included in this report for additional details on our revenue recognition policy.

Contingencies and Environmental Liabilities

We are involved in various claims and legal proceedings of a nature considered normal to our business, including product liability, intellectual property, and commercial litigation, as well as certain additional matters including governmental and environmental matters. See Note 12 "Contingencies" to the Consolidated Financial Statements included in this report. We record accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated.

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable.

We believe that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on us. Expenditures for remediation and environmental liabilities were $4 million in 2022, and are estimated at $16 million in the aggregate for the years 2023 through 2027. In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $20 million and $24 million at December 31, 2022 and 2021, respectively. These liabilities are undiscounted, do not consider potential recoveries from other parties and will be paid out over the periods of remediation for the applicable sites, which are expected to occur primarily over the next 15 years. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed $20 million in the aggregate. Management also does not believe that these expenditures should result in a material adverse effect on our financial condition, results of operations or liquidity for any year.

Impairments of Long-Lived Assets

We assess changes in economic, regulatory and legal conditions and make assumptions regarding estimated future cash flows in evaluating the value of our property, plant and equipment, goodwill and intangible assets. The judgments made in evaluating impairment of long-lived intangibles can materially affect our results of operations.

We periodically evaluate whether current facts or circumstances indicate that the carrying values of our long-lived assets to be held and used may not be recoverable. If such circumstances are determined to exist, an estimate of the undiscounted future cash flows of these assets, or appropriate asset groupings, is compared to the carrying value to determine whether an impairment exists. If the asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. If quoted market prices are not available, we estimate fair value using a discounted value of estimated future cash flows approach.

Goodwill represents the excess of the consideration transferred over the fair value of net assets of businesses acquired. Goodwill is evaluated for impairment as of October 1 each year, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that fair value is less than carrying value. Some of the factors considered in the assessment include general macroeconomic conditions, conditions specific to the industry and market, cost factors which could have a significant effect on earnings or cash flows, and overall financial performance. If we conclude it is more likely than not that fair value is less than carrying value, a quantitative fair value test is performed. If carrying value is greater than fair value, a goodwill impairment charge will be recorded for the difference (up to the carrying value of goodwill). We completed the annual qualitative goodwill impairment test as of October 1, 2022 and concluded that there was no impairment to goodwill as the fair value of the reporting unit was significantly in excess of the carrying value.

Acquired intangible assets are initially recorded at fair value, assigned an estimated useful life, and amortized primarily on a straight-line basis over their estimated useful lives. When events or circumstances warrant a review, we will assess recoverability from future operations using pretax undiscounted cash flows derived from the lowest appropriate asset groupings. Potential risks leading to impairment could include loss of exclusivity occurring earlier than expected, competition, pricing reductions, and other macroeconomic changes. Impairments are recognized in operating results to the extent that the carrying value of the intangible asset exceeds its fair value, which is determined based on the net present value of estimated future cash flows. Organon recorded impairment charges of $9 million and $7 million as of December 31, 2022 and 2021 respectively. See Note 10 "Intangibles" to the Consolidated Financial Statements included in this report for additional details on Intangibles.

Taxes on Income

Deferred taxes are recognized for the future tax effects of temporary differences between financial and income tax reporting based on enacted tax laws and rates. We establish valuation allowances for our deferred tax assets when the amount of expected future taxable income is not likely to support the use of the deduction or credit. We evaluate tax positions to determine whether the benefits of tax positions are more likely than not of being sustained upon audit based on the technical merits of the tax position. For tax positions that are more likely than not of being sustained upon audit, we recognize the largest amount of the benefit that is greater than 50% likely of being realized upon ultimate settlement in the financial statements. For tax positions that are not more likely than not of being sustained upon audit, we do not recognize any portion of the benefit in the financial statements. We recognize interest and penalties associated with uncertain tax positions as a component of *Taxes on Income* in the consolidated statement of income.

Prior to the Separation, we did not maintain an income taxes payable to or from account as it is deemed to be settled with the tax paying entities in the respective jurisdictions. These settlements are reflected as changes in accumulated deficit in the consolidated balance sheet. However, our consolidated balance sheet reflects balances with taxing authorities and the one-time transition tax resulting from the Tax Cuts and Jobs Act enacted in 2017, as well as for unrecognized income tax benefits along with related interest and penalties.

Prior to the Separation, income tax expense and deferred tax balances in the consolidated financial statements were calculated on a separate tax return basis. We relied on certain assumptions, one of them that as a standalone basis we would not benefit from certain tax incentives that historically benefited Merck. We believe the assumptions supporting the allocation and presentation of income taxes on a separate return basis were reasonable.

Inventory Valuation

Inventories consist of currently marketed products and are valued at the lower of cost or net realizable value. Inventories are assessed regularly for impairment and valuation reserves are established when necessary based on a number of factors including, but not limited to, product obsolescence and changes in estimates of future product demand and expiry. The determination of events and the assumptions utilized in our quantification of valuation reserves may require judgment. No material adjustments have been required to our inventory reserve estimates for the periods presented. Adverse changes in assumptions utilized in our inventory reserve calculations could result in an increase to our inventory valuation reserves and higher cost of sales.

Acquisitions

Business combinations are evaluated in order to determine whether transactions should be accounted for as acquisitions of assets or businesses. The Company makes certain judgments, which include assessment of the inputs, processes, and outputs associated with the acquired set of activities. If the Company determines that substantially all of the fair value of gross assets included in a transaction is concentrated in a single asset (or a group of similar assets), the Company accounts for the transaction as an asset acquisition. In an asset acquisition, acquired IPR&D with no alternative future use is charged to expense and contingent consideration is not recognized at the acquisition date. Product development milestones are recognized upon achievement and sales-based milestones are recognized when the milestone is deemed probable of being achieved.

To be considered a business, the assets in a transaction need to include an input and a substantive process that together significantly contribute to the ability to create outputs. Businesses acquired are consolidated upon obtaining control. The fair value of assets acquired and liabilities assumed are recognized at the date of acquisition. Assets acquired and liabilities assumed in a business combination that arise from contingencies are generally recognized at fair value. If fair value cannot be determined, the asset or liability is recognized if probable and reasonably estimable; if these criteria are not met, no asset or liability is recognized. Any excess of the purchase price over the estimated fair values of the net assets acquired is recognized as goodwill. Business acquisition costs are expensed when incurred.

The fair values of intangible assets are determined utilizing information available near the acquisition date based on expectations and assumptions that are deemed reasonable by management.

Pension

Our pension plans are calculated using actuarial assumptions including a discount rate for plan benefit obligations and an expected rate of return on plan assets. These significant assumptions are reviewed annually and are disclosed in Note 14 "Pension and Other Postretirement Benefit Plans" to the Consolidated Financial Statements.

For our pension plans, the discount rate is evaluated on measurement dates and modified to reflect the prevailing market rate of a portfolio of high-quality fixed-income debt instruments that would provide the future cash flows needed to pay the benefits included in the benefit obligation as they come due.

The expected rate of return for the pension plans represents the average rate of return to be earned on plan assets over the period the benefits included in the benefit obligation are to be paid. In developing the expected rate of return, the Company considers long-term compound annualized returns of historical market data, current market conditions and actual returns on the Company's plan assets. Using this reference information, the Company develops forward-looking return expectations for each asset category and a weighted-average expected long-term rate of return for a target portfolio allocated across these investment categories. The expected portfolio performance reflects the contribution of active management as appropriate.

Stock-Based Compensation

We expense all stock-based payment awards to employees, including grants of stock options, over the requisite service period based on the grant date fair value of the awards. The fair value of certain stock-based awards is determined using the Black-Scholes option-pricing model which uses both historical and current market data to estimate the fair value. This method incorporates various assumptions such as the risk-free interest rate, expected volatility, expected dividend yield and expected life of the options.

Recently Issued Accounting Standards

For a discussion of recently issued accounting standards, see Note 3 "Summary of Accounting Policies" to the Consolidated Financial Statements included in this report.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Foreign Currency Risk

We operate on a global basis and are exposed to the risk that our earnings, cash flows and equity could be adversely affected by fluctuations in foreign exchange rates. We are primarily exposed to foreign exchange risk with respect to forecasted transactions and net assets denominated in the euro, Swiss franc, and Japanese yen. We established a balance sheet risk management program and a net investment hedge to partially mitigate against volatility of changes in foreign exchange rates. See Note 7 "Financial Instruments" to the Consolidated Financial Statements included in this report for further information on Organon's risk management.

Interest Rate Risk

Our long-term debt portfolio consists of both fixed and variable-rate instruments. For any variable rate debt, interest rate changes in the underlying index rates will impact future interest expense. We do not hold any derivative contracts that hedge our interest rate risk; however, we may consider entering into such contracts in the future.

We estimate a hypothetical 10% adverse movement in interest rates of our variable rate debt would not materially change annual interest expense.

Item 8. Financial Statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Organon & Co.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Organon & Co. and its subsidiaries (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of income, of comprehensive income, of stockholders' equity (deficit) and of cash flows for each of the three years in the period ended December 31, 2022, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

U.S. Rebate Accruals – Medicaid and Managed Care Rebates

As described in Note 3 to the consolidated financial statements, the Company records certain variable consideration including discounts, which are estimated at the time of sale generally using the expected value method. Amounts accrued, included in accrued and other current liabilities, for aggregate customer discounts as of December 31, 2022 in the United States was $307 million, of which the majority related to U.S. rebate accruals - Medicaid and Managed Care. These rebate accruals are evaluated on a quarterly basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers, federal and state agencies, and other customers to the amounts accrued. Certain of these discounts are in the form of rebates, which are amounts owed based upon definitive contractual agreements or legal requirements with private sector (Managed Care) and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. The provision for rebates is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. Management uses historical customer segment utilization mix, sales, changes to product mix and price, inventory levels in the distribution channel, government pricing calculations and prior payment history in order to estimate the expected provision.

The principal considerations for our determination that performing procedures relating to U.S. rebate accruals – Medicaid and Managed Care is a critical audit matter are the significant judgment by management due to the significant measurement uncertainty involved in developing the rebate accruals, as the accruals are based on assumptions developed using pricing information and historical customer segment utilization mix, and a high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating evidence related to these assumptions.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to provisions for Medicaid and Managed Care rebates, including controls over the assumptions used to estimate these rebates. These procedures also included, among others, (i) developing an independent estimate of the rebate accruals by utilizing third-party data on historical customer segment utilization mix in the U.S., pricing information, the terms of the specific rebate programs, and the historical trends of actual rebate claims paid, (ii) comparing the independent estimate to the rebate accruals recorded by management, and (iii) testing actual rebate claims paid, including evaluating those claims for consistency with the contractual terms of the Company's rebate agreements.

/s/ PricewaterhouseCoopers LLP

Florham Park, New Jersey

February 27, 2023

We have served as the Company's auditor since 2019.

Organon & Co.
Consolidated Statements of Income
($ in millions except shares in thousands and per share amounts)

	Year Ended December 31,		
	2022	2021	2020
Revenues	$ 6,174	$ 6,304	$ 6,532
Costs, Expenses and Other			
Cost of sales	2,294	2,382	2,119
Selling, general and administrative	1,704	1,668	1,356
Research and development	471	339	210
Acquired in-process research and development and milestones	107	104	—
Restructuring costs	28	3	60
Interest expense	422	258	—
Exchange losses	11	4	44
Other expense (income), net	15	17	(9)
	5,052	4,775	3,780
Income From Continuing Operations Before Income Taxes	1,122	1,529	2,752
Taxes on Income	205	178	496
Net Income From Continuing Operations	917	1,351	2,256
Loss From Discontinued Operations - Net of Tax	—	—	(96)
Net Income	$ 917	$ 1,351	$ 2,160
Earnings per Share - Basic:			
Continuing operations	$ 3.61	$ 5.33	$ 8.90
Discontinued operations	—	—	(0.38)
Net Earnings per Share - Basic	$ 3.61	$ 5.33	$ 8.52
Earnings per Share - Diluted:			
Continuing operations	$ 3.59	$ 5.31	$ 8.90
Discontinued operations	—	—	(0.38)
Net Earnings per Share - Diluted	$ 3.59	$ 5.31	$ 8.52
Weighted Average Shares Outstanding:			
Basic	254,082	253,538	253,516
Diluted	255,169	254,193	253,516

The accompanying notes are an integral part of these Consolidated Financial Statements.

Organon & Co.
Consolidated Statements of Comprehensive Income
($ in millions)

	Year Ended December 31,		
	2022	2021	2020
Net Income	$ 917	$ 1,351	$ 2,160
Other Comprehensive (Loss) Income, Net of Taxes:			
Benefit plan net gain (loss) and prior service credit, net of amortization	23	8	(143)
Cumulative translation adjustment	(74)	90	(30)
	(51)	98	(173)
Comprehensive Income	$ 866	$ 1,449	$ 1,987

The accompanying notes are an integral part of these Consolidated Financial Statements.

Organon & Co.
Consolidated Balance Sheets
($ in millions except shares in thousands)

	December 31, 2022	December 31, 2021
Assets		
Current Assets		
Cash and cash equivalents	$ 706	$ 737
Accounts receivable (net of allowance for doubtful accounts of $9 in 2022 and $7 in 2021)	1,475	1,382
Inventories (excludes inventories of $148 in 2022 and $76 in 2021 classified in Other assets)	1,003	915
Other current assets	747	726
Total current assets	3,931	3,760
Property, plant and equipment, net	1,018	973
Goodwill	4,603	4,603
Intangibles, net	649	651
Other assets	754	694
	$ 10,955	$ 10,681
Liabilities and Equity		
Current Liabilities		
Current portion of long-term debt	$ 8	$ 9
Trade accounts payable	1,132	1,382
Accrued and other current liabilities	1,188	1,021
Income taxes payable	184	185
Total current liabilities	2,512	2,597
Long-term debt	8,905	9,125
Deferred income taxes	19	4
Other noncurrent liabilities	411	463
Contingencies (Note 12)		
Organon & Co. Stockholders' Deficit		
Common stock, $0.01 par value Authorized - 500,000 Issued and outstanding - 254,370 in 2022 and 253,550 in 2021	3	3
Accumulated deficit	(331)	(998)
Accumulated other comprehensive loss	(564)	(513)
Total Stockholders' Deficit	(892)	(1,508)
	$ 10,955	$ 10,681

The accompanying notes are an integral part of these Consolidated Financial Statements.

Organon & Co.
Consolidated Statements of Stockholders' Equity (Deficit)
($ in millions, except shares in thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Net Investment from Merck & Co., Inc.	Accumulated Other Comprehensive Loss	Total
	Shares	Par Value					
Balance at December 31, 2019	—	$ —	$ —	$ —	$ 7,949	$ (914)	$ 7,035
Net income	—	—	—	—	2,160	—	2,160
Other comprehensive loss, net of taxes	—	—	—	—	—	(173)	(173)
Net transfers to Merck & Co., Inc.	—	—	—	—	(4,001)	465	(3,536)
Balance at December 31, 2020	—	$ —	$ —	$ —	$ 6,108	$ (622)	$ 5,486
Net income	—	—	—	621	730	—	1,351
Other comprehensive income, net of taxes	—	—	—	—	—	98	98
Cash dividends declared on common stock ($0.56 per share)	—	—	—	(145)	—	—	(145)
Stock-based compensation plans and other	34	—	—	38	—	—	38
Net transfers from Merck & Co., Inc., including Separation Adjustments	—	—	—	65	588	11	664
Net consideration paid to Merck & Co., Inc. in connection with Separation	—	—	—	—	(9,000)	—	(9,000)
Issuance of common stock in connection with the Separation and reclassification of Net investment from Merck & Co., Inc.	253,516	3	—	(1,577)	1,574	—	—
Balance at December 31, 2021	253,550	$ 3	$ —	$ (998)	$ —	$ (513)	$ (1,508)
Net income	—	—	—	917	—	—	917
Other comprehensive loss, net of taxes	—	—	—	—	—	(51)	(51)
Cash dividends declared on common stock ($1.12 per share)	—	—	—	(290)	—	—	(290)
Stock-based compensation plans and other	820	—		64	—	—	64
Net transfers from Merck & Co., Inc., including Separation Adjustments	—	—	—	(24)	—	—	(24)
Balance at December 31, 2022	254,370	$ 3	$ —	$ (331)	$ —	$ (564)	$ (892)

The accompanying notes are an integral part of these Consolidated Financial Statements.

Organon & Co.
Consolidated Statements of Cash Flows
($ in millions)

	Year Ended December 31,		
	2022	2021	2020
Cash Flows from Operating Activities			
Net income from continuing operations	$ 917	$ 1,351	$ 2,256
Adjustments to reconcile net income from continuing operations to net cash flows provided by operating activities:			
Depreciation	96	92	56
Amortization	116	103	86
Impairment of assets	9	7	—
Acquired in-process research and development and milestones	107	104	—
Deferred income taxes	(18)	(288)	(32)
Stock-based compensation	75	59	40
Unrealized foreign exchange loss (gain)	(18)	18	(5)
Other	26	12	—
Net changes in assets and liabilities			
Accounts receivable	(123)	(277)	13
Inventories	(220)	(138)	34
Other current assets	(43)	353	80
Trade accounts payable	(237)	663	37
Accrued and other current liabilities	172	329	12
Due from/due to related party	—	(164)	(155)
Income taxes payable	7	(119)	(118)
Other	(8)	55	(20)
Net Cash Flows Provided by Operating Activities from Continuing Operations	858	2,160	2,284
Cash Flows from Investing Activities			
Capital expenditures	(196)	(192)	(255)
Proceeds from sale of property, plant and equipment	7	7	5
Acquired in-process research and development and milestones	(107)	(104)	—
Purchase of product rights and asset acquisition, net of cash acquired	(124)	(192)	—
Net Cash Flows Used in Investing Activities from Continuing Operations	(420)	(481)	(250)
Cash Flows from Financing Activities			
Proceeds from issuance of long-term debt	—	9,470	—
Repayments of debt	(108)	(112)	—
Payment of long-term debt issuance costs	—	(118)	—
Proceeds from short-term borrowings from Merck & Co, Inc.	—	—	1,512
Repayments of short-term borrowings from Merck & Co., Inc., net	—	(1,512)	—
Net consideration paid to Merck & Co. Inc. in connection with the Separation	—	(9,000)	—
Net transfers (to) from Merck & Co., Inc.	(24)	440	(3,534)
Employee withholding taxes related to stock-based awards	(11)	—	—
Dividend payments	(290)	(145)	—
Net Cash Flows Used in Financing Activities from Continuing Operations	(433)	(977)	(2,022)
Discontinued Operations			
Net Cash Provided by (Used in) Operating Activities	—	298	(97)
Net Cash Used in Investing Activities	—	—	(8)
Net Cash Used in Financing Activities	—	(356)	(153)
Net Cash Flows Used in Discontinued Operations	—	(58)	(258)
Effect of Exchange Rate Changes on Cash and Cash Equivalents from Continuing Operations	(36)	23	—
Effect of Exchange Rate Changes on Cash and Cash Equivalents from Discontinued Operations	—	—	(3)
Net (Decrease) Increase in Cash and Cash Equivalents	(31)	667	(249)
Cash and Cash Equivalents, Beginning of Period	737	12	—
Cash and Cash Equivalents of Discontinued Operations, Beginning of Period	—	58	319
Total Cash and Cash Equivalents, End of Period	706	737	70
Less: Cash and Cash Equivalents of Discontinued Operations, End of Period	—	—	58
Cash and Cash Equivalents, End of Period	$ 706	$ 737	$ 12

The accompanying notes are an integral part of these Consolidated Financial Statements.

1. Background and Nature of Operations

Organon & Co. ("Organon" or the "Company") is a global health care company with a focus on improving the health of women throughout their lives. Organon develops and delivers innovative health solutions through a portfolio of prescription therapies and medical devices within women's health, biosimilars and established brands (the "Organon Products"). Organon has a portfolio of more than 60 medicines and products across a range of therapeutic areas. The Company sells these products through various channels including drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. The Company operates six manufacturing facilities, which are located in Belgium, Brazil, Indonesia, Mexico, the Netherlands and the United Kingdom. Unless otherwise indicated, trademarks appearing in italics throughout this document are trademarks of, or are used under license by, the Organon group of companies.

The Company's operations include the following product portfolios:

- *Women's Health*: Organon's women's health products are sold by prescription primarily in two therapeutic areas, contraception, with key brands such as *Nexplanon*® (etonogestrel implant) (sold as *Implanon NXT*™ [1] in some countries outside the United States) and *NuvaRing*® (etonogestrel / ethinyl estradiol vaginal ring), and fertility, with key brands such as *Follistim*® *AQ* (follitropin beta injection) and *Elonva*™ [1] (corifollitropin alfa). *Nexplanon*®, a long-acting reversible contraceptive, which is a class of contraceptives that is recognized as one of the most effective types of hormonal contraception available to patients with a low long-term average cost. The *Jada*® System is intended to provide control and treatment of abnormal postpartum uterine bleeding or hemorrhage when conservative management is warranted. Organon acquired *Jada* through its acquisition of Alydia Health. *Elonva* is a sustained follicle stimulant for controlled ovarian stimulation in women participating in assisted reproductive technologies. It is marketed in certain European countries. In addition, Organon has a license from Daré Biosciences for the global commercial rights to *Xaciato*™ (clindamycin phosphate vaginal gel, 2%), an FDA-approved medication for the treatment of bacterial vaginosis ("BV") in females 12 years of age and older.

- *Biosimilars*: Organon's current portfolio spans across immunology and oncology treatments. Organon's oncology biosimilars have been launched in more than 20 countries and Organon's immunology biosimilars have been launched in five countries. All five biosimilars in Organon's portfolio have launched in Canada, and two biosimilars; *Ontruzant*® (trastuzumab-dttb) and *Renflexis*® (infliximab-abda) have been launched in the United States.

- *Established Brands*: Organon has a portfolio of established brands, which generally are beyond market exclusivity, including leading brands in cardiovascular, respiratory, dermatology and non-opioid pain management. A number of Organon's established brands lost exclusivity years ago and have faced generic competition for some time.

On June 2, 2021, Organon and Merck & Co. ("Merck") entered into a Separation and Distribution Agreement (the "Separation and Distribution Agreement"). Pursuant to the Separation and Distribution Agreement, Merck agreed to spin off the Organon Products into Organon, a new, publicly-traded company (the "Separation").

In connection with the Separation, on June 2, 2021, Merck distributed (the "Distribution"), on a pro rata basis, to holders of the outstanding shares of common stock of Merck, par value $0.50 per share (the "Merck Common Stock") on May 17, 2021 (the "Record Date"), all of the outstanding shares of common stock, par value $0.01 per share, of Organon (the "Common Stock"). Each Merck stockholder was entitled to receive one-tenth of a share of the Common Stock for each share of Merck Common Stock held on the Record Date. As a result, Organon became a standalone publicly-traded company and on June 3, 2021 regular-way trading of the Common Stock commenced on the New York Stock Exchange under the ticker symbol "OGN."

The Separation was completed pursuant to the Separation and Distribution Agreement and other agreements with Merck related to the Separation, including, but not limited to a tax matters agreement (the "Tax Matters Agreement" or "TMA"), an employee matters agreement (the "Employee Matters Agreement" or "EMA") and a transition services agreement (the "Transition Service Agreement" or "TSA"). Following the Separation, certain functions continue to be provided by Merck under the TSA or are being performed using the Company's own resources or third-party service providers. Under the TSA, Merck is providing Organon various services and, similarly, Organon is providing Merck various services. The provision of services under the TSA generally will terminate within 25 months following the spin-off; however, the provision of certain services has been extended to at least 35 months. Additionally, under manufacturing and supply agreements, the Company manufactures certain products for Merck, or its applicable affiliate and Merck manufactures certain products for the Company or its applicable affiliate (see Note 18 "Third-Party Arrangements and Related Party Disclosures" for additional details). The Company incurred certain costs

in its establishment as a standalone public company and expects to incur ongoing additional costs associated with operating as an independent, publicly-traded company.

2. Basis of Presentation

On June 2, 2021, the Company became a standalone publicly traded company, and its financial statements are now presented on a consolidated basis. Prior to the Separation on June 2, 2021, the Company's historical combined financial statements were prepared on a standalone basis and were derived from Merck's consolidated financial statements and accounting records. The financial statements for all periods presented, including the historical results of the Company prior to June 2, 2021, are now referred to as "Consolidated Financial Statements," and have been prepared pursuant to the rules and regulations for reporting on Form 10-K.

Periods Prior to Separation

The assets, liabilities, revenue and expenses of the Company were reflected in the Consolidated Financial Statements on a historical cost basis, as included in the consolidated financial statements of Merck, using the historical accounting policies applied by Merck. The Consolidated Financial Statements did not purport to reflect what the Company's results of operations, comprehensive income, financial position, equity or cash flows would have been had the Company operated as a standalone public company during the periods presented.

The Consolidated Financial Statements were prepared following a legal entity approach, which resulted in the inclusion of the following:

- Certain assets and liabilities, results of operations and cash flows attributable to the sales of Organon Products that were contributed to Organon prior to the consummation of the Separation.
- The Transferred Entities, which have historically included the results from the sales of both Organon Products and the Merck Retained Products. Each Transferred Entity's historical operations, including its results of operations, assets and liabilities, and cash flows have been fully reflected in the Consolidated Financial Statements.
- In contemplation of the Separation, the Merck Retained Products business of the Transferred Entities was distributed to Merck and its affiliates ("MRP Distribution") and, accordingly, the historical results of operations, assets and liabilities, and the cash flows of the Merck Retained Products for such Transferred Entities are reflected as discontinued operations.

The Company's businesses had historically functioned together with the other businesses controlled by Merck. Accordingly, the Company relied on Merck's corporate and other support functions for its business. Therefore, for the period prior to the Separation, certain corporate and shared costs were allocated to the Company based on a specific identification basis or, when specific identification was not practicable, a proportional cost allocation method, including:

(i) expenses related to Merck support functions, including expenses for facilities, executive oversight, treasury, finance, legal, human resources, shared services, compliance, procurement, information technology and other corporate functions.
(ii) certain manufacturing and supply costs incurred by Merck's manufacturing division, including facility management, distribution, logistics, planning and global quality.
(iii) certain costs incurred by Merck's human health division in relation to selling and marketing activities, and related administrative support functions, that are not routinely allocated to therapeutic areas.
(iv) certain costs incurred by Merck's research laboratories for activities related to drug discovery and development, as well as medical and regulatory affairs.
(v) restructuring costs (see Note 6 "Restructuring") and stock-based compensation expenses (see Note 13 "Stock-Based Compensation Plans"); and
(vi) certain compensation expenses maintained on a centralized basis such as certain employee benefit expenses.

Management believes these cost allocations were a reasonable reflection of the utilization of services provided to, or the benefit derived by, the Company during the period prior to the Separation, though the allocations may not be indicative of the actual costs that would have been incurred had the Company operated as a standalone public company. Actual costs that may have been incurred if the Company had been a standalone company would depend on a number of factors, including the chosen organizational structure, whether functions were outsourced or performed by Company's employees, and strategic decisions made in areas such as manufacturing, selling and marketing, research and development, information technology and infrastructure.

Merck maintains various employee benefit plans in which the Company's employees participated during periods prior to the Separation, and a portion of the costs associated with these plans was included in the Company's Consolidated Financial Statements. Certain pension assets and obligations were transferred by Merck into legal entities established to operate the Organon Products business (the "Organon Entities") that are the plan sponsor and, accordingly, the Consolidated Balance Sheet at December 31, 2022 and 2021 includes assets and liabilities of the newly established plans of Organon.

Merck utilized a centralized approach to cash management and the financing of its operations. Cash generated by the Company was routinely transferred into accounts managed by Merck's centralized treasury function and cash disbursements for the Company's operations prior to the Separation were funded as needed by Merck. Cash and cash equivalents of the Organon Entities and the Transferred Entities were reflected in the Company's Consolidated Balance Sheet. Balances held by the Organon Entities and the Transferred Entities with Merck for cash transfers and loans were reflected as *Due to related party* prior to Separation. All other cash, cash equivalents, short-term investments and related transfers between Merck and the Company were generally held centrally through accounts controlled and maintained by Merck and were not specifically identifiable to the Company. Accordingly, such balances were accounted for through *Net investment from Merck & Co., Inc*. Merck's third-party debt and related interest expense were not attributed to the Company because the Company was not the legal obligor of the debt and the borrowings were not specifically identifiable to the Company.

For the Organon Entities and the Transferred Entities, transactions with Merck affiliates were included in the Consolidated Statement of Income and related balances were reflected as *Due to related party* or *Due from related party* in the continuing operations and discontinued operations of the Consolidated Balance Sheet, as applicable. Other balances between the Company and Merck were considered to be effectively settled in the Consolidated Financial Statements at the time the transactions were recorded. See Note 18 "Third-Party Arrangements and Related Party Disclosures" for additional details.

As the separate legal entities that made up the Company's business were not historically held by a single legal entity, *Net investment from Merck & Co., Inc.* was shown in lieu of stockholders' equity in these Consolidated Financial Statements. *Net investment from Merck & Co., Inc.* represented Merck's interest in the recorded assets of the Company and the cumulative investment by Merck in the Company through the date of Separation, inclusive of operating results.

Income tax expense and tax balances in the Consolidated Financial Statements were calculated on a separate tax return basis. The Company's operations are included in the tax returns of certain Organon Entities, Transferred Entities or the respective Merck entities of which the Company's business was a part.

As of Separation Date

Certain assets and liabilities, including accounts receivables, inventories and trade payables included on the Consolidated Balance Sheet prior to the Separation, have been retained by Merck post-Separation and therefore were transferred to Merck through *Net investment from Merck & Co., Inc.* in the Company's Consolidated Financial Statements. Additionally, certain amounts previously included in *Due to related party* or *Due from related party* are reflected in accounts receivable and trade accounts payable as of December 31, 2021. As part of the Separation, *Net investment from Merck & Co., Inc.* was reclassified to *Common Stock* and *Accumulated Deficit*.

In connection with the Separation, additional pension assets and obligations were transferred to Organon through *Net investment from Merck & Co., Inc.*, and the Company recorded these in the Consolidated Balance Sheet. See Note 14 "Pension and Other Postretirement Benefits Plans" for details. Additionally, stock-based awards were converted in accordance with the Employee Matters Agreement. See Note 13 "Share-Based Compensation Plans" for details.

During the second quarter of 2021, an aggregate of $9.5 billion of debt was issued in connection with the Separation. See Note 11 "Long-Term Debt and Leases" for additional details. The Company distributed $9.0 billion of the $9.5 billion proceeds to Merck in accordance with the terms of the Separation.

Periods Post Separation

Following the Separation, certain functions continue to be provided by Merck under the Transition Services Agreement or are being performed using the Company's own resources or third-party service providers. Additionally, under manufacturing and supply agreements, the Company manufactures certain products for Merck or its applicable affiliate, and Merck manufactures certain products for the Company or its applicable affiliate. The Company incurred certain costs in its establishment as a standalone public company and expects to incur ongoing additional costs associated with operating as an independent, publicly traded company.

Property, plant and equipment reflected in the Consolidated Balance Sheet is primarily attributable to the six manufacturing facilities the Company operates and certain information technology assets.

In June 2021, the Company established a balance sheet risk management and a net investment hedging program to partially mitigate against volatility of changes in foreign exchange rates.

As a standalone entity, the Company files tax returns on its own behalf, and tax balances and effective income tax rate may differ from the amounts reported in the historical periods. As of June 2, 2021 and in connection with the Separation, the Company adjusted its deferred tax balances and computed its related tax provision to reflect operations as a standalone entity.

All intercompany transactions and accounts within Organon have been eliminated.

Certain amounts presented in the prior year *Income Statement* have been reclassified to conform to the current year presentation. As a result, $104 million of *Acquired in-process research and development and milestones* which was presented within *Research and development* in 2021 is now presented separately on the *Income Statement.*

The historical results prior to Separation included certain Merck non-U.S. legal entities that were conveyed to Organon in connection with the Separation (collectively, the "Transferred Entities" and each, a "Transferred Entity") and included operations related to other Merck products that were retained by Merck ("Merck Retained Products"). The Merck Retained Products business of the Transferred Entities was contributed by the Company to Merck and its affiliates and any remaining assets and liabilities were transferred as of June 2, 2021. Accordingly, the historical results of operations of the Merck Retained Products have been reflected as discontinued operations in these Consolidated Financial Statements. See Note 2 "Basis of Presentation — Periods Prior to Separation" for additional details.

During the fourth quarter of 2022, the Company recorded an out-of-period adjustment primarily related to a misstatement of employee related expenses prior to the Separation. During the year ended 2021, *Net Income* was understated by approximately $19 million. These amounts were corrected in 2022 and as a result 2022 *Net Income* is overstated by approximately $19 million. The Company concluded that these adjustments were not material to the Consolidated Financial Statements for either the current period or any of the prior periods previously reported.

3. Summary of Accounting Policies

Revenue Recognition — Recognition of revenue requires evidence of a contract, probable collection of sales proceeds and completion of substantially all performance obligations. The Company acts as the principal in its customer arrangements and therefore records revenue on a gross basis. The majority of the Company's contracts have a single performance obligation — the promise to transfer goods. Shipping is considered immaterial in the context of the overall customer arrangement and damages or loss of goods in transit are rare. Therefore, shipping is not deemed a separately recognized performance obligation.

Revenues from sales of products, including tenders, are recognized at a point in time when control of the goods is transferred to the customer, which the Company has determined is when title and risks and rewards of ownership transfer to the customer and the Company is entitled to payment.

The nature of the Company's business gives rise to several types of variable consideration including discounts and returns, which are estimated at the time of sale generally using the expected value method, although the most likely amount method is used for prompt pay discounts.

In the United States, sales discounts are issued to customers at the point-of-sale, through an intermediary wholesaler (known as chargebacks), or in the form of rebates. Additionally, sales are generally made with a limited right of return under certain conditions. Revenues are recorded net of provisions for sales discounts and returns, which are established at the time of sale. In addition, revenues are recorded net of time value of money discounts if collection of accounts receivable is expected to be in excess of one year.

Chargebacks are discounts that occur when a contracted customer purchases through an intermediary wholesaler. The contracted customer generally purchases product from the wholesaler at its contracted price plus a mark-up. The wholesaler, in turn, charges the Company back for the difference between the price initially paid by the wholesaler and the contract price paid to the wholesaler by the customer. The Company estimates the provision for chargebacks based on expected sell-through levels by the Company's wholesale customers to contracted customers, as well as estimated wholesaler inventory levels. Rebates are amounts owed based upon definitive contractual agreements or legal requirements with private sector, (Managed Care), and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a

benefit plan participant. The provision for rebates is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. The Company uses historical customer segment utilization mix, sales, changes to product mix and price, inventory levels in the distribution channel, government pricing calculations and prior payment history to estimate the expected provision.

The Company continually monitors the provision for aggregate customer discounts. There were no material adjustments to estimates associated with the aggregate customer discount provision in 2022, 2021, or 2020.

Summarized information about changes in the aggregate customer discount accrual related to sales in the United States is as follows:

	Year Ended December 31,		
($ in millions)	2022	2021	2020
Balance January 1	$ 329	$ 343	$ 365
Provision	2,221	2,000	1,770
Payments[(1)]	(2,165)	(2,014)	(1,792)
Balance December 31	$ 385	$ 329	$ 343

(1) Includes 2021 payments made by Merck on behalf of Organon for the period prior to the Separation date.

Amounts accrued for aggregate customer discounts are evaluated on a quarterly basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers, federal and state agencies, and other customers to the amounts accrued. The accrued balances relative to the provisions for chargebacks and rebates in the United States included in *Accounts receivable* and *Accrued and other current* liabilities were $78 million and $307 million, respectively, at December 31, 2022 and $54 million and $275 million, respectively, at December 31, 2021.

Outside of the United States, variable consideration in the form of discounts and rebates are a combination of commercially-driven discounts in highly competitive product classes, discounts required to gain or maintain reimbursement, or legislatively mandated rebates. Rebates may also be required based on specific product sales thresholds. The Company applies an estimated factor against its actual invoiced sales to represent the expected level of future discount or rebate obligations associated with the sale. At December 31, 2022 and 2021, the accrued balances related to the provision for rebates and discounts included in other current liabilities were approximately $109 million and $90 million, respectively.

The Company maintains a returns policy that allows customers in certain countries to return product within a specified period prior to and subsequent to the expiration date (generally, three to six months before and 12 months after product expiration). The estimate of the provision for returns is based upon historical experience with actual returns and consideration of other relevant factors.

The Company's payment terms for U.S. customers are typically 36 days from receipt of invoice. Outside of the United States, payment terms are typically 30 days to 90 days, although certain markets have longer payment terms. See Note 17 "Product and Geographic Information" for disaggregated revenue disclosures.

Cash Equivalents — Cash equivalents are comprised of certain highly liquid investments with original maturities of three months or less.

Inventories — Inventories are valued at the lower of cost or net realizable value. The cost of a substantial majority of U.S. inventories is determined using the last-in, first-out ("LIFO") method for both financial reporting and tax purposes. The cost of all other inventories is determined using the first-in, first-out ("FIFO") method.

Value Added Tax — The Company's purchases, sales and intercompany transfers of goods are subject to value added tax (VAT) and VAT receivables are recognized for amounts that represent credits against future VAT obligations. VAT receivables included in *Other current asset*s were $110 million and $115 million as of December 31, 2022 and 2021, respectively. VAT payables included in *Accrued and other current liabilities* were $9 million and $9 million as of December 31, 2022 and 2021, respectively. The related expense is included in the Company's operating expenses.

Depreciation — Depreciation is provided over the estimated useful lives of the assets, principally using the straight-line method. The estimated useful lives primarily range from 25 to 40 years for buildings, and from 3 to 15 years for machinery,

equipment and office furnishings. Depreciation expense was $96 million in 2022, $92 million in 2021, and $56 million in 2020. Repairs and maintenance costs are expensed as incurred as they do not extend the economic life of an asset.

Advertising and Promotion Costs — Advertising and promotion costs are expensed as incurred and included in *Selling, general and administrative expenses*. The Company recorded advertising and promotion expenses of $255 million, $236 million, and $198 million in 2022, 2021 and 2020, respectively.

Goodwill — Goodwill represents the excess of the consideration transferred over the fair value of net assets of businesses acquired. Goodwill is evaluated for impairment as of October 1 each year, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that fair value is less than carrying value. If the Company concludes it is more likely than not that fair value is less than carrying value, a quantitative fair value test is performed. If carrying value is greater than fair value, a goodwill impairment charge will be recorded for the difference (up to the carrying value of goodwill). The Company completed the annual qualitative goodwill impairment test as of October 1, 2022 and concluded that there was no impairment to goodwill as the fair value of the reporting unit was significantly in excess of the carrying value.

Acquired Intangibles — Acquired intangibles include products and product rights and licenses, which are initially recorded at fair value, assigned an estimated useful life, and amortized on a straight-line basis over their estimated useful lives. The Company's intangibles also include the products and product rights intangible assets attributed to Organon from Merck. The intangible assets attributable to the Company's operations have been reflected in the consolidated financial statements based on Merck's historical cost. Licenses include milestone payments made to collaborative partners upon or subsequent to regulatory approval. The estimated useful lives of acquired intangibles range from 5 to 15 years. The Company periodically evaluates whether current facts or circumstances indicate that the carrying values of its acquired intangibles may not be recoverable. If such circumstances are determined to exist, an estimate of the undiscounted future cash flows of these assets, or appropriate asset groupings, is compared to the carrying value to determine whether an impairment exists. If the asset is determined to be impaired, the loss is measured based on the difference between the carrying value of the intangible asset and its fair value, which is determined based on the net present value of estimated future cash flows. See Note 10 "Intangibles" for additional details.

Acquired In-Process Research and Development ("IPR&D") — IPR&D that the Company acquires in conjunction with the acquisition of a business represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. The amounts are capitalized and are accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, Organon will make a determination as to the then-useful life of the intangible asset, generally determined by the period in which the substantial majority of the cash flows are expected to be generated, and begin amortization. The Company evaluates IPR&D for impairment as of October 1 each year, or more frequently if impairment indicators exist, by performing a quantitative test that compares the fair value of the IPR&D intangible asset with its carrying value. If the fair value is less than the carrying amount, an impairment loss is recognized in operating results. There were no IPR&D intangible assets as of December 31, 2022, 2021 and 2020.

Research and Development — Research and development costs associated with clinical development programs that have not yet received regulatory approval, are expensed as incurred.

Foreign Currency Translation — The net assets of international operations where the local currencies have been determined to be the functional currencies are translated into U.S. dollars using current exchange rates. The U.S. dollar effects that arise from translating the net assets of these subsidiaries at changing rates are recorded in the foreign currency translation account, which is included in *Accumulated other comprehensive loss* and reflected as a separate component of equity. For those operations that operate in highly inflationary economies and for those operations where the U.S. dollar has been determined to be the functional currency, non-monetary foreign currency assets and liabilities are translated using historical rates, while monetary assets and liabilities are translated at current rates, with the U.S. dollar effects of rate changes included in *Exchange losses*.

Organon calculates foreign currency translation on its consolidated assets and liabilities. For periods prior to the Separation, these consolidated financial statements include Merck's foreign currency translation for the Organon Entities.

Stock-Based Compensation — Prior to the Separation, certain of the Company's employees historically participated in Merck's stock-based compensation plans. Stock-based compensation expense was either allocated to the Company based on a proportionate cost allocation method or recorded based on specific identification. Effective June 3, 2021, Organon established the 2021 Incentive Stock Plan (the "Plan"). A total of 35 million shares of Common Stock are authorized under the Plan. The plan provides for the grant of various types of awards, including restricted stock unit awards, stock appreciation rights, stock

options, performance-based awards and cash awards. Under the Plan, the exercise price of awards, if any, is set on the grant date and may not be less than the fair market value per share on that date. The Company measures stock-based compensation for equity awards at fair value on the date of grant and records stock-based compensation as a charge to earnings net of the estimated impact of forfeited awards. Accordingly, the Company recognizes stock-based compensation cost only for those stock-based awards that are estimated to ultimately vest over their requisite service period, based on the vesting provisions of the individual grants. The cumulative effect on current and prior periods of a change in the estimated forfeiture rate is recognized as compensation cost in earnings in the period of the change. See Note 13 "Stock-Based Compensation Plans" for additional details.

Pension and Other Postretirement Benefit Plans — Prior to the Separation, the defined benefit plans in which the Company participated related primarily to plans sponsored by Merck and for which other businesses of Merck also participate ("Shared Plans"). The Company accounted for the Shared Plans as multiemployer plans and therefore the related assets and liabilities were not reflected in the Consolidated Balance Sheet. For such periods prior to Separation, the Consolidated Statement of Income reflects a proportional allocation of net periodic benefit cost for the Shared Plans associated with the Company. For certain defined benefit plans attributable to the Organon Entities, the over funded or underfunded status of the plan was recognized as an asset or liability on the consolidated balance sheet. The Company's participation in the defined pension and postretirement benefit plans sponsored by Merck concluded upon the completion of the Separation on June 2, 2021. At Separation, Organon became the plan sponsor for certain non-U.S. defined benefit pension plans. See Note 14 "Pension and Other Postretirement Benefits Plans" for additional details.

Restructuring Costs — Costs associated with exit or disposal activities are recognized in the period in which they are incurred. Costs for one-time termination benefits in which the employee is required to render service until termination in order to receive the benefits are recognized ratably over the future service period.

Contingencies and Legal Defense Costs — The Company records accruals for contingencies and legal defense costs expected to be incurred in connection with a loss contingency when it is probable that a liability has been incurred and the amount can be reasonably estimated.

Taxes on Income — Prior to the Separation, income tax expense and deferred tax balances were calculated on a separate tax return basis. The Company's operations were included in the tax returns of certain Organon Entities, Transferring Entities or the respective Merck entities of which the Company's business was a part.

Deferred taxes are recognized for the future tax effects of temporary differences between financial and income tax reporting based on enacted tax laws and rates. The Company establishes valuation allowances for its deferred tax assets when the amount of expected future taxable income is not likely to support the use of the deduction or credit.

The Company evaluates tax positions to determine whether the benefits of tax positions are more likely than not of being sustained upon audit based on the technical merits of the tax position. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the largest amount of the benefit that is greater than 50% likely of being realized upon ultimate settlement in the financial statements. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit in the financial statements. The Company recognizes interest and penalties associated with uncertain tax positions as a component of *Taxes on Income* in the Consolidated Statement of Income. The Company accounts for the tax effects of the tax on global intangible low-taxed income ("GILTI") of certain foreign subsidiaries in the income tax provision in the period the tax arises. The Company and Merck entered into the Tax Matters Agreement in connection with the Separation. See Note 18 "Third-Party Arrangements and Related Party Disclosures" for additional details.

Leases — The Company has operating leases primarily for real estate. The Company determines if an arrangement is a lease at inception. When evaluating contracts for embedded leases, the Company exercises judgment to determine if there is an explicit or implicit identified asset in the contract and if the Company controls the use of that asset. Embedded leases are immaterial. The lease term includes options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. The Company has made an accounting policy election not to record short-term leases (leases with an initial term of 12 months or less) on the balance sheet. Lease expense associated with short term leases is not material for all periods presented.

Lease expense for operating lease payments is recognized on a straight-line basis over the term of the lease. Operating lease assets and liabilities are recognized based on the present value of lease payments over the lease term. Since most of the Company's leases do not have a readily determinable implicit discount rate, the Company uses its incremental borrowing rate to calculate the present value of lease payments. On a quarterly basis, an updated incremental borrowing rate is determined based

on the weighted average remaining lease term of each asset class and the Company's pretax cost of debt for that same term. The updated rates for each asset class are applied prospectively to new leases. The Company does not separate lease components (e.g. payments for rent, real estate taxes and insurance costs) from non-lease components (e.g. common-area maintenance costs) in the event that the agreement contains both. The Company includes both the lease and fixed non-lease components for purposes of calculating the lease liability and the related right-of-use asset. See Note 11 "Long-Term Debt and Leases" for additional details.

Use of Estimates — The presentation of these Consolidated Financial Statements and accompanying notes in conformity with U.S. GAAP require management to make estimates and assumptions that affect the amounts reported. Estimates are used in determining such items as provisions for sales discounts and returns, depreciable and amortizable lives, recoverability of inventories, amounts recorded for contingencies, environmental liabilities, pension and other postretirement benefit plan assumptions, stock-based compensation assumptions, restructuring costs, impairments of long-lived assets (including intangible assets and goodwill), investments, and taxes on income. Additionally estimates are used in acquisitions, including initial fair value determinations of assets and liabilities (primarily IPR&D, intangible assets and contingent consideration), as well as subsequent fair value measurements.

For periods prior to Separation, estimates were used in determining the allocation of costs and expenses from Merck, and were used in determining such items as provisions for sales discounts and returns, depreciable and amortizable lives, recoverability of inventories, valuation of goodwill and intangibles, amounts recorded for contingencies, environmental liabilities and other reserves, pension and stock-based compensation assumptions, restructuring costs, and taxes on income.

Because of the uncertainty inherent in such estimates, actual results may differ from these estimates.

Net Investment from Merck & Co., Inc. — Net investment from Merck & Co., Inc. represented Merck's interest in the recorded assets of the Company and the cumulative investment by Merck in the Company through the date of Separation, inclusive of operating results and the net effect of the transactions with and allocations from Merck. See Notes 2 "Basis of Presentation" and 18 "Third-Party Arrangements and Related Party Disclosures" for additional information.

Recently Adopted Accounting Standards

There were no recently issued accounting standards adopted by the Company during the year ended December 31, 2022.

Recently Issued Accounting Standards Not Yet Adopted

The following summarizes recent Accounting Standards Updates ("ASUs") issued by the FASB that could have a material impact on our consolidated financial statements.

In October 2021, the FASB issued ASU 2021-08, *Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers*, guidance to improve the accounting for contract assets and contract liabilities from acquired revenue contracts with customers in a business combination. The guidance addresses diversity in practice and inconsistency related to the recognition of an acquired contract liability, payment terms and their effect on subsequent revenue recognized by an acquirer. The guidance became effective for the Company on January 1, 2023 and its amendments will be applied prospectively to business combinations occurring on or after the effective date of the guidance. The adoption of this guidance will not have an impact on the Company's Consolidated Financial Statements for prior acquisitions; however, the impact in future periods will be dependent upon the contract assets and contract liabilities acquired in future business combinations.

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*, optional guidance to ease the potential burden in accounting for (or recognizing the effects of) reference rate reform on financial reporting and subsequently issued clarifying amendments. The guidance provides optional expedients and exceptions for applying GAAP to contracts, hedging relationships, and other transactions that reference the London Interbank Offered Rate ("LIBOR") or another reference rate expected to be discontinued because of reference rate reform. The optional guidance is effective upon issuance and can be applied on a prospective basis at any time between January 1, 2020 and December 31, 2022, the sunset date was subsequently deferred to December 31, 2024 based on the amendment issued in December 2022 under ASU 2022-06, *Reference Rate Reform (Topic 848)*. The Company is still evaluating the impact to its LIBOR-based debt. Based on the evaluation thus far, the Company does not anticipate a material impact to the Consolidated Financial Statements as a result of reference rate reform.

4. Samsung Collaboration

The Company has an agreement with Samsung Bioepis Co., Ltd. ("Samsung Bioepis") to develop and commercialize multiple pre-specified biosimilar candidates, which have since launched and are part of the Company's product portfolio. Under the agreement, Samsung Bioepis is responsible for preclinical and clinical development, process development and manufacturing, clinical trials and registration of product candidates, and the Company has an exclusive license for worldwide commercialization with certain geographic exceptions specified on a product-by-product basis. The Company's access rights to each product under the agreement last for 10 years from each product's launch date on a market-by-market basis. Gross profits are shared equally in all markets with the exception of certain markets in Brazil where gross profits are shared 65% to Samsung Bioepis and 35% to the Company. Since the Company is the principal on sales transactions with third parties, the Company recognizes sales, cost of sales and selling, general and administrative expenses on a gross basis. Generally, profit sharing adjustments are recorded either to *Cost of sales* (after commercialization) or *Selling, general and administrative* expenses (prior to commercialization).

In August 2022, the U.S. Food and Drug Administration ("FDA") approved the citrate-free, high-concentration (100 mg/mL) formulation of *Hadlima*™ (adalimumab-bwwd), a biosimilar referencing *Humira*[2] (adalimumab). During the third quarter of 2022, Organon paid Samsung Bioepis $18 million. This amount was recognized as an intangible asset which will be amortized over the estimated useful life of approximately 10 years.

Samsung Bioepis is eligible for additional payments associated with pre-specified clinical and regulatory milestones. As of December 31, 2022, potential future regulatory milestone payments of $25 million remain under the agreement.

Summarized information related to this collaboration is as follows:

	Year Ended December 31,		
($ in millions)	2022	2021	2020
Sales	$ 481	$ 424	$ 330
Cost of sales	315	248	208
Selling, general and administrative	86	83	87

($ in millions)	December 31, 2022	December 31, 2021
Receivables from Samsung included in *Other current assets*	$ 21	$ 15
Payables to Samsung included in *Trade accounts payable*	72	21

5. Acquisitions and Licensing Arrangements

2022 Transactions

Cirqle Biomedical ("Cirqle")

In July 2022, the Company entered into a research collaboration and license agreement with Cirqle for a novel investigational non-hormonal, on-demand contraceptive candidate. Under the terms of the agreement, Cirqle is responsible for conducting preclinical studies according to the mutually agreed research plan. Organon obtained exclusive worldwide rights to develop and commercialize the asset.

Under the terms of the research collaboration and license agreement, Organon recorded a $10 million upfront payment during 2022 as *Acquired in-process research and development and milestones*. Cirqle is eligible to receive potential regulatory and commercial milestone payments of up to $360 million and tiered royalties based on net sales. The remaining potential milestone payments will be recognized by Organon when achievement of the contractual milestones is probable.

Shanghai Henlius Biotech, Inc. ("Henlius")

In June 2022, Organon and Henlius, a global biopharmaceutical company, entered into a definitive agreement whereby Organon is licensing commercialization rights for biosimilar candidates HLX11, referencing *Perjeta*[2] (pertuzumab), used for the treatment of certain patients with HER2+ breast cancer in combinations with trastuzumab and chemotherapy and HLX14, referencing *Prolia*[2]/*Xgeva*[2] (denosumab), used for the treatment of certain patients with osteoporosis with high risk of fracture and for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastasis from solid tumors. Organon obtained exclusive global commercialization rights except for China; including Hong Kong, Macau and Taiwan. The agreement includes an option to negotiate an exclusive license for global commercialization rights for biosimilar candidate HLX13 referencing *Yervoy*[2] (ipilimumab) used for the treatment of certain patients with unresectable or metastatic melanoma, as adjuvant treatment of certain patients with cutaneous melanoma, certain patients with renal cell carcinoma, colorectal cancer, hepatocellular carcinoma, non-small cell lung cancer, malignant pleural mesothelioma and esophageal cancer.

Under the terms of the license agreement, Organon paid a $73 million upfront payment during 2022, of which $3 million was reflected in *Other current assets* and the remainder was recognized as *Acquired in-process research and development and milestones*. Henlius is eligible to receive potential developmental, regulatory and commercial milestone payments of up to $468 million. During the year ended December 31, 2022, the Company paid an additional $27 million related to certain development milestones which were recognized as *Acquired in-process research and development and milestones.* The remaining potential milestone payments will be recognized by Organon when achievement of the contractual milestones is probable. Henlius will be responsible for development and, if approved, will supply the products to Organon.

Daré Bioscience, Inc. ("Daré")

In March 2022, Organon and Daré, a leader in women's health innovation, entered into an agreement whereby Organon licensed the global commercial rights to *Xaciato*. *Xaciato* is an FDA-approved medication for the treatment of bacterial vaginosis ("BV") in females 12 years of age and older. *Xaciato* received both Qualified Infectious Disease Product ("QIDP") and Fast Track designations from the FDA for the treatment of bacterial vaginosis.

Under the terms of the license agreement, Organon paid a $10 million upfront payment during 2022. Daré is eligible to receive potential regulatory and commercial milestone payments of up to $182.5 million and tiered double-digit royalties based on net sales. *Xaciato* is expected to be available commercially in the U.S. in the first half of 2023. During the year ended December 31, 2022 management determined that the first commercial milestone was deemed probable of occurring, and recognized an intangible asset of $12.5 million reflecting the $10 million upfront payment and $2.5 million commercial milestone. The intangible asset will be amortized over its useful life of 12 years. The remaining potential milestone payments will be recognized by Organon when achievement of the contractual milestones is probable.

Bayer AG

In February 2022, Organon acquired the product rights and related inventory from Bayer AG to *Marvelon*™ [1] (ethinylestradiol, desogestrel) and *Mercilon*™ [1] (ethinylestradiol, desogestrel), combined oral hormonal daily contraceptive pills, in China, including Hong Kong and Macau, and entered into an agreement to acquire the rights to these products in Vietnam. *Marvelon* and *Mercilon* are already owned, manufactured, and marketed by Organon as prescription oral contraceptives in 20 other markets. The transaction was accounted for as an asset acquisition. In 2022, Organon paid $95 million to acquire the product

rights and inventory in China and Vietnam. This resulted in Organon recognizing an intangible asset of $72 million in total related to the product rights with the remainder of the consideration recorded to *Inventories* for the fair value of acquired inventory during 2022. The intangible assets related to currently marketed products will be amortized over their estimated useful lives of 10 years.

2021 Transactions

Forendo Pharma

In December 2021, Organon completed its acquisition of Forendo Pharma, a clinical-stage drug development company focused on novel treatments in women's health. Forendo is pioneering the science of intracrinology, addressing disease through a novel, tissue-specific approach. Its lead clinical compound is an investigational, potentially first-in-class oral 17β-hydroxysteroid dehydrogenase type 1 inhibitor ("HSD17B1 inhibitor") in early development for endometriosis, being evaluated for its potential effect on endometriotic lesions. Total consideration includes a $75 million upfront payment, the assumption of approximately $10 million of Forendo debt, payments upon the achievement of certain development and regulatory milestones of up to $270 million and commercial milestones payments of up to $600 million, which together could amount to total consideration of $955 million. Contingent consideration will be paid by Organon upon achievement and the liability recorded once it is deemed probable of occurrence. The transaction was accounted for in 2021 as an asset acquisition, as substantially all of the value was concentrated in a single identifiable asset, the HSD17B1 inhibitor. During the year ended December 31, 2021, the Company recorded $79 million, which consisted of the $75 million upfront payment, the assumption of debt of $10 million, and other net assets, as *Acquired in-process research and development and milestones*. During the year ended December 31, 2021, the Company incurred $5.0 million of transaction related expenses reflected in *Selling, General and Administrative expenses*.

XOMA

In July 2021, Organon entered into the ebopiprant license with ObsEva SA, which was subsequently assigned to XOMA Corporation ("XOMA"), whereby Organon licensed the global development, manufacturing and commercial rights to ebopiprant (OBE022). Ebopiprant is an investigational, orally active, selective prostaglandin F2α (PGF2α) receptor antagonist being evaluated as a potential treatment for preterm labor by reducing inflammation and uterine contractions. Under the terms of the license agreement, Organon gained exclusive worldwide rights to develop and commercialize ebopiprant. XOMA is entitled to receive tiered double-digit royalties on commercial sales, up to $90 million in development and regulatory milestone payments, and up to $385 million in sales-based payments that will be paid by Organon upon achievement of the contractual milestone and the liability recorded once it is deemed probable of occurrence. Upon execution of the agreement, Organon made a $25 million upfront payment pursuant to the ebopiprant license, which was recorded as *Acquired in-process research and development and milestones* during 2021.

Alydia Health ("Alydia")

In June 2021, Organon acquired Alydia, a commercial-stage medical device company. Alydia's device, *Jada*, is intended to provide control and treatment of abnormal postpartum uterine bleeding or hemorrhage when conservative management is warranted. Organon's acquisition of Alydia expanded its portfolio into the medical device category and underscores its commitment to identifying innovative treatment options in the maternal health space. Total consideration included a $219 million upfront payment. Additionally, there is a $25 million sales-based contingent milestone payment that will be paid by Organon upon achievement and the liability recorded once it is deemed probable of occurrence. The transaction was accounted for as an asset acquisition, as substantially all of the value was concentrated in a single identifiable asset. This resulted in an intangible of $247 million attributed to *Jada*, which was recorded to *Intangibles* as of December 31, 2021. This asset is subject to amortization on a straight-line basis over its expected useful life of 11 years. In addition to the intangible asset, as of December 31, 2021, the Company also recorded other net liabilities of $7 million, a deferred tax liability of $44 million related to the intangible asset, and compensation expenses of $23 million, which were recorded in *Selling General and Administrative Expense*s. Of the $23 million of compensation expense, $19 million were related to accelerated vesting of Alydia stock-based compensation awards.

During the third quarter of 2022, a cumulative sales-based contingent milestone payment, related to *Jada*, was determined to be probable of being achieved and the Company recognized an intangible asset and noncurrent liability of $25 million. The intangible asset is subject to amortization over its estimated useful life of 12 years.

6. Restructuring

In 2022 Organon initiated restructuring activities to optimize its internal operations by reducing headcount through selected markets and functions. As a result of this program, the Company intends to restructure approximately 130 positions, with the majority of the position eliminations occurring in selected markets outside of the U.S. in our commercial organizations. The Company expects the majority of the severance payments will be paid by the end of the 2023 fiscal year. For the year ended December 31, 2022, the Company recorded restructuring charges of $28 million, which relate to severance costs for eliminated positions.

Restructuring costs for 2021 and 2020 were $3 million and $60 million, respectively. The restructuring costs for 2020 were comprised of $30 million of separation costs and $30 million related to other restructuring activities. Restructuring costs for 2021 and 2020 reflect only charges allocated to Organon from Merck prior to separation.

Liabilities for costs associated with restructuring activities were $20 million at December 31, 2022 and are included primarily in *Accrued and other current liabilities*. There were no liabilities for costs associated with restructuring activities at December 31, 2021.

7. Financial Instruments

Foreign Currency Risk Management

The Company has a balance sheet risk management and a net investment hedging program to mitigate against volatility of changes in foreign exchange rates.

The Company uses a balance sheet risk management program to partially mitigate the exposure of net monetary assets of its subsidiaries that are denominated in a currency other than a subsidiary's functional currency from the effects of volatility in foreign exchange. In these instances, Organon principally utilizes forward exchange contracts to partially offset the effects of exchange on exposures denominated in developed country currencies, primarily the euro, Swiss franc and Japanese yen. For exposures in developing country currencies, the Company enters into forward contracts to partially offset the effects of exchange on exposures when it is deemed economical to do so based on a cost-benefit analysis that considers the magnitude of the exposure, the volatility of the exchange rate and the cost of the hedging instrument.

Monetary assets and liabilities denominated in a currency other than the functional currency of a given subsidiary are remeasured at spot rates in effect on the balance sheet date with the effects of changes in spot rates reported in *Exchange losses.* The forward contracts are not designated as hedges and are marked to market through *Exchange losses.* Accordingly, fair value changes in the forward contracts help mitigate the changes in the value of the remeasured assets and liabilities attributable to changes in foreign currency exchange rates, except to the extent of the spot-forward differences. These differences are not significant due to the short-term nature of the contracts, which typically have average maturities at inception of less than one year. The notional amount of forward contracts was $1.5 billion as of December 31, 2022 and $2.1 billion as of December 31, 2021. The cash flows from these contracts are reported as operating activities in the Consolidated Statements of Cash Flows.

The Company measures fair value based on the prices that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value measurements are based on a three-tier hierarchy that prioritizes the inputs used to measure fair value. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs for which little or no market data exists, therefore requiring an entity to develop its own assumptions.

The following financial instruments were recorded at their estimated fair value. The recurring fair value measurement of our assets and liabilities were as follows:

($ in millions)	Fair Value Measurement Level	December 31, 2022	December 31, 2021
Forward contracts in *Other current assets*	2	$ 6	$ 19
Forward contracts in *Accrued and other current liabilities*	2	24	5

Foreign exchange risk is also managed through the use of economic hedges on foreign currency balances. See Note 11 "Long-Term Debt and Leases" for additional details. Subsequent to the Separation, €1.75 billion in the aggregate of both the euro-

denominated term loan (€750 million) and of the 2.875% euro-denominated secured notes (€1.25 billion) was designated and was effective as an economic hedge of the net investment in euro-denominated subsidiaries.

In December 2022, the Company de-designated the economic hedge of the net investment in euro denominated subsidiaries and designated €1.989 billion in the aggregate of both the euro-denominated term loan (€739 million) and the 2.875% euro-denominated secured notes (€1.25 billion) as an effective economic hedge of the net investment in euro-denominated subsidiaries.

Foreign currency gains due to spot rate fluctuations on the euro-denominated debt instruments included in foreign currency translation adjustments resulting from hedge designation were as follows:

	Year Ended December 31,		
($ in millions)	2022	2021	2020
Foreign currency gains in *Other comprehensive income*	$ 111	$ 162	$ —

Prior to the Separation, Merck managed the impact of foreign exchange rate movements on its affiliates' earnings, cash flows and fair values of assets and liabilities through operational means and through the use of various financial instruments, including derivative instruments. Merck established revenue hedging and balance sheet risk management programs that the Company participated in to protect against the volatility of future foreign currency cash flows and changes in fair value caused by volatility in exchange rates.

The Consolidated Statements of Income include the impact of actual net gains and losses of Organon's derivative financial instruments, as well as the impact of Merck's derivative financial instruments prior to the Separation allocated to the Company utilizing a proportional allocation method:

	Year Ended December 31,		
($ in millions)	2022	2021	2020
Allocated net loss in *Revenues*	$ —	$ 56	$ 3
Foreign exchange loss in *Exchange losses*[(1)]	11	4	44

[(1)] *Includes net gains and losses and foreign exchange gains and losses allocated for the period prior to the Separation, as well as actual net gains and losses and foreign exchange gains and losses post-Separation.*

Organon has established accounts receivable factoring agreements with financial institutions in certain countries to sell accounts receivable. Under these agreements, Organon factored $43 million and $87 million of accounts receivable as of December 31, 2022 and December 31, 2021, respectively, which reduced outstanding accounts receivable. The cash received from the financial institutions is reported within operating activities in the Consolidated Statements of Cash Flows.

Concentrations of Credit Risk

The Company monitors credit exposures through limits that were established to limit a concentration with any single issuer or institution. The majority of the Company's accounts receivable arise from product sales in the United States, Europe and China and are primarily due from drug wholesalers and retailers, hospitals, government agencies, managed health care providers and pharmacy benefit managers. The Company's customers with the largest accounts receivable balances are Curascript Specialty Distribution, McKesson Corporation and Amerisource Bergen Corporation which, represented approximately 9%, 8% and 7%, respectively, of total gross account receivable at December 31, 2022. Bad debts have been minimal. The Company does not normally require collateral or other security to support credit sales.

8. Inventories

Inventories consisted of:

($ in millions)	December 31, 2022	December 31, 2021
Finished goods	$ 482	$ 377
Raw materials	44	95
Work in process	601	490
Supplies	44	40
Total (approximates current cost)	$ 1,171	$ 1,002
Decrease to LIFO costs	(20)	(11)
	$ 1,151	$ 991
Recognized as:		
Inventories	$ 1,003	$ 915
Other assets	148	76
Inventories valued under the last in, first out ("LIFO") method	77	52

Amounts recognized as *Other assets* are comprised primarily of raw materials and work in process inventories and are not expected to be converted to finished goods that will be sold within one year. The Company has a long-term vendor supply contract conveyed as part of the Separation that includes certain annual minimum purchase commitments. During 2022 and 2021, the Company recorded $5 million and $24 million, respectively, due to estimated unavoidable losses associated with a long-term vendor supply contract. The charge was recognized as a component of *Cost of sales* during 2022 and 2021, respectively.

During 2022, the Company recorded $36 million relating to a regulatory inspection finding at the Heist manufacturing location which impacts selected injectable steroids brands. The charge was recognized as a component of *Cost of sales* and reduced the Company's *Inventory* balance during 2022.

As of December 31, 2022, total inventory purchase obligations are $1.2 billion and extend through 2030. Inventory purchase obligations due within the next twelve months amount to $343 million.

9. Property, Plant and Equipment

($ in millions)	December 31, 2022	December 31, 2021
Land	$ 13	$ 14
Buildings	694	667
Machinery, equipment and office furnishings	935	917
Construction in progress	278	257
Less: accumulated depreciation	(902)	(882)
Property, Plant and Equipment, net	$ 1,018	$ 973

Construction in progress includes amounts capitalized associated with the implementation of Organon's new enterprise resource planning system.

10. Intangibles

Intangibles consists of:

	December 31, 2022			December 31, 2021		
($ in millions)	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Products and product rights	$ 24,285	$ 23,746	$ 539	$ 24,195	$ 23,654	$ 541
Licenses	231	121	110	201	91	110
	$ 24,516	$ 23,867	$ 649	$ 24,396	$ 23,745	$ 651

Acquired intangibles include products and products rights, and licenses, which are initially recorded at fair value, assigned an estimated useful life, and amortized on a straight-line basis over their estimated useful lives.

During 2022 and 2021, due to increased competition which resulted in the loss of contract tenders in certain markets and pricing pressure, the Company recorded impairment charges of $9 million and $7 million, respectively, related to a product right for a biosimilar product within *Cost of sales*.

Aggregate amortization expense recorded within *Cost of sales* was $116 million in 2022, $103 million in 2021 and $86 million in 2020.

The estimated aggregate future amortization expense is as follows:

($ in millions)	
2023	$ 116
2024	112
2025	111
2026	105
2027	48
Thereafter	157

11. Long-Term Debt and Leases

The following is a summary of Organon's total debt:

($ in millions)	December 31, 2022	December 31, 2021
Term Loan B Facility:		
LIBOR plus 300 bps term loan due 2028	$ 2,793	$ 2,893
LIBOR plus 300 bps euro-denominated term loan due 2028 (€750 million)	787	843
4.125% secured notes due 2028	2,100	2,100
2.875% euro-denominated secured notes due 2028 (€1.25 billion)	1,331	1,412
5.125% notes due 2031	2,000	2,000
Other borrowings	7	10
Other (discounts and debt issuance costs)	(105)	(124)
Total principal long-term debt	$ 8,913	$ 9,134
Less: Current portion of long-term debt	8	9
Total Long-term debt, net of current portion	$ 8,905	$ 9,125

Term Loan B Facility

On June 2, 2021, Organon entered into a credit agreement with JPMorgan Chase Bank, N.A., as administrative agent and collateral agent (the "Senior Credit Agreement"), providing for:

- a Term Loan B Facility ("Term Loan B Facility"), consisting of (i) a U.S. dollar denominated senior secured "tranche B" term loan in the amount of $3.0 billion, and (ii) a euro denominated senior secured "tranche B" term loan in the amount of €750 million, in each case with a seven-year term that matures in 2028; and
- a Revolving Credit Facility ("Revolving Credit Facility" and, together with the Term Loan B Facility, the "Senior Credit Facilities"), in an aggregate principal amount of up to $1 billion, with a five-year term that matures in 2026.

Borrowings made under the Senior Credit Agreement initially bear interest, in the case of:

- term loans under the Term Loan B Facility (i) denominated in U.S. Dollars, at 3.00% in excess of Adjusted LIBOR (subject to a floor of 0.50%) or 2.00% in excess of an alternate base rate ("ABR"), at our option and (ii) denominated in euros, at 3.00% in excess of an adjusted Euro Interbank Offer Rate ("Adjusted EURIBOR") (subject to a floor of 0.00%); and
- revolving loans under the Revolving Credit Facility (i) in U.S. Dollars, at 2.00% in excess of an Adjusted LIBOR (subject to a floor of 0.00%) or 1.00% in excess of ABR, at our option and (ii) in euros, at 2.00% in excess of an Adjusted EURIBOR.

Interest payments on the term loans are due quarterly in March, June, September and December. Principal payments on the term loans are based on 0.25% of the principal amount outstanding on the Closing Date and due on the last business day of each March, June, September and December, commencing with the last business day of September 2021 (the "Principal Payments"). These Principal Payments are reduced by the amount of any voluntary prepayments.

Organon used the net proceeds from the notes offering, together with available cash on its balance sheet and borrowings under senior secured credit facilities, to distribute $9.0 billion to Merck and to pay fees and expenses related to the Separation. There were no outstanding balances under the Revolving Credit Facility as of December 31, 2022 or December 31, 2021.

The Senior Credit Agreement contains customary financial covenants, including a total leverage ratio covenant, which measures the ratio of (i) consolidated total debt to (ii) consolidated earnings before interest, taxes, depreciation and amortization, and subject to other adjustments, that must meet certain defined limits which are tested on a quarterly basis. In addition, the Senior Credit Agreement contains covenants that limit, among other things, Organon's ability to prepay, redeem or repurchase its subordinated and junior lien debt, incur additional debt, make acquisitions, merge with other entities, pay dividends or distributions, redeem or repurchase equity interests, and create or become subject to liens. As of December 31, 2022, the Company is in compliance with all financial covenants and no default or event of default has occurred.

Notes

In April 2021, in connection with the Separation, Organon Finance 1 LLC ("Organon Finance 1"), a subsidiary of Merck, issued €1.25 billion aggregate principal amount of 2.875% senior secured notes due 2028, $2.1 billion aggregate principal amount of 4.125% senior secured notes due 2028 and $2.0 billion aggregate principal amount of 5.125% senior unsecured notes due 2031 (collectively, the "Notes"). Interest payments are due semiannually on October 30 and April 30. As part of the Separation, on June 2, 2021, Organon and a wholly-owned Dutch subsidiary of Organon, (the "Dutch Co-Issuer") assumed the obligations under the Notes as co-issuers, Organon Finance 1 was released as an obligor under the Notes, and certain subsidiaries of Organon agreed to guarantee the Notes. Each series of Notes was issued pursuant to an indenture dated April 22, 2021, between Organon and U.S. Bank National Association. Organon and the Dutch Co-Issuer assumed the obligations under the Notes pursuant to a first supplemental indenture to the relevant indenture, and the guarantors agreed to guarantee the Notes pursuant to a second supplemental indenture to the relevant indenture.

Other Borrowings

Other borrowings represent debt assumed in connection with the acquisition of Forendo Pharma in December 2021.

In 2021 the Company recorded approximately $117 million of debt issuance costs related to the long-term debt and $19 million of discounts on the term loans. Debt issuance costs and discounts are presented as a reduction of debt on the Consolidated Balance Sheets and are amortized as a component of interest expense over the term on the related debt using the effective interest method.

Long-term debt was recorded at the carrying amount. The estimated fair value of *long-term debt* (including current portion) is as follows:

($ in millions)	December 31, 2022	December 31, 2021
Long-term debt (includes a reduction for amortized debt issuance costs)	$ 8,294	$ 9,412

Fair value was estimated using inputs other than quoted prices in active markets for identical assets and liabilities that are observable either directly or indirectly for substantially the full term of the asset or liability and would be considered Level 2 in the fair value hierarchy.

The Company made interest payments of $379 million for the year ended December 31, 2022 related to its debt instruments. The average maturity of the Company's long-term debt as of December 31, 2022 is approximately 6.0 years and the weighted-average interest rate on total borrowings as of December 31, 2022 is 4.9%.

In both the second quarter of 2022 and the fourth quarter of 2021, the Company made a discretionary prepayment of $100 million on the U.S. Dollar-denominated term loan. As a result of these discretionary prepayments, the quarterly Principal Payments on the U.S. Dollar-denominated term loan are no longer required.

The schedule of principal payments required on long-term debt for the next five years and thereafter is as follows:

($ in millions)	
2023	$ 8
2024	9
2025	9
2026	9
2027	9
Thereafter	8,974

Leases

For periods prior to the Separation, lease costs were allocated to the Company based on a specific identification basis or, when specific identification was not practicable, a proportional cost allocation method. Allocated operating lease costs for periods prior to Separation and actual operating lease costs were $61 million, $66 million and $40 million for the year ended December 31, 2022, 2021, and 2020, respectively.

None of the Company's lease agreements contain variable lease payments. Sublease income is immaterial and there are no sale-leaseback transactions. The Company's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

Cash paid for amounts included in the measurement of operating lease liabilities was $55 million, $41 million and $5 million for the year ended December 31, 2022, 2021 and 2020, respectively. Operating lease assets obtained in exchange for new operating lease liabilities were $28 million and $241 million and $23 million for the year ended December 31, 2022, 2021 and 2020, respectively, and primarily consists of real estate operating leases entered into in connection with establishing Organon as a standalone Company.

Supplemental balance sheet information related to operating leases is as follows:

($ in millions)	December 31, 2022	December 31, 2021
Assets		
Other Assets	$ 215	$ 230
Liabilities		
Accrued and other current liabilities	49	46
Other Noncurrent Liabilities	150	184
	$ 199	$ 230
Weighted-average remaining lease term (years)	5.3	5.8
Weighted-average discount rate	4.0%	3.3%

Maturities of operating lease liabilities as of December 31, 2022 are as follows ($ in millions):

2023	$ 56
2024	49
2025	46
2026	18
2027	12
Thereafter	39
Total lease payments	$ 220
Less: Imputed interest	21
	$ 199

12. Contingencies

Organon is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property, and commercial litigation, as well as certain additional matters including governmental and environmental matters.

Given the nature of the litigation discussed in this note and the complexities involved in these matters, Organon is unable to reasonably estimate a possible loss or range of possible loss for such matters until Organon knows, among other factors, (i) what claims, if any, will survive dispositive motion practice, (ii) the extent of the claims, including the size of any potential class, particularly when damages are not specified or are indeterminate, (iii) how the discovery process will affect the litigation, (iv) the settlement posture of the other parties to the litigation, and (v) any other factors that may have a material effect on the litigation.

Organon records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. Individually significant contingent losses are accrued when probable and reasonably estimable. Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable.

Organon's decision to obtain insurance coverage is dependent on market conditions, including cost and availability, existing at the time such decisions are made. Organon has evaluated its risks and has determined that the cost of obtaining product liability

insurance outweighs the likely benefits of the coverage that is available and, as such, has no insurance for most product liabilities.

Reference is made below to certain litigation in which Merck, but not Organon, is named as a defendant. Pursuant to the Separation and Distribution Agreement, Organon is required to indemnify Merck for liabilities relating to, arising from, or resulting from such litigation.

Product Liability Litigation

Fosamax

Merck is a defendant in product liability lawsuits in the United States involving *Fosamax*® (alendronate sodium) (the "Fosamax Litigation"). As of December 31, 2022, approximately 3,275 cases comprising the Fosamax Litigation are pending against Merck in either federal or state court. Plaintiffs in the vast majority of these cases generally allege that they sustained femur fractures and/or other bone injuries ("Femur Fractures") in association with the use of *Fosamax*.

All federal cases involving allegations of Femur Fractures have been or will be transferred to a multidistrict litigation in the District of New Jersey ("Femur Fracture MDL"). In the only bellwether case tried to date in the Femur Fracture MDL, *Glynn v. Merck*, the jury returned a verdict in Merck's favor. In addition, in June 2013, the Femur Fracture MDL court granted Merck's motion for judgment as a matter of law in the *Glynn* case and held that the plaintiff's failure to warn claim was preempted by federal law.

In August 2013, the Femur Fracture MDL court entered an order requiring plaintiffs in the Femur Fracture MDL to show cause why those cases asserting claims for a femur fracture injury that took place prior to September 14, 2010, should not be dismissed based on the court's preemption decision in the *Glynn* case. Pursuant to the show cause order, in March 2014, the Femur Fracture MDL court dismissed with prejudice approximately 650 cases on preemption grounds. Plaintiffs in approximately 515 of those cases appealed that decision to the U.S. Court of Appeals for the Third Circuit ("Third Circuit"). In March 2017, the Third Circuit issued a decision reversing the Femur Fracture MDL court's preemption ruling and remanding the appealed cases back to the Femur Fracture MDL court. In May 2019, the U.S. Supreme Court decided that the Third Circuit had incorrectly concluded that the issue of preemption should be resolved by a jury, and accordingly vacated the judgment of the Third Circuit and remanded the proceedings back to the Third Circuit to address the issue in a manner consistent with the Supreme Court's opinion. In November 2019, the Third Circuit remanded the cases back to the District Court in order to allow that court to determine in the first instance whether the plaintiffs' state law claims are preempted by federal law under the standards described by the Supreme Court in its opinion. On March 23, 2022, the District Court granted Merck's motion and ruled that plaintiffs' failure to warn claims are preempted as a matter of law to the extent they assert that Merck should have added a Warning or Precaution regarding atypical femur fractures prior to October 2010. On July 11, 2022, the District Court entered an Order to Show Cause as to why the Court should not dismiss either with prejudice or conditionally all of plaintiffs' claims that are not dependent on the preempted failure to warn claims. On November 18, 2022, as a result of the Order to Show Cause, the District Court entered a Final Judgment resulting in the dismissal with prejudice of all plaintiffs in the MDL. On December 16, 2022, those plaintiffs filed their Notice of Appeal to the Third Circuit challenging the District Court's preemption ruling. 974 of the 975 cases previously pending in the Femur Fracture MDL have either been dismissed or are on appeal to the Third Circuit. Plaintiff's motion to remand one case back to its transferor court is pending.

As of December 31, 2022, approximately 2,020 cases alleging Femur Fractures have been filed in New Jersey state court and are pending in Middlesex County. The parties selected an initial group of cases to be reviewed through fact discovery, and Merck has continued to select additional cases to be reviewed.

As of December 31, 2022, approximately 275 cases alleging Femur Fractures have been filed and are pending in California state court. All of the Femur Fracture cases filed in California state court have been coordinated before a single judge in Orange County, California.

Additionally, there are four Femur Fracture cases pending in other state courts.

Discovery is presently stayed in the Femur Fracture MDL and in the state court in California.

Nexplanon/Implanon

Merck is a defendant in lawsuits brought by individuals relating to the use of *Nexplanon* and *Implanon*™ (etonogestrel implant). There are two filed product liability actions involving *Implanon*, both of which are pending in the Northern District of Ohio as well as 56 unfiled cases involving *Implanon* alleging similar injuries, which have been tolled under a written tolling agreement. The product liability action involving *Nexplanon* that had been pending in the Western District of Arkansas has been resolved. As of December 31, 2022, Merck had 18 cases pending outside the United States, of which 12 relate to *Implanon* and six relate to *Nexplanon*.

Propecia/Proscar

Merck is a defendant in product liability lawsuits in the United States involving *Propecia*® (finasteride) and/or *Proscar*® (finasteride). The federal lawsuits were consolidated for pretrial purposes in federal multidistrict litigation in the Eastern District of New York (the "MDL"), and the matters in state court in New Jersey were consolidated in Middlesex County ("N.J. Coordinated Proceedings"). In 2018, Merck and the plaintiffs' Executive Committee in the MDL and the plaintiffs' Liaison Counsel in the N.J. Coordinated Proceedings entered into an agreement to resolve the lawsuits for an aggregate amount of $4.3 million. The settlement was subject to certain contingencies, including 95% plaintiff participation and a per plaintiff clawback if the participation rate was less than 100%. The contingencies were satisfied and the settlement agreement has been finalized. The MDL was officially closed by court order on January 18, 2023, and the N.J. Coordinated Proceedings were previously concluded by court order in September 2021.

As of December 31, 2022, one case remains pending in the United States, a matter involving *Proscar* in the United States District Court for the Eastern District of California in which Merck's motion to dismiss was granted by the District Court, but the plaintiff can appeal the decision. The individual cases involving *Propecia* that had been pending in the MDL and California state court have been resolved. The Company is also defending 15 product liability cases outside the United States, two of which are class actions and three of which are putative class actions.

Governmental Proceedings

From time to time, Organon's subsidiaries may receive inquiries and may be the subject of preliminary investigation activities from competition and/or other governmental authorities, including in markets outside the United States. These authorities may include regulators, administrative authorities, and law enforcement and other similar officials, and these preliminary investigation activities may include site visits, formal or informal requests or demands for documents or materials, inquiries or interviews and similar matters. Certain of these preliminary inquiries or activities may lead to the commencement of formal proceedings. Should those proceedings be determined adversely to Organon, monetary fines and/or remedial undertakings may be required. Subject to certain exceptions specified in the Separation and Distribution Agreement, Organon assumed liability for all pending and threatened legal matters related to products transferred to Organon, including competition investigations resulting from enforcement activity concerning Merck's conduct involving Organon's products. Organon could be obligated to indemnify Merck for fines or penalties, or a portion thereof, resulting from such investigations. In one such enforcement matter in Spain concerning *NuvaRing*, the National Commission on Markets and Competition ("CNMC") recently imposed a fine on Merck in the amount of €39 million for abuse of a dominant position in the market for contraceptive vaginal rings from June 2017 to April 2018. The CNMC decision to impose the fine is appealable to the National High Court in Spain. If the fine ultimately stands, Organon could be obligated to indemnify Merck for a portion thereof.

Hadlima

In July 2021, Organon received a Civil Investigation Demand ("CID") from the Office of the Attorney General for the State of Washington. The CID requests answers to interrogatories, as well as various documents, regarding certain activities related to adalimumab and adalimumab biosimilars. Organon is cooperating with the government's investigation and has produced information in response to the CID.

Patent Litigation

From time to time, generic manufacturers of pharmaceutical products file Abbreviated New Drug Applications ("ANDAs") with the FDA seeking to market generic forms of Organon's products prior to the expiration of relevant patents owned by Organon. To protect its patent rights, Organon may file patent infringement lawsuits against such generic companies. Similar lawsuits defending Organon's patent rights may exist in other countries. Organon intends to vigorously defend its patents, which it believes are valid, against infringement by companies attempting to market products prior to the expiration of such patents. As with any litigation, there can be no assurance of the outcomes, which, if adverse, could result in significantly shortened periods of exclusivity for these products, potential payment of damages and legal fees, and, with respect to products acquired through acquisitions, potentially significant intangible asset impairment charges.

Nexplanon

In June 2017, Microspherix LLC ("Microspherix") sued Organon in the U.S. District Court for the District of New Jersey asserting that the manufacturing, use, sale and importation of *Nexplanon* infringed several of Microspherix's patents that claim radio-opaque, implantable drug delivery devices. Microspherix is claiming damages from September 2014 until the patents expired in May 2021. Organon brought *Inter Partes* Review ("IPR") proceedings in the United States Patent and Trademark Office ("USPTO") and successfully stayed the district court action. The USPTO invalidated some, but not all, of the claims asserted against Organon. Organon appealed the decisions that found claims valid, and the Court of Appeals for the Federal Circuit affirmed the USPTO's decisions. The matter is no longer stayed in the district court, and Organon is currently litigating the invalidity and non-infringement of the remaining asserted claims. A claim construction hearing was held on March 2, 2022, and any further dates in the schedule will be set based on the date the court issues a claim construction order.

Other Litigation

In addition to the matters described above, there are various other pending legal proceedings involving Organon, principally product liability and intellectual property lawsuits. While it is not feasible to predict the outcome of such proceedings, in the opinion of Organon as of December 31, 2022, either the likelihood of loss is remote or any reasonably possible loss associated with the resolution of such proceedings is not expected to be material to Organon's financial condition, results of operations or cash flows either individually or in the aggregate.

Legal Defense Reserves

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by Organon; the development of Organon's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against Organon; and the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The legal defense reserve as of December 31, 2022 and 2021 was $17 million and $9 million, respectively, and represented Organon's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by Organon. Organon will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

Environmental Matters

In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $20 million and $24 million at December 31, 2022 and 2021, respectively. These liabilities are undiscounted, do not consider potential recoveries from other parties and will be paid out over the periods of remediation for the applicable sites, which are expected to occur primarily over the next 15 years. It is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation. Management also does not believe that these expenditures should result in a material adverse effect on the Company's financial condition, results of operations or liquidity for any period presented.

13. Stock-Based Compensation Plans

In connection with the Separation, and in accordance with the Employee Matters Agreement, Organon's employees with outstanding former Merck stock-based awards received replacement stock-based awards under the 2021 Incentive Stock Plan at Separation. The ratio used to convert the Merck stock-based awards was designed to preserve the aggregate intrinsic value of the award immediately after the Separation when compared to the aggregate intrinsic value of the award immediately prior to Separation. Due to the conversion, Organon incurred $17 million of incremental stock-based compensation expense in 2021. Of this amount, $4 million was related to vested option awards and was recognized immediately into earnings in connection with the Separation, and the remainder is recognized ratably over the option awards' remaining weighted average vesting period.

The Company grants stock option awards, performance share units ("PSUs") and restricted share units ("RSUs") pursuant to its 2021 Incentive Stock Plan.

Employee stock options are granted to purchase shares of Company stock at the fair market value at the time of grant. Generally, stock options have a contractual term of ten years and vest one-third each year over a three-year period, subject to limited exceptions.

RSUs are stock awards that are granted to employees and entitle the holder to shares of common stock as the awards vest. RSU awards generally vest one-third each year over a three-year period. The fair value of the stock option and RSU awards is determined and fixed on the grant date based on the Company's stock price.

The terms of the Company's PSU awards allow the recipients of such awards to earn a variable number of common shares based on the cumulative results of specified performance factors. The Company has PSU awards based on the following performance factors:

- total stockholder return of the Company relative to an index of peer companies ("relative TSR") specified in the awards
- the results of the cumulative free cash flow ("FCF") of the Company over a three year period

For FCF and TSR awards, the Company recognizes compensation costs ratably over the performance period. The PSU Awards will generally vest at the end of the three year performance period, however, the number of shares delivered will vary based upon the attained level of performance. For PSUs with a performance-based FCF goal, stock-based compensation expense is recognized based on the probability of the achievement of the financial performance metric for the respective vesting period and is assessed at each reporting date. For PSUs with a market-based relative TSR goal, stock-based compensation expense is recognized based on the estimated fair value of the award at the grant date regardless of the actual number of shares earned. PSU awards generally vest after three years.

For RSUs and PSUs, dividends declared during the vesting period are payable to the employees only upon vesting. RSU and PSU distributions will be in shares of Company stock after the end of the vesting or performance period, subject to the terms applicable to such awards.

Stock-based compensation expense incurred by the Company was as follows:

	Year Ended December 31,		
($ in millions)	2022	2021	2020
Stock-based compensation expense recognized in:			
Cost of sales	$ 13	$ 11	$ 17
Selling, general and administrative	51	36	19
Research and development	11	12	4
Total	$ 75	$ 59	$ 40
Income tax benefits	$ 16	$ 12	$ 8

In connection with the Separation, in 2021, Merck's PSUs and RSUs were converted into 3.3 million Organon RSUs at a weighted average grant date fair value of $36.77 and Merck's stock options were converted into 4.1 million Organon stock options at a weighted average grant date fair value of $8.55. Stock options at Separation were valued using a combination of option models. The Company used the Black-Scholes model as the basis for the original fair value of the options, and the Hull-White I Lattice option pricing model calculated the incremental fair value. In applying these models, the Company used both historical data and current market data to estimate the fair value of its options. The Black-Scholes model assumptions include expected dividend yield, risk-free interest rate, volatility, and term of the options. The Hull-White I Lattice model requires several assumptions including expected exercise barrier, dividend yield, risk-free interest rate, remaining vesting life and remaining contractual life. These fair value assumptions were based on the awards and terms previously granted under the Merck incentive compensation plans to Organon employees. At December 31, 2022, the unrecognized portion of the incremental stock-based expense was $5 million.

The Company uses the Black-Scholes model to determine the fair value of the stock options as of the grant date. In applying this model, the Company uses both historical data and current market data to estimate the fair value of its options. The expected dividend yield is based on forecasted patterns of dividend payments. The risk-free interest rate is based on the rate at grant date of zero-coupon U.S. Treasury Notes with a term equal to the expected term of the option. Expected volatility is estimated using historical volatility. Due to the lack of trading history of Organon's stock at the time of valuation efforts, the historical component of expected volatility is based on historical monthly price changes of the peer group within the industry. Merck's historical data for Organon employees was used to estimate equity award exercise and employee termination behavior within the valuation model. The expected term represents the amount of time that options granted are expected to be outstanding based on historical and forecasted exercise behavior.

The weighted average fair value of options was determined using the following assumptions:

	Year Ended December 31,	
	2022	2021
Expected dividend yield	3.12 %	3.22 %
Risk-free interest rate	2.47	0.92
Expected volatility	43.43	45.80
Expected life (years)	5.89	5.89

A summary of the equity award transactions for the year ended December 31, 2022 are as follows:

	Stock Options			Restricted Share Units		Performance Share Units	
(shares in thousands)	Shares	Weighted average exercise price	Weighted average grant date fair value	Shares	Weighted average grant date fair value	Shares	Weighted average grant date fair value
Outstanding as of January 1, 2022	4,394	$ 34.35	$ 8.63	3,280	$ 36.69	120	$ 51.63
Granted	556	34.93	11.34	3,269	31.65	373	45.23
Vested/Exercised	(15)	37.39	9.72	(1,259)	37.48	—	—
Forfeited/Cancelled	(206)	35.80	9.47	(242)	35.76	(7)	51.63
Outstanding as of December 31, 2022	4,729	$ 34.34	$ 8.91	5,048	$ 33.27	486	$ 46.72

The following table summarizes information about equity awards outstanding that are vested and expected to vest and equity awards outstanding that are exercisable as of December 31, 2022:

	Equity Awards Vested and Expected to Vest				Equity Awards That are Exercisable			
(shares in thousands; aggregate intrinsic value in millions)	Awards	Weighted Average Exercise Price	Aggregate Intrinsic Value	Remaining Term	Awards	Weighted Average Exercise Price	Aggregate Intrinsic Value	Remaining Term
Stock Options	4,576	$ 34.34	$ 1	7.22	2,383	$ 32.92	$ 1	5.94
Restricted Share Units	4,730		141	1.92				
Performance Share Units	380		12	2.39				

The amount of unrecognized compensation costs as of December 31, 2022 was $145 million, which will be recognized in operating expense ratably over the weighted average vesting period of 1.93 years.

14. Pension and Other Postretirement Benefit Plans

Prior to the Separation on June 2, 2021, Organon participated in Merck's U.S. and non-U.S. plans. Merck has defined benefit pension plans covering eligible employees in the United States and in certain of its international subsidiaries. Merck also provides medical benefits, principally to its eligible U.S. retirees and their dependents, through its other postretirement benefit plans. The Company participated in Merck's benefit plans as though it was a participant in a multi-employer plan with the other businesses of Merck. The retirement benefits guidance provides that liabilities beyond any contributions currently due and unpaid are not required to be reported. Accordingly, no assets or liabilities associated with plans where the Company was a participant in a multi-employer plan with the other businesses of Merck have been reflected in the Company's Consolidated Balance Sheet. The Consolidated Statements of Income includes expense allocations for these benefits, which were determined using a proportional allocation method. Total benefit plan expense allocated to the Company for the years ended December 31, 2021 and 2020 was $29 million and $55 million, respectively. The Company's participation in the defined pension and postretirement benefit plans sponsored by Merck concluded upon the completion of the Separation on June 2, 2021.

In accordance with the terms of the Employee Matter Agreement, prior to the Separation, Merck continued to provide service crediting to employees that transferred to Organon under Merck's U.S. defined benefit pension plan, supplemental executive retirement, and retiree medical plans for purposes of early retirement eligibility and subsidies, as well as for certain service crediting bridges. Although Merck is responsible for providing these benefits, Organon recorded the portion of the aggregate incremental cost of providing early retirement subsidies, service crediting bridges, and retiree health care benefits under these programs that is attributable to future service. Accordingly, upon Separation, the Company recorded a "grow-in" provision granted to employees transferred to Organon of $50 million, which represented the future service earned with Organon for these transferred employees for the pension and other postretirement benefits. The "grow-in" provision was recorded as an asset and will be expensed over the estimated average service period of eight years since the Separation, in operating expenses. The unamortized balance of the asset is $40 million as of December 31, 2022, of which $34 million is reflected in *Other Assets* and $6 million is reflected in *Other current assets.*

As of June 2, 2021, Organon became the plan sponsor for certain non-U.S. defined benefit pension plans. These Consolidated Financial Statements reflect the periodic benefit costs and funded status of such plans. Organon pension plans are primarily comprised of plans in Switzerland, Belgium, Korea, Germany and Italy. The Company uses December 31 as the year-end measurement date for these plans.

Net Periodic Benefit Cost

The net periodic benefit cost for pension plans consisted of the following components:

($ in millions)	Year Ended December 31, 2022	2021	2020
Service cost	$ 22	$ 17	$ 4
Interest cost	2	2	1
Expected return on plan assets	(4)	(3)	(1)
Net loss amortization	—	2	—
Net periodic benefit cost	$ 20	$ 18	$ 4

The components of net periodic benefit cost other than the service cost component are included in *Other (income) expense, net.*

Obligations and Funded Status

Summarized information about changes in plan assets and benefit obligations, the funded status and the amounts recorded is as follows:

($ in millions)	December 31, 2022	December 31, 2021
Fair value of plan assets January 1	$ 117	$ 40
Actual return on plan assets	(10)	6
Company contributions	14	19
Effects of exchange rate changes	(4)	(6)
Benefits paid	(7)	2
Other	3	—
Net transfer of plan assets from Merck affiliates	1	56
Fair value of plan assets December 31	$ 114	$ 117
Benefit obligation January 1	$ 189	$ 76
Service cost	22	17
Interest cost	2	2
Actuarial gains	(41)	(17)
Benefits paid	(7)	2
Effects of exchange rate changes	(7)	(10)
Other	1	—
Net transfer of benefit obligations from Merck affiliates	2	119
Benefit obligation December 31	$ 161	$ 189
Funded status December 31	$ (47)	$ (72)
Recognized as:		
Other assets	$ 1	$ 1
Accrued and other current liabilities	(1)	(1)
Other Noncurrent liabilities	(47)	(72)

Information related to the funded status of materially significant pension plans is as follows:

($ in millions)	December 31, 2022	December 31, 2021
Pension plans with a projected benefit obligation in excess of plan assets		
Projected benefit obligation	$ 150	$ 176
Fair value of plan assets	103	104
Pension plans with an accumulated benefit obligation in excess of plan assets		
Accumulated benefit obligation	$ 113	$ 154
Fair value of plan assets	73	97

Plan Assets

The fair values of the Company's pension plan assets at December 31 by asset category are as follows:

	Fair Value Measurements Using				Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
($ in millions)	2022				2021			
Cash and cash equivalents	$ 4	$ —	$ —	$ 4	$ 3	$ —	$ —	$ 3
Investment funds								
Developed markets equities	34	3	—	37	28	3	—	31
Government and agency obligations	25	1	—	26	21	1	—	22
Emerging markets equities	5	—	—	5	5	—	—	5
Other	3	—	—	3	3	1	—	4
Equity income securities								
Developed markets equities	—	—	—	—	1	—	—	1
Fixed income securities								
Government and agency obligations	—	2	—	2	—	3	—	3
Corporate Obligations	—	2	—	2	—	2	—	2
Other investments								
Insurance contracts	—	33	—	33	—	33	—	33
Other	1	1	—	2	12	1	—	13
Plan assets at fair value	$ 72	$ 42	$ —	$ 114	$ 73	$ 44	$ —	$ 117

The targeted investment portfolio for the Company's pension plans that are sponsored outside the United States varies based on the duration of pension liabilities and local government rules and regulations. There are no unfunded commitments or redemption restrictions related to these investments.

Expected Contributions

Expected contributions during 2023 are approximately $11 million for the Company's pension plans.

Expected Benefit Payments

Expected benefit payments are as follows ($ in millions):

2023	2024	2025	2026	2027	Thereafter
$ 9	$ 7	$ 6	$ 8	$ 8	$ 53

Expected benefit payments are based on the same assumptions used to measure the benefit obligations and include estimated future employee service.

Amounts Recognized in Other Comprehensive Income

Net loss amounts reflect differences between expected and actual returns on plan assets as well as the effects of changes in actuarial assumptions. Net loss amounts in excess of certain thresholds are amortized into net periodic benefit cost over the average remaining service life of employees.

	Year Ended December 31,		
($ in millions)	2022	2021	2020
Net gain (loss) arising during the period	$ 28	$ 4	$ 6
Net loss amortization included in benefit cost	—	2	—

Actuarial Assumptions

The Company reassesses its benefit plan assumptions on a regular basis. The weighted average assumptions used in determining pension plan information are as follows:

	Year Ended December 31,		
($ in millions)	2022	2021	2020
Net periodic benefit cost			
Discount rate	1.49 %	1.48 %	3.91 %
Expected rate of return on plan assets	4.05	4.50	2.62
Salary growth rate	2.75	3.18	3.63
Benefit obligation			
Discount rate	3.82	1.49	1.52
Salary growth rate	2.98	2.75	3.63

The discount rate is evaluated on measurement dates and modified to reflect the prevailing market rate of a portfolio of high-quality, fixed-income debt instruments that would provide the future cash flows needed to pay the benefits included in the benefit obligation as they come due.

The expected rate of return represents the average rate of return to be earned on plan assets over the period the benefits included in the benefit obligation are to be paid and is determined on a plan basis. The expected rate of return for each plan is developed considering long-term historical returns data, current market conditions, and actual returns on the plan assets. Using this reference information, the long-term return expectations for each asset category and a weighted-average expected return for each plan's target portfolio is developed according to the allocation among those investment categories. The expected portfolio performance reflects the contribution of active management as appropriate.

Savings Plan

Prior to June 2, 2021, the Company participated in certain Merck defined contribution savings plans. After the Separation, Organon maintains a defined contribution savings plan in the United States. The Company matches a percentage of employees' contributions consistent with the provisions of the plan. In addition, since Separation, the Company makes retirement contributions calculated based on a predetermined formula that considers years of service and the employee's age. Total actual employer contributions to this plan in 2022 were $32 million. Total allocated and actual employer contributions to this plan in 2021 were $23 million. The amount allocated for total employer contributions in 2020 was $18 million.

15. Taxes on Income

A reconciliation between the effective tax rate and the U.S. statutory rate is as follows:

	Year Ended December 31,					
	2022		2021		2020	
($ in millions)	Amount	Tax Rate	Amount	Tax Rate	Amount	Tax Rate
U.S. statutory rate applied to income before taxes	$ 236	21.0 %	$ 321	21.0 %	$ 578	21.0 %
Differential arising from:						
Foreign earnings	(109)	(9.7)	(43)	(2.8)	(93)	(3.4)
Tax settlements	(2)	(0.1)	(32)	(2.1)	—	—
Amortization of intangible assets	—	—	(75)	(4.9)	12	0.4
State taxes	(2)	(0.2)	(3)	(0.2)	—	—
Global Intangible Low-Taxed Income	57	5.1	17	1.1	—	—
Interest expense disallowance	13	1.2	—	—	—	—
Other	12	1.0	(7)	(0.4)	(1)	—
	$ 205	18.3 %	$ 178	11.7 %	$ 496	18.0 %

Prior to the Separation, income taxes were calculated as if the Company filed income tax returns on a standalone basis. For those years, the Company believes the assumptions supporting its allocation and presentation of income taxes on a separate return basis are reasonable.

The Company has no remaining transition tax liability as of December 31, 2021 under the Tax Cuts and Jobs Act ("TCJA") that was enacted in 2017. The transition tax liability was $1.5 billion at December 31, 2020, of which $161 million was included in *Income Taxes Payable* and the remainder of $1.3 billion was included in *Other Noncurrent Liabilities*. As a result of the TCJA, the Company has made a determination it is no longer indefinitely reinvested with respect to a majority of its previously taxed undistributed earnings from foreign subsidiaries and provided for a deferred tax liability for withholding taxes due upon future remittances, net of certain foreign income tax credits. At December 31, 2022 and 2021, the deferred income tax liabilities on undistributed earnings for certain subsidiaries that are deemed indefinitely reinvested are immaterial.

The tax effects of foreign earnings in the tax rate reconciliation above primarily reflect the effects of operations in jurisdictions with different tax rates than the United States thereby yielding a favorable impact on the effective tax rate compared with the U.S. statutory rate of 21%. The favorable impact is primarily attributable to a reduced tax rate arrangement that was agreed to in Switzerland for an active legal entity.

The effective income tax rates were 18.3%, 11.7% and 18.0% for 2022, 2021 and 2020, respectively. These effective income tax rates reflect the beneficial impact of foreign earnings, offset by the impact of U.S. inclusions under the Global Intangible Low-Taxed Income regime. During 2021, the Company recorded a $75 million tax benefit relating to a portion of the non-U.S. step-up of tax basis associated with the Company's Separation from Merck. The effective income tax rate for 2021 also reflects the Internal Revenue Service ("IRS") conclusion of its examinations of Merck's 2015-2016 U.S. federal income tax returns as further detailed below.

Income before taxes consisted of:

	Year Ended December 31,		
($ in millions)	2022	2021	2020
Domestic	$ (451)	$ (96)	$ 532
Foreign	1,573	1,625	2,220
	$ 1,122	$ 1,529	$ 2,752

Taxes on income consisted of:

($ in millions)	Year Ended December 31, 2022	2021	2020
Current provision			
Federal	$ 51	$ 41	$ 91
Foreign	172	435	435
State	—	(10)	2
	$ 223	$ 466	$ 528
Deferred provision			
Federal	$ (38)	$ (64)	$ 11
Foreign	22	(220)	(44)
State	(2)	(4)	1
	$ (18)	$ (288)	$ (32)
	$ 205	$ 178	$ 496

Deferred income taxes at December 31 consisted of:

	December 31,			
	2022		2021	
($ in millions)	Assets	Liabilities	Assets	Liabilities
Product intangibles and licenses	$ 164	$ —	$ 105	$ —
Inventory related	—	10	15	—
Reserves and allowances	51	—	40	—
Accrued expenses	22	—	23	—
Accelerated depreciation	—	11	—	15
Unremitted foreign earnings	—	3	—	2
Right of use asset	44	—	51	—
Lease liability	—	44	—	51
Interest expense limitation carryforward	37	—	23	—
Compensation related	26	—	23	—
Hedging	—	59	—	36
Net operating losses and other tax credit carryforwards	65	—	103	—
Other	18	—	24	—
Subtotal	$ 427	$ 127	$ 407	$ 104
Valuation allowance	(52)	—	(35)	—
Total deferred taxes	$ 375	$ 127	$ 372	$ 104
Net deferred income taxes	$ 248		$ 268	
Recognized as:				
Other Assets	$ 267		$ 272	
Deferred Income Taxes		$ 19		$ 4

The Company has recognized $65 million and $103 million deferred taxes on net operating loss ("NOL") carryforwards in multiple jurisdictions as of December 31, 2022 and 2021, respectively. Valuation allowances of $52 million have been established on $39 million of foreign deferred tax assets and $13 million of US deferred tax assets. The $17 million increase in the valuation allowance in 2022 is primarily due to a disallowed interest expense in the US. During 2021, the Company reduced valuation allowances by $42 million as a result of the Separation.

Income taxes paid in 2022 and 2021, were $214 million and $131 million, respectively. Income taxes paid by Merck with respect to Organon for 2020 were $416 million.

As of December 31, 2022 and 2021, the Company deferred the income tax consequences resulting from intra-entity transfers of inventory totaling $368 million and $377 million, respectively. These amounts are reflected in *Other current assets.*

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	Year Ended December 31,		
($ in millions)	2022	2021	2020
Balance January 1	$ 78	$ 219	$ 213
Additions related to current year tax positions	30	23	15
Additions related to prior year tax positions	3	18	23
Reductions for tax positions of prior years	(3)	(49)	(3)
Spinoff related adjustments [(1)]	—	(108)	—
Settlements	(12)	(15)	(19)
Lapse of statute of limitations	(3)	(10)	(10)
Balance December 31	$ 93	$ 78	$ 219

(1) Unrecognized tax benefits were reduced by $108 million in 2021 related to positions taken prior to the spinoff for which Merck, as the Company's former Parent, is the primary obligor and is responsible for settlement and payment of any resulting tax obligation.

If the Company were to recognize the unrecognized tax benefits of $93 million, at December 31, 2022, the income tax provision would reflect a favorable net impact of $93 million.

In 2022, foreign tax authorities concluded its examinations of certain foreign income tax returns. As a result, the Company reflected a payment of $12 million in the consolidated financial statements and a reduction of $11 million in reserves for unrecognized tax benefits for tax positions relating to the years that were under examination.

Prior to June 2, 2021, the Company was part of Merck's consolidated U.S. federal income tax return, as well as separate and combined Merck income tax returns in numerous state and international jurisdictions. Merck was under examination by numerous tax authorities in various jurisdictions globally. During 2021, the IRS concluded its examinations of Merck's 2015-2016 U.S. federal income tax returns. As a result, the Company reflected an allocation from Merck of $18 million representing the Company's portion of the payment made to the IRS in the Consolidated Financial Statements. The Company's portion of reserves for unrecognized tax benefits for the years under examination exceeded the allocated adjustments relating to this examination period and therefore the Company included a $29 million net tax benefit for the year ended December 31, 2021. This net benefit reflects reductions in reserves for unrecognized tax benefits and other related liabilities for tax positions relating to the years that were under examination.

The Company is subject to income tax in the United States (federal, state and local) as well as other jurisdictions outside of the United States in which we operate. As part of the Separation from Merck, $79.3 million of liabilities for unrecognized tax benefits associated with uncertain tax positions for jurisdictions outside of the United States were conveyed to Organon.

The Company believes that it is reasonably possible that the total amount of unrecognized tax benefits as of December 31, 2022 could decrease by up to $15 million in the next 12 months as a result of various audit closures, settlements or the expiration of the statute of limitations. The Company believes that its reserves for uncertain tax positions are adequate to cover existing risks or exposures.

Interest and penalties associated with uncertain tax positions were immaterial in 2022 and 2021 and resulted in an expense of $11 million in 2020. These amounts reflect the beneficial impacts of various tax settlements. Liabilities for accrued interest and penalties were $35 million and $39 million as of December 31, 2022 and 2021, respectively.

Various state and foreign tax examinations are in progress and for these jurisdictions, income tax returns are open for examination for the period 2006 through 2022.

16. Accumulated Other Comprehensive Income (Loss)

Changes in *Accumulated other comprehensive income (loss)* by component are as follows:

($ in millions)	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Loss (Income)
Balance at January 1, 2020, net of taxes	$ (354)	$ (560)	$ (914)
Other comprehensive loss, pretax	(172)	(30)	(202)
Tax	29	—	29
Other comprehensive loss, net of taxes	(143)	(30)	(173)
Net Transfer of benefit plans to Merck affiliates	465	—	465
Balance at December 31, 2020, net of taxes	$ (32)	$ (590)	$ (622)
Other comprehensive income, pretax	21	90	111
Tax	(13)	—	(13)
Other comprehensive income, net of taxes	8	90	98
Net transfer of benefit plans to Merck affiliates	11	—	11
Balance at December 31, 2021, net of taxes	$ (13)	$ (500)	$ (513)
Other comprehensive income (loss), pretax	28	(74)	(46)
Tax	(5)	—	(5)
Other comprehensive income (loss), net of taxes	23	(74)	(51)
Balance at December 31, 2022, net of taxes	$ 10	$ (574)	$ (564)

17. Product and Geographic Information

The Company's operations include the following product portfolios, which constitute one operating segment engaged in developing and delivering innovative health solutions through its portfolio of prescription therapies within women's health, biosimilars and established brands.

Revenues of the Company's products were as follows:

	Year Ended December 31,								
	2022			2021			2020		
($ in millions)	U.S.	Int'l	Total	U.S.	Int'l	Total	U.S.	Int'l	Total
Women's Health									
Nexplanon/Implanon NXT	$ 573	$ 261	$ 834	$ 532	$ 237	$ 769	$ 488	$ 192	$ 680
Follistim AQ	105	124	229	110	127	237	84	108	193
NuvaRing	85	88	173	85	106	191	111	126	236
Ganirelix Acetate Injection	26	97	123	22	88	111	11	69	81
Marvelon/Mercilon	—	110	110	—	98	98	—	95	95
Other Women's Health [(1)]	110	94	204	96	111	206	165	105	270
Biosimilars									
Renflexis	196	30	226	164	21	186	123	12	135
Ontruzant	48	74	122	34	92	126	3	113	115
Brenzys	—	75	75	—	63	63	—	74	74
Aybintio	—	39	39	—	36	36	—	6	6
Hadlima	—	19	19	—	13	13	—	—	—
Established Brands									
Cardiovascular									
Zetia	8	350	357	10	368	378	(1)	483	482
Vytorin	8	123	130	11	153	164	12	170	182
Atozet	—	457	457	—	458	458	—	453	453
Rosuzet	—	71	71	—	68	68	—	130	130
Cozaar/Hyzaar	13	310	323	12	345	357	21	365	386
Other Cardiovascular [(1)]	3	156	159	4	187	191	3	237	239
Respiratory									
Singulair	11	400	411	15	398	413	18	444	462
Nasonex	10	229	238	4	201	206	12	206	218
Dulera	140	40	180	154	36	190	188	34	222
Clarinex	4	121	125	6	106	111	7	123	130
Other Respiratory [(1)]	46	36	83	56	33	89	79	40	118
Non-Opioid Pain, Bone and Dermatology									
Arcoxia	—	241	241	—	244	244	—	258	258
Fosamax	4	148	152	4	172	175	4	176	180
Diprospan	—	122	122	—	125	125	—	118	118
Other Non-Opioid Pain, Bone and Dermatology [(1)]	15	257	273	16	269	286	10	268	278
Other									
Proscar	1	99	101	1	116	117	2	174	176
Propecia	7	118	125	9	127	136	10	119	129
Other [(1)]	24	302	326	41	318	360	54	324	379
Other [(2)]	—	146	146	(3)	205	200	4	102	107
Revenues	$ 1,437	$ 4,737	$ 6,174	$ 1,383	$ 4,921	$ 6,304	$ 1,408	$ 5,124	$ 6,532

Totals may not foot due to rounding. Trademarks appearing above in italics are trademarks of, or are used under license by, the Organon group of companies.

[(1)] Includes sales of products not listed separately. Revenues from Marvelon/Mercilon were previously reported as part of Other Women's Health. Revenue from an arrangement for the sale of generic etonogestrel/ethinyl estradiol vaginal ring is included in Other Women's Health.

[(2)] Includes manufacturing sales to Merck and third parties for current and prior periods and allocated amounts from revenue hedging activities through the date of Separation.

Revenues by geographic area where derived are as follows:

($ in millions)	Year Ended December 31, 2022	2021	2020
Europe and Canada	$ 1,631	$ 1,741	$ 1,726
United States	1,437	1,383	1,408
Asia Pacific and Japan	1,143	1,173	1,535
China	917	933	873
Latin America, Middle East, Russia and Africa	895	841	857
Other [(1)]	151	233	133
Revenues	$ 6,174	$ 6,304	$ 6,532

[(1)] Primarily reflects manufacturing sales to Merck and third parties for current and prior periods and allocated amounts from revenue hedging activities through the date of Separation.

As of December 31, 2022, approximately 70% of the Company's long-lived fixed assets are located in Europe and Canada, and 20% are in the United States. The Company does not disaggregate assets on a products and services basis for internal management reporting and, therefore, such information is not presented.

18. Third-Party Arrangements and Related Party Disclosures

Pursuant to the Separation, Merck ceased to be a related party to Organon and accordingly, no related party transactions or balances have been reported since June 2, 2021.

In connection with the Separation, the Company entered into the Separation and Distribution Agreement, which contains provisions that, among other things, relate to (i) assets, liabilities and contracts to be transferred, assumed and assigned to each of Organon and Merck as part of the Separation, (ii) cross-indemnities principally designed to place financial responsibility for the obligations and liabilities of the Organon business with Organon and financial responsibility for the obligations and liabilities of Merck's remaining business with Merck, (iii) procedures with respect to claims subject to indemnification and related matters, (iv) the allocation between Organon and Merck of rights and obligations under existing insurance policies with respect to occurrences prior to completion of the Distribution, as well as the right to proceeds and the obligation to incur certain deductibles under certain insurance policies, and (v) procedures governing Organon's and Merck's obligations and allocations of liabilities with respect to ongoing litigation matters that may implicate each of Merck's business and Organon's business.

Agreements that Organon entered into with Merck that govern aspects of Organon's relationship with Merck following the Separation include:

- Transition Services Agreements - Under the TSA, (i) Merck and certain of its affiliates provide Organon and certain of its affiliates, on an interim, transitional basis, various services, and (ii) Organon and certain of its affiliates provide Merck and certain of its affiliates, on an interim, transitional basis, various services. The services provided by Merck will include, among others, information technology, human resources, finance, quality, regulatory, supply chain management, promotional services, distribution services and certain other services, and will provide on a cost or, where applicable, a cost-plus basis. The Merck services generally commenced on the date of the Separation and generally terminate within 25 months following the date of Separation. Organon generally has the right to request the early termination of any or all services with advance notice. The services provided by Organon include quality, regulatory, supply chain management, promotional services, distribution services and certain other services and is provided on a cost or, where applicable, a cost-plus basis. The provisions of Organon services under the TSA generally commenced on the date of Separation and terminate within 25 months following the Separation. Merck will generally have the right to request the early termination of any or all services with advance notice.
- Interim Operating Agreements - Merck and Organon entered into a series of interim operating model ("IOM") - Merck and Organon entered into a series of IOM agreements pursuant to which Merck and certain of its affiliates that held licenses, permits and other rights in connection with marketing, import and/or distribution of Organon products in various jurisdictions prior to the Separation, will continue to market, import and distribute such products until such time as the relevant licenses and permits are transferred to Organon or its affiliates, while permitting Organon (or Merck, as applicable) to recognize revenue relating to the sale of its respective products, to the extent practicable. Under such IOM agreements and in accordance with the Separation and Distribution Agreement, the relevant Merck entity will continue operations in the affected market on behalf of Organon, with Organon receiving all of the economic benefits and burdens of such activities. Organon began receiving these economic benefits as of June 2, 2021.

Based on the terms of the IOM agreements, the Company determined it is the Principal under these arrangements. Organon holds all risks and rewards of ownership inclusive of risk of loss, market risk and benefits related to the inventory. Additionally, Organon has latitude in pricing, has the ability to direct Merck regarding decisions over inventory, and is responsible for all credit and collections risks and losses associated with the related receivables. As such, Organon recognizes these sales on a gross basis.

- Manufacturing and Supply Agreements - Merck and Organon and/or their applicable affiliates entered into a number of manufacturing and supply agreements pursuant to which the relevant Merck entity will (a) manufacture and supply certain active pharmaceutical ingredients for the relevant Organon entity, (b) toll manufacture and supply certain formulated pharmaceutical products for such Organon entity, and (c) package and label certain finished pharmaceutical products for such Organon entity. Similarly, the relevant Organon entity will (a) manufacture and supply certain formulated pharmaceutical products for the relevant Merck entity, and (b) package and label certain finished pharmaceutical products for such Merck entity.
- Tax Matters Agreement - The TMA allocates responsibility for all U.S. federal income, state and foreign income, franchise, capital gain, withholding and similar taxes, as well as all non-income taxes. The TMA also provides for cooperation between Merck and Organon with respect to tax matters, the exchange of information and the retention of records that may affect the tax liabilities of the parties to the TMA. Merck generally is responsible for any income taxes reportable on an originally filed consolidated, combined or unitary return that includes Merck or any of its subsidiaries (and Organon and/or any of its subsidiaries) for any periods or portions thereof ending on or prior to the Distribution. Organon generally is responsible for any income taxes that are reportable on originally filed returns that include only Organon and/or any of its subsidiaries, for all tax periods. Additionally, as a general matter, Merck is responsible for certain income and non-income taxes imposed as the direct result of the Separation or of an internal separation transaction. Organon is responsible for certain taxes that exclusively relate to Organon's business and for taxes resulting from any breach of certain representations or covenants that Organon made in the TMA. The TMA imposes restrictions on Organon and its subsidiaries during the two-year period following the Distribution. The restrictions are intended to prevent the Distribution and certain related transactions from failing to qualify as tax-free for U.S. federal income tax purposes. During such period, Organon and its subsidiaries generally are prohibited from, among other things, entering into transactions in which all or a portion of the shares of the Common Stock would be acquired or all or a portion of certain assets of Organon and its subsidiaries would be acquired. Organon and its subsidiaries also are prohibited, during such period, from merging or consolidating with any other person, issuing equity securities beyond certain thresholds, and repurchasing Common Stock other than in certain open-market transactions. Certain amounts are estimates and subject to possible adjustment in future periods.
- Employee Matters Agreement - The agreement allocated assets, liabilities and responsibilities relating to employee compensation and benefit plans and programs and other related matters in connection with the Separation.
- Other agreements that Organon entered into with Merck include the Intellectual Property License Agreements and Regulatory Agreements.

The amounts due under such agreements were:

($ in millions)	December 31, 2022	December 31, 2021
Due from Merck in *Accounts receivable*	$ 374	$ 403
Due to Merck in *Accounts payable*	543	928

Sales and cost of sales resulting from the manufacturing and supply agreements with Merck were:

	Year Ended December 31,	
($ in millions)	2022	2021
Sales	$ 127	$ 90
Cost of sales	116	85

Prior to the Separation, the Company did not operate as a standalone business and the Consolidated Financial Statements were derived from the consolidated financial statements and accounting records of Merck. The following disclosure summarizes activity between the Company and Merck up to the Separation, including the affiliates of Merck that were not part of the Separation.

Cost allocations from Merck

Merck provided significant corporate, manufacturing, selling, marketing, administrative, research services and resources to the Company. The Consolidated Financial Statements reflect an allocation of these costs. Some of these services continue to be provided by Merck to the Company on a temporary basis under the Transition Services Agreement. The allocations reflected in the Consolidated Statements of Income for continuing operations are as follows:

	Year Ended December 31,	
($ in millions)	2021 [1]	2020
Cost of sales	$ 69	$ 452
Selling, general and administrative	134	658
Research and development	35	152
	$ 238	$ 1,262

[1] *Includes costs through the Separation Date.*

Management believes these cost allocations are a reasonable reflection of the utilization of services provided to, or the benefit derived by, the Company during the periods presented. The allocations may not, however, be indicative of the actual expenses that would have been incurred had the Company operated as a standalone public company at the time. Actual costs that may have been incurred if the Company had been a standalone public company would depend on a number of factors, including the chosen organizational structure, whether functions were outsourced or performed by the Company's employees and strategic decisions made in areas such as manufacturing, selling, information technology and infrastructure.

Related party transactions

The following transactions represent activity between Organon Entities and Transferred Entities with other Merck affiliates prior to the Separation:

	Year Ended December 31,	
($ in millions)	2021	2020
Included in continuing operations		
Supply sales to Merck affiliates	$ 143	$ 57
Purchases from Merck affiliates	65	657
Cost reimbursements and fees from Merck affiliates	1	—
Included in discontinued operations		
Supply sales to Merck affiliates	$ 12	$ 542
Purchases from Merck affiliates	53	382
Cost reimbursements and fees (to) from Merck affiliates	—	22
Interest expense, net on loans and advances with Merck affiliates	—	2

The Company had the following balances with Merck affiliates:

($ in millions)	December 31, 2020
Included in continuing operations	
Short term borrowings, net	$ 1,512
Trade payables (receivables), net	(173)
Due to related party	$ 1,339
Included in discontinued operations	
Short term loans receivables, net	$ 247
Short term notes payable, net	(25)
Trade payables, net	(33)
Due from related party	$ 189

Net transfers to Merck & Co., Inc.

Prior to the Separation, net transfers to Merck were included within *Net investment from Merck & Co., Inc.* on the Consolidated Statement of Equity and represent the net effect of transactions between the Company and Merck. The components of *Net transfers to Merck & Co., Inc.* were as follows:

	Year Ended December 31,	
($ in millions)	2021 [1]	2020
Cash pooling and general financing activities	$ 168	$ 5,216
Cost allocations, excluding non-cash stock-based compensation	(209)	(1,222)
Taxes deemed settled with Merck	(259)	(409)
Allocated derivative and hedging (losses) gains	(88)	(51)
Net transfers (from) to Merck & Co., Inc. as reflected in the Consolidated Statement of Cash Flows for Continuing Operations [2]	$ (388)	$ 3,534
Net transfers to (from) Merck included in Net Cash Provided by (Used in) Discontinued Operations	597	(194)
Total net transfers to Merck as included in the Consolidated Statement of Cash Flows	$ 209	$ 3,340
Stock-based compensation expense (includes $3 and 7 of discontinued operations for the year ended December 31, 2021 and 2020, respectively)	(32)	(54)
Net assets contributed by Merck affiliates	(778)	250
Derecognition of amounts in *Accumulated other comprehensive loss* related to employee benefit plan transfers to Merck affiliates	13	465
Net transfers (from) to Merck & Co., Inc. as reflected in the Consolidated Statement of Equity	$ (588)	$ 4,001

[1] *Amounts represent activity through the date of the Separation.*

[2] *Net transfers (from) to Merck & Co., Inc. as reflected in the Consolidated Statement of Cash Flows for Continuing Operations for the year ended December 31, 2021 include Separation adjustments of $52 million, identified after the date of the Separation.*

Prior to the Separation, transfers between the Organon Entities, the Transferred Entities and Merck affiliates were recognized in Net transfers to Merck & Co., Inc. in the Consolidated Statement of Equity at Merck's historical cost. Additionally, in connection with the Separation, certain assets and liabilities included in the pre-Separation balance sheet were retained by Merck and certain assets and liabilities not included in the pre-Separation balance sheet were transferred to Organon.

Separation-related adjustments were also recognized in Net transfers to Merck & Co., Inc. Adjustments for transfers and separations are reflected in the Company's Consolidated Financial Statements for the year ended December 31, 2021 and were comprised of (i) the retention of assets and liabilities by Merck affiliates including accounts receivable, net of $751 million, inventories of $265 million, transition tax liabilities of $1.4 billion and certain liabilities net of other assets of $210 million,

partially offset by (ii) the contribution of assets and liabilities to Organon Entities from Merck affiliates, including assets of $59 million and liabilities of $35 million.

Merck conveyed to Organon $79.3 million of reserves for unrecognized tax benefits associated with uncertain tax positions for jurisdictions outside of the United States. See Note 15 "Taxes on Income" for further details. The Company also incurred costs related to employee matters in connection with the Separation, primarily related to stock-based and pension related compensation costs. See Notes 13 "Stock-Based Compensation Plans" and 14 "Pension and Other Postretirement Benefits Plans" for further details.

19. Discontinued Operations

In contemplation of the Separation, the Merck Retained Products business in the Transferred Entities was distributed to Merck affiliates and, accordingly, the historical results of operations, assets and liabilities, and the cash flows of the Merck Retained Products for such Transferred Entities are reflected as discontinued operations.

The components of Loss from discontinued operations, net of tax for the Merck Retained Products business are as follows:

	Year Ended December 31,	
($ in millions)	2021	2020
Sales	$ 93	$ 1,564
Costs, Expenses and Other		
Cost of Sales	65	1,228
Selling, general and administrative	15	310
Research and development	4	94
Restructuring Costs	—	10
Other expense (income), net	4	(6)
Loss from discontinued operations before taxes	$ 5	$ (72)
Taxes on income	5	24
Loss from discontinued operations, net of taxes	$ —	$ (96)

Discontinued operations include related party sales of $12 million and $542 million for the year ended December 31, 2021 and 2020, respectively. Costs for inventory purchases from related parties were $53 million and $382 million for the year ended December 31, 2021 and 2020, respectively.

The components of assets and liabilities of discontinued operations that are stated separately as of December 31, 2020 in the Consolidated Balance Sheets are comprised of the following items:

($ in millions)	December 31, 2020
Assets	
Cash and cash equivalents	$ 58
Accounts receivable	322
Inventories	58
Due from related party	189
Other current assets	47
Total current assets of discontinued operations	674
Property, Plant and Equipment, net	14
Other Noncurrent Assets	77
Total Noncurrent Assets of Discontinued Operations	91
Total Assets of Discontinued Operations	$ 765
Liabilities	
Trade accounts payable	$ 35
Accrued and other current liabilities	93
Total current liabilities of discontinued operations	128
Deferred Income Taxes	—
Other Noncurrent Liabilities	83
Total Noncurrent Liabilities of Discontinued Operations	83
Total Liabilities of Discontinued Operations	$ 211

20. Earnings per Share ("EPS")

On June 2, 2021, the date of the Separation, 253,516,000 shares of the Common Stock were distributed to Merck stockholders of record as of the Record Date. This share amount is utilized for the calculation of basic and diluted earnings per share for all periods presented prior to the Separation. For the year ended December 31, 2021 and 2020, these shares are treated as issued and outstanding as of January 1, 2021 and 2020, respectively, for purposes of calculating historical basic and diluted earnings per share.

The calculation of basic and diluted earnings per common share for the year ended December 31, 2022 and 2021 was as follows:

	Year Ended December 31,		
($ in millions and shares in thousands, except per share amounts)	2022	2021	2020
Net income:			
Income from continuing operations	$ 917	$ 1,351	$ 2,256
Income from discontinued operations	—	—	(96)
Net income	$ 917	$ 1,351	$ 2,160
Basic weighted average number of shares outstanding	254,082	253,538	253,516
Stock awards and equity units (share equivalent)	1,087	655	—
Diluted weighted average common shares outstanding	255,169	254,193	253,516
Earnings per Share - Basic:			
Continuing operations	$ 3.61	$ 5.33	$ 8.90
Discontinued operations	—	—	(0.38)
Net Earnings per Share - Basic	$ 3.61	$ 5.33	$ 8.52
Earnings per Share - Diluted:			
Continuing operations	$ 3.59	$ 5.31	$ 8.90
Discontinued operations	—	—	(0.38)
Net Earnings per Share - Diluted	$ 3.59	$ 5.31	$ 8.52
Anti-dilutive shares excluded from the calculation of EPS	4,375	4,871	—

For periods prior to the Separation, it is assumed that there were no dilutive equity instruments as there were no equity awards of Organon outstanding prior to the Separation.

For periods subsequent to the Separation and the Distribution, diluted earnings per share is computed by giving effect to all potentially dilutive stock awards that are outstanding. The computation of diluted earnings per share excludes the effect of the potential exercise of stock-based awards, when the effect of the potential exercise would be anti-dilutive.

21. Subsequent Events

In January 2023, the Company made a strategic investment in Claria Medical, Inc. ("Claria"), a privately-held company developing an investigational medical device being studied for use during minimally invasive laparoscopic hysterectomy. Under the terms of the agreement, Organon paid $8 million upfront and has the option to acquire Claria for pre-defined terms at a later date. The upfront payment will be expensed as *Acquired in-process research and development and milestones* in our statement of income in the first quarter of 2023.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosures

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures. Based on their evaluation, as of the end of the period covered by this Form 10-K, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934, as amended (the Act)) are effective.

Changes in Internal Control Over Financial Reporting

In 2022, the Company began an implementation of an enterprise resource planning, or ERP, system, which will replace the existing core financial system. The ERP system is designed to accurately maintain the Company's financial records used to report operating results. The implementation of the consolidated financial reporting module will be completed during the 2023 fiscal year and the implementation of the general ledger modules will occur in phases and will be completed by the first half of 2024. The Company will evaluate each quarter whether there are changes that materially affect, or are reasonably likely to materially affect our internal control over financial reporting.

For the fourth quarter of 2022, there have been no changes in internal control over financial reporting that materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. Management conducted an evaluation of the effectiveness of internal control over financial reporting as of December 31, 2022 based on the framework in Internal Control — Integrated Framework issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2022.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2022, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdiction that Prevent Inspections

None.

Part III

Item 10. Directors, Executive Officers and Corporate Governance

Organon has a Code of Conduct applicable to all employees, including the principal executive officer, principal financial officer, principal accounting officer, and controller, and all directors. The Code of Conduct is available at organon.com/about-organon/mission-vision-and-values/code-of-conduct. To the extent required by the rules of the U.S. Securities and Exchange

Commission (the "SEC") or the New York Stock Exchange (the "NYSE"), Organon intends to disclose amendments to and waivers of the Code of Conduct applicable to executive officers and directors, if any, on that website within four business days following the date of any such amendment or waiver.

Additional information required by this item will be included in the 2023 Proxy Statement and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this item will be included in the 2023 Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item will be included in the 2023 Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item will be included in the 2023 Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information required by this item will be included in the 2023 Proxy Statement and is incorporated herein by reference.

Part IV

Items 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed as part of this report:

1. Financial Statements: The following financial statements are included in Part II, Item 8 of this Annual Report on Form 10-K.

- Report of Independent Registered Public Accounting Firm
- Consolidated Statement of Income and Consolidated Statement of Comprehensive Income
- Consolidated Balance Sheet
- Consolidated Statement of Equity
- Consolidated Statement of Cash Flows
- Notes to the Consolidated Financial Statements

2. Exhibits: See Item 15(b) below.

(b) Exhibits

The exhibits listed on the Exhibit Index beginning on page 114, which is incorporated herein by reference, are filed or furnished as part of this report or are incorporated into this report by reference.

Number		Description
2.1	—	Separation and Distribution Agreement, dated as of June 2, 2021, by and between Merck & Co., Inc. and Organon & Co. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K (File No. 001-40235) filed on June 3, 2021
3.1	—	Amended and Restated Certificate of Incorporation of Organon & Co. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-40235) filed on June 3, 2021)
3.2	—	Amended and Restated Bylaws of Organon & Co. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-40235) filed on December 9, 2022)
4.1	—	Form of Specimen Common Stock Certificate (incorporated herein by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-K (File No. 001-40235) filed on March 21, 2022)
4.2	—	Description of Registrant's Securities (incorporated herein by reference to Exhibit 4.2 to the Company's Annual Report on Form 10-K (File No. 001-40235) filed on March 21, 2022)
†10.1	—	Tax Matters Agreement, dated as of June 2, 2021, by and between Merck & Co., Inc. and Organon & Co. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-40235) filed on June 3, 2021)
10.2	—	Employee Matters Agreement, dated as of June 2, 2021, by and between Merck & Co., Inc. and Organon & Co. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 001-40235) filed on June 3, 2021)
†10.3	—	Transition Services Agreement, dated as of June 2, 2021, by and between Merck & Co., Inc. and Organon & Co. (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K (File No. 001-40235) filed on June 3, 2021)
†10.4	—	Transition Services Agreement, dated as of June 2, 2021, by and between Merck & Co., Inc. and Organon & Co. (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K (File No. 001-40235) filed on June 3, 2021)
10.5	—	Indenture, dated as of April 22, 2021, among Organon Finance 1 LLC, Organon Foreign Debt Co-Issuer B.V., U.S. Bank National Association, as trustee and collateral agent, and Elavon Financial Services DAC, UK Branch, as principal paying agent, transfer agent and registrar, with respect to 2.875% Senior Secured Notes due 2028 (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K (File No. 001-40235) filed on June 3, 2021)
10.6	—	Indenture, dated as of April 22, 2021, among Organon Finance 1 LLC, Organon Foreign Debt Co-Issuer B.V. and U.S. Bank National Association, as trustee and collateral agent, with respect to 4.125% Senior Secured Notes due 2028 (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K (File No. 001-40235) filed on June 3, 2021)
10.7	—	Indenture, dated as of April 22, 2021, among Organon Finance 1 LLC, Organon Foreign Debt Co-Issuer B.V. and U.S. Bank National Association, as trustee, with respect to 5.125% Senior Notes due 2031 (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K (File No. 001-40235) filed on June 3, 2021)
10.8	—	First Supplemental Indenture, dated as of June 2, 2021, among Organon & Co., Organon Foreign Debt Co-Issuer B.V., Organon Finance 1 LLC and U.S. Bank National Association, as trustee and collateral agent, with respect to 2.875% Senior Secured Notes due 2028 (incorporated by reference to Exhibit 10.8 to the Company's Current Report on Form 8-K (File No. 001-40235) filed on June 3, 2021)
10.9	—	First Supplemental Indenture, dated as of June 2, 2021, among Organon & Co., Organon Foreign Debt Co-Issuer B.V., Organon Finance 1 LLC and U.S. Bank National Association, as trustee and collateral agent, with respect to 4.125% Senior Secured Notes due 2028 (incorporated by reference to Exhibit 10.9 to the Company's Current Report on Form 8-K (File No. 001-40235) filed on June 3, 2021)
10.10	—	First Supplemental Indenture, dated as of June 2, 2021, among Organon & Co., Organon Foreign Debt Co-Issuer B.V., Organon Finance 1 LLC and U.S. Bank National Association, as trustee, with respect to 5.125% Senior Notes due 2031 (incorporated by reference to Exhibit 10.10 to the Company's Current Report on Form 8-K (File No. 001-40235) filed on June 3, 2021)

10.11	—	Second Supplemental Indenture, dated as of June 2, 2021, among Organon LLC, Organon Global Inc., Organon Trade LLC, Organon Pharma Holdings LLC, Organon USA LLC, Organon Canada Holdings LLC, Organon & Co., Organon Foreign Debt Co-Issuer B.V. and U.S. Bank National Association, as trustee and collateral agent, with respect to 2.875% Senior Secured Notes due 2028 (incorporated by reference to Exhibit 10.11 to the Company's Current Report on Form 8-K (File No. 001-40235) filed on June 3, 2021)
10.12	—	Second Supplemental Indenture, dated as of June 2, 2021, among Organon LLC, Organon Global Inc., Organon Trade LLC, Organon Pharma Holdings LLC, Organon USA LLC, Organon Canada Holdings LLC, Organon & Co., Organon Foreign Debt Co-Issuer B.V. and U.S. Bank National Association, as trustee and collateral agent, with respect to 4.125% Senior Secured Notes due 2028 (incorporated by reference to Exhibit 10.12 to the Company's Current Report on Form 8-K (File No. 001-40235) filed on June 3, 2021)
10.13	—	Second Supplemental Indenture, dated as of June 2, 2021, among Organon LLC, Organon Global Inc., Organon Trade LLC, Organon Pharma Holdings LLC, Organon USA LLC, Organon Canada Holdings LLC, Organon & Co., Organon Foreign Debt Co-Issuer B.V. and U.S. Bank National Association, as trustee, with respect to 5.125% Senior Notes due 2031 (incorporated by reference to Exhibit 10.13 to the Company's Current Report on Form 8-K (File No. 001-40235) filed on June 3, 2021)
10.14	—	Senior Secured Credit Agreement, dated as of June 2, 2021, by and among Organon & Co., Organon Foreign Debt Co-Issuer B.V., JPMorgan Chase Bank, N.A., as Administrative Agent, Collateral Agent, and the L/C Issuers and Lenders party thereto (incorporated by reference to Exhibit 10.14 to the Company's Current Report on Form 8-K (File No. 001-40235) filed on June 3, 2021)
+10.15	—	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.15 to the Company's Current Report on Form 8-K (File No. 001-40235) filed on June 3, 2021)
+10.16	—	Organon & Co. 2021 Incentive Stock Plan (incorporated by reference to Exhibit 10.16 to the Company's Current Report on Form 8-K (File No. 001-40235) filed on June 3, 2021)
+10.17	—	Organon & Co. Annual Incentive Plan (incorporated by reference to Exhibit 10.17 to the Company's Current Report on Form 8-K (File No. 001-40235) filed on June 3, 2021)
+10.18	—	Organon & Co. Executive Change in Control Severance Program (incorporated by reference to Exhibit 10.18 to the Company's Current Report on Form 8-K (File No. 001-40235) filed on June 3, 2021)
+10.19	—	Organon & Co. Executive Severance Program (incorporated by reference to Exhibit 10.19 to the Company's Current Report on Form 8-K (File No. 001-40235) filed on June 3, 2021)
+10.20	—	Organon Non-Employee Director Savings Plan (incorporated by reference to Exhibit 10.20 to Organon's Quarterly Report on Form 10-Q (File No. 001-40235) filed on November 12, 2021)
+10.21	—	Form of Global Terms for 2021 Restricted Stock Unit Grants Under the Organon & Co. 2021 Incentive Stock Plan (incorporated by reference to Exhibit 10.21 to Organon's Quarterly Report on Form 10-Q (File No. 001-40235) filed November 12, 2021)
+10.22	—	Form of Global Terms for 2021 Performance Share Unit Award Under the Organon & Co. 2021 Incentive Stock Plan (incorporated by reference to Exhibit 10.22 to Organon's Quarterly Report on Form 10-Q (File No. 001-40235) filed November 12, 2021)
+10.23	—	Form of Global Terms for 2021 Non-qualified Stock Option Grants Under the Organon & Co. 2021 Incentive Stock Plan (incorporated by reference to Exhibit 10.23 to Organon's Quarterly Report on Form 10-Q (File No. 001-40235) filed on November 12, 2021
†10.24	—	Development and Commercialization Agreement by and between Samsung Bioepis Co., Ltd., and Merck Sharp & Dohme Corp., dated February 18, 2013 (incorporated by reference to Exhibit 10.4 to Organon's Registration Statement on Form 10 (File No. 001-40235) filed on April 14, 2021)
†10.25	—	Amendment No. 1 to Development and Commercialization Agreement by and between Samsung Bioepis Co., Ltd., and Merck Sharp & Dohme Corp., dated July 21, 2014 (incorporated by reference to Exhibit 10.5 to Organon's Registration Statement on Form 10 (File No. 001-40235) filed on April 14, 2021)
†10.26	—	Amendment No. 2 to Development and Commercialization Agreement by and between Samsung Bioepis Co., Ltd., and Merck Sharp & Dohme Corp., dated August 2, 2017 2014 (incorporated by reference to Exhibit 10.6 to Organon's Registration Statement on Form 10 (File No. 001-40235) filed on April 14, 2021)

10.27	—	Amendment No. 3 to Development and Commercialization Agreement by and between Samsung Bioepis Co., Ltd., and Merck Sharp & Dohme Corp., dated October 1, 2017 (incorporated by reference to Exhibit 10.7 to Organon's Registration Statement on Form 10 (File No. 001-40235) filed on April 14, 2021)
10.28	—	Amendment No. 4 to Development and Commercialization Agreement by and between Samsung Bioepis Co., Ltd., and Merck Sharp & Dohme Corp., dated September 1, 2018 (incorporated by reference to Exhibit 10.8 to Organon's Registration Statement on Form 10 (File No. 001-40235) filed on April 14, 2021)
10.29	—	Amendment No. 5 to Development and Commercialization Agreement by and between Samsung Bioepis Co., Ltd., and Merck Sharp & Dohme Corp., dated October 15, 2018 (incorporated by reference to Exhibit 10.9 to Organon's Registration Statement on Form 10 (File No. 001-40235) filed on April 14, 2021)
†10.30	—	Amendment No. 6 to Development and Commercialization Agreement by and between Samsung Bioepis Co., Ltd., and Merck Sharp & Dohme Corp., dated December 19, 2018 (incorporated by reference to Exhibit 10.10 to Organon's Registration Statement on Form 10 (File No. 001-40235) filed on April 14, 2021)
†10.31	—	Amendment No. 7 to Development and Commercialization Agreement by and between Samsung Bioepis Co., Ltd., and Merck Sharp & Dohme Corp., dated May 15, 2020 (incorporated by reference to Exhibit 10.11 to Organon's Registration Statement on Form 10 (File No. 001-40235) filed on April 14, 2021)
†10.32	—	Specified Technology License Agreement (Nexplanon Rod Technology) by and between Merck Sharp & Dohme B.V. and Merck Sharp & Dohme RT B.V., dated October 28, 2020 (incorporated by reference to Exhibit 10.12 to Organon's Registration Statement on Form 10 (File No. 001-40235) filed on March 17, 2021)
+10.33	—	Letter Agreement between Kevin Ali and Merck & Co., Inc. dated October 14, 2020 (incorporated by reference to Exhibit 10.15 to Organon's Registration Statement on Form 10 (File No. 001-40235) filed on April 29, 2021)
+10.34	—	Letter Agreement between Matthew M. Walsh and Merck Sharp & Dohme Corp. dated March 24, 2020 (incorporated by reference to Exhibit 10.16 to Organon's Registration Statement on Form 10 (File No. 001-40235) filed on April 29, 2021)
10.35	—	Supplemental License Agreement (Nexplanon Rod Technology) by and between Merck Sharp & Dohme B.V. and Merck Sharp & Dohme RT B.V., dated December 13, 2021 (filed on March 21, 2022)
*21.1	—	List of Subsidiaries
*23.1	—	Consent of PricewaterhouseCoopers LLP
*24.1	—	Power of Attorney (included on signature page)
*31.1	—	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer
*31.2	—	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer
**32.1	—	Section 1350 Certification of Chief Executive Officer
**32.2	—	Section 1350 Certification of Chief Financial Officer
101.INS	—	XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	—	XBRL Taxonomy Extension Schema Document.
101.CAL	—	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	—	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	—	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	—	XBRL Taxonomy Extension Presentation Linkbase Document.
104	—	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

+	Management contract or compensatory plan or arrangement.
*	Filed herewith.
**	Furnished herewith.
†	Certain schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant agrees to furnish a copy of any omitted schedule or exhibit to the SEC upon request; provided, however, that the registrant may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act for any document so furnished.

[1] Indicates, in this 2022 Form 10-K, brand names of products, which are not available in the United States.

[2] Indicates, in this 2022 Form 10-K, brand names of products, which are registered trademarks not owned by the Company or its subsidiaries. *Prolia* and *Xgeva* are trademarks registered in the U.S. in the name of Amgen Inc.; *Humira* is a trademark registered in the U.S. in the name of Abbvie Biotechnology Ltd.; *Enbrel* is a trademark registered in the U.S. in the name of Immunex Corporation; *Remicade* is a trademark registered in the U.S. in the name of Janssen Biotech, Inc.; *Avastin, Perjeta* and *Herceptin* are trademarks registered in the U.S. in the name of Genentech, Inc.; *Yervoy* is a trademark registered in the U.S. in the name of Bristol-Myers Squibb Company; *Clarinex* is a trademark registered in the U.S. in the name of Bayer Healthcare LLC (used under license); and *Vioxx* is a trademark registered in the name of Merck in several countries. Brand names of products that are in all italicized letter, without the footnote, are registered trademarks of Organon and/or one of its subsidiaries.

Item 16. Form 10-K Summary

None.

Signatures

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ORGANON & CO.

Date: February 27, 2023

/s/ Matthew Walsh
Matthew Walsh
Chief Financial Officer

We, the undersigned directors and officers of Organon, hereby severally constitute Kevin Ali and Matthew Walsh, and each of them singly, our true and lawful attorneys with full power to them and each of them to sign for us, in our names in the capacities indicated below, any and all amendments to this Annual Report on Form 10-K filed with the Securities and Exchange Commission.

Pursuant to the requirements of the Securities and Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

SIGNATURE		TITLE		DATE
/s/ Kevin Ali		Chief Executive Officer and Director		February 27, 2023
/s/ Matthew Walsh		Chief Financial Officer		February 27, 2023
/s/ Kathryn DiMarco		SVP Finance – Corporate Controller		February 27, 2023
/s/ Carrie Cox		Chairman of the Board of Directors		February 27, 2023
/s/ Robert Essner		Director		February 27, 2023
/s/ Alan Ezekowitz		Director		February 27, 2023
/s/ Ma Fatima de Vera Francisco		Director		February 27, 2023
/s/ Helene Gayle		Director		February 27, 2023
/s/ Rochelle Lazarus		Director		February 27, 2023
/s/ Deborah Leone		Director		February 27, 2023
/s/ Martha McGarry		Director		February 27, 2023
/s/ Philip Ozuah		Director		February 27, 2023
/s/ Cynthia Patton		Director		February 27, 2023
/s/ Grace Puma		Director		February 27, 2023
/s/ Shalini Sharp		Director		February 27, 2023