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, 2023

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, 2023, was $5.3 billion.
The number of shares of Common Stock outstanding as of the close of business on February 20, 2024: 255,638,256

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III will be incorporated by reference from the Registrant's definitive proxy statement for its 2024 Annual Meeting of Stockholders (the "2024 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.

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The following notations in this Annual Report on Form 10-K (this "2023 Form 10-K") have the meanings as set forth below:

[1] Indicates, in this 2023 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 2023 Form 10-K.

PART I
Item 1. Business

Overview

Organon & Co. ("Organon," the "Company," "we," "our," or "us") is a global health care company with a focus on improving the health of women throughout their lives. We develop and deliver innovative health solutions through a portfolio of prescription therapies and medical devices within women's health, biosimilars and established brands. We have a portfolio of more than 60 medicines and products across a range of therapeutic areas. We sell 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. We operate 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.

Our operations include the following product portfolios:

- *Women's Health*: Our 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*™ 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) (marketed in most countries outside the United States as *Puregon*™). *Nexplanon* is a long-acting reversible contraceptive, and is in 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. Our other women's health products include the *Jada*® System, which is intended to provide control and treatment of abnormal postpartum uterine bleeding or hemorrhage when conservative management is warranted, and 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. In October 2023, we launched *Xaciato* in the United States.

- *Biosimilars*: Our current portfolio spans across immunology and oncology treatments. Our oncology biosimilars; *Ontruzant*® (trastuzumab-dttb) and *Aybintio*™ [1] (bevacizumab), have been launched in more than 20 countries and our immunology biosimilars; *Brenzys*™ [1] (etarnarcept), *Renflexis*® (infliximab-abda) and *Hadlima*® (adalimumab-bwwd), have been launched in five countries. All five biosimilars in our portfolio have launched in Canada, and three biosimilars; *Ontruzant*, *Renflexis* and *Hadlima* have been launched in the United States.

- *Established Brands*: We have 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 our established brands lost exclusivity years ago and have faced generic competition for some time.

Led by the women's health portfolio, coupled with an expanding biosimilars business and stable franchise of established medicines, our products produce sufficient cash flows to support investments in innovation and future growth opportunities in women's health. In addition, we are pursuing opportunities to collaborate with biopharmaceutical innovators looking to commercialize their products by leveraging our scale and presence in fast growing international markets.

We have expanded our product portfolios through the following 2023 acquisitions and licenses:

- In December 2023, we announced an agreement with Lilly to become the sole distributor and promoter for the migraine medicines *Emgality*® [2] (galcanezumab) and *Rayvow*™ [2] (lasmiditan) in Europe.

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

Products

We are engaged in both developing and delivering innovative health solutions through a diverse portfolio of products. These products serve 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. Our sales for each of our product groups are as follows:

	Year Ended December 31,		
($ in millions)	**2023**	**2022**	**2021**
Women's Health	$ 1,702	$ 1,673	$ 1,612
Biosimilars	593	481	424
Established Brands	3,847	3,874	4,068

In 2023, we recorded revenues of $6.3 billion. We operate on a global scale and our global network enables us to distribute products to patients in more than 140 countries and territories, with approximately 76% of 2023 revenues, or $4.8 billion, generated outside the United States.

The following highlights key products in our portfolios:

Women's Health

Nexplanon (etonogestrel implant) 68mg Radiopaque

NUVARING (etonogestrel/ethinyl estradiol vaginal ring)

Follistim AQ Cartridge (follitropin beta injection) For use only with Follistim Pen

elonva corifolitropina alfa

Jada System

Biosimilars

RENFLEXIS (infliximab-abda) for injection, for intravenous use 100 mg

BRENZYS etanercept

Ontruzant trastuzumab

Aybintio bevacizumab

HADLIMA adalimumab

Established Brands

Zetia (ezetimibe) 10 mg Tablets

SINGULAIR (MONTELUKAST SODIUM)

Propecia (finasteride)

HYZAAR

Atozet (ezetimibe and atorvastatin, MSD)

NASONEX (mometasone furoate monohydrate) Nasal Spray, 50 mcg*

Women's Health Portfolio

In 2023, our women's health portfolio accounted for $1.7 billion, or approximately 27%, of our total revenues, with $805 million, or approximately 47%, generated outside the United States. Our 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*™ [1] *(corifolitropina alfa)*. Additionally, we continue to assess commercialization opportunities in conditions that are either unique to women or disproportionally affect women, such as *Jada,* acquired as a part of our acquisition of Alydia Health and the licensing agreement with Daré for global commercial rights to *Xaciato*. Our 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

Our 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. The product lasts 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 that is pre-loaded into an applicator. It is typically prescribed to 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,* are typically used by women who want hormonal contraception but for whom estrogen-containing contraceptives may not be medically appropriate. *Cerazette* 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, and are 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 in China and Vietnam as a result of the transaction with Bayer Healthcare in which we gained rights to *Marvelon* and *Mercilon* in these markets.

Fertility

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

Follistim AQ, which is marketed as *Puregon* 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 procedures include 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 is 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*™) is an injectable ("GnRH") antagonist. Ganirelix acetate injection is used in fertility treatments in combination with FSH.

Postpartum Hemorrhage

We acquired *Jada* as part of our 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 this version of the device officially launched in February 2022.

Jada is currently available in nine markets outside of the United States (Hong Kong, Chile, New Zealand, Singapore, United Arab Emirates, Qatar, Bahrain, Oman and most recently, Brazil). We continue to work with health authorities to gain marketing authorization for *Jada* globally. We anticipate receiving additional approvals throughout Asia, Middle East, Latin America, Europe, and Canada in 2024.

Bacterial Vaginosis

In March 2022, we 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 Qualified Infectious Disease Product ("QIDP") and Fast Track designations from the FDA for the treatment of BV.

We launched *Xaciato* in the United States in the fourth quarter of 2023, and currently plan to assess opportunities to seek potential further marketing authorizations for countries outside the United States.

Biosimilars Portfolio

In 2023, our biosimilars portfolio accounted for $593 million, or approximately 9%, of our total revenues, with $295 million, or approximately 50%, generated outside the United States. The assets in our biosimilars portfolio, coupled with our commercial experience in biosimilars, provide an opportunity to benefit from future growth anticipated in this area.

Our Biosimilars Products

Our biosimilars portfolio consists of therapies in immunology and oncology for which we have worldwide commercialization rights with certain geographic exceptions specified on a product-by-product basis. Such exceptions are governed by agreements that we entered into with Samsung Bioepis and Shanghai Henlius Biotech, Inc. ("Henlius"). The marketed portfolio consists of three immunology products, *Hadlima* (Originator brand name: *Humira*®; generic name: adalimumab), *Brenzys* (Originator brand name: *Enbrel*®; generic name: etanercept), and *Renflexis* (Originator brand name: *Remicade*®; generic name: infliximab). The marketed portfolio also consists of two oncology products, *Ontruzant* (Originator brand name: *Herceptin*®; generic name: trastuzumab) and *Aybintio* (Originator brand name: *Avastin*®; generic name: bevacizumab).

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, plaque psoriasis, suppurativa and uveitis. We have worldwide commercialization rights to *Hadlima* in countries outside 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 July 2023. *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*. In November 2023, the FDA accepted for review the Supplemental Biologics License Application (sBLA) for the interchangeability designation for *Hadlima*.

Brenzys (SB4)

Brenzys (etanercept) is a TNF antagonist biosimilar to Amgen / Pfizer's *Enbrel* (etanercept) product. It is approved for use in certain patients for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and plaque psoriasis. We have 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. It is 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. We have worldwide commercialization rights to *Renflexis* in countries outside the EU, Korea, China, Turkey and Russia. 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 and Canada 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. We have commercialization rights to *Aybintio* in the United States, Canada, Germany, Italy, France, the UK and Spain. We are seeking approval of *Aybintio* in the United States, however, the timing of any such approval is not yet 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, thereby allowing us to launch *Ontruzant* worldwide. We have 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. Our established brands portfolio contributed approximately $3.8 billion of our total revenues in 2023, with approximately 93%, or $3.6 billion, generated outside the United States. Generic competition varies significantly across geographies.

<u>*Cardiovascular*</u>

In 2023, our cardiovascular portfolio accounted for $1.5 billion, or approximately 23%, of our total revenues, nearly all of which were generated outside the United States.

Our cardiovascular portfolio consists of several cholesterol-modifying medicines, including: *Zetia*® (ezetimibe), which is marketed as *Ezetrol*™ in most countries outside the United States; *Vytorin*® (ezetimibe / simvastatin), which is marketed as *Inegy*™ 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. Our cardiovascular portfolio also includes *Cozaar*® (losartan) and *Hyzaar*® (losartan / hydrochlorothiazide), which are cardiovascular drugs for the treatment of hypertension.

<u>*Respiratory*</u>

In 2023, our respiratory portfolio accounted for $1.1 billion, or approximately 17% of our total revenues, with approximately 79%, or $843 million, generated outside the United States.

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

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

Dermatology, Bone Health and Non-Opioid Pain Management

In 2023, our dermatology, bone health and non-opioid pain management portfolios accounted for $782 million, or approximately 12%, of our total revenues, nearly all of which were generated outside the United States.

- Our 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.
- Our 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.
- Our 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 our other mature products, some of which remain significant to our 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 $97 million of revenues in 2023. In addition, *Propecia*, used for the treatment of male pattern hair loss, accounted for $125 million of revenues in 2023. Nearly all sales of *Proscar* and *Propecia* were generated outside the United States.

Research and Development

As part of our growth strategy, we seek to continue to identify scientific collaborations and acquisitions to further build and maintain an industry leading pipeline across Women's Health with both early- and late-stage assets that enables scientific and commercial leadership and continue to solidify our position as a Women's Health partner of choice. Our 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, 2023, we have licenses to commercialize the following development stage products:

- An investigational non-hormonal, on-demand contraceptive candidate. We have entered into a research collaboration and exclusive license agreement with Cirqle Biomedical ("Cirqle") 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. We obtained exclusive worldwide rights to develop and commercialize the product.

- HLX14, a biosimilar candidate to Amgen's *Prolia*[2]*/Xgeva*[2] (denosumab), is a recombinant anti-RANKL human monoclonal antibody, *Prolia* is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, and *Xgeva* is indicated for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors. We have worldwide commercialization rights to HXL14 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 us.

- HLX11, a biosimilar candidate to Roche's *Perjeta*[2] (pertuzumab), is an anti-HER2 domain II humanized monoclonal antibody. Pertuzumab, in combinations with trastuzumab and chemotherapy, is used for the treatment of certain patients with HER2+ breast cancer. We have 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 us.

- 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. The condition causes abdominal pain and is associated with infertility.

- 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 us.

We rely on internal scientific expertise and close collaborations with partners, and expect to advance product development opportunities, data generation, product registration, and licensing on a global scale.

Sales, Marketing and Distribution Capabilities

Sales and Marketing

We have approximately 4,000 employees worldwide focused on commercialization activities, such as marketing, direct sales, digital and omni-channel and insight generation, covering data stewardship, data analytics and data science. We have a global team of experienced marketers, pricing and access professionals, and data scientists. We believe our commercialization capabilities allow us to execute customer engagement strategies optimized across preferred channels and aimed at health care providers, patients and payors. Our 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 our websites. In addition, we believe we have the knowledge, capabilities, and resources to achieve optimal local market access for our portfolio in a changing external environment.

We have a trade channel strategy that provides a robust capability framework for our activities, including the selection of channel partners, commercial terms and supportive health care services that promote the efficient, safe and cost-effective delivery of our products. We have 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 our trade partners.

We do not have any single customer that, if such customer were lost, would have a material adverse effect on our business.

Distribution

Our global network enables us to distribute products directly and indirectly to patients in more than 140 countries and territories, including through our regional distribution centers. We sell our 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. We also sell our pharmaceutical products through third-party distributors and agents for smaller markets. Our professional representatives communicate the effectiveness, safety and value of our pharmaceutical products to health care professionals in private practice, group practices, hospitals and managed care organizations.

Manufacturing Capabilities and Global Supply Chain

We have high quality manufacturing capabilities, including development and improvement of manufacturing processes. Our 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

We own and operate six manufacturing sites, as shown in the table below, where we manufacture 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 our internal manufacturing sites have long-standing, deep technical capabilities across the broad base of manufacturing platforms that are required to support our product portfolio. We also manufacture a range of Merck & Co., Inc. ("Merck") products at each of our six manufacturing sites pursuant to agreements with Merck entered into at the time of our 2021 spinoff from Merck (the "spinoff").

Global Supply Chain

We manage our global supply chain through a centralized supply planning organization and regional demand management, with distribution and logistics teams structured around North America, Europe, Middle East and Africa, Asia-Pacific and Latin America. We purchase certain raw materials, active pharmaceutical ingredients, components, devices and other supplies necessary for the commercial production of our products from a variety of third-party suppliers. We utilize third-party contract manufacturers for packaging, formulation and fill-and-finish for our products, as well as a combination of logistics service providers as part of our global supply chain, primarily for storage and for shipping.

A number of our materials and components are sole-sourced. Certain of these sole-sourced materials are critical to our key products, including women's health and established brands. In particular, we rely heavily on one supplier for formulation and/or packaging as our gateway to sales in both Japan and China.

To mitigate supply risk, we maintain a conservative inventory posture and keeps an internal function focused on maintaining an external manufacturing network with operational, quality, technology and procurement capabilities. Our manufacturing network and supply chains are designed to provide us with a flexible and scalable global platform for continued expansion, including in emerging markets.

Quality Management

Our facilities and supporting functions, along with our external contractors, suppliers, and partners, make up an integrated, interdependent global network. This network is dedicated to consistently delivering compliant, reliable product supply to health care providers and patients. We have one quality management system deployed globally that enables the development, manufacturing, packaging, labeling, handling, and distribution of our products, such that they conform to applicable regulatory requirements in every country we serve. Our 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

Our human resources organization is led by an experienced team that monitors our employee base and sets annual targets for managing our human capital. These include employee retention, engagement, and training targets. The talent committee of our Board regularly reviews and discusses our diversity, inclusion and leadership development initiatives, objectives, and progress with management.

We have established benefit and incentive compensation plans, including comprehensive medical and life insurance coverage, 401(k) matching programs and other incentive compensation programs that we believe aligns employee incentives directly with our future performance.

As of December 31, 2023, we had approximately 10,000 employees worldwide with approximately 1,700 (16%) employees in the United States (including Puerto Rico). Approximately 85% of our employees work in key functional areas (Commercial, Research & Development, and Manufacturing/Supply) and 15% are in support functions. We have approximately 4,000 employees worldwide focused on commercialization activities, such as marketing, direct sales, digital and omni-channel and insight generation, covering data stewardship, data analytics and data science. Approximately 900 employees are focused on clinical development, safety, and medical affairs and product registration.

We strive to build a strong culture with inclusion and belonging at our core, believing that this is fundamental to success and future innovation. More than 30% of our employees in the United States identify as part of an underrepresented ethnic group. We support our workforce through innovative talent and performance programs and has additionally founded ten Employee Resource Groups. We also regularly assesses our employees' experience, including measures of engagement, well-being, inclusion, and core cultural values through annual surveys and regular check-ins.

Our employees are at the core of our mission to improve the health of women and, given our global nature, we have a strong focus on female representation. Globally, over 50% of our employees are female, and women comprise approximately 60% of our senior leadership (nearly 75% of our Board of Directors; 40% of our Executive Committee).

Intellectual Property

Patents, Trademarks and Licenses

Patent protection is important to the marketing of certain of our products in the United States and in most major international 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, we consider the patents that cover the rod technology in *Nexplanon* to be material to our 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 material contested proceedings or third-party claims that involve these patents. We have 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. In December 2021, we also 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, for example: (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; and (iii) patents relating to novel compositions and formulations. In addition, in the United States and certain other countries, an additional period of market or data exclusivity that may be available under relevant law. For example, *Nexplanon* may be eligible for an additional three years of market exclusivity on the five-year efficacy indication in the United States from the of FDA approval of this indication. 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 our patents, see the sections entitled "Risk Factors" and Note 20 "Contingencies—Patent Litigation" to the Financial Statements included in this report.

Worldwide, all of our 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 2023 on patent and know-how licenses and other rights amounted to $6 million. We also incurred royalty expenses totaling $6 million in 2023 under patent and know-how licenses we hold.

Privacy and Data Protection

We are subject to a significant number of privacy and data protection laws and regulations globally, many of which place restrictions on our ability to transfer, access and use personal data across our business. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there are privacy and data protection frameworks with the potential to directly affect our 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, and China's Personal Information Protection Law ("PIPL"), which came into effect November 1, 2021. The data protection regulatory environment in China has been evolving quickly, including regulations regarding cross-border transfers of personal data (CBDT). These laws regulate the processing of personal information and increase the obligations of companies to protect and safeguard information. Certain of these regulations also require organizations to evaluate cross-border transfers of personal information and may require localization of certain data if specific conditions are met.

Additional laws and regulations continue to be adopted in various jurisdictions. These include: the California Consumer Privacy Act, the California Privacy Rights Act, Virginia's Consumer Data Protection Act, Colorado's Privacy Act, and the United Arab Emirates' Protection of Personal Data Protection. These changing requirements could cause us to incur substantial costs or require us to change our business practices or compliance procedures in a manner adverse to our business.

Competition

We conduct our business in highly competitive markets which mirror the equally competitive pharmaceutical industry. Our competitors include other worldwide research-based pharmaceutical companies, smaller research companies with more limited therapeutic focus and generic drug manufacturers. Our operations may be adversely affected by generic and biosimilar competition as our 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 continue to intensify as the industry grows.

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. We plan to continue to acquire and market products through external alliances, such as licensing arrangements and collaborations, and have designed our sales and marketing efforts to address changing industry conditions.

In the United States private sector, consolidation and integration among health care providers is a major factor in the competitive pharmaceutical products marketplace. Private third-party insurers, as well as federal and state governments, employ formularies to control costs by negotiating discounted prices in exchange for formulary inclusion. 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 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 further concentrates, 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 international importation of medicines, may be considered.

We face increasing pricing pressure globally from managed care organizations and government agencies and programs. This pricing pressure could negatively affect our sales and profit margins. In the United States, these concerns include: (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.

United States

In the United States, we are impacted by expanded Medicaid rebates, Medicaid-managed care utilization, and increases in the types of entities eligible for the federal 340B drug discount program. These programs require pharmaceutical manufacturers to pay a percentage 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") until January 1, 2025. Pharmaceutical manufacturers must pay a percentage of the negotiated price of branded pharmaceuticals, biologics and biosimilar products, when Medicare Part D beneficiaries are in the initial coverage phase, and another percentage of the negotiated price in the catastrophic phase of Medicare Part D coverage. Increases in these percentages or changes in the timing of their implementation could increase our cost-sharing responsibility for any approved product. We recorded approximately $15 million, $16 million and $17 million revenue reduction in 2023, 2022 and 2021, respectively. This reduction was related to the coverage gap or "donut hole" provision. We recorded approximately $3 million, $3 million and $10 million of costs within selling, general and administrative expenses in 2023, 2022 and 2021, respectively, for the annual health care reform fee. In the future, our drugs could be subject to a higher Medicaid rebate liability.

We may also be affected by developments relating to the federal 340B drug discount program. In June 2023, we implemented a policy to reduce diversion and inappropriate claims for discounts and rebates by contract pharmacies that were affiliated with 340B-eligible entities. Multiple manufacturers have adopted similar policies, and the Department of Health and Human Services has sent several of these manufacturers letters claiming that the policies violate the 340B statute and referring the manufacturers for potential enforcement action. Certain drug manufacturers challenged these letters in federal court. The U.S. Court of Appeals for the Third Circuit recently ruled in favor of several manufacturers. To date, other challenges are still pending. We believe that our policy complies with the 340B statute. At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing.

European Union

Pricing and reimbursement of medicinal products are not harmonized at the EU level, but rather controlled by individual EU Member States. These Member States have attempted to contain drug costs by engaging in reference pricing. Reference pricing allows authorities to examine pre-determined markets for published prices of drugs. The downward pressure on health care costs in general, particularly prescription drugs, has intensified. As a result, manufacturers are erecting increasingly high entry barriers to new products. Additionally, EU Member States have the power to restrict the range of pharmaceutical products for which their national health insurance systems provide reimbursement. To obtain reimbursement or pricing approval in some EU Member States, we may be required to conduct studies that compare the cost-effectiveness of our 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 our products, or that it will be feasible to conduct additional cost-effectiveness studies, if required.

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

Our business in China has grown rapidly in the past few years, and the importance of China to our overall pharmaceutical business has increased accordingly. Continued growth of our business in China depends upon ongoing development of a favorable environment for innovative pharmaceutical products, sustained access for our 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. The Chinese government updated the National Reimbursement Drug List ("NRDL") for the government-administered insurance plans; however, every two years regular access to the NRDL is coupled with significant price reductions and 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"). The Chinese VBP program operates 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 nine rounds of VBP have had, on average, a price reduction of over 50%. VBP

has been a roughly semi-annual process that will have a significant impact on mature products moving forward, which we expect to increase pricing pressure on our products in China. There are 374 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, multiple Chinese provinces are piloting a Universal Reimbursement Payment Standard ("URPS") program in their respective provinces. Under the URPS, the government may determine the reimbursement prices by referring to the prices of the lowest-priced VBP winning products, with any remaining costs 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 our business and results of operations.

In July 2023, the Chinese government began an industry-wide anti-corruption campaign that increased scrutiny on the health care industry. The campaign caused disruptions to academic activities across the health care industry, which negatively affected our business in late 2023. We believe that the health care industry will continue to be subject to increasing scrutiny in the China market.

Other Markets

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. We anticipate that pricing pressures and market access challenges will continue in the future to varying degrees in such markets.

In addressing cost containment pressures, we engage in public policy advocacy with policymakers and continues to work to demonstrate that our medicines provide value to patients and to those who pay for health care. We advocate 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, we encourage those governments to increase their investments and adopt market reforms to improve their citizens' access to appropriate health care, including medicines.

Regulation of Our Products

The pharmaceutical and medical device industries are also subject to regulation by regional, country, state and local authorities around the world, focused on standards and processes for determining drug and device safety and effectiveness, as well as conditions for sale or reimbursement. In the United States, the FDA administers requirements covering the testing, approval, safety, effectiveness, manufacturing, labeling and marketing of pharmaceuticals and medical devices.

The EU has also 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.

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, which can be a phased process. As a manufacturer and distributor of drug products, our activities are regulated under various federal and state statutes and state manufacturer and wholesaler laws. Manufacturers and distributors of controlled substances must also 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.

The FDA imposes medical device regulations that govern requirements for design, development, testing, manufacturing, labeling, clinical trials, and pre-market clearance and approval, among other requirements. 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 practices. Although physicians are permitted to use their medical judgment to use medical devices for indications other than those cleared or approved by the FDA, we may not promote our products for such "off-label" uses and can only market our products for cleared or approved uses.

Before our pharmaceutical products can be marketed outside the United States, they are also subject to regulatory approvals in those countries. Each country has a separate and independent review process and timeline, which varies significantly between jurisdictions. In certain countries, the sales price of a product must also be approved by the applicable regulator.

Failure by us or by any of our third-party partners, including suppliers, manufacturers and distributors, to comply with laws 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.

We and our 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 regulatory authorities. Companies may be subject to civil, criminal or administrative sanctions if they fail to comply with these practices.

The advertising and promotion of our products are also subject to laws, rules, regulations, 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.

Climate and Environmental Matters

We believe that climate change will present some degree of risk to our business. Some of the potential effects of climate change to our business could include increased operating costs due to additional regulatory requirements, changes in supply and suppliers due to regulatory requirements, physical risks to our facilities, water limitations and disruptions to our supply chain. Some potential risks are integrated into our business planning, including investment in reducing energy, water use and greenhouse gas emissions. We do not believe these potential risks are material to our business at this time.

We are not aware of any compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on our business. Expenditures for remediation and environmental liabilities are estimated to be approximately $15 million in the aggregate for the years 2024 through 2028. For additional information, please see "Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Estimates" and Note 20 "Contingencies —Environmental Matters" to the Financial Statements included in this report. Notwithstanding the foregoing, various legislation, regulations and international accords pertaining to climate change have been implemented or are being considered for implementation, particularly as they relate to the reduction of greenhouse gas emissions, such as the EU's Corporate Sustainability Reporting Directive ("CSRD"), California's Climate Corporate Data Accountability Act and Climate Related Financial Risk Act, and similar regulations under consideration by the SEC.

Third-Party Agreements

Samsung Bioepis Development and Commercialization Agreement

Merck had a development and commercialization agreement with Samsung Bioepis (as subsequently amended, the "Samsung Bioepis Agreement") for which all of the rights and obligations of Merck were transferred to us in connection with the spinoff. The Samsung Bioepis Agreement grants us 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—Biosimilars Portfolio" for a description of each product and the geographic areas in which we have 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. Our 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. We may terminate the agreement with respect to a particular region or product if a product fails to meet certain milestones in such region. We 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. We 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 our 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 us. 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, 2023, 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 18 "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.

Henlius

In June 2022, we entered into an exclusive license agreement with Henlius, whereby we received worldwide commercialization rights in countries except for China (including Hong Kong, Macau and Taiwan) for biosimilar candidates (i) HLX11, referencing *Perjeta*, used for the treatment of certain patients with HER2+ breast cancer in combinations with trastuzumab and chemotherapy, and (ii) HLX14, referencing *Prolia*/*Xgeva*, used for the treatment of post-menopausal women with osteoporosis at high risk for fracture and for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastasis from solid tumors.

Additional Information

We are a Delaware corporation incorporated on March 11, 2020, and was spun off from Merck in 2021. Our corporate offices are located at 30 Hudson Street, 33rd Floor, Jersey City, New Jersey 07302.

We file 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. We maintain an investor relations page on our website (*www.organon.com*) where such filings made pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (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. Our website address is not intended to function as a hyperlink and the information contained on our 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 us and deciding to invest in our Common Stock. Any of the following risks could materially and adversely affect our results of operations, financial condition and the price of our Common Stock.

Summary of Risk Factors

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

Risks Related to Our Business

- Key products generate a significant amount of our profits and cash flows, and any events that adversely affect the markets for our leading products could adversely affect our results of operations and financial condition.
- We face continued pricing pressure with respect to our products.

- We face intense competition from competitors' products.
- We have limited in-house discovery and early research capabilities and will continue to rely on future acquisitions, partnerships and collaborations to expand our innovative pipeline and early discovery and research capabilities, which may limit our ability to discover or develop new products or expand our existing products into new markets to replace the sales of products that lose patent protection and therefore we may not be able to maintain our current levels of profitability.
- Our growth could be limited by the scope of our intellectual property licenses for certain women's health care products.
- We may experience difficulties identifying acquisition opportunities or completing such transactions.
- We or our partners may fail to demonstrate the safety and efficacy of any of our product candidates in pre-clinical and clinical trials, which would prevent or delay development, regulatory approval or clearance, and commercialization of our product candidates.
- We may be unable to market our pharmaceutical products or medical devices if we do not obtain and maintain required regulatory approvals or marketing authorizations.
- Developments following regulatory approval or marketing authorization may adversely affect sales of our pharmaceutical products or medical devices.
- Issues with product quality could have an adverse effect on our business or cause a loss of customer confidence in us or our products, among other negative consequences.
- Certain of our products currently benefit from patent protection and market exclusivity. When the patent protection and market exclusivity periods for such products expire, a significant and rapid loss of sales from those products is generally experienced. Expiry of patent protection and market exclusivity for products that contribute significantly to our sales will adversely affect our business.
- We depend on our patent rights for the marketing of certain of our products, and invalidation or circumvention of our patent rights would adversely affect our business.
- We have incurred substantial indebtedness, which could adversely affect our financial condition and results of operations.
- We are subject to minimum purchase obligations under certain supply agreements, and if we fail to meet those minimum purchase requirements, our financial results may be unfavorably impacted.

Risks Related to the Spinoff

- Merck may not satisfy its obligations under various transition agreements that have been or will be executed as part of the spinoff or we may not have necessary systems and services in place when certain of the transition agreements expire.
- Potential indemnification liabilities to Merck pursuant to the Separation and Distribution Agreement could adversely affect us.
- There could be significant income tax liability to us if the spinoff or certain related transactions are determined to be taxable for U.S. federal income tax purposes.

Risks Related to Our Common Stock

- The price and trading volume of our Common Stock may be volatile, and stockholders could lose all or part of their investment.
- We cannot guarantee the timing, amount or payment of any dividends on our Common Stock.
- Certain provisions in our amended and restated certificate of incorporation and bylaws, and of Delaware law, may prevent or delay an acquisition of Organon, which could decrease the trading price of our Common Stock.
- Our amended and restated bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, and the United States federal district courts as the exclusive forum for claims under the Securities Act of 1933, as amended (the "Securities Act"), which could limit our stockholders' ability to obtain what such stockholders believe to be a favorable judicial forum for disputes with us or our directors, officers or employees.

Risks Related to Our Business

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

Our ability to generate profits and operating cash flow depends largely upon the continued profitability of our key products, such as *Nexplanon*, *Cozaar*/*Hyzaar*, *Singulair* and the ezetimibe family of products. As a result of our dependence on key products, any event that adversely affects any of these products or the markets for any of these products could adversely affect our sales, results of operations or cash flows. These adverse events could include increased costs associated with manufacturing, product shortages, increased generic or over-the-counter availability of our products or competitive products, the discovery of previously unknown side effects, results of post-approval trials, increased competition from the introduction of new, more effective treatments and discontinuation or removal from the market of these products for any reason. We also expect that competition will continue to adversely affect the sales of these products.

We face continued pricing pressure with respect to our products.

We face continued pricing pressure in the United States and globally and, particularly in the EU, the UK, China and Japan, from managed care organizations, government agencies and programs that could adversely affect our sales and profit margins. We expect pricing pressure to continue in the future.

Changes to the health care system enacted as part of health care reform in the United States, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, could result in further pricing pressures.

In addition, in the United States, larger customers have received higher rebates on drugs in certain highly competitive categories. We must also compete to be placed on formularies of managed care organizations and other payors. Exclusion of a product from a formulary can lead to reduced usage in the population covered by the managed care organization or other payor. Outside the United States, numerous major markets, including 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, we are subject to government decision-making and budgetary actions with respect to our products. Cost containment efforts by governments and private organizations are described in greater detail in the Business-Regulatory section above.

We face intense competition from competitors' products.

Our products face intense competition from competitors' products, including lower cost generic versions of our products that have lost market exclusivity. Competitors' products may be equally safe and as effective as our products but sold at a substantially lower price than our products. Alternatively, our competitors' products may be safer or more effective, more convenient to use, have better insurance coverage or reimbursement levels or be more effectively marketed and sold than our products. Our efforts to compete with other companies or our failure to maintain our competitive position could adversely affect our business, cash flow, results of operations, financial condition or prospects.

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

We have limited in-house discovery and early research staff and facilities, and we do not currently intend to extensively hire or acquire such staff or facilities in the near future. Instead, we intend to continue to rely on future acquisitions, partnerships and collaborations with third parties to expand our innovative pipeline, existing portfolio and innovation and early research capabilities. However, we may be unable to establish any agreements with third-party developers or manufacturers or do so on favorable terms. Further, should we be able to enter into such agreements, these agreements may pose risks, including that we would be reliant on and accountable for the third-party's knowledge and capabilities, data, quality of operations and compliance to regulations, and other systems to conduct clinical trials, prepare regulatory application submissions and required post-approval reports, manufacture or distribute product, or other activities.

Our growth could be limited by the scope of our intellectual property licenses for certain women's health care products.

We intend to grow our business through new indications or formulations of our existing products or expansion of existing products into new markets or new geographies. However, we expect that our ability to do so could be limited by the scope of our limited intellectual property licenses for certain women's health products. For example, a license from Merck for *Nexplanon* permits use of the underlying technology solely as a contraceptive implant containing only the active pharmaceutical ingredient currently used in the product. Additionally, in December 2021, we signed a supplemental license with Merck that provides a limited expansion of the fields in which we may use the underlying technology of *Nexplanon* beyond contraception in exchange for milestone payments. We may not be able to offset any sales losses for products that lose or do not have exclusivity by growing sales in other markets. If we cannot produce sufficient revenues from expansion into new products, new indications or formulations of our existing products or expansion of existing products into new markets or new geographies, then we may not be able to maintain our current levels of profitability, and this could adversely affect our business, cash flow, results of operations, financial condition or prospects.

We rely on third parties for activities related to preclinical and clinical testing.

We rely on third parties to manufacture and distribute and conduct certain preclinical and clinical testing activities for our products. Oversight of these third parties can require substantial resources and creates potential risks to us, including: we may be unable to establish agreements with third parties, including third party manufacturers, on acceptable terms or even at all; we may not have sufficient quantities of product; third parties may fail to perform delegated responsibilities to an acceptable level of quality, or may fail to comply with regulatory requirements; or third parties may misappropriate or disclose our proprietary information, including trade secrets and know-how. Our reliance on third parties for research and development activities will also reduce our control over these activities but does not relieve us of our responsibilities, including that we must ensure that clinical trials are conducted in accordance with the general investigational plan and protocols for the trial; ensure compliance with regulatory standards like good clinical practices; and register ongoing clinical trials and results to government-sponsored databases. Our failures, or the failure of third parties, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions. Further, issues related to manufacture of product, preclinical testing, and/or clinical testing may affect our ability to obtain or maintain marketing approval for our products in a timely manner, or at all. This may hinder or delay efforts to successfully commercialize our product candidates.

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

We intend to continue pursuing acquisitions of complementary businesses, licensing arrangements and strategic partnerships to expand our product offerings and geographic presence as part of our business strategy. We may not complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the expected benefits of any acquisition, license arrangement or strategic partnerships. Such opportunities may relate to products, technologies or operations with which we have limited or no historical experience. Many of our competitors for these opportunities are well established and have extensive experience identifying and effecting these types of strategic acquisitions. Moreover, some of these competitors may possess greater financial, technical, human and other resources than we do. Even if we are successful in making acquisitions, the products and technologies we acquire may not be successful or may require significantly greater resources and investments than we originally anticipated. We could experience negative effects on our results of operations and financial condition from acquisition-related charges, amortization of intangible assets and asset impairment charges. We could experience difficulties in integrating geographically separated organizations, systems and facilities, and personnel with diverse backgrounds. If an acquired business fails to operate as anticipated or cannot be successfully integrated with our existing business, our business, financial condition, results of operations or cash flows could be materially and adversely affected.

We may be unable to market our pharmaceutical products or medical devices if we do not obtain and maintain required regulatory approvals or marketing authorizations.

Our activities, including the manufacturing and marketing of our pharmaceutical products and medical devices, are subject to extensive regulation by numerous federal, state and local / provincial state governmental authorities in the United States, including the FDA, and by foreign regulatory authorities, including in the EU, the UK, China and Japan. In the United States, the FDA administers requirements covering the laboratory testing, clinical trials, clearance, approval, safety, effectiveness, manufacturing, labeling and marketing of prescription pharmaceuticals and medical devices. Regulation of our pharmaceutical products outside the United States also is primarily focused on drug safety and effectiveness and, in many cases, reduction in the cost of drugs. In addition, regulatory authorities in the United States and internationally have increased their focus on safety when assessing the benefit/risk balance of drugs. These regulatory authorities, including in China and Japan, also have substantial discretion to require additional testing in local populations, to delay or withhold registration and marketing approval

and to otherwise preclude distribution and sale of a product. We currently market one product in the United States regulated as a medical device, Jada (acquired through our acquisition of Alydia Health, as described elsewhere in this report). We currently market *Jada* outside of the United States in a number of international markets and is subject to the regulatory requirements imposed in those jurisdictions. In the future, we also plan to continue to sell our medical devices in additional major international markets and will be subject to the regulatory requirements imposed in those jurisdictions. For example, in order to sell medical devices in EU member countries, we will need to comply with the MDR. Foreign sales outside the EU (including in the UK) are subject to the foreign government regulations of the relevant jurisdiction, and we will need to obtain approval or marketing authorization by the appropriate regulatory authorities before we can commence clinical trials or marketing activities in those countries.

We cannot market our pharmaceutical products or medical devices or new indications or modifications to our existing products unless and until we have obtained all required regulatory approvals or marketing authorizations in each relevant jurisdiction. Our applications or submissions for regulatory approval or marketing authorization may be rejected or otherwise delayed by the FDA or other foreign regulatory authorities. For example, the FDA may issue complete response letters indicating that our applications for our pharmaceutical products are not ready for approval. Once obtained, we must maintain approval or marketing authorization as long as we plan to market products in each jurisdiction where approval or marketing authorization is required. The FDA or other regulators may change their policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay regulatory approval or marketing authorization of our future products or impact our ability to modify our currently marketed products on a timely basis. Our failure to obtain approval or marketing authorization, significant delays in the approval or marketing authorization process or our failure to maintain approval or marketing authorization in any jurisdiction will prevent us from selling the products in that jurisdiction. We would not be able to realize revenues for our pharmaceutical products or medical devices in any jurisdiction where we do not have required approval or marketing authorization.

We or our partners may fail to adequately demonstrate the safety and efficacy of any of our pharmaceutical product candidates or medical devices in pre-clinical studies and clinical trials, which would prevent or delay development, regulatory approval or marketing authorization and commercialization of our product candidates.

Before obtaining regulatory approval from the FDA or other comparable foreign regulatory authorities for the sale of our pharmaceutical product candidates, we must demonstrate through pre-clinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication and population. Obtaining marketing authorization for our devices may also require pre-clinical and clinical trials. Pre-clinical and clinical trials are difficult to design and implement, and can take many years to complete, and their ultimate outcome is uncertain. Failure can occur at any time during the pre-clinical study and clinical trial processes. Accordingly, there is a high risk of failure and we may never succeed in obtaining regulatory approval or marketing authorization of our product candidates.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent receipt of regulatory approval or marketing authorization, or our ability to commercialize our product candidates, including for example, issues with study execution including timely access to study drugs; inability to recruit and enroll study subjects; failure of our product candidates in pre-clinical studies or clinical trials to demonstrate safety and efficacy; receipt of feedback from the FDA or other regulatory authorities that require us to modify the design of our clinical trials; and negative or inconclusive clinical trial results that may require us to conduct additional clinical trials or abandon certain research and/or development programs.

We may be required to conduct additional pre-clinical studies, clinical trials or other testing of our product candidates beyond those that we currently contemplate, or we may be unable to successfully complete pre-clinical studies or clinical trials of our product candidates or other testing in a timely manner. If the results of these studies, trials or tests are not positive (or are only modestly positive), or if there are safety concerns, we may incur unplanned costs, as well as delays in our efforts to obtain regulatory approval or marketing authorization. Even if we receive such approval, we 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 our pharmaceutical products or medical devices.

Even after a pharmaceutical product or medical device reaches the market, we continue to be subject to significant post-marketing regulatory requirements and oversight. The regulatory approvals or marketing authorizations that we may receive for our pharmaceutical products and medical devices will require the submission of reports to regulatory authorities and on-going surveillance to monitor the safety and efficacy of our products, may contain significant limitations related to use restrictions for specified groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. In addition, even after a pharmaceutical product or device has obtained marketing authorization or clearance, the manufacturing processes, labeling, packaging, distribution, adverse event and device malfunction reporting, storage, advertising, promotion, import, export, recalls and recordkeeping for our products will be subject to ongoing regulatory requirements, and we will be subject to periodic inspections. Failure to comply with any of these requirements could subject us to a variety of formal or informal enforcement actions by the FDA or other regulators, result in a recall or market withdrawal of our products, require us to cease manufacturing and distribution of the products, trigger product liability or other litigation, or otherwise impact our ability to realize revenues for our products. As previously disclosed, we voluntarily initiated market actions, including recalls, in certain markets with respect to our suspension injections *Diprospan*, *Celestone, Chronodose*™ [1] (betamethasone), and *Celestone Soluspan*® (betamethasone) related to a non-conforming component of a manufacturing line at our Heist, Belgium plant. We do not believe this development will materially impact us. It is possible that future recalls or similar developments could materially and adversely impact our business, result of operations, and financial condition.

Likewise, if previously unknown side effects, adverse events, malfunctions or other quality or safety concerns are discovered or if there is an increase in negative publicity regarding known side effects of any of our products, it could significantly reduce demand for the product or require us to take actions that could negatively affect sales, including initiating corrections of a marketed product or removing the product from the market, restricting our distribution of the product or applying for marketing authorization for labeling changes. The FDA could also require us to conduct post-marketing studies of our products. Further, we are at risk for product liability and consumer protection claims and civil and criminal governmental actions related to our products, research and marketing activities. In addition, dissemination of promotional materials through evolving digital channels serves to increase visibility and scrutiny in the marketplace.

Certain developments may decrease demand for our products, including the following:

- scrutiny of advertising and promotion;
- negative results in post-approval Phase 4 trials or other studies;
- review by regulatory authorities or other expert bodies of our products that are already marketed based on new data or other developments in the field;
- the recall, loss or modification of regulatory approval or marketing authorization of products that are already marketed; and
- changing government regulations regarding safety, efficacy, quality or labeling.

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 or a loss of customer confidence in us or our current or future products, which may result in the loss of sales and difficulty in successfully launching new products.

Certain of our products currently benefit from patent protection and market exclusivity. When the patent protection and market exclusivity periods for such products expire, a significant and rapid loss of sales from those products is generally experienced. Expiry of patent protection and market exclusivity for products that contribute significantly to our sales will adversely affect our business.

We depend upon patents to provide us with exclusive marketing rights for certain of our products for some period of time. Loss of patent protection typically leads to a significant and rapid loss of sales for that product where lower priced generic versions of that drug or other competitors become available. In the case of current or future products that contribute significantly to our sales, a loss of market exclusivity could materially adversely affect our business, cash flow, results of operations, financial condition or prospects. We expect market exclusivity for *Nexplanon* in the United States to expire in 2027, and market exclusivity for the majority of countries where *Nexplanon* is commercialized outside the United States will expire in 2025. See "Business—Products and "—Intellectual Property" for details, including the patent protection for certain of our marketed products.

We depend on our patent rights for the marketing of certain of our products, and invalidation or circumvention of our patent rights would adversely affect our business.

Patent protections are important to the marketing of certain of our products, particularly certain of our women's health products in the United States and in most major non-U.S. markets. Patents covering products that we have introduced normally provide market exclusivity, which is important for the successful marketing and sale of certain of our products.

Even if we succeed in obtaining patents covering our products, third parties or government authorities may challenge or seek to invalidate or circumvent our patents and patent applications. It is important for our business to successfully defend the patent rights that provide market exclusivity for our products. We are involved in patent disputes relating to challenges to our patents or claims by third parties of infringement against their patents. We defend our patents both within and outside the United States, including by filing claims of infringement against other parties. In particular, manufacturers of generic pharmaceutical products from time to time file abbreviated new drug applications with the FDA seeking to market generic forms of our products prior to the expiration of relevant patents owned or licensed by it. Patent litigation and other challenges to our patents are costly and unpredictable and may deprive us of market exclusivity for a patented product or, in some cases, third-party patents may prevent us from marketing and selling a product in a particular geographic area, negatively affecting our business and results of operations.

Additionally, certain foreign governments have indicated that compulsory licenses to patents may be granted in the case of national emergencies or in other circumstances, which could diminish or eliminate sales and profits from those regions and negatively affect our business and results of operations. Further, court decisions relating to other companies' patents, potential legislation in both the United States and certain foreign markets relating to patents, as well as regulatory initiatives, may result in a more general weakening of intellectual property protection.

If one or more of our important products lose patent protection in profitable markets, sales of those products are likely to decline significantly as a result of generic versions of those products becoming available. Our results of operations may be adversely affected by the lost sales unless and until we have launched commercially successful products that replace the lost sales. In addition, if products with intangible assets that were measured at fair value and capitalized in connection with acquisitions experience difficulties in the market that negatively affect product cash flows, we may recognize material non-cash impairment charges with respect to the value of those products.

We have incurred substantial indebtedness, which could adversely affect our financial condition and results of operations.

At December 31, 2023, we had outstanding indebtedness of approximately $8.8 billion, as described more fully in the Notes to our financial statements. In addition, we may incur additional debt from time to time to finance acquisitions or for other purposes, subject to the restrictions contained in the documents that govern our indebtedness. Current or future levels of indebtedness may increase the possibility that we will be unable to generate cash sufficient to pay amounts due in respect of such indebtedness.

Our ability to issue additional debt or enter into other financing arrangements on acceptable terms could be adversely affected if there is a material decline in the demand for our products, if our customers or suppliers are unable to pay amounts due to us or there are other significantly unfavorable changes in economic conditions. Volatility in the world financial markets could increase borrowing costs or affect our ability to access the capital markets. These conditions may adversely affect our ability to obtain and maintain our credit ratings.

We are subject to minimum purchase obligations under certain supply agreements, and if we fail to meet those minimum purchase requirements, our financial results may be unfavorably impacted.

We are subject to minimum purchase obligations under certain supply agreements, which requires us to purchase minimum amounts of materials critical to our product manufacturing over specified time periods. If we fail to meet these minimum purchase requirements, we may still be required to pay for the cost of the minimum inventory purchases. If we are unable to offset these payments, it could result in a lower margin. During the year ended December 31, 2022 and 2021, we recognized $5 million and $24 million, respectively, in Cost of Sales pertaining to estimated unavoidable losses associated with a long-term vendor supply contract conveyed as part of the spinoff. We are also aware of a limited number of other arrangements that have similar provisions which could result in these types of payments. We do not currently expect these payments to be material; however, in the aggregate they may become material if additional amounts are identified in the future, and they could have a material adverse effect on our financial condition, results of operations or cash flows.

The health care industry in the United States has been, and will continue to be, subject to increasing regulation and political action.

We believe that the health care industry will continue to be subject to increasing regulation and political and legal action at both the federal and state levels in the United States and internationally, and it is uncertain how this will affect our business.

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. There are pending legal and legislative developments relating to the 340B drug pricing program, including ongoing litigation challenging federal enforcement actions against manufacturers and recently introduced and enacted state legislation.

We cannot predict the likelihood of additional future changes in the health care industry in general, the pharmaceutical industry in particular, or what impact they may have on our business, cash flow, results of operations, financial condition or prospects.

We are subject to a variety of laws and regulations, and we may face serious consequences for violations if we fail to meet the applicable legal and regulatory requirements.

We are currently subject to a number of government laws and regulations and, in the future, could become subject to new government laws and regulations. The costs of compliance with such laws and regulations, or the negative results of non-compliance, could adversely affect our business, cash flow, results of operations, financial condition or prospects. The costs of compliance and penalties for non-compliance may be particularly significant with respect to health care reform initiatives in the United States or in other countries, including additional mandatory discounts or fees; new laws, regulations and judicial or other governmental decisions affecting pricing, reimbursement, and market access or marketing within or across jurisdictions; new and increasing data privacy regulations and enforcement, particularly in the EU, the UK, the United States, and China; legislative mandates or preferences for local manufacturing of medical products; emerging and new global regulatory requirements for reporting payments and other value transfers to health care professionals and health care organizations; environmental regulations; and emerging and new regulations on human rights and environmental matters in the supply chain and importation restrictions, embargoes, trade sanctions and legislative or other regulatory changes. We will also be subject to and are monitoring the passage through the legislative process of the proposed draft directive and regulation intending to reform EU pharmaceutical legislation, (generally known as the "EU Pharma Package"), which is intended to promote innovation and competitiveness through a simplified regulatory framework, provide access to innovative and affordable medicines to patients, recognize innovation with effective incentives, address shortages and supply security, and provide enhanced protection for the environment. We are still evaluating the potential impacts of the EU Pharma Package on our business.

Because of our U.S. and international operations, we are also subject to anti-corruption laws and regulations, in the United States and internationally, including but not limited to U.S. domestic bribery laws, the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"), the U.K. Bribery Act 2010, and other applicable anti-bribery and corruption laws. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other third-party collaborators from authorizing, promising, offering, providing, soliciting and/or receiving, directly or indirectly, improper payments or anything else of value to or from foreign officials or other persons in the public or private sector. The FCPA also requires U.S. public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Recent years have seen substantial increase in the global enforcement of anti-corruption laws. Our operations outside the United States could increase the risk of

such violations. Our business is also heavily regulated and involves significant interaction with foreign officials. In many countries outside the U.S., prescribers of our products are employed by government entities, and purchasers are themselves government entities. As such, our interactions with such prescribers and purchasers are subject to regulation under the FCPA, as well as other similar under anti-corruption laws and/or regulations enacted by other countries. The failure to comply with the FCPA and similar such laws could result in civil or criminal sanctions or other adverse consequences.

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

Enforcement activities under the laws and regulations described above may subject us to administrative and legal proceedings and actions, which could result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, preclusion from participating in public tenders, breach of contract and fraud litigation, reputational harm, and other consequences.

We have significant global operations, which expose us to additional risks, and any adverse event could adversely affect our results of operations and financial condition.

The extent of our operations outside the United States is significant. For example, in 2023, we generated $4.8 billion in revenues outside the United States, representing approximately 76% of our total revenues. Risks inherent in conducting a global business include:

- changes in medical reimbursement policies and programs and pricing restrictions in key markets;
- multiple regulatory requirements that could restrict our ability to manufacture and sell our products in key markets;
- multiple, conflicting and changing laws 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 our products;
- volatility of commodity prices, fuel, shipping rates that impact the costs and/or ability to supply our products;
- diminished protection of intellectual property in some countries; and
- possible nationalization and expropriation.

In addition, there may be changes to our business and strategic position if there is instability, disruption or destruction in a significant geographic region, regardless of cause, including health epidemics or pandemics, riot, civil insurrection or social unrest, and natural or man-made disasters, including famine, flood, fire, earthquake, storm or disease. In addition, our operations and performance may be affected by political or civil unrest or military action. As a result of global economic conditions, some parties may delay or be unable to satisfy their payment or reimbursement obligations. In addition, patients' ability to afford health care may also be affected by job losses or other economic hardships, increased co-pay or deductible obligations, greater cost sensitivity to existing co-pay or deductible obligations, and lost health care insurance coverage. Further, with rising international trade tensions or sanctions, our business may be adversely affected following new or increased tariffs, as well as increased costs of materials, products, and commodities upon which we rely. As a result, changes in international trade policy, changes in trade agreements and the imposition of tariffs or sanctions by the U.S. or other countries could materially adversely affect our results of operations and financial condition.

In February 2022, in response to the armed conflict between Ukraine and Russia, trade sanctions, travel bans and asset/financial freezes were announced by the United States, European Union 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 we conduct business and therefore may negatively impact us. In addition, although we do not expect the recent Israel-Hamas war to have a direct material impact on our business, the war and escalating tensions in the region may impact global markets or affect our supply chain.

We are subject to a significant number of privacy and data protection laws and regulations globally, many of which place restrictions on our ability to transfer, access and use personal data across our business.

The legislative and regulatory landscape for privacy and data protection continues to evolve.

The GDPR and related implementing laws in individual EU or the Member States of the European Economic Area ("EEA") govern the collection and use of personal health data and other personal data in the EU. The GDPR increased responsibility and liability in relation to personal data that we process. It also imposes several obligations and restrictions on the ability to process (which includes collection, storage and access, analysis, and transfer of) personal data, including health data from clinical trials and adverse event reporting. The GDPR also includes requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals prior to processing their personal data or personal health data, potential notification of personal data breaches to the national data protection authorities, potential consultation obligations to national data protection authorities for certain high-risk data processing, and the security and confidentiality of the personal data. There are also accountability requirements, such as maintaining a record of data processing, conducting data protection impact assessments and appointing data protection officers. Further, the GDPR prohibits the transfer of personal data to countries outside of the EEA that are not considered by the European Commission to provide an adequate level of data protection, including to the United States, except if the data controller meets very specific requirements.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU Member States may result in significant monetary fines and other administrative penalties as well as civil liability claims from individuals whose personal data was processed. Data protection authorities from the different EU Member States may still enforce the GDPR differently, reflecting variations that arise under national-level regulations and guidelines (e.g., labor laws, processing of national identification numbers), which adds to the complexity of processing personal data in the EU. Guidance at both EU level and at the national level in individual EU Member States concerning implementation and compliance practices is often updated or otherwise revised, resulting in a challenging regulatory environment.

There is, moreover, a growing trend towards required public disclosure of clinical trial data in the EU, which adds to the complexity of obligations relating to processing health data from clinical trials. Failing to comply with these obligations could lead to government enforcement actions and significant penalties against us, harm to our reputation, and adversely impact our business and operating results. The uncertainty regarding the interplay between different regulatory frameworks further adds to the complexity that we face with regard to data protection regulation.

Additional laws and regulations enacted in the United States, Europe, Asia and Latin America have increased enforcement and litigation activity in the United States and other developed markets, as well as increased regulatory cooperation among privacy authorities globally. The data protection regulatory environment in China has been evolving quickly, including regulations regarding cross-border transfers of personal data (CBDT). These laws, including the PIPL, regulate the processing of personal information and increase obligations on companies to protect and safeguard information. These regulations also require organizations to evaluate cross-border transfer of personal information and may require localization of certain data if specific conditions are met. We have adopted a comprehensive global privacy program to help manage these evolving risks, adjust to the changing regulatory landscape and facilitate the transfer of personal information across international borders.

We depend on sophisticated software applications and computing infrastructure. Cyberattacks affecting our IT systems could result in exposure of confidential information, the modification of critical data or the disruption of our worldwide operations, including manufacturing and sales operations.

We depend on sophisticated software applications (including artificial intelligence), complex information technology systems, computing infrastructure and cloud service providers (collectively, "IT systems") to conduct critical operations. Certain of these systems are managed, hosted, provided or used by third parties, including Merck pursuant to a transition services agreement (the "Transition Services Agreement" or "TSA"), to assist in conducting our business. Disruption, degradation, destruction or manipulation of these IT systems through intentional or accidental means by our employees, third parties with authorized access or cyber threat actors could adversely affect key business processes. The size and complexity of our IT systems, and those of our third-party providers with whom we contract, make such systems potentially vulnerable to service interruptions. In addition, we and our third-party providers have experienced and expect to continue to experience phishing attempts, scanning attempts of our network, and other attempts of unauthorized access to our computer environment. Such attacks are increasingly sophisticated and are made by groups and individuals with a wide range of motives and expertise, including state and quasi-state actors, criminal groups, "hackers" and others. These attacks could lead to loss of confidentiality, integrity and/or availability of our data, applications or systems.

In the ordinary course of business, we and our third-party providers collect, store and transmit large amounts of confidential information (including trade secrets or other intellectual property, proprietary business information and personal information), and we must do so in a secure manner to maintain the confidentiality and integrity of such confidential information. The size

and complexity of we and our third-party providers' systems and the large amounts of confidential information present on them also makes them potentially vulnerable to security breaches from inadvertent or intentional actions by our employees, partners or vendors, or from attacks by malicious third parties. Maintaining the confidentiality, integrity, and availability of this confidential information (including trade secrets or other intellectual property, proprietary business information and personal information) is important to our competitive business position. However, such information can be difficult to protect and could be compromised.

While we have taken steps to protect such information, and to ensure that the third-party providers on which we rely have taken adequate steps to protect such information, there can be no assurance that our efforts to protect our data and IT systems or the efforts of third-party providers to protect their IT systems will be successful in preventing disruptions. A breach of our IT systems or our third-party providers' IT systems, such as cloud-based systems, or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, fraud, trickery, other forms of deception, or any other cause, could enable others to produce competing products, use our proprietary technology or information, and/or adversely affect our business position.

Further, any such interruption, security breach, or loss, misappropriation, and/or unauthorized access, use or disclosure of confidential information, including personal information regarding our patients and employees, or the modification of critical data, could result in financial, legal, business, and reputational harm to us, including loss of revenue, loss of critical or sensitive information from our or our third-party providers' databases or IT systems, and substantial remediation and recovery costs.

We may experience difficulties or delays, or incur unforeseen expenses in connection with the manufacturing certain of our products.

We or our suppliers and other manufacturing partners may experience difficulties or delays in connection with manufacturing our products that may lead to increased costs, such as: failure to comply with applicable regulations and quality assurance guidelines; delays related to the construction of new facilities or the expansion of existing facilities; delays related to the supply of key ingredients or other components of our products; increased costs of key materials, packaging, or operational procedures; difficulties obtaining materials of adequate quality and quantity and other manufacturing or distribution problems, including, but not limited to, changes in manufacturing production sites and limits to manufacturing capacity resulting from regulatory requirements and changes in types of products produced and physical limitations that could impact supply. In addition, we could experience difficulties or delays in manufacturing our products caused by natural disasters, such as hurricanes, and public health crises and epidemics/pandemics. Any of the foregoing could result in product shortages, lost sales, government agency actions, and reputational harm to us, which could have a material adverse effect on our business, results of operations, and financial condition.

We may be unable to obtain sufficient components or raw materials on a timely basis or for a cost-effective price, or we may experience other supply difficulties that could adversely affect both our ability to deliver our products and our results of operations and financial condition.

We acquire our components, materials and other requirements for manufacturing from many suppliers and vendors in various countries, including sometimes from itself for self-supplied requirements. We endeavor to achieve, either alone or by working closely with our suppliers, continuity of our inputs and supplies, but we cannot guarantee these efforts will always be successful. Further, while efforts are made to diversify certain of our sources of components and materials, in certain instances there is only a sole source or it would require months or years to establish an alternative supplier. For many of our components and materials for which a single source or supplier is used, alternative sources or suppliers may exist, but we have made a strategic determination to use the single source or supplier. Although we carry strategic inventory and maintain insurance to help mitigate the potential risk related to any related supply disruption, we cannot assure investors that such measures will always be sufficient or effective. Further, if we do seek recovery or damages from such supplier for any supply shortages or disruptions, such recovery or damages may be limited and not include indirect or consequential losses or any loss of revenue or lost profits. Our ability to achieve continuity of our supply may also be affected by public health crises and epidemics/ pandemics. A reduction or interruption in supply and an inability to quickly develop acceptable alternative sources for such supply could adversely affect our ability to manufacture and distribute our products in a timely or cost-effective manner, negatively impacting our ability to sell our products.

We may not realize benefits from our investments in China and emerging markets.

We have been taking steps to increase our sales in China and emerging markets; however, our efforts to expand sales in these markets may not succeed. Some countries may be especially vulnerable to periods of global financial instability or may have

very limited resources to spend on health care. In order for us to successfully implement our strategy, we must attract and retain qualified personnel. We may also be required to increase our reliance on third-party agents within less developed markets. In addition, many of these countries have currencies that fluctuate substantially and, if such currencies devalue and we cannot offset the devaluations, our financial performance within such countries could be adversely affected.

For example, our business in China is growing, and China is now our second largest market, thereby increasing the importance of China to our overall pharmaceutical business. Continued growth of our business in China depends upon ongoing development of a favorable regulatory environment, sustained availability of our currently marketed products within China, and our ability to mitigate the impact of any trade impediments or adverse pricing controls.

China has made reduction of costs and provision of affordable drugs to patients a key priority and has implemented reimbursement and procurement programs to achieve these goals, such as VBP and URPS. These programs regularly reduce the price and/or reimbursement rate for drugs by over 50%. These and other such programs could adversely affect our business in China.

In addition, we currently rely on a third-party manufacturer to import, repackage and then sell a significant portion of our products in China. China's drug regulatory system is regularly changing in response to new policy trends. If these trends and the related changes to the requirements for development, importation, registration, distribution, and manufacturing of our drugs disrupt our business model that would adversely affect our business in China.

Finally, we plan to pivot in China from a primary focus on the public tender market to growth opportunities in the private retail segment. A failure to make such pivot effectively, or a failure to develop and maintain a presence in China or emerging markets could adversely affect our business, cash flow, results of operations, financial condition or prospects.

Current market conditions and recessionary pressures in one or more of our markets could impact our ability to grow our business.

Over the last few years in the United States and globally, market and economic conditions have been challenging. Non-U.S. countries, particularly in Europe, have experienced recessionary pressures and face continued concerns about the systemic impacts of adverse economic conditions and geopolitical issues. Any negative impact on economic conditions and international markets, continued volatility or deterioration in the capital markets, inflation, deflation or other adverse economic conditions may limit our ability to replace maturing liabilities and to access the capital markets to meet liquidity needs, which could have a material adverse effect on our financial condition and results of operations.

Ongoing uncertain economic and financial market conditions may also adversely affect the financial condition of our customers, suppliers and other business partners. If our customers' financial conditions are adversely affected, those customers may reduce their purchases of our products or we may not be able to collect accounts receivable, each of which could have a material adverse impact on our business operations or financial results, and we may not be able to fully absorb any such additional costs or revenue declines in the prices for our products and services.

Our reputation and promising pipeline render our products prime targets for counterfeiters.

Counterfeit products pose a significant risk to patient health and safety because of the conditions under which they are manufactured—often in unregulated, unlicensed, uninspected and unsanitary sites—as well as the lack of regulation of their contents. Failure to mitigate this threat could adversely impact our customers, potentially causing them harm. This, in turn, may result in the loss of confidence in our products' reputation and integrity, and potentially impact our business through lost sales, product recalls, and possible litigation.

Inflation could materially adversely affect our business and operations.

Our operating results could be materially impacted by changes in the overall macroeconomic environment and other economic factors that impact our cost structure and revenue results. Changes in economic conditions, supply chain constraints, logistics challenges, labor shortages, the war in Ukraine, and steps taken by governments and central banks, as well as other stimulus and spending programs, have led to higher inflation, which is likely to lead to an increase in costs and may cause changes in fiscal and monetary policy, including increased interest rates. In a higher inflationary environment, we may be unable to raise the prices of our products and services sufficiently to keep up with the rate of inflation.

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

We operate in multiple jurisdictions and virtually all of our sales outside the United States are denominated in currencies other than the United States dollar. Additionally, we have historically entered into, and will in the future enter into, business development transactions, borrowings or other financial transactions that may give rise to currency and interest rate exposure. Since we cannot, with certainty, foresee and mitigate against such adverse fluctuations in currency exchange rates, interest rates and inflation could negatively affect our business, cash flow, results of operations, financial condition or prospects.

In order to mitigate the adverse impact of these market fluctuations, we enter into hedging agreements from time to time. While hedging agreements, such as currency options and forwards and interest rate swaps, may limit some of the exposure to exchange rate and interest rate fluctuations, such attempts to mitigate these risks may be costly and not always successful. As a result, currency fluctuations among our reporting currency, the U.S. dollar, and other currencies in which we do business will affect our operating results, often in unpredictable ways.

Reliance on third-party relationships and outsourcing arrangements could materially adversely affect our business.

We depend on third parties, including other suppliers, alliances with other pharmaceutical and biotechnology companies, (including Merck), and third-party service providers, for key aspects of our business, including development, manufacture and commercialization of our products (including supplying our products or key ingredients of our products) and support for our IT systems. Reliance on third parties and their systems poses risks, including that the third parties will not comply with applicable legal or regulatory requirements for activities conducted on our behalf or for our benefit. This could lead to penalties that flow to us, require us to undertake costly corrective measures such as recalling product, interrupt our business plans such as by rendering clinical data not usable for regulatory submissions, or other adverse consequences on our business. We may also learn of certain issues after entering into an agreement that were not identified during diligence and may impact the ability to realize the projected business goals of the agreement. We may enter into agreements with third-parties in certain jurisdictions, including China, to continue our business operations in compliance with local regulatory requirements. Failure of these third parties to meet their contractual, regulatory and other obligations to us or the development of factors that materially disrupt the relationships between us and these third parties could adversely affect our business. Please see the risk factor above entitled, "we depend on sophisticated software applications and computing infrastructure. Cyberattacks affecting our IT systems could result in exposure of confidential information, the modification of critical data or the disruption of our worldwide operations, including manufacturing and sales operations," for a description of additional risks relating to our third-party providers that collect, store and transmit large amounts of confidential information.

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

Our focus on women's health is a key component of our strategy. Our ability to successfully execute our growth strategy in this area is subject to numerous risks, including:

- uncertainty of the development of a market for such products;
- trends relating to, or the introduction or existence of, competing products, technologies or alternative treatments or therapies that may be more effective, safer or easier to use than our products, technologies, treatments or therapies;
- the perception of our products as compared to other products;
- recommendation and support for the use of our products or treatments by influential customers, such as obstetricians, gynecologists, reproductive endocrinologists and treatment centers;
- changes in government policy or regulations could impair or repeal contraception coverage mandates under the ACA or state laws, which may affect payments to us or impose additional coverage limitations or cost-sharing obligations on our patients;
- the availability and extent of data demonstrating the clinical efficacy of our products or treatments;
- competition, including the presence of competing products sold by companies with longer operating histories, more recognizable names and more established distribution networks; and
- other technological developments.

If we are unable to successfully commercialize and create a significant market for our women's health products, our business or prospects could be harmed.

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

We believe that global climate change will present some degree of risk to our business. Natural disasters, extreme weather and other conditions caused by or related to climate change could adversely impact our supply chain, including manufacturing and distribution networks, the availability and cost of raw materials and components, energy supply, transportation, or other inputs

necessary for the operation of our business. Climate change and natural disasters could also result in physical damage to our facilities as well as those of our suppliers, customers, and other business partners, which could cause disruption in our business and operations or increase costs to operate our business. Additionally, increased environmental, social and governance regulations, including to address climate change, may result in increases in our costs to operate our business or restrict certain aspects of our activities. Additional potential effects of climate change to our business could include increased operating costs due to additional regulatory requirements, changes in supply and suppliers due to regulatory requirements, water limitations and disruptions to our supply chain. For example, concern over climate change continues to result in new legal or regulatory requirements designed to mitigate the effects of climate change on the environment, such as the EU's CSRD, California's Climate Corporate Data Accountability Act and Climate Related Financial Risk Act, and similar regulations under consideration by the SEC. Some potential risks are integrated into our business planning, including investment in reducing energy, water use and greenhouse gas emissions. The extent and severity of climate change impacts are unknown, and therefore, the scope of potential impact on our business is difficult to predict, and it may be difficult to adequately prepare for such impact.

Biosimilars carry unique regulatory risks and uncertainties, which could adversely affect our results of operations and financial condition.

There are unique regulatory risks and uncertainties related to biosimilars. The regulation of the testing, approval, safety, effectiveness, manufacturing, labeling and marketing of biosimilars are subject to regulation by the FDA, the EMA and other regulatory bodies. These laws and regulations differ from, and are not as well-established as, those governing pharmaceutical products or the approval of generic pharmaceutical products. In addition, manufacturing biosimilars, especially in large quantities, is often complex and may require the use of innovative technologies to handle living cells and microorganisms. Any changes to the regulatory framework governing biosimilars or in the ability of our partners to manufacture an adequate supply of biosimilars may adversely affect our ability to commercialize the biosimilars in our portfolio.

We rely on our collaboration with Samsung Bioepis and Henlius for the successful development and manufacture of our biosimilars products and expect to do so for the foreseeable future.

Our current biosimilars portfolio consists primarily of products developed and manufactured by Samsung Bioepis for which we have worldwide commercialization rights, with certain geographic exceptions specified on a product-by-product basis. Our access rights to each product under our agreement with Samsung Bioepis last for 10 years from each such product's launch date on a market-by-market basis. In addition, we are party to a license agreement with Henlius, whereby we have worldwide commercialization rights, in countries except for China (including Hong Kong, Macau, and Taiwan) for biosimilar candidates HLX11 referencing *Perjeta*, and HLX14, referencing *Prolia*/*Xgeva*. See "Business—Third-Party Agreements". Our ability to successfully commercialize products in our biosimilars portfolio may depend upon maintaining a successful relationship with Samsung Bioepis and Henlius. The success of our commercialization activities may also depend, in part, on the performance, operations and regulatory compliance of Samsung Bioepis and Henlius and their suppliers, over which we do not have control. If we fail to achieve the benefits of our collaborations, our business, financial condition, and results of operations could be adversely impacted.

We or our suppliers may not be able to obtain materials or supplies or capacity necessary to conduct clinical trials or to manufacture and sell our products, which could limit our ability to generate revenues.

We and our suppliers need access to certain supplies and products and capacity to ensure supply that is used to conduct our clinical trials and to manufacture and sell our products. If we or our suppliers are unable to purchase enough of these materials or find suitable alternative materials in a timely manner, our development efforts for our product candidates may be delayed or our ability to manufacture and sell our products could be limited.

We are subject to a number of restrictive covenants under our indebtedness, including customary operating restrictions and financial covenants, which could restrict our ability to pay dividends or adversely affect our financing options and liquidity position.

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

- limiting our ability to obtain additional financing in the future for working capital, capital expenditures and acquisitions;
- limiting our ability to refinance our indebtedness on terms acceptable to us or at all;

- restricting our operations or development plans;
- requiring us to dedicate a significant portion of our cash flows from operations to paying amounts due under our indebtedness, thereby reducing funds available for other corporate purposes;
- impeding our ability to pay dividends;
- making us more vulnerable to economic downturns; or
- limiting our ability to withstand competitive pressures.

Any of these restrictions on our ability to operate our business in our discretion could adversely affect our business by, among other things, limiting our ability to adapt to changing economic, financial or industry conditions and to take advantage of corporate opportunities, including opportunities to obtain debt financing, repurchase stock, refinance or pay principal on our outstanding debt, dispose of property, complete acquisitions for cash or debt, or make other investments. In addition, events beyond our control, including prevailing economic, financial, and industry conditions, could affect our ability to satisfy applicable financial covenants, and we cannot assure you that we will satisfy them.

Any failure to comply with the restrictions of our current indebtedness, or any future financing agreements, including as a result of events beyond our control, may result in an event of default under these agreements, which in turn may result in defaults or acceleration of obligations under these agreements and other agreements, giving our lenders and other debt holders the right to terminate any commitments they may have made to provide us with further funds and to require us to repay all amounts then outstanding.

Changes in tax laws or other tax guidance could adversely affect our effective tax rates, financial condition and results of operations.

We expect recent changes in tax laws around the world, including as led by the Organization for Economic Cooperation and Development ("OECD"), such as the adoption by the EU and the enactment by additional countries of a global minimum tax, to negatively impact our effective tax rate and results of operations. Other changes in tax laws or regulations around the world, including in the United States, could negatively impact our cash tax liability, and will likely have a negative impact on our effective tax rate, and results of operations.

Social media and mobile messaging platforms present risks and challenges.

The inappropriate and/or unauthorized use of certain social media and mobile messaging channels could cause brand damage or information leakage or could lead to legal implications, including from the improper collection and/or dissemination of personally identifiable information. In addition, negative or inaccurate posts or comments about us or our products on any social networking platforms could damage our reputation, brand image and goodwill. Further, the disclosure of non-public Organon-sensitive information by our workforce or others through external media channels could lead to information loss. Although there are internal Organon policies that guide employees on appropriate personal and professional use of these platforms for communication about us, it may not completely secure and protect information. Identifying new points of entry as new communication tools expand also presents new challenges.

Risks Related to the Spinoff

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

In connection with the spinoff, we entered into a Separation and Distribution Agreement with Merck (the "Separation and Distribution Agreement"), the Transition Services Agreement, manufacturing and supply agreements, trademark license agreements, intellectual property license agreements, an employee matters agreement, a tax matters agreement and certain other commercial or operating agreements. These agreements are discussed in greater detail in Note 19 "Third-Party Arrangements and Related Party Disclosures." Certain of these agreements provide for the performance of services by each company for the benefit of the other for a period of time after the distribution. We may rely on Merck to satisfy our performance and payment obligations under these agreements. If Merck is unable to satisfy its obligations under these agreements, including its indemnification obligations, we could experience operational difficulties or losses.

In addition, in connection with the spinoff, we have established operations in most markets, but is unable to import, distribute, or trade certain products in some markets due to pending licenses, permits, and regulatory approvals, among other requirements. Until all required approvals are received, we rely upon Merck to perform certain activities in these markets. We

may incur additional costs during the period of time before all necessary approvals are granted, which may affect our business and result in additional costs in these markets.

If we do not have our own systems and services in place, or if we do not have agreements with other providers of these services, when these agreements terminate, we may not be able to operate our business effectively and our profitability may decline. We are in the process of creating our own, or engaging third parties to provide, systems and services to replace many of the systems and services Merck is providing, and is expected to provide, during the transition period to us. We may not be successful in effectively or efficiently implementing these systems and services or in transitioning data from Merck's systems to our 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 us.

The Separation and Distribution Agreement with Merck provides for indemnification obligations designed to make us financially responsible for many liabilities that may exist relating to our business activities, whether incurred prior to or after the distribution, including any pending or future legal matters. These liabilities, which could be material to us, include a general obligation to indemnify Merck for litigation or governmental proceedings relating to our products, including, but not limited to, currently pending litigation relating to *Fosamax*, *Nexplanon*, and *Propecia* / *Proscar*. More specifically, our obligations to indemnify Merck may in some cases include liability for antitrust litigation; provided, however, that we will not be liable for the results of the antitrust litigation related to *Zetia* or the product liability litigation in Brazil related to *Vioxx²* (rofecoxib). For a description of the related legal matters, see Note 20 "Contingencies" to the Financial Statements included in this report. These indemnification liabilities are intended to ensure that, as between Merck and us, we are responsible for all liabilities we assume in connection with the spinoff and that we pay for any liability incurred by Merck (including directors, officers, employees and agents) related to our failure to satisfy such obligations or otherwise in respect of the operation of our business, or any breach by us of the Separation and Distribution Agreement or any ancillary agreement. Our indemnity obligations to Merck as set forth in the Separation and Distribution Agreement may be substantial.

There could be significant income tax liability if the spinoff or certain related transactions are determined to be taxable for U.S. federal income tax purposes.

Prior to completion of the spinoff, Merck received the tax opinions from its tax advisors that concluded, among other things, that the distribution of all of the outstanding Organon shares to Merck stockholders and certain related transactions qualify as tax-free to Merck and its stockholders under Sections 355 and 368 of the U.S. Internal Revenue Code, except to the extent of any cash received in lieu of fractional shares of our Common Stock. The Tax Opinions are not binding on the Internal Revenue Service ("IRS"). Accordingly, the IRS may reach conclusions with respect to the spinoff that are different from the conclusions reached in the Tax Opinions. The Tax Opinions rely on certain facts, assumptions, representations and undertakings from Merck and Organon regarding the past and future conduct of the companies' respective businesses and other matters, which, if incomplete, incorrect or not satisfied, could alter the conclusions of the party giving such Tax Opinion.

If the spinoff is ultimately determined to be taxable, the spinoff could be treated as a taxable dividend to Merck's stockholders for U.S. federal income tax purposes, and Merck's stockholders could incur significant U.S. federal income tax liabilities. In addition, Merck would recognize a taxable gain to the extent that the fair market value of our Common Stock exceeds Merck's tax basis in such stock on the date of the spinoff. Each of Merck and Organon generally will be responsible for any tax-related losses imposed on Merck or Organon, respectively, as a result of the failure of a transaction to qualify for tax-free treatment, to the extent that the failure to so qualify is attributable to actions, events or transactions relating to Merck's or Organon's respective stock, assets or business, or a breach of the relevant covenants made by Merck or Organon in the tax matters agreement. Please also see "Contractual restrictions limit our ability to engage in certain corporate transactions that stockholders may consider favorable" below.

Contractual restrictions limit our ability to engage in certain corporate transactions that stockholders may consider favorable.

To preserve the tax-free treatment to Merck of the spinoff, we entered into a tax matters agreement (the "Tax Matters Agreement" or "TMA") with Merck, which restricted us from taking any action that would have prevented the distribution and related transactions from being tax-free for U.S. federal income tax purposes. In addition, we are required to indemnify Merck against any tax liabilities as a result of such actions, even if we did not participate in or otherwise facilitate such actions. In the event the spinoff fails to be tax-free as a result of such actions, our indemnity obligation for Merck's tax liability under the tax matters agreement would be substantial and could materially affect our cash flow. In addition, certain provisions of the agreements that we entered into with Merck require Merck's consent to any assignment by us of our rights and obligations

under the agreements. The consent and termination rights set forth in these agreements might discourage, delay or prevent a change of control that stockholders may consider favorable.

Certain of our executive officers and directors may have actual or potential conflicts of interest because of their previous positions at Merck.

Because of their former positions with Merck, certain of our executive officers and directors own shares of Merck Common Stock and continue to participate in certain Merck benefit programs. Even though our Board of Directors consists of a majority of directors who are independent, and our executive officers who were previously employees of Merck ceased to be employees of Merck in connection with the spinoff, some of our executive officers and directors continue to have financial interests in Merck. Continuing ownership of Merck Common Stock and continued participation in Merck benefit programs could create, or appear to create, potential conflicts of interest if we and Merck pursue the same corporate opportunities or face decisions that could have different implications for us and Merck.

Risks Related to Our Common Stock

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

The trading volume and market price of our Common Stock may be volatile. This volatility could negatively impact our ability to raise additional capital or utilize equity as consideration in any acquisition transactions we may seek to pursue, and could make it more difficult for existing stockholders to sell their shares of our Common Stock at a price they consider acceptable or at all. This volatility is caused by a variety of factors, including, among the other risks described in this report:

- our liquidity and ability to obtain additional capital, including the market's reaction to any capital-raising transaction we may pursue;
- declining working capital to fund operations, or other signs of financial uncertainty;
- any negative decisions by the FDA or comparable regulatory bodies outside the United States regarding our products and product candidates;
- market assessments of any strategic transaction or collaboration arrangement we may pursue;
- sales of substantial amounts of our Common Stock, or the perception that substantial amounts of our Common Stock may be sold, by stockholders in the public market;
- changes in earnings estimated by securities analysts or our ability to meet those estimates;
- issuance of new or updated research or reports by securities analysts or changed recommendations for our Common Stock; and
- significant advances made by competitors that adversely affect our competitive position.

In addition, the stock market in general, and the market for stock of companies in the life sciences and pharmaceutical industries in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of comparable companies. In the past, following periods of volatility in the overall market and the market price of a particular Company's securities, securities class action litigation has often been instituted against a company. This type of litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

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

We currently expect that we will continue to pay quarterly cash dividends. The timing, declaration, amount and payment of any future dividends to stockholders will fall within the discretion of our Board of Directors. The Board of Directors' decisions regarding the payment of dividends will depend on many factors, such as our financial condition, earnings, corporate strategy, capital requirements, debt service obligations, industry practice, legal requirements, regulatory constraints, and other factors that the Board deems relevant. our ability to pay any dividends will depend on our ongoing ability to generate cash from operations and access capital markets.

Certain provisions in our amended and restated certificate of incorporation and bylaws, and of Delaware law, may prevent or delay an acquisition of us, which could decrease the trading price of our Common Stock.

We are a Delaware corporation, and our amended and restated certificate of incorporation, bylaws, and Delaware law each contain provisions that are intended to deter coercive takeover practices and inadequate takeover bids by making such practices or bids unacceptably expensive to the bidder and encouraging prospective acquirors to negotiate with our Board of Directors rather than to attempt a hostile takeover. Specifically, because we have not chosen to be exempt from Section 203 of the Delaware General Corporation Law, this provision could also delay or prevent a change of control that stockholders may favor.

Section 203 provides that, subject to limited exceptions, persons that acquire, or are affiliated with a person that acquires, more than 15% of the outstanding voting stock of a Delaware corporation may not engage in any business combination with that corporation, including by merger, consolidation or acquisitions of additional shares, for a three-year period following the date on which that person or their affiliates becomes the holder of more than 15% of the corporation's outstanding voting stock.

In addition, our amended and restated certificate of incorporation and bylaws include additional provisions that may have anti-takeover effects and may delay, deter or prevent a takeover attempt that our stockholders might consider in their best interests. For example, our amended and restated certificate of incorporation and bylaws:

- permit our Board of Directors to issue one or more series of preferred stock with such powers, rights and preferences as the Board of Directors shall determine;
- subject to a three-year sunset starting with our first annual meeting of stockholders, provide for a classified Board of Directors, with each class serving a staggered three-year term, which could have the effect of making the replacement of incumbent directors more time consuming and difficult;
- provide that as long as our Board of Directors is classified, our directors can be removed for cause only;
- prohibit stockholder action by written consent;
- provide that special meetings of stockholders can be called only by the Board of Directors;
- provide that vacancies on the Board of Directors could be filled only by a majority vote of directors then in office, even if less than a quorum, or by a sole remaining director; and
- establish advance notice requirements for stockholder proposals and nominations of candidates for election as directors.

We believe these provisions will protect our stockholders from coercive or otherwise unfair takeover tactics by requiring potential acquirors to negotiate with our Board of Directors and by providing our Board of Directors with more time to assess any acquisition proposal. These provisions are not intended to make us immune from takeovers. However, these provisions will apply even if the offer may be considered beneficial by some stockholders and could delay or prevent an acquisition that our Board of Directors determines is not in the best interests of us and our stockholders. These provisions may also prevent or discourage attempts to remove and replace incumbent directors. In addition, these limitations may adversely affect the prevailing market price and market for our Common Stock if they are viewed as limiting the liquidity of our stock or discouraging takeover attempts in the future.

Our amended and restated bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, and the United States federal district courts as the exclusive forum for claims under the Securities Act, which could limit our stockholders' ability to obtain what such stockholders believe to be a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws provide that, unless we select or consent to the selection, in writing, of an alternative forum, all internal corporate claims, which include claims in the right of Organon (i) that are based upon a violation of a duty by a current or former director, officer, employee or stockholder in such capacity or (ii) as to which the Delaware General Corporation Law confers jurisdiction upon the Court of Chancery, will, to the fullest extent permitted by law, be exclusively brought in the Court of Chancery of the State of Delaware or, if such court does not have jurisdiction, another state court or a federal court located within the State of Delaware.

Furthermore, unless we select or consent to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Our exclusive forum provision does not apply to suits brought to enforce any liability or duty created by the Exchange Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

These exclusive provisions may limit a stockholder's ability to bring a claim in a judicial forum that he, she or it believes to be favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits. It is possible

that a court could find these exclusive forum provisions inapplicable or unenforceable with respect to one or more of the specified types of actions or proceedings, and we may incur additional costs associated with resolving such matters in other jurisdictions, which could materially adversely affect our business, financial condition and results of operations and result in a diversion of the time and resources of our management and board of directors.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 1C. Cybersecurity

Cybersecurity Risk Management and Strategy. We depend on sophisticated software applications, complex information technology systems, computing infrastructure and cloud service providers (collectively, "Information 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 our business.

We implement processes for the assessment, identification, and management of material risks from cybersecurity threats; however, disruption, degradation, destruction or manipulation of our Information Systems through intentional or accidental means by our employees, third parties with authorized access or cyber threat actors could adversely affect key business processes. The size and complexity of our Information Systems, and those of our third-party providers with whom we contract, make such systems potentially vulnerable to service interruptions. In addition, we and our third-party providers have experienced and expect to continue to experience phishing attempts, scanning attempts of our network, and other attempts of unauthorized access to our computers, digital systems, networks, or devices. Such attacks are increasingly sophisticated and are made by groups and individuals with a wide range of motives and expertise, including state and quasi-state actors, criminal groups, "hackers" and others. These attacks could lead to loss of confidentiality, integrity and/or availability of our data and Information Systems.

In the ordinary course of business, we and our third-party providers collect, store and transmit large amounts of confidential information (including trade secrets or other intellectual property, proprietary business information and personal information), and we must do so in a secure manner to maintain the confidentiality and integrity of such confidential information. While we have processes to protect such information, and to ensure that the third-party providers on which we rely have taken adequate steps to protect such information, a breach of our Information Systems or those of our third-party providers, such as cloud-based systems, or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, fraud, trickery, other forms of deception, or any other cause, could enable others to produce competing products, use our proprietary technology or information, and/or adversely affect our business position. Further, any such interruption, security breach, or loss, misappropriation, and/or unauthorized access, use or disclosure of confidential information, including personal information regarding our patients and employees, or the modification of critical data, could result in financial, legal, business, and reputational harm to us, including loss of revenue, loss of critical or sensitive information from our or our third-party providers' databases or Information Systems, and substantial remediation and recovery costs. Although such risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we have, from time to time, experienced threats to our data and systems, including malware and computer virus attacks.

We use multi-layered information security and data privacy programs and practices designed to foster the safe, secure, and responsible use of the information and data our stakeholders entrust to us. We work with our customers, governments, policymakers, and others to help develop and implement standards for safe and secure transactions, as well as privacy-centric data practices. Independent third parties test our cyber capabilities and audit our cloud security. We regularly test our systems to discover and address any potential vulnerabilities.

Cybersecurity Governance. Our Audit Committee has primary responsibility for overseeing our risk-management program relating to cybersecurity, although the Board participates in periodic reviews and discussion dedicated to cyber risks, threats, and protections. Our information security and privacy programs provide that the Board receives annual reports from our Chief Information Security Officer and Chief Ethics and Compliance Officer to discuss our program for managing information security risks, including data security risks, the risk of cybersecurity incidents and, if applicable, remediation of any potential cybersecurity incidents. The Audit Committee receives regular briefings on both information security and data privacy from the Chief Information Security Officer and Chief Ethics and Compliance Officer, respectively, and meets at least annually with our Chief Information Security Officer regarding our information technology. The Audit Committee receives periodic updates regarding our cybersecurity risk management program, and reports to the Board on the principal risks facing us and the steps

being taken to manage and mitigate these risks. Both the Board and the Audit Committee receive periodic reports on our cyber readiness, security controls and our cybersecurity investments. In addition, our directors are apprised of incident simulations and response plans, including for cyber and data breaches.

Item 2. Properties

Our corporate headquarters is located in Jersey City, New Jersey. We also maintain operational headquarters in Pennsylvania. We own and operate six manufacturing facilities in Campinas, Brazil, Cramlington, United Kingdom, Heist, Belgium, Oss, Netherlands, Pandaan, 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, 2023, please See Note 20 "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

Our Common Stock is listed on the New York Stock Exchange under the symbol "OGN." As of February 20, 2024, there were 69,973 holders of record of our Common Stock. This number does not include persons who hold our Common Stock in nominee or "street name" accounts through brokers or banks.

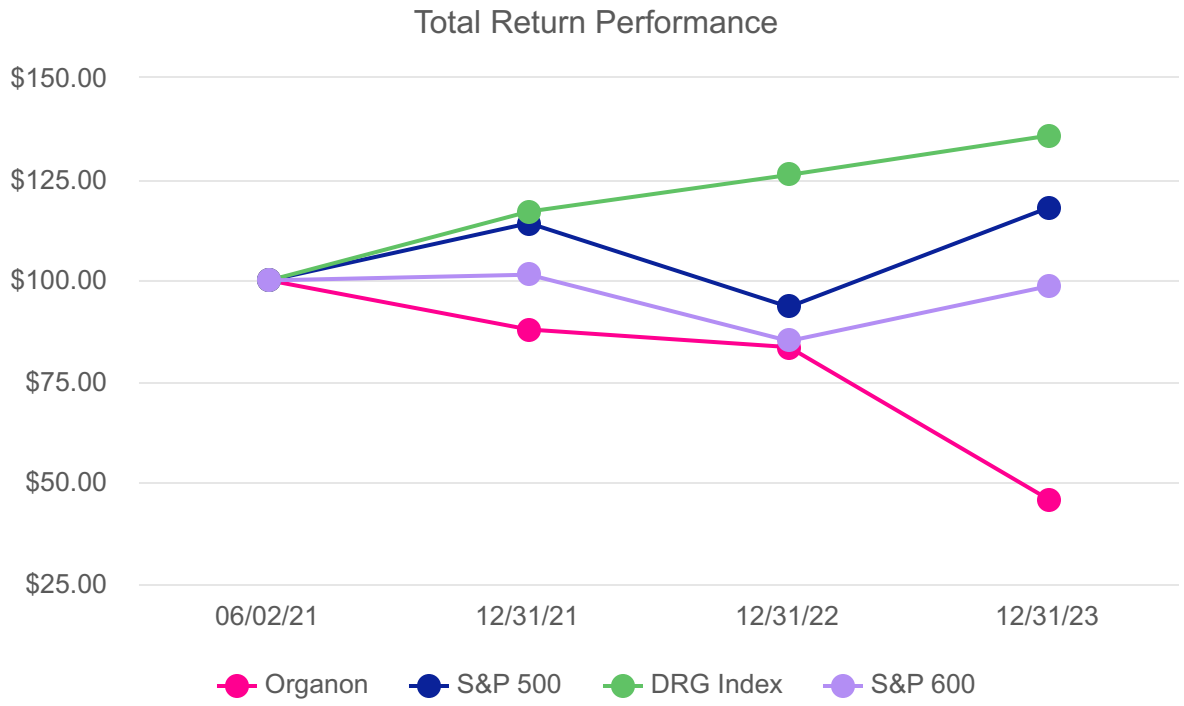
Dividends

During the fourth quarter of 2023, we paid cash dividends of $0.28 per share. On February 15, 2024, our Board of Directors declared a quarterly dividend of $0.28 for each issued and outstanding share of our Common Stock. The dividend is payable on March 14, 2024, to stockholders of record at the close of business on February 26, 2024.

The declaration of dividends is subject to the discretion of our Board. Our Board is committed to continuing to pay regular cash dividends; however, there can be no assurance as to future dividends. Our 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 —We cannot guarantee the timing, amount or payment of any dividends on our Common Stock".

Performance Graph

The following graph compares the cumulative total stockholder returns for the period from June 2, 2021 (the effective date of our Separation from Merck) to December 31, 2023 for (i) our Common Stock; (ii) the S&P 500 Index; (iii) the NYSE Arca Pharmaceutical Index ("DRG"); and the S&P 600 Index. The graph assumes an investment of $100 on June 2, 2021 through the last trading day of 2023. The calculation of cumulative stockholder return on our Common Stock, the S&P 500 Index, DRG and the S&P 600 Index include reinvestment of dividends. The performance shown is not necessarily indicative of future performance. Effective October 18, 2023, we were deleted from the S&P 500 index and added to the S&P SmallCap 600 index.



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

We make statements in this Annual Report on Form 10-K, and we may from time to time make other written reports and oral statements, regarding our outlook or expectations for financial, business or strategic matters regarding or affecting us 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," "believes," "would," "potentially," "intends," "seeks," 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 our 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 our 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 our filings with the SEC, provide examples of risks, uncertainties and events that may cause our actual results to differ materially from the expectations expressed in our forward-looking statements, including, but not limited to:

- expanded brand and class competition in the markets in which we operate;
- difficulties with performance of third parties we rely on for our 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 our products lose patent protection;
- any failure by us to obtain an additional period of market exclusivity in the United States for *Nexplanon* subsequent to the expiration of certain key patents in 2027;
- difficulties and uncertainties inherent in the implementation of our 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 higher selling and promotional costs;
- 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 our products and related intellectual property, environmental regulations, and the enforcement thereof affecting our business;
- efficacy, safety or other quality concerns with respect to our 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 our product candidates in pre-clinical and clinical trials, which may prevent or delay the development, approval, clearance, or commercialization of our 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, our or third-party providers' information technology systems, which could disrupt our operations;
- increased focus on privacy issues in countries around the world, including the United States, the EU, 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 our 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;

- the impact of any future pandemic, epidemic, or similar public health threat on our business, operations and financial performance;
- 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 us; and
- economic factors over which we have 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 we undertake 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 our financial condition and results of operations for the years ended December 31, 2023 and 2022 and should be read in conjunction with our 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. Additionally, this section should be read in connection with Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC and available on the SEC's website at www.sec.gov, which includes a discussion regarding our financial condition and results of operations for the years ended December 31, 2022 and 2021.

We are a global health care company with a focus on improving the health of women throughout their lives. We develop and deliver innovative health solutions through a portfolio of prescription therapies and medical devices within women's health, biosimilars and established brands. We have a portfolio of more than 60 medicines and products across a range of therapeutic areas. We sell 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. We operate 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 our companies.

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. In addition, *Nexplanon* may be eligible for an additional three years of market exclusivity in the United States subsequent to the expiration of certain key patents in 2027, although there can be no assurance that such an additional term will be granted.
- *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 electing 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 2020 and 2021 due to clinic closures and the postponement of non-essential medical procedures during country lockdowns. The LARC segment began to rebound in 2021 and 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*: With the global trend toward declining birthrates, governments and payors are implementing favorable policies across major markets that, in turn, improve access to care and drives growth for infertility therapies.
- *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

Eli Lilly ("Lilly")

In December 2023, we announced an agreement with Lilly to become the sole distributor and promoter of the migraine medicines *Emgality* and *Rayvow* in Europe. Lilly will remain the marketing authorization holder and will manufacture the products for sale. Under the terms of the agreement, we paid an upfront payment of $50 million, upon closing of the transaction in January 2024, and will pay sales-based milestone payments. The upfront payment and certain sales-based milestone payments, which were deemed probable of being achieved, are recognized as an intangible asset in the first quarter of 2024.

Claria Medical, Inc. ("Claria")

In January 2023, we 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, we paid $8 million upfront and have the option to acquire Claria for an additional $47 million, payable if and when the option is exercised. The $8 million was expensed as *Acquired in-process research and development and milestones* in our Condensed Consolidated Statement of Income for the year ended December 31, 2023.

COVID-19 Update

COVID-19 related disruptions, including patients' inability to access health care providers, negatively affected our results during 2022 and the first half of 2023, specifically, in China. The China economy has had a slower recovery from COVID-19 and this, coupled with healthcare budget deficits, has created cost containment measures post-COVID that have primarily impacted our retail business, and to a lesser extent has impacted the hospital side.

Operating Results

Sales Overview

	Year Ended December 31,			% Change	% Change Excluding Foreign Exchange	% Change	% Change Excluding Foreign Exchange
($ in millions)	2023	2022	2021	2023 vs. 2022		2022 vs. 2021	
United States	$ 1,478	$ 1,437	$ 1,383	3 %	3 %	4 %	4 %
International	4,785	4,737	4,921	1	4	(4)	4
Total	$ 6,263	$ 6,174	$ 6,304	1 %	3 %	(2)%	4 %

Worldwide sales were $6.3 billion for the year ended December 31, 2023, an increase of 1% compared with 2022. Worldwide sales were negatively impacted by approximately 2%, or $117 million, due to unfavorable foreign exchange. Excluding foreign exchange, sales increases primarily reflect the performance of; *Atozet* due to increased demand in various international markets; *Renflexis* driven primarily by continued patient growth in the United States and Canada; *Follistim AQ* due to a one-time buy-in as a result of the exit of the IOM in the United States, increased patient demand in the United States and volume recovery in China related to the COVID-19 negative impact during the first half of the year; *Ontruzant* driven by the timing of tenders and increased demand; *Jada* due to continued uptake in the United States following the launch; and *Marvelon* and *Mercilon,* resulting from the transaction with Bayer Healthcare where we gained rights in China during the second quarter of 2022 and in Vietnam during the third quarter of 2022. This performance was offset by: decreased sales of *Zetia* and *Vytorin* driven by the negative impact of VBP in China; the impact of the *Diprospan* regulatory inspection finding at the Heist manufacturing location

that impacted the manufacturing of selected injectable steroid brands in the first quarter of 2023 (the "Market Action"); and decreased sales of *Cozaar* and *Hyzaar* (a combination of losartan potassium and hydrochlorothiazide that is marketed in Japan as *Preminent™*), primarily due to ongoing generic competition.

The loss of exclusivity negatively impacted sales of certain of our products by approximately $18 million during the year ended December 31, 2023, compared to the year ended December 31, 2022, due to the decrease in volume period over period, which mainly impacted *NuvaRing* in the United States. VBP in China had a $95 million negative impact on our sales during the year ended December 31, 2023, compared to the year ended December 31, 2022. We expect VBP to impact our established brands product portfolio for the next several quarters.

Our operations include a portfolio of products. Highlights of the sales of our products for the year ended December 31, 2023 and 2022 are provided below. See Note 6 "Product and Geographic Information" to the Consolidated Financial Statements for further details on sales of our products.

Women's Health

	Year Ended December 31,			% Change	% Change Excluding Foreign Exchange	% Change	% Change Excluding Foreign Exchange
($ in millions)	2023	2022	2021	2023 vs. 2022		2022 vs. 2021	
Nexplanon/Implanon NXT	$ 830	$ 834	$ 769	(1)%	1 %	8 %	11 %
NuvaRing	152	173	191	(12)	(11)	(9)	(6)
Marvelon/Mercilon	134	110	98	22	24	12	20
Follistim AQ	262	229	237	14	16	(3)	—
ganirelix acetate injection	110	123	111	(10)	(8)	11	18
Jada	43	20	3	113	113	*	*

Contraception

Worldwide sales of *Nexplanon,* a single-rod subdermal contraceptive implant, declined 1% for the year ended December 31, 2023, compared to 2022, primarily due to the impact of foreign exchange, unfavorable discount rates, the result of distributor purchasing patterns associated with the timing of the increase in Nexplanon list price in the United States and the impact of the limited participation of a tender in Mexico. This was partially offset by price increases.

Worldwide sales of *NuvaRing*, a vaginal contraceptive product, declined 12% for the year ended December 31, 2023, compared to 2022, due to ongoing generic competition in the United States. We expect a continued decline in *NuvaRing* sales as a result of generic competition.

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 22% for the year ended December 31, 2023, compared to 2022, as a result of the transaction with Bayer Healthcare where we gained rights in China during the second quarter of 2022 and in Vietnam during the third quarter of 2022.

Fertility

Worldwide sales of *Follistim AQ*, a fertility treatment, increased 14% for the year ended December 31, 2023, compared to 2022, due to a one-time buy-in as a result of the exit of the IOM in the United States, increased patient demand in the United States and volume recovery in China related to the COVID-19 negative impact during the first half of the year. This was partially offset by the negative impact of unfavorable discount rates in the United States.

Worldwide sales of ganirelix acetate injection, a fertility treatment, declined 10% for the year ended December 31, 2023, compared to 2022, primarily due to unfavorable discount rates in the United States and increased generic competition in Europe.

Other Women's Health

Worldwide sales of *Jada,* a device intended to provide control and treatment of abnormal postpartum uterine bleeding or hemorrhage when conservative management is warranted, increased 113% for the year ended December 31, 2023, compared to 2022. The sales increase is due to continued uptake in the United States following the *Jada* launch in early 2022.

Biosimilars

	Year Ended December 31,			% Change	% Change Excluding Foreign Exchange	% Change	% Change Excluding Foreign Exchange
($ in millions)	2023	2022	2021	2023 vs. 2022		2022 vs. 2021	
Renflexis	$ 278	$ 226	$ 186	23 %	24 %	21 %	22 %
Ontruzant	155	122	126	28	27	(4)	—
Brenzys	73	75	63	(2)	1	19	24
Hadlima	44	19	13	125	130	51	57

Renflexis is a biosimilar to *Remicade* (infliximab) for the treatment of certain inflammatory diseases. Sales increased 23% for the year ended December 31, 2023, compared to 2022, driven primarily by continued demand growth in the United States and Canada. We have commercialization rights to *Renflexis* in countries outside Europe, Korea, China, Turkey, and Russia.

Ontruzant is a biosimilar to *Herceptin* (trastuzumab) for the treatment of HER2-overexpressing breast cancer and HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. Sales for the year ended December 31, 2023, compared to 2022, increased 28% driven by the timing of tenders in Brazil and increased demand partially offset by the competitive pressures in Europe. We have commercialization rights to *Ontruzant* in countries outside of Korea and China.

Brenzys is a biosimilar to *Enbrel* (etanercept) for the treatment of certain inflammatory diseases. Sales in the year ended December 31, 2023, compared to 2022, remained substantially consistent. We have commercialization rights to *Brenzys* in countries outside of the United States, Europe, Korea, China, and Japan.

Hadlima is a biosimilar to *Humira* (adalimumab) for the treatment of certain inflammatory diseases. We have commercialization rights to *Hadlima* in countries outside of the EU, Korea, China, Turkey, and Russia. We recorded sales of $44 million during the year ended December 31, 2023, reflecting an increase from modest sales during 2022 in markets outside of the United States and the launch in the United States in July 2023. *Hadlima* is currently approved in the United States, Australia, Canada, and Israel.

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

	Year Ended December 31,			% Change	% Change Excluding Foreign Exchange	% Change	% Change Excluding Foreign Exchange
($ in millions)	2023	2022	2021	2023 vs. 2022		2022 vs. 2021	
Zetia/Vytorin	$ 436	$ 488	$ 542	(11)%	(9)%	(10)%	(3)%
Atozet	519	457	458	14	13	—	11
Cozaar/Hyzaar	281	323	357	(13)	(9)	(10)	(3)

Combined global sales of *Zetia* and *Vytorin*, medicines for lowering LDL cholesterol, declined 11% for the year ended December 31, 2023, compared to 2022, primarily driven by the negative impact of VBP in China.

Sales of *Atozet*, a medicine for lowering LDL cholesterol, increased 14% for the year ended December 31, 2023, compared to 2022, primarily due to increased demand in various international markets.

Combined global sales of *Cozaar* and *Hyzaar*, medicines for the treatment of hypertension, declined 13% for the year ended December 31, 2023, compared to 2022, primarily due to ongoing generic competition.

Respiratory

	Year Ended December 31,			% Change	% Change Excluding Foreign Exchange	% Change	% Change Excluding Foreign Exchange
($ in millions)	2023	2022	2021	2023 vs. 2022		2022 vs. 2021	
Singulair	$ 404	$ 411	$ 413	(2)%	3 %	(1)%	9 %
Nasonex	253	238	206	6	10	16	22
Dulera	194	180	190	8	9	(5)	(5)

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 2% for the year ended December 31, 2023, compared to 2022, due to the impact of foreign exchange partially offset by increased demand due to higher incidences of respiratory conditions across many international markets during the fourth quarter of 2023 compared to 2022.

Global sales of *Nasonex*, an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, increased 6% for the year ended December 31, 2023, compared to 2022, due to increased demand across several markets partially offset by a $10 million milestone related to a regulatory approval received during the first quarter of 2022.

Global sales of *Dulera*, a combination medicine for the treatment of asthma, increased 8% for the year ended December 31, 2023, compared to 2022, primarily due to the favorable impact from price and increased demand 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)	2023	2022	2021	2023 vs. 2022		2022 vs. 2021	
Arcoxia	$ 257	$ 241	$ 244	7 %	12 %	(1)%	4 %
Diprospan	91	122	125	(25)	(22)	(3)%	2 %

Sales of *Arcoxia*, a medicine for the treatment of arthritis and pain, increased 7% for the year ended December 31, 2023, compared to 2022, primarily due to customers buying patterns and higher demand in various international markets.

Sales of *Diprospan*, a corticosteroid approved for treatment of a wide range of inflammatory conditions, declined 25% for the year ended December 31, 2023, compared to 2022, due to manufacturing issues resulting from the Market Action. In the first quarter of 2023, we resolved the regulatory inspection findings. Sales have not yet recovered. We expect the sales recovery to continue over the next twelve months.

Other

	Year Ended December 31,			% Change	% Change Excluding Foreign Exchange	% Change	% Change Excluding Foreign Exchange
($ in millions)	2023	2022	2021	2023 vs. 2022		2022 vs. 2021	
Proscar	$ 97	$ 101	$ 117	(3)%	1 %	(14)%	(9)%

Worldwide sales of *Proscar*, a medicine for the treatment of symptomatic benign prostate enlargement, for the year ended December 31, 2023, compared to 2022 were substantially consistent.

Costs, Expenses and Other

($ in millions)	Year Ended December 31, 2023	2022	2021	% Change 2023 vs. 2022	2022 vs. 2021
Cost of sales	$ 2,515	$ 2,294	$ 2,382	10 %	(4)%
Selling, general and administrative	1,893	1,704	1,668	11	2
Research and development	528	471	339	12	39
Acquired in-process research and development and milestones	8	107	104	(93)	3
Restructuring costs	62	28	3	*	*
Interest expense	527	422	258	25	64
Exchange losses	42	11	4	*	*
Other expense, net	15	15	17	—	(12)
	$ 5,590	$ 5,052	$ 4,775	11 %	6 %

** Calculation not meaningful.*

Cost of Sales

Cost of sales increased 10% for the year ended December 31, 2023, compared to 2022, primarily due to foreign exchange translation, higher employee-related and material and distribution related costs, which increased as a result of inflationary pressures, and product mix. During the year ended December 31, 2022, we recorded a $36 million inventory charge relating to the Market Action and an impairment charge of $9 million related to a product right for a biosimilar product. Cost of sales includes amortization of intangible assets which totaled $116 million in 2023, $116 million in 2022 and $103 million in 2021.

Selling, General and Administrative

Selling, general and administrative expenses increased 11% for the year ended December 31, 2023, compared to 2022, due to higher employee-related costs, costs incurred in connection with the separation from Merck, which includes the implementation of the enterprise resource planning system, and the $80 million charge related to the Microspherix legal matter as discussed in Note 20. "Contingencies" to the Consolidated Financial Statements. This was partially offset by lower promotional expenses.

Research and Development

Research and development expenses increased 12% for the year ended December 31, 2023, compared to 2022, primarily due to higher costs associated with our 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, 2023, acquired in-process research and development and milestones of $8 million related to the Claria transaction. For the year ended December 31, 2022 acquired in-process research and development and milestones represents the upfront and development milestones related to our research collaboration and license agreement with Cirqle and our agreement with Henlius for the license of certain biosimilar candidates.

Restructuring Costs

For the year ended December 31, 2023, we incurred $62 million of headcount-related restructuring expense, of which $58 million is due to activities initiated in the fourth quarter related to the ongoing optimization of our internal operations.

Interest Expense

Interest expense increased 25% for the year ended December 31, 2023, compared to 2022, due to increased interest rates, and debt fees and discounts expensed as part of the prepayment on the U.S. Dollar-denominated term loan and the impact of exchange rates.

Exchange Losses

For the year ended December 31, 2023, the change in exchange losses was driven by foreign currency exchange translation losses and the impact of the portion of Euro-denominated debt not designated as a net investment hedge in the prior year period.

Other Expense, net

For the year ended December 31, 2023, other expense, net, remained relatively consistent with the prior year.

Taxes on Income

The effective income tax rates were (52.2)% and 18.3% for the year ended December 31, 2023 and 2022, 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 and a partial valuation allowance recorded against non-deductible U.S. interest expense. In the fourth quarter of 2023, we recorded a $476 million tax benefit comprised of a gross benefit of $686 million, net of a $210 million valuation allowance, resulting from the termination of a Swiss tax arrangement. Our valuation allowance was determined based on expected future income and the terms of the remaining tax arrangement.

On August 16, 2022, the United States 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 2023 results. We will continue to assess future impacts of this legislation.

Liquidity and Capital Resources

As of December 31, 2023, we had cash and cash equivalents of $693 million. We have historically generated and expect to continue to generate positive cash flow from operations. 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. 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.

Working capital was $1.6 billion and $1.4 billion as of December 31, 2023 and December 31, 2022, respectively. The increase in working capital was primarily driven by an increase in inventory and the timing of collection of receivables.

Net cash provided by operating activities was $799 million for the year ended December 31, 2023 compared to $858 million for the same period in the prior year. The decrease in cash provided by operating activities was primarily attributable to the changes in working capital balances, offset by an increase in net income.

Net cash used in investing activities was $260 million for the year ended December 31, 2023 compared to $420 million for the same period in the prior year, primarily reflecting lower investment in business development transactions in the year ended December 31, 2023 compared to the prior year, partially offset by an increase in capital expenditures.

Net cash used in financing activities was $569 million for the year ended December 31, 2023 compared to $433 million for the same period in the prior year. The increase in cash used in financing activities was driven by the $250 million voluntary prepayment on the U.S. Dollar-denominated term loan in 2023 compared to the $100 million voluntary prepayment in 2022.

Capital expenditures were $251 million and $196 million for the years ended December 31, 2023 and 2022, respectively. Capital expenditures in 2023 and 2022 reflect investments in new capital projects focused primarily on establishing us as an independent Company. We estimate that we will continue to invest in new capital projects in 2024, for ongoing projects to stand up Organon, principally related to investments in information technology.

As part of our post-spinoff plan, we have approved an initiative to further optimize our manufacturing and supply network. As part of this initiative, we will continue to separate our supply chain through planned exits from supply agreements from Merck through 2031. This will enable us to redefine our appropriate sourcing strategy, and move to fit-for-purpose supply chains, while focusing on delivering efficiencies. We anticipate we will incur costs associated with this separation, including but not limited to accelerated depreciation, exit premiums and fees, technology transfer costs, stability and qualification batch costs, one-time resourcing costs, regulatory and filing costs, capital investment, and inventory stock bridges.

For the year ended December 31, 2023 and 2022, our combined revenues from Ukraine, Russia and Israel were approximately 2% of total revenues. While we will continue to monitor the impacts of the Ukraine-Russia war and the Hamas-Israel war, as of December 31, 2023, our assets in Ukraine, Russia and Israel are not material.

Contractual Obligations

Our contractual obligations as of December 31, 2023, 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 our collaborative partners achieve contractually defined success-based milestones such as the advancement of the specified research and development programs or the receipt of regulatory approval for the specified compounds or products and/or we reach 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, 2023, total potential payments due for contractual milestones are $1.9 billion. Potential amounts due within the next twelve months are $98 million.

Purchase obligations are enforceable and legally binding obligations for purchases of goods and services which include inventory purchase commitments. As of December 31, 2023, total payments due for purchase obligations are $1.2 billion and extend through 2031. Amounts due within the next twelve months are $376 million.

Long-term debt consists of both fixed and variable-rate instruments. As of December 31, 2023, total payments due for debt obligations are $8.8 billion and extend through 2031. Amounts due within the next twelve months are $9 million.

Lease obligations exclude reasonably certain lease renewals that have not yet been executed. As of December 31, 2023, total payments due for lease obligations are $189 million and extend through 2041. Amounts due within the next twelve months are $52 million.

During the 2024 fiscal year, we anticipate paying higher cash taxes than the 2023 fiscal year. In addition, we are responsible for settlement of certain tax matters, of which we expect to pay approximately $56 million within the next year.

During 2023, we paid cash dividends of $1.12 per share. On February 15, 2024, our Board of Directors declared a quarterly dividend of $0.28 for each issued and outstanding share of our common stock. The dividend is payable on March 14, 2024, to stockholders of record at the close of business on February 26, 2024.

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 2023, 2022, or 2021.

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)	2023	2022	2021
Balance January 1	$ 385	$ 329	$ 343
Provision	2,640	2,221	2,000
Payments[(1)]	(2,521)	(2,165)	(2,014)
Balance December 31	$ 504	$ 385	$ 329

[(1)] Includes 2021 payments made by Merck on behalf of us 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 $87 million and $417 million, respectively, at December 31, 2023, $78 million and $307 million, respectively, at December 31, 2022 and $54 million and $275 million, respectively, at December 31, 2021. The increase in accrued rebates in 2023 is attributable to a wholesaler buy-in in conjunction with the exit of the IOM with Merck for the *Follistim* product.

Outside of the United States, variable consideration in the form of discounts and rebates is 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 20 "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 $2 million in 2023, and are estimated at $15 million in the aggregate for the years 2024 through 2028. Liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $19 million and $20 million at December 31, 2023 and 2022, 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, we do not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed $24 million in the aggregate. We also do 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, 2023 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. We did not have impairment charges as of December 31, 2023. We recorded impairment charges of $9 million and $7 million as of December 31, 2022 and 2021 respectively. See Note 13 "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 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, 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 on 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. We make certain judgments, which include assessment of the inputs, processes, and outputs associated with the acquired set of activities. If we determine 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), we account 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 we deem reasonable.

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 15 "Pension and Other Postretirement Benefit Plans" to the Consolidated Financial Statements.

For our pension plans, the discount rate is evaluated on measurement dates 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, we consider long-term compound annualized returns of historical market data, current market conditions and actual returns on our plan assets. Using this reference information, we develop 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 mitigate against volatility of changes in foreign exchange rates. See Note 14 "Financial Instruments" to the Consolidated Financial Statements included in this report for further information on our 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, 2023 and 2022, 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, 2023, 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, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023 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, 2023, 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 matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Income Taxes - Valuation of Certain Deferred Tax Assets in Switzerland

As described in Notes 3 and 10 to the consolidated financial statements, as of December 31, 2023, the Company has $863 million of net deferred tax assets, inclusive of valuation allowances totaling $309 million, of which $210 million of the valuation allowances relate to certain Switzerland deferred tax assets. In 2023, the Company recorded a $476 million tax benefit comprised of a gross benefit of $686 million, net of a $210 million valuation allowance, resulting from the termination of a tax arrangement in Switzerland. The valuation allowance was determined based on expected future income and the terms of the remaining Switzerland tax arrangement. 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 income is not likely to support the use of the deduction or credit. Management assesses all available evidence to estimate whether a valuation allowance should be recorded against existing deferred tax assets.

The principal considerations for our determination that performing procedures relating to the valuation of certain deferred tax assets in Switzerland is a critical audit matter are (i) the significant judgment by management when determining whether these deferred tax assets are more likely than not to be realized in the future; (ii) a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating audit evidence related to management's significant assumption related to expected future income by year for Switzerland; and (iii) the audit effort involved the use of professionals with specialized skill and knowledge.

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 the realizability of the deferred tax assets, including controls over management's assessment of expected future income for Switzerland. These procedures also included, among others, testing management process by (i) evaluating evidence available to support management's assessment of the realizability of certain deferred tax assets in Switzerland; (ii) testing the completeness and accuracy of underlying data used in management's assessment; (iii) evaluating the terms of the Company's existing tax arrangement in Switzerland and the appropriateness of enacted tax rates; and (iv) evaluating the reasonableness of management's significant assumption related to expected future income by year for Switzerland. Evaluating the reasonableness of expected future income by year for Switzerland involved considering (i) the current and past performance of the Switzerland entity and (ii) whether the assumption was consistent with evidence obtained in other areas of the audit. Professionals with specialized skill and knowledge were used to assist in evaluating the reasonableness of certain inputs used by management in developing the significant assumption related to expected future income for Switzerland.

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, 2023 in the United States was $417 million, of which the majority related to U.S. rebate accruals for 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 for Medicaid and Managed Care is a critical audit matter are (i) the significant judgment by management when developing these rebate accruals; (ii) a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating management's significant assumptions related to pricing information and historical customer segment utilization mix; and (iii) the audit effort involved the use of professionals with specialized skill and knowledge.

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 U.S. Medicaid and Managed Care rebates. These procedures also included, among others (i) developing an independent estimate of the U.S. rebate accruals for Medicaid and Managed Care 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 U.S. rebate accruals for Medicaid and Managed Care recorded by management; and (iii) testing, on a sample basis, actual rebate claims paid for U.S. Medicaid and Managed Care, including evaluating those claims for consistency with the contractual terms of the Company's rebate agreements. Professionals with specialized skill and knowledge were used to assist in evaluating the reasonableness of the pricing information used in the Medicaid portion of the accrual.

/s/ PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 26, 2024
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,		
	2023	2022	2021
Revenues	$ 6,263	$ 6,174	$ 6,304
Costs, Expenses and Other			
Cost of sales	2,515	2,294	2,382
Selling, general and administrative	1,893	1,704	1,668
Research and development	528	471	339
Acquired in-process research and development and milestones	8	107	104
Restructuring costs	62	28	3
Interest expense	527	422	258
Exchange losses	42	11	4
Other expense, net	15	15	17
	5,590	5,052	4,775
Income Before Income Taxes	673	1,122	1,529
Taxes on income	(350)	205	178
Net Income From Continuing Operations	1,023	917	1,351
Loss From Discontinued Operations - Net of Tax	—	—	—
Net Income	$ 1,023	$ 917	$ 1,351
Earnings per Share - Basic:			
Continuing operations	$ 4.01	$ 3.61	$ 5.33
Discontinued operations	—	—	—
Net Earnings per Share - Basic	$ 4.01	$ 3.61	$ 5.33
Earnings per Share - Diluted:			
Continuing operations	$ 3.99	$ 3.59	$ 5.31
Discontinued operations	—	—	—
Net Earnings per Share - Diluted	$ 3.99	$ 3.59	$ 5.31
Weighted Average Shares Outstanding:			
Basic	255,239	254,082	253,538
Diluted	256,270	255,169	254,193

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,		
	2023	2022	2021
Net income	$ 1,023	$ 917	$ 1,351
Other Comprehensive Income (Loss), Net of Taxes:			
Benefit plan net (loss) gain and prior service (cost) credit, net of amortization	(25)	23	8
Cumulative translation adjustment	48	(74)	90
	23	(51)	98
Comprehensive income	$ 1,046	$ 866	$ 1,449

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

Organon & Co.
Consolidated Balance Sheets
($ in millions except shares in thousands and per share amounts)

	December 31, 2023	December 31, 2022
Assets		
Current Assets:		
Cash and cash equivalents	$ 693	$ 706
Accounts receivable (net of allowance for doubtful accounts of $9 in 2023 and $9 in 2022)	1,744	1,475
Inventories (excludes inventories of $110 in 2023 and $148 in 2022 classified in Other assets)	1,315	1,003
Other current assets	756	747
Total Current Assets	4,508	3,931
Property, plant and equipment, net	1,183	1,018
Goodwill	4,603	4,603
Intangibles, net	533	649
Other assets	1,231	754
Total Assets	$ 12,058	$ 10,955
Liabilities and Equity		
Current Liabilities:		
Current portion of long-term debt	$ 9	$ 8
Trade accounts payable	1,314	1,132
Accrued and other current liabilities	1,389	1,188
Income taxes payable	206	184
Total Current Liabilities	2,918	2,512
Long-term debt	8,751	8,905
Deferred income taxes	47	19
Other noncurrent liabilities	412	411
Total Liabilities	12,128	11,847
Contingencies (Note 20)		
Organon & Co. Stockholders' Deficit:		
Common stock, $0.01 par value Authorized - 500,000 Issued and outstanding - 255,626 in 2023 and 254,370 in 2022	3	3
Additional paid-in capital	25	—
Retained earnings and accumulated (deficit)	443	(331)
Accumulated other comprehensive loss	(541)	(564)
Total Stockholders' Deficit	(70)	(892)
Total Liabilities and Stockholders' Deficit	$ 12,058	$ 10,955

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 and per share amounts)

	Common Stock		Additional Paid-In Capital	Retained Earnings and Accumulated (Deficit)	Net Investment from Merck & Co., Inc.	Accumulated Other Comprehensive Loss	Total
	Shares	Par Value					
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 to Merck & Co., Inc. including Separation Adjustments	—	—	—	(24)	—	—	(24)
Balance at December 31, 2022	254,370	$ 3	$ —	$ (331)	$ —	$ (564)	$ (892)
Net income	—	—	—	1,023	—	—	1,023
Other comprehensive income, net of taxes	—	—	—	—	—	23	23
Cash dividends declared on common stock ($1.12 per share)	—	—	—	(295)	—	—	(295)
Stock-based compensation plans and other	1,256	—	25	59	—	—	84
Net transfers to Merck & Co., Inc. including Separation Adjustments	—	—	—	(13)	—	—	(13)
Balance at December 31, 2023	255,626	$ 3	$ 25	$ 443	$ —	$ (541)	$ (70)

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,		
	2023	2022	2021
Cash Flows from Operating Activities			
Net income from continuing operations	$ 1,023	$ 917	$ 1,351
Adjustments to reconcile net income from continuing operations to net cash flows provided by operating activities:			
Depreciation	120	96	92
Amortization	116	116	103
Impairment of assets	—	9	7
Acquired in-process research and development and milestones	8	107	104
Deferred income taxes	(485)	(18)	(288)
Stock-based compensation	101	75	59
Unrealized foreign exchange loss (gain)	40	(18)	18
Other	31	26	12
Net changes in assets and liabilities			
Accounts receivable	(212)	(123)	(277)
Inventories	(230)	(220)	(138)
Other current assets	(10)	(43)	353
Trade accounts payable	163	(237)	663
Accrued and other current liabilities	102	172	329
Due from/due to related party	—	—	(164)
Income taxes payable	16	7	(119)
Other	16	(8)	55
Net Cash Flows Provided by Operating Activities from Continuing Operations	799	858	2,160
Cash Flows from Investing Activities			
Capital expenditures	(251)	(196)	(192)
Proceeds from sale of property, plant and equipment	1	7	7
Acquired in-process research and development and milestones	(8)	(107)	(104)
Purchase of product rights and asset acquisition, net of cash acquired	(2)	(124)	(192)
Net Cash Flows Used in Investing Activities from Continuing Operations	(260)	(420)	(481)
Cash Flows from Financing Activities			
Proceeds from debt	80	—	9,470
Repayments of debt	(338)	(108)	(112)
Payment of long-term debt issuance costs	—	—	(118)
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 Merck & Co., Inc.	—	(24)	440
Employee withholding taxes related to stock-based awards	(17)	(11)	—
Dividend payments	(294)	(290)	(145)
Net Cash Flows Used in Financing Activities from Continuing Operations	(569)	(433)	(977)
Discontinued Operations			
Net Cash Provided by (Used in) Operating Activities	—	—	298
Net Cash Used in Financing Activities	—	—	(356)
Net Cash Flows Used in Discontinued Operations	—	—	(58)
Effect of Exchange Rate Changes on Cash and Cash Equivalents from Continuing Operations	17	(36)	23
Net (Decrease) Increase in Cash and Cash Equivalents	(13)	(31)	667
Cash and Cash Equivalents, Beginning of Period	706	737	12
Cash and Cash Equivalents of Discontinued Operations, Beginning of Period	—	—	58
Total Cash and Cash Equivalents, End of Period	693	706	737
Less: Cash and Cash Equivalents of Discontinued Operations, End of Period	—	—	—
Cash and Cash Equivalents, End of Period	$ 693	$ 706	$ 737

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*™ 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) (marketed in most countries outside the United States as *Puregon*™). *Nexplanon* is 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. Other women's health products include the *Jada*® System, which is intended to provide control and treatment of abnormal postpartum uterine bleeding or hemorrhage when conservative management is warranted and 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. In October 2023, *Xaciato* was launched in the United States.

- *Biosimilars*: Organon's current portfolio spans across immunology and oncology treatments. Organon's oncology biosimilars; *Ontruzant*® (trastuzumab-dttb) and *Aybintio*™ [1] (bevacizumab), have been launched in more than 20 countries and Organon's immunology biosimilars; *Brenzys*™ [1] (etarnarcept), *Renflexi*s® (infliximab-abda) and *Hadlima*® (adalimumab-bwwd), have been launched in five countries. All five biosimilars in Organon's portfolio have launched in Canada, and three biosimilars; *Ontruzant*, *Renflexis* and *Hadlima* 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.

2. Basis of Presentation

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"). 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.

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.

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 8 "Restructuring") and stock-based compensation expenses (see Note 7 "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 maintained various employee benefit plans in which the Company's employees participated during periods prior to the Separation, 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.

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 that 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 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 19 "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. 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 15 "Pension and Other Postretirement Benefit Plans" for details. Additionally, stock-based awards were converted in accordance with the employee matters agreement (the "Employee Matters Agreement") entered into between Organon and Merck in connection with the spinoff. See Note 7 "Stock-Based Compensation Plans" for details.

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.

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.

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 2023, 2022, or 2021.

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)	2023	2022	2021
Balance January 1	$ 385	$ 329	$ 343
Provision	2,640	2,221	2,000
Payments[(1)]	(2,521)	(2,165)	(2,014)
Balance December 31	$ 504	$ 385	$ 329

[(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 $87 million and $417 million, respectively, at December 31, 2023 and $78 million and $307 million, respectively, at December 31, 2022.

Outside of the United States, variable consideration in the form of discounts and rebates is a combination of commercially-driven discounts in highly competitive product classes, discounts required to gain or maintain reimbursement, or legislatively mandated rebates. The accrued balances relative to the provision for chargebacks and rebates, based on the terms and nature of the rebate, are included in *Accounts receivable* and *Accrued and other current liabilities*. 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, 2023 and 2022, the accrued balances related to the provision for rebates and discounts included in other current liabilities were approximately $126 million and $109 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 are typically 30 days to 90 days, although certain markets have longer payment terms. See Note 6 "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 $113 million and $110 million as of December 31, 2023 and 2022, respectively. VAT payables included in *Accrued and other current liabilities* were $18 million and $9 million as of December 31, 2023 and 2022, 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 $120 million in 2023, $96 million in 2022, and $92 million in 2021. 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 $209 million, $255 million, and $236 million in 2023, 2022 and 2021, 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, 2023 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 13 "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, 2023, 2022 and 2021.

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

Acquired in-process research and development and milestones — Acquired IPR&D and milestones includes upfront and milestone payments related to asset acquisitions, licensing or collaborative arrangements that are not considered an acquisition of a business and involve clinical development programs that have not yet received regulatory approval.

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 7 "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 15 "Pension and Other Postretirement Benefit 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 income is not likely to support the use of the deduction or credit. The Company assesses all available evidence to estimate whether a valuation allowance should be recorded against existing deferred tax assets. The amounts of the deferred tax asset considered realizable, however, could be adjusted in future periods if estimates of future income are reduced or increased.

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 19 "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) 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 16 "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 19 "Third-Party Arrangements and Related Party Disclosures" for additional information.

Recently Adopted Accounting Standards

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 applied this guidance to the Senior Credit Agreement, as amended on June 30, 2023. The impact to the Consolidated Financial Statements as a result of the application of the reference rate reform guidance is not material. See Note 16 "Long-Term Debt and Leases" for additional details.

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 did 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.

Recently Issued Accounting Standards Not Yet Adopted

In December 2023, the FASB issued ASU No. 2023-09, *Improvements to Income Tax Disclosures*, which requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. The standard is intended to benefit investors by providing more detailed income tax disclosures that would be useful in making capital allocation decisions. The amendments in this ASU are effective for annual periods beginning on January 1, 2025, and should be applied on a prospective basis with the option to apply the standard retrospectively. Early adoption is permitted. This ASU will have no impact on the Company's consolidated financial condition or results of operations. The Company is currently evaluating the impact to its income tax disclosures.

In November 2023, the FASB issued ASU No. 2023-07, *Improvements to Reportable Segment Disclosure*s, which improves reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. In addition, the amendments enhance interim disclosure requirements, clarify circumstances in which an entity can disclose multiple segment measures of profit or loss, provide new segment disclosure requirements for entities with a single reportable segment, and contain other disclosure requirements. The purpose of the amendments is to enable investors to better understand an entity's overall performance and assess potential future cash flows. The amendments in this ASU are effective for annual periods beginning on January 1, 2024 and interim periods beginning on January 1, 2025, and should be applied on a retrospective basis for all periods presented. This ASU will have no impact on the Company's consolidated financial condition or results of operations. The Company is currently evaluating the impact to its segment disclosures.

4. Acquisitions and Licensing Arrangements

2023 Transactions

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 an additional $47 million, payable if and when the option is exercised. The $8 million was expensed as *Acquired in-process research and development and milestones* in the Consolidated Statement of Income for the year ended December 31, 2023.

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 worldwide 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. 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. In October 2023, *Xaciato* was launched in the United States.

Bayer Healthcare

In February 2022, Organon acquired the product rights and related inventory from Bayer Healthcare to *Marvelon*™ [1] (ethinylestradiol, desogestrel) and *Mercilon*™ [1] (ethinylestradiol, desogestrel), combined oral hormonal daily contraceptive pills, in China (including Hong Kong and Macau). In August 2022, Organon acquired 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.

5. 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. For the year ended December 31, 2021 these shares are treated as issued and outstanding as of January 1, 2021 for purposes of calculating historical basic and diluted earnings per share.

The calculations of basic and diluted earnings per common share are as follows:

	Year Ended December 31,		
($ in millions and shares in thousands, except per share amounts)	2023	2022	2021
Net income:			
Income from continuing operations	$ 1,023	$ 917	$ 1,351
Income from discontinued operations	—	—	—
Net income	$ 1,023	$ 917	$ 1,351
Basic weighted average number of shares outstanding	255,239	254,082	253,538
Stock awards and equity units (share equivalent)	1,031	1,087	655
Diluted weighted average common shares outstanding	256,270	255,169	254,193
EPS:			
Continuing operations	$ 4.01	$ 3.61	$ 5.33
Discontinued operations	—	—	—
Net Earnings per Share - Basic	$ 4.01	$ 3.61	$ 5.33
Earnings per Share - Diluted:			
Continuing operations	$ 3.99	$ 3.59	$ 5.31
Discontinued operations	—	—	—
Net Earnings per Share - Diluted	$ 3.99	$ 3.59	$ 5.31
Anti-dilutive shares excluded from the calculation of EPS	9,025	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, diluted EPS was computed using the treasury stock method for stock option awards, performance share units and restricted share units. The computation of diluted EPS excludes the effect of the potential exercise of stock-based awards when the effect of the potential exercise would be anti-dilutive.

6. 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 and medical devices within women's health, biosimilars and established brands.

Revenues of the Company's products were as follows:

	Year Ended December 31,								
	2023			2022			2021		
($ in millions)	U.S.	Int'l	Total	U.S.	Int'l	Total	U.S.	Int'l	Total
Women's Health									
Nexplanon/Implanon NXT	$ 572	$ 257	$ 830	$ 573	$ 261	$ 834	$ 532	$ 237	$ 769
Follistim AQ	125	136	262	105	124	229	110	127	237
NuvaRing	66	86	152	85	88	173	85	106	191
Ganirelix Acetate Injection	19	91	110	26	97	123	22	88	111
Marvelon/Mercilon	—	134	134	—	110	110	—	98	98
Jada	43	—	43	20	—	20	3	—	3
Other Women's Health [(1)]	72	101	171	90	94	184	96	111	206
Biosimilars									
Renflexis	234	43	278	196	30	226	164	21	186
Ontruzant	46	109	155	48	74	122	34	92	126
Brenzys	—	73	73	—	75	75	—	63	63
Aybintio	—	43	43	—	39	39	—	36	36
Hadlima	17	26	44	—	19	19	—	13	13
Established Brands									
Cardiovascular									
Zetia	8	299	306	8	350	357	10	368	378
Vytorin	6	124	129	8	123	130	11	153	164
Atozet	—	519	519	—	457	457	—	458	458
Rosuzet	—	70	70	—	71	71	—	68	68
Cozaar/Hyzaar	10	272	281	13	310	323	12	345	357
Other Cardiovascular [(1)]	2	151	155	3	156	159	4	187	191
Respiratory									
Singulair	11	393	404	11	400	411	15	398	413
Nasonex	—	252	253	10	229	238	4	201	206
Dulera	156	38	194	140	40	180	154	36	190
Clarinex	5	132	136	4	121	125	6	106	111
Other Respiratory [(1)]	49	28	77	46	36	83	56	33	89
Non-Opioid Pain, Bone and Dermatology									
Arcoxia	—	257	257	—	241	241	—	244	244
Fosamax	3	156	159	4	148	152	4	172	175
Diprospan	—	91	91	—	122	122	—	125	125
Other Non-Opioid Pain, Bone and Dermatology [(1)]	14	261	275	15	257	273	16	269	286
Other									
Proscar	1	96	97	1	99	101	1	116	117
Propecia	7	118	125	7	118	125	9	127	136
Other [(1)]	13	308	319	24	302	326	38	318	357
Other [(2)]	(1)	121	121	—	146	146	(3)	205	200
Revenues	$ 1,478	$ 4,785	$ 6,263	$ 1,437	$ 4,737	$ 6,174	$ 1,383	$ 4,921	$ 6,304

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 **Jada** 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 & Co., Inc. ("Merck") and third parties for current and prior periods.

Revenues by geographic area where derived are as follows:

($ in millions)	Year Ended December 31, 2023	2022	2021
Europe and Canada	$ 1,673	$ 1,631	$ 1,741
United States	1,478	1,437	1,383
Asia Pacific and Japan	1,129	1,143	1,173
China	864	917	933
Latin America, Middle East, Russia, and Africa	965	895	841
Other [(1)]	154	151	233
Revenues	$ 6,263	$ 6,174	$ 6,304

[(1)] *Primarily reflects manufacturing sales to Merck and third parties for current and prior periods.*

As of December 31, 2023, approximately 71% of the Company's long-lived fixed assets are located in Europe and Canada, and 18% 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.

7. 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 PSU awards are 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; and
- the results of the cumulative free cash flow ("FCF") of the Company over a three-year period.

For FCF and relative 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. The Company uses the Monte Carlo simulation to determine the fair value of the relative TSR awards as of the grant date.

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 expenses incurred by the Company were as follows:

	Year Ended December 31,		
($ in millions)	2023	2022	2021
Stock-based compensation expense recognized in:			
Cost of sales	$ 17	$ 13	$ 11
Selling, general and administrative	68	51	36
Research and development	16	11	12
Total	$ 101	$ 75	$ 59
Income tax benefits	$ 21	$ 16	$ 12

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, 2023, the unrecognized portion of the incremental stock-based expense was $1 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. In 2023, the historical component of expected volatility is based on historical monthly price changes of a combination of the peer group within the industry and Organon's historical monthly price changes. In 2022 and 2021, the historical component of expected volatility is based only on historical monthly price changes of a combination 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 granted was determined using the following assumptions:

	Year Ended December 31,		
	2023	2022	2021
Expected dividend yield	4.82 %	3.12 %	3.22 %
Risk-free interest rate	3.56	2.47	0.92
Expected volatility	42.30	43.43	45.80
Expected life (years)	5.89	5.89	5.89

A summary of the equity award transactions for the year ended December 31, 2023 is 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, 2023	4,729	$ 34.34	$ 9.00	5,048	$ 33.27	486	$ 39.29
Granted	1,124	23.52	6.55	5,090	20.84	636	23.20
Vested/Exercised	—	—	—	(1,958)	33.83	—	—
Forfeited/Cancelled	(95)	36.12	9.71	(669)	29.40	—	—
Outstanding as of December 31, 2023	5,758	$ 32.20	$ 8.51	7,511	$ 25.05	1,122	$ 30.16

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, 2023:

	Equity Awards Vested and Expected to Vest				Equity Awards That are Exercisable			
(awards in thousands; aggregate intrinsic value in millions)	Awards	Weighted Average Exercise Price	Aggregate Intrinsic Value	Remaining Term (in years)	Awards	Weighted Average Exercise Price	Aggregate Intrinsic Value	Remaining Term (in years)
Stock Options	5,623	$ 32.20	$ —	6.79	3,311	$ 33.79	$ —	5.61
Restricted Share Units	7,023		108	1.93				
Performance Share Units	610		10	1.60				

The amount of unrecognized compensation costs as of December 31, 2023 was $153 million, which will be recognized in operating expense ratably over the weighted average vesting period of 1.86 years.

8. 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 restructured approximately 130 positions, with the majority of the position eliminations occurring in selected markets outside of the United States in the commercial organizations.

In the fourth quarter of 2023, Organon implemented additional restructuring activities related to the ongoing optimization of its internal operations by reducing headcount in certain markets and functions. As a result of these activities, the Company's headcount will be reduced by approximately 3% over the next twelve months.

Organon expects the remaining severance payments associated with the restructuring activities to be paid by the end of 2024.

The following is a summary of changes in severance liabilities related to the restructuring activities included within *Accrued and other current liabilities*:

	December 31, 2023	December 31, 2022
Beginning balance	20	—
Severance & severance related costs	62	28
Cash payments and other	(21)	(8)
Ending Balance	61	20

9. 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:

($ in millions)	Year Ended December 31, 2021
Sales	$ 93
Costs, Expenses and Other	
Cost of Sales	65
Selling, general and administrative	15
Research and development	4
Restructuring Costs	—
Other expense, net	4
Loss from discontinued operations before taxes	$ 5
Taxes on income	5
Loss from discontinued operations, net of taxes	$ —

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

10. Taxes on Income

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

	Year Ended December 31,					
	2023		2022		2021	
($ in millions)	Amount	Tax Rate	Amount	Tax Rate	Amount	Tax Rate
U.S. statutory rate applied to income before taxes	$ 141	21.0 %	$ 236	21.0 %	$ 321	21.0 %
Differential arising from:						
Foreign earnings	(91)	(13.6)	(113)	(10.1)	(39)	(2.5)
Tax settlements	(13)	(1.9)	(2)	(0.1)	(32)	(2.1)
Amortization of intangible assets	(686)	(102.0)	—	—	(75)	(4.9)
State taxes	(5)	(0.8)	(2)	(0.2)	(3)	(0.2)
Global Intangible Low-Taxed Income	54	8.0	57	5.1	17	1.1
Interest expense disallowance	46	6.8	13	1.2	—	—
Valuation allowance	208	30.9	4	0.4	(4)	(0.3)
Other	(4)	(0.6)	12	1.0	(7)	(0.4)
	$ (350)	(52.2)%	$ 205	18.3 %	$ 178	11.7 %

Prior to the Separation, income taxes were calculated as if the Company filed income tax returns on a separate return 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. 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, 2023, the deferred income tax liabilities on undistributed earnings for certain subsidiaries that are deemed indefinitely reinvested was $4 million. At December 31, 2022 the deferred tax balance was 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 (52.2)%, 18.3% and 11.7% for 2023, 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 and a partial valuation allowance recorded against non-deductible U.S. interest expense, as well as a $476 million tax benefit comprised of a gross benefit of $686 million, net of a $210 million valuation allowance, resulting from the termination of a tax arrangement in Switzerland recorded in the fourth quarter 2023. The valuation allowance was determined based on expected future income and the terms of the remaining Swiss tax arrangement. 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)	2023	2022	2021
Domestic	$ (554)	$ (451)	$ (96)
Foreign	1,227	1,573	1,625
	$ 673	$ 1,122	$ 1,529

Taxes on income consisted of:

	Year Ended December 31,		
($ in millions)	2023	2022	2021
Current provision			
Federal	$ 47	$ 51	$ 41
Foreign	87	172	435
State	1	—	(10)
	$ 135	$ 223	$ 466
Deferred provision			
Federal	$ (52)	$ (38)	$ (64)
Foreign	(428)	22	(220)
State	(5)	(2)	(4)
	$ (485)	$ (18)	$ (288)
	$ (350)	$ 205	$ 178

Deferred income taxes at December 31 consisted of:

	December 31,			
	2023		2022	
($ in millions)	Assets	Liabilities	Assets	Liabilities
Product intangibles and licenses	$ 927	$ —	$ 164	$ —
Inventory related	3	—	—	10
Reserves and allowances	38	—	51	—
Accrued expenses	5	—	22	—
Accelerated depreciation	—	18	—	11
Unremitted foreign earnings	—	5	—	3
Right of use asset	38	—	44	—
Lease liability	—	38	—	44
Interest expense limitation carryforward	72	—	37	—
Compensation related	17	—	26	—
Hedging	—	41	—	59
Net operating losses and other tax credit carryforwards	35	—	65	—
Other	37	—	18	—
Subtotal	$ 1,172	$ 102	$ 427	$ 127
Valuation allowance	(309)	—	(52)	—
Total deferred taxes	$ 863	$ 102	$ 375	$ 127
Net deferred income taxes	$ 761		$ 248	
Recognized as:				
Other Assets	$ 808		$ 267	
Deferred Income Taxes		$ 47		$ 19

A reconciliation of the beginning and ending amount of the valuation allowance is as follows:

	Years Ended December 31,	
	2023	2022
Beginning balance	$ (52)	$ (35)
Additions charged to expense	(257)	(17)
Ending balance	$ (309)	$ (52)

The Company has recognized $35 million and $65 million deferred taxes on net operating loss ("NOL") carryforwards in multiple jurisdictions as of December 31, 2023 and 2022, respectively. Valuation allowances of $309 million have been established on $250 million of foreign deferred tax assets and $59 million of U.S. deferred tax assets. The $257 million increase in the valuation allowance in 2023 is primarily due to a $210 million valuation allowance recorded in connection with the future benefit of a Swiss tax arrangement and $46 million of a valuation allowance recorded in connection with disallowed interest expense in the United States. The valuation allowance on the Swiss deferred tax assets was determined based on expected future income and the terms of the remaining Swiss tax arrangement. During 2022, the Company increased its valuation allowance by $17 million primarily due to disallowed interest expense in the United States.

Income taxes paid in 2023, 2022 and 2021, were $135 million, $214 million and $131 million, respectively.

As of December 31, 2023 and 2022, the Company deferred the income tax consequences resulting from intra-entity transfers of inventory totaling $396 million and $368 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)	2023	2022	2021
Balance January 1	$ 93	$ 78	$ 219
Additions related to current year tax positions	32	30	23
Additions related to prior year tax positions	7	3	18
Reductions for tax positions of prior years	(8)	(3)	(49)
Spinoff related adjustments [(1)]	—	—	(108)
Settlements	(7)	(12)	(15)
Lapse of statute of limitations	(2)	(3)	(10)
Balance December 31	$ 115	$ 93	$ 78

(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 $115 million, at December 31, 2023, the income tax provision would reflect a favorable net impact of $115 million.

In 2023 and 2022, foreign tax authorities concluded their examinations of certain foreign income tax returns. As a result, the Company reflected a payment of $7 million and $12 million in the consolidated financial statements in 2023 and 2022, respectively. A corresponding reduction in reserves of $15 million and $11 million were also reflected in 2023 and 2022, respectively, 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 Organon operates. 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, 2023 could decrease by up to $27 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 resulted in $3 million of expense in 2023 and were immaterial in 2022 and 2021. These amounts reflect the beneficial impacts of various tax settlements. Liabilities for accrued interest and penalties were $40 million and $35 million as of December 31, 2023 and 2022, respectively.

Various foreign tax examinations are in progress and for these jurisdictions, income tax returns are open for examination for the period 2007 through 2023.

11. Inventories

Inventories consisted of:

($ in millions)	December 31, 2023	December 31, 2022
Finished goods	$ 566	$ 482
Raw materials	110	44
Work in process	684	601
Supplies	65	44
Total (approximates current cost)	$ 1,425	$ 1,171
Decrease to LIFO costs	—	(20)
	$ 1,425	$ 1,151
Recognized as:		
Inventories	$ 1,315	$ 1,003
Other assets	110	148
Inventories valued under the last in, first out ("LIFO") method	105	77

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 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, 2023, total inventory purchase obligations are $1.0 billion and extend through 2031. Inventory purchase obligations due within the next twelve months amount to $318 million.

12. Property, Plant and Equipment

($ in millions)	December 31, 2023	December 31, 2022
Land	$ 14	$ 13
Buildings	721	694
Machinery, equipment and office furnishings	1,191	935
Construction in progress	274	278
Less: accumulated depreciation	(1,017)	(902)
Property, Plant and Equipment, net	$ 1,183	$ 1,018

13. Intangibles

Intangibles consists of:

	December 31, 2023			December 31, 2022		
($ in millions)	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Products and product rights	$ 24,290	$ 23,845	$ 445	$ 24,285	$ 23,746	$ 539
Licenses	231	143	88	231	121	110
	$ 24,521	$ 23,988	$ 533	$ 24,516	$ 23,867	$ 649

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.

The Company did not have impairment charges in 2023. 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 2023, $116 million in 2022 and $103 million in 2021.

The estimated aggregate future amortization expense is as follows:

($ in millions)	
2024	$ 112
2025	111
2026	105
2027	48
2028	40
Thereafter	117

14. 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 $1.4 billion and $1.5 billion as of December 31, 2023 and December 31, 2022, respectively. The cash flows and the related gains and losses 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 the assets and liabilities were as follows:

($ in millions)	Fair Value Measurement Level	December 31, 2023	December 31, 2022
Forward contracts in *Other current assets*	2	$ 9	$ 6
Forward contracts in *Accrued and other current liabilities*	2	16	24

Foreign exchange risk is also managed through the use of economic hedges on foreign currency balances. See Note 16 "Long-Term Debt and Leases" for additional details. €1.981 billion in the aggregate of both the euro-denominated term loan (€731 million) and the 2.875% euro-denominated secured notes (€1.25 billion) has been designated and is effective as an economic hedge of the net investment in euro-denominated subsidiaries.

Foreign currency (loss) gain 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)	2023	2022	2021
Foreign currency (loss) gain in *Other comprehensive income*	$ (84)	$ 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 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)	2023	2022	2021
Allocated net loss in *Revenues*	$ —	$ —	$ 56
Foreign exchange loss in *Exchange losses*	$ 42	$ 11	4

Concentrations of Credit Risk

Organon has established accounts receivable factoring agreements with financial institutions in certain countries to sell accounts receivable. Under these agreements, Organon factored $66 million and $43 million of accounts receivable as of December 31, 2023 and December 31, 2022, 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.

The Company monitors credit exposures through limits that were established to limit 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 McKesson Corporation, Amerisource Bergen Corporation and Curascript Specialty Distribution which represented approximately 9%, 8%

and 7%, respectively, of total gross account receivable at December 31, 2023. Bad debts have been minimal. The Company does not normally require collateral or other security to support credit sales.

15. 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 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 was $29 million. 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 $34 million as of December 31, 2023, of which $28 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:

	Year Ended December 31,		
($ in millions)	2023	2022	2021
Service cost	$ 17	$ 22	$ 17
Interest cost	5	2	2
Expected return on plan assets	(6)	(4)	(3)
Net loss amortization	(1)	—	2
Net periodic benefit cost	$ 15	$ 20	$ 18

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, 2023	December 31, 2022
Fair value of plan assets January 1	$ 114	$ 117
Actual return on plan assets	10	(10)
Company contributions	16	14
Effects of exchange rate changes	9	(4)

Benefits paid	(5)	(7)
Other	2	3
Net transfer of plan assets from Merck affiliates	3	1
Fair value of plan assets December 31	$ 149	$ 114
Benefit obligation January 1	$ 161	$ 189
Service cost	17	22
Interest cost	5	2
Actuarial gains	31	(41)
Benefits paid	(5)	(7)
Effects of exchange rate changes	12	(7)
Other	2	1
Net transfer of benefit obligations from Merck affiliates	3	2
Benefit obligation December 31	$ 226	$ 161
Funded status December 31	$ (77)	$ (47)
Recognized as:		
Other assets	$ —	$ 1
Accrued and other current liabilities	(1)	(1)
Other Noncurrent liabilities	(76)	(47)

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

($ in millions)	December 31, 2023	December 31, 2022
Pension plans with a projected benefit obligation in excess of plan assets		
Projected benefit obligation	$ 218	$ 150
Fair value of plan assets	141	103
Pension plans with an accumulated benefit obligation in excess of plan assets		
Accumulated benefit obligation	$ 171	$ 113
Fair value of plan assets	107	73

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)	2023				2022			
Cash and cash equivalents	$ 5	$ —	$ —	$ 5	$ 4	$ —	$ —	$ 4
Investment funds								
Developed markets equities	51	3	—	54	34	3	—	37
Government and agency obligations	35	1	—	36	25	1	—	26
Emerging markets equities	7	—	—	7	5	—	—	5
Other	4	—	—	4	3	—	—	3
Equity income securities								
Developed markets equities	—	—	—	—	—	—	—	—
Fixed income securities								
Government and agency obligations	—	2	—	2	—	2	—	2
Corporate Obligations	—	1	—	1	—	2	—	2
Other investments								
Insurance contracts	—	38	—	38	—	33	—	33
Other	1	1	—	2	1	1	—	2
Plan assets at fair value	$ 103	$ 46	$ —	$ 149	$ 72	$ 42	$ —	$ 114

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 2024 are approximately $15 million for the Company's pension plans.

Expected Benefit Payments

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

2024	2025	2026	2027	2028	Thereafter
$ 9	$ 8	$ 9	$ 10	$ 11	$ 70

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 gain or 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)	2023	2022	2021
Net (loss) gain arising during the period	$ (28)	$ 28	$ 4
Net (gain) loss amortization included in benefit cost	(1)	—	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)	2023	2022	2021
Net periodic benefit cost			
Discount rate	3.82 %	1.49 %	1.48 %
Expected rate of return on plan assets	4.44	4.05	4.50
Salary growth rate	2.98	2.75	3.18
Benefit obligation			
Discount rate	2.77	3.82	1.49
Salary growth rate	2.83	2.98	2.75

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 2023 and 2022 were $39 million and $32 million, respectively. Total allocated and actual employer contributions to this plan in 2021 was $23 million.

16. Long-Term Debt and Leases

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

($ in millions)	December 31, 2023	December 31, 2022
Term Loan B Facility:		
SOFR plus 300 bps plus SOFR adjustment term loan due 2028	$ 2,543	$ 2,793
EURIBOR plus 300 bps euro-denominated term loan due 2028 (€731 million in 2023 and €739 million in 2022)	809	787
4.125% secured notes due 2028	2,100	2,100
2.875% euro-denominated secured notes due 2028 (€1.25 billion)	1,384	1,331
5.125% notes due 2031	2,000	2,000
Other borrowings	8	7
Other (discounts and debt issuance costs)	(84)	(105)
Total principal long-term debt	$ 8,760	$ 8,913
Less: Current portion of long-term debt	9	8
Total Long-term debt, net of current portion	$ 8,751	$ 8,905

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.

On June 30, 2023, the Company entered into Amendment No. 1 to the Senior Credit Agreement. Amendment No. 1 replaces LIBOR-based rates with Adjusted Term Secured Overnight Financing Rate ("SOFR")-based rates and updates certain other provisions of the Senior Credit Agreement to reflect the transition from LIBOR to the Adjusted Term SOFR.

Borrowings made under the Senior Credit Agreement 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 Term SOFR (subject to a floor of 0.50%) plus a SOFR adjustment, or 2.00% in excess of an alternate base rate ("ABR"), at Organon's 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 Term SOFR (subject to a floor of 0.00%) plus a SOFR Adjustment, or 1.00% in excess of ABR, at Organon's option and (ii) in euros, at 2.00% in excess of an Adjusted EURIBOR.

The SOFR adjustment is an additional interest amount per annum of 11.448 bps for a one-month interest period, 26.161 bps for a three-month interest period, or 42.826 bps for a six-month interest period, at Organon's option.

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. As a result of discretionary prepayments discussed below, the quarterly Principal Payments on the U.S. Dollar-denominated term loan are no longer required.

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, 2023 or December 31, 2022.

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, 2023, 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, 2023	December 31, 2022
Long-term debt	$ 8,253	$ 8,294

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 related to its debt instruments of $495 million for the year ended December 31, 2023. The average maturity of the Company's long-term debt as of December 31, 2023 is approximately 5.0 years and the weighted-average interest rate on total borrowings as of December 31, 2023 is 5.7%.

On March 30, 2023, the Company made a discretionary prepayment of $250 million on the U.S. Dollar-denominated term loan.

On June 21, 2023, the Company borrowed $80 million on the Revolving Credit Facility and subsequently repaid the amount on June 30, 2023.

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.

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

($ in millions)	
2024	$ 9
2025	10
2026	10
2027	9
2028	6,803
Thereafter	2,003

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. Actual operating lease costs and allocated operating lease costs for periods prior to Separation were $67 million, $61 million and $66 million for the year ended December 31, 2023, 2022, and 2021, 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 $56 million, $55 million and $41 million for the year ended December 31, 2023, 2022 and 2021, respectively. Operating lease assets obtained in exchange for new operating lease liabilities were $25 million, $28 million and $241 million for the year ended December 31, 2023, 2022 and 2021, 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, 2023	December 31, 2022
Assets		
Other Assets	$ 173	$ 215
Liabilities		
Accrued and other current liabilities	46	49
Other Noncurrent Liabilities	125	150
	$ 171	$ 199
Weighted-average remaining lease term (years)	5.0	5.3
Weighted-average discount rate	4.8%	4.0%

Maturities of operating lease liabilities as of December 31, 2023 are as follows ($ in millions):

2024	$ 52
2025	48
2026	29
2027	14
2028	13
Thereafter	33
Total lease payments	$ 189
Less: Imputed interest	18
	$ 171

17. 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
Balance at January 1, 2021, 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)
Other comprehensive (loss) income, pretax	(29)	48	19
Tax	4	—	4
Other comprehensive (loss) income, net of taxes	(25)	48	23
Balance at December 31, 2023, net of taxes	$ (15)	$ (526)	$ (541)

18. 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).

Samsung Bioepis is eligible for additional payments associated with pre-specified clinical and regulatory milestones. As of December 31, 2023, potential future regulatory milestone payments of $25 million remain under the agreement.

In November 2023, the U.S. Food and Drug Administration accepted for review the Supplemental Biologics License Application (sBLA) for the interchangeability designation for *Hadlima*.

In July 2023, the Company began selling *Hadlima*, a biosimilar referencing *Humira*[2] (adalimumab), in the United States.

In August 2022, the U.S. Food and Drug Administration ("FDA") approved the citrate-free, high-concentration (100 mg/mL) formulation of *Hadlima*, a biosimilar referencing *Humira*. 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.

Summarized information related to this collaboration is as follows:

($ in millions)	Year Ended December 31, 2023	2022	2021
Sales	$ 593	$ 481	$ 424
Cost of sales	406	315	248
Selling, general and administrative	72	86	83

($ in millions)	December 31, 2023	December 31, 2022
Receivables from Samsung included in *Other current assets*	$ —	$ 21
Payables to Samsung included in *Trade accounts payable*	104	72

19. 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 includes, among others, information technology, human resources, finance, quality, regulatory, supply chain management, promotional services, distribution services and certain other services, and provides on a cost or, where applicable, a cost-plus basis. The Merck services generally commenced on the date of the Separation and the majority of the services terminated 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 provision of certain services under the TSA expired as of July 2, 2023, however, certain services have been extended to at least 35 months. 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") 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, 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 control 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. As of December 31, 2023, only one jurisdiction remains under an IOM.

- 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 (a) manufactures and supplies certain active pharmaceutical ingredients for the relevant Organon entity, (b) toll manufactures and supplies certain formulated pharmaceutical products for such Organon entity, and (c) packages and labels certain finished pharmaceutical products for such Organon entity. Similarly, the relevant Organon entity (a) manufactures and supplies certain formulated pharmaceutical products for the relevant Merck entity, and (b) packages and labels 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. 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.

For the year ended December 31, 2023, material transactions occurred in connection with the IOM Agreements.

The amounts due under such agreements were:

($ in millions)	December 31, 2023	December 31, 2022
Due from Merck in *Accounts receivable*	$ 583	$ 374
Due to Merck in *Accounts payable*	619	543

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

	Year Ended December 31,		
($ in millions)	2023	2022	2021
Sales	$ 122	$ 127	$ 90
Cost of sales	114	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:

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

[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:

($ in millions)	Year Ended December 31, 2021
Included in continuing operations	
Supply sales to Merck affiliates	$ 143
Purchases from Merck affiliates	65
Cost reimbursements and fees from Merck affiliates	1
Included in discontinued operations	
Supply sales to Merck affiliates	$ 12
Purchases from Merck affiliates	53

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:

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

[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 10 "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 7 "Stock-Based Compensation Plans" and 15 "Pension and Other Postretirement Benefit Plans" for further details.

20. 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.

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.

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'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, 2023, approximately 3,125 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. The Third Circuit has scheduled oral arguments for March 5, 2024.

As of December 31, 2023, approximately 1,870 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 continued to select additional cases to be reviewed.

As of December 31, 2023, 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 consolidated 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, all of which have been tolled under a written tolling agreement. As of December 31, 2023, Merck had 20 cases pending outside the United States, of which 13 relate to *Implanon* and seven relate to *Nexplanon*.

Propecia/Proscar

As of December 31, 2023, one case involving *Proscar*® (finasteride) remains pending in the United States 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 Company is also defending 12 product liability cases involving *Propecia*® (finasteride) 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 from Merck to Organon in connection with the spinoff, 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*, in October 2022, the National Commission on Markets and Competition ("CNMC") 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 has been appealed 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 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 claimed damages from September 2014 until the patents expired in May 2021. Organon brought Inter Partes Review 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. A claim construction hearing was held on March 2, 2022, and a claim construction order issued on February 27, 2023. This case was scheduled for trial before a jury in Camden, New Jersey starting on October 16, 2023. On October 13, 2023, the parties informed the district court that an agreement in principle of the key terms of a settlement was reached. In December 2023, the parties executed the settlement agreement and the district court dismissed the case. Organon reserved $80 million to cover the settlement in 2023.

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, 2023, 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, 2023 and December 31, 2022 was $20 million and $17 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 $19 million and $20 million at December 31, 2023 and 2022, 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.

21. Subsequent Events

In December 2023, Organon announced an agreement with Lilly to become the sole distributor and promoter of the migraine medicines *Emgality*® (galcanezumab) and *Rayvow*™ (lasmiditan) in Europe. Lilly will remain the marketing authorization holder and will manufacture the products for sale. Under the terms of the agreement, Organon paid an upfront payment of $50 million, upon closing of the transaction in January 2024, and will pay sales-based milestone payments. The upfront payment and certain sales-based milestone payments, which were deemed probable, are recognized as an intangible asset in the first quarter of 2024.

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

Our management with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures. Based on their evaluation, as of the end of the period covered by this Form 10-K, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) promulgated under the Exchange Act) are effective.

Changes in Internal Control Over Financial Reporting

We began an implementation of an enterprise resource planning, ("ERP") system, which will replace the existing core financial system. The ERP system is designed to accurately maintain our financial records used to report operating results. The implementation of the consolidated financial reporting module was completed during the 2023 fiscal year. The implementation of the general ledger module is in progress and occurring in phases and is expected to be completed by the first half of 2024. The changes in process under the new ERP will continue to be subject to our evaluation of the operating effectiveness of internal control over financial reporting.

Except for the implementation of an ERP system, there was no change in our internal control over financial reporting that occurred during the fourth quarter of 2023, that has materially affected, or is reasonably likely to materially affect, our 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 Exchange Act. Our 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, 2023 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, 2023.

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 our internal control over financial reporting as of December 31, 2023, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Item 9B. Other Information

During the three months ended December 31, 2023, none of our directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement, as each term is defined in Item 408(a) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdiction that Prevent Inspections

None.

Part III

Item 10. Directors, Executive Officers and Corporate Governance

We have a Code of Conduct applicable to all of our employees, including our principal executive officer, principal financial officer, principal accounting officer, and controller, and all directors. Our 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 SEC or the New York Stock Exchange, we intend to disclose amendments to and waivers of the Code of Conduct applicable to our 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 2024 Proxy Statement and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this item will be included in the 2024 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 2024 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 2024 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 2024 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 96, 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	—	Amendment No. 1 to Senior Secured Credit Agreement, dated as of June 30, 2023, to the Credit Agreement 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 10.1 to the Company's Current Report on Form 8-K (File No. 001-40235) filed on July 7, 2023).
+10.16	—	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)
+10.17	—	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)
+10.18	—	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)
+10.19	—	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)
+10.20	—	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)
*10.21		Organon & Co. Executive Severance Program, as amended and restated on February 8, 2024.
+10.22	—	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)
+10.23	—	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)
+10.24	—	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)
†10.25	—	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
†10.26	—	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)
†10.27	—	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)

†10.28	—	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)
10.29	—	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)
10.30	—	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)
10.31	—	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)
†10.32	—	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)
†10.33	—	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)
+10.34	—	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)
+10.35	—	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)
10.36	—	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)
10.37		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)
*10.38		Form of Executive Separation Agreement
*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
*97.1	—	Organon & Co. Dodd-Frank Policy On Recoupment Of Incentive Compensation
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 2023 Form 10-K, brand names of products, which are not available in the United States.

[2] Indicates, in this 2023 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); *Vioxx* is a trademark registered in the name of Merck in several countries: *Emgality* is a trademark registered in the U.S. in the name of Eli Lilly and Company (used under license); and *Rayvow* is a registered trademark of Eli Lilly in the European Union and other countries (used under license). Brand names of products that are in all italicized letters, 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 26, 2024

/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 26, 2024
/s/ Matthew Walsh		Chief Financial Officer		February 26, 2024
/s/ Kathryn DiMarco		SVP Finance – Corporate Controller		February 26, 2024
/s/ Carrie Cox		Chairman of the Board of Directors		February 26, 2024
/s/ Robert Essner		Director		February 26, 2024
/s/ Alan Ezekowitz		Director		February 26, 2024
/s/ Ma Fatima de Vera Francisco		Director		February 26, 2024
/s/ Helene Gayle		Director		February 26, 2024
/s/ Rochelle Lazarus		Director		February 26, 2024
/s/ Deborah Leone		Director		February 26, 2024
/s/ Martha McGarry		Director		February 26, 2024
/s/ Philip Ozuah		Director		February 26, 2024
/s/ Cynthia Patton		Director		February 26, 2024
/s/ Grace Puma		Director		February 26, 2024
/s/ Shalini Sharp		Director		February 26, 2024