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, 2024

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.:

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, 2024, was approximately $5.3 billion.
The number of shares of Common Stock outstanding as of the close of business on February 25, 2025: 257,950,149

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III will be incorporated by reference from the Registrant's definitive proxy statement for its 2025 Annual Meeting of Stockholders (the "2025 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 “2024 Form 10-K”) have the meanings as set forth below:

[1] Indicates, in this 2024 Form 10-K, brand names of products, which are not available in the United States.

[2] Indicates brand names of products that are trademarks not owned by Organon. Specific trademark ownership information is included in the Exhibit Index at the end of this 2024 Form 10-K.

PART I
Item 1. Business

Overview

Organon & Co. ("Organon," the "Company," "we," "our," or "us") is a global healthcare company with a primary 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 70 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 portfolio of 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.

- *Biosimilars*: Our current biosimilars 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] (etanercept), *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 launched in the United States.

- *Established Brands*: We have a portfolio of established brands, which includes leading brands in cardiovascular, respiratory, dermatology and non-opioid pain management. Most brands in our established brands portfolio (with the exception of *Emgality*® [2] (galcanezumab-gnlm), *Rayvow*™ [2] (lasmiditan) and *Vtama*® (tapinarof)) 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 a stable franchise of established brands 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 2024, we expanded our product portfolios through the following acquisitions and licenses:

- In October 2024, we acquired Dermavant Sciences Ltd. ("Dermavant"), a company dedicated to developing and commercializing innovative therapeutics in immuno-dermatology. Dermavant's novel product, *Vtama* 1%, for the topical treatment of mild, moderate, and severe plaque psoriasis in adults, was approved by the U.S. Food and Drug Administration ("FDA") in May 2022. In December 2024, the FDA approved *Vtama* for an additional indication of topical treatment of atopic dermatitis, also known as eczema, in adults and children two years of age and older. Atopic dermatitis is one of the most common inflammatory dermatological conditions in adults, presenting a higher disease burden for women compared to men.

- In September 2024, we entered into license and supply agreements with Suzhou Centergene Pharmaceuticals ("Centergene") acquiring the exclusive commercialization rights to Centergene's investigational asset, SJ02, in China. SJ02 is a long-acting recombinant human follicle-stimulating hormone carboxyl-terminal peptide fusion protein (FSH-CTP) designed for controlled ovarian stimulation ("COS") in combination with a gonadotropin-releasing hormone ("GnRH") antagonist. It is used to facilitate the development of multiple follicles in women undergoing assisted

reproductive technology ("ART") programs.

- In August of 2024, we expanded our agreement with Eli Lilly ("Lilly") to become the sole distributor and promoter for *Emgality* in the following additional markets: Canada, Colombia, Israel, South Korea, Kuwait, Mexico, Qatar, Saudi Arabia, Taiwan, Turkey, and the United Arab Emirates. Our original agreement with Lilly provided us with sole distribution rights only in Europe. *Emgality*, a humanized monoclonal antibody calcitonin gene-related peptide ("CGRP") antagonist, is indicated for the preventive treatment of migraine in adults, and in some markets, the indication specifies prophylaxis for those with at least four migraine days per month. *Emgality* is also indicated in some markets for the treatment of episodic cluster headache in adults.

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 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)	**2024**	**2023**	**2022**
Women's Health	$ 1,777	$ 1,702	$ 1,673
Biosimilars	662	593	481
Established Brands	3,849	3,847	3,874

In 2024, we recorded revenues of $6.4 billion. We operate on a global scale through a global network that enables us to distribute products to patients in more than 140 countries and territories, with approximately 75% of our 2024 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 corifollitropina alfa

Jada System

XACIATO (clindamycin phosphate) vaginal gel 2%

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

VTAMA (tapinarof) cream 1%

SINGULAIR (MONTELUKAST SODIUM)

Propecia (finasteride)

HYZAAR

Atozet (ezetimibe and atorvastatin, MSD)

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

Emgality (galcanezumab-gnlm) 120 mg injection/300 mg injection

Women's Health Portfolio

In 2024, our women's health portfolio accounted for $1.8 billion, or approximately 28% of our total revenues, with $846 million, or approximately 48%, generated outside the United States. Our women's health products are sold by prescription primarily in two therapeutic areas: contraception (which includes key brands such as *Nexplanon* and *NuvaRing*), and fertility (which includes 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, disproportionally affect women, or impact women differently than men. 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 (the "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. It consists of 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. The product is currently indicated for a period of up to three years of use (at which point the insertion must be removed). It is also reversible, meaning that a woman can have it removed at any time after insertion. An application for a five-year duration period of use was submitted to the FDA in December 2024 and is currently undergoing regulatory review. Subject to such review, we currently expect that any US approval could occur as early as 2025. If approved, we could receive an additional three years of market exclusivity for *Nexplanon* in the United States. We currently plan to make a similar application for review by EU regulators in 2025. Subject to such review, we currently expect that any potential EU approval could occur as early as 2026. Notwithstanding the foregoing, there can be no assurance that the additional periods of market exclusivity referred to above will be granted.

NuvaRing is a monthly vaginal contraceptive ring with a combination of progestin and estrogen used to prevent pregnancy in women. *NuvaRing* is typically 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 that are used as daily pills to prevent pregnancy. *Marvelon* contains a higher daily dose of estrogen than *Mercilon*. These medicines are not approved or marketed in the United States but are available in certain countries outside the United States. *Mercilon* is being evaluated for treatment of dysmenorrhea (lower abdominal pain immediately prior to or during menstruation), and we currently expect to make a regulatory submission for the same indication to Japan's Pharmaceutical and Medical Device Agency (the "PMDA") in 2025. Subject to such review, we currently expect that any potential Japanese PMDA approval could occur as early as 2026*;* however, there can be no assurance that such approval will be granted.

Fertility

Our fertility brands include the following products, which are primarily used for medically-assisted reproduction ("MAR") and/or 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 MAR procedures. Such procedures include IVF, intracytoplasmic sperm injection, and embryo transfer. *Follistim AQ* belongs to the group of gonadotropic hormones used by women trying to conceive using IVF.

Elonva (which is not available in the United States) is a sustained follicle stimulant with the same mechanism of action as recombinant FSH. 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 gonadotropin preparation in an ovarian stimulation treatment cycle. *Elonva* belongs to the group of gonadotropic hormones used by women trying to conceive using MAR and/or IVF.

Ganirelix acetate injection (marketed in certain countries outside the United States as *Orgalutran*™) is an injectable GnRH antagonist used to prevent luteinizing hormone surges. Ganirelix acetate injection is used in fertility treatments in combination with FSH.

Postpartum Hemorrhage

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* is currently available in the United States at a majority of hospitals that offer labor and delivery services and is also available in several markets outside of the United States. We are considering options for future market expansion in additional markets globally.

Bacterial Vaginosis

Xaciato is an FDA-approved medication for the treatment of BV in females 12 years of age and older, which is licensed through an agreement with Daré Biosciences.

Xaciato is currently available in the United States; however, we plan to assess opportunities to seek potential further marketing authorizations for countries outside the United States.

Biosimilars Portfolio

A biosimilar is a biological medicine that is highly similar to another biological medicine that has already been approved by the FDA. In 2024, our biosimilars portfolio accounted for $662 million, or approximately 10% of our total revenues, with $310 million, or approximately 47%, 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, Brazil, Ukraine, New Zealand, Qatar, Israel, and Saudi Arabia, and marketed in the United States, Australia, Canada, Puerto Rico, Brazil and Saudi Arabia. *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 *Brenzys* is currently approved in Australia, Canada, Brazil, Israel, Ukraine, New Zealand, the United Arab Emirates, Qatar, and Kuwait. It is also 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 for commercialization in the United States, Australia, Canada, Ukraine, Saudi Arabia, New Zealand, the United Arab Emirates, Qatar and Kuwait and commercialized in the United States, Puerto Rico, Australia, Canada and Brazil.

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.

Ontruzant (SB3)

Ontruzant (trastuzumab-dttb) is an HER2/neu receptor antagonist biosimilar to Roche's *Herceptin* (trastuzumab) product for the treatment of HER2 overexpressing breast cancer and HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma consistent with *Herceptin*. We have worldwide commercialization rights to *Ontruzant* in countries outside of Korea and China. Ontruzant is approved in the United States, Canada, Australia, New Zealand, EU countries, the United Kingdom, Brazil, Ukraine, Saudi Arabia, Qatar and Kuwait and marketed in the United States, Puerto Rico, Canada, EU countries, Ukraine and Brazil.

Established Brands Portfolio

Our established brands portfolio includes leading brands in cardiovascular, respiratory, dermatology and non-opioid pain management. Most brands in our established brands portfolio (with the exception of *Emgality*, *Rayvow* and *Vtama*) lost exclusivity years ago and have faced generic competition for some time. In 2024, our established brands portfolio contributed approximately $3.8 billion of our total revenues, with approximately 92%, or $3.6 billion, generated outside the United States. Generic competition varies significantly across geographies.

Cardiovascular

In 2024, our cardiovascular portfolio accounted for $1.3 billion, or approximately 21% 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.

Respiratory

In 2024, our respiratory portfolio accounted for $1.0 billion, or approximately 16% of our total revenues, with approximately 79%, or $806 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*® (mometasone furoate).

Our established brands 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 2024, our dermatology, bone health and non-opioid pain management portfolios accounted for $867 million, or approximately 14% of our total revenues, nearly all of which were generated outside the United States.

- Our dermatology portfolio currently consists of three core products, including: *Vtama*, a topical treatment for mild, moderate and severe plaque psoriasis in adults and atopic dermatitis, also known as eczema, in adults and children two years of age and older, which was acquired through our acquisition of Dermavant in October 2024; *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

In 2024, this category accounted for $641 million, or approximately 10% of our total revenues, nearly all of which were generated outside the United States. This category includes our mature products across various therapeutic areas, which remain significant to our product portfolio.

We are party to a distribution agreement with Lilly for Emgality in Canada, Colombia, Europe, Israel, South Korea, Kuwait, Mexico, Qatar, Saudi Arabia, Taiwan, Turkey and the United Arab Emirates.

Additionally, this category covers other mature products such as: *Proscar*® (finasteride), used for the treatment of symptomatic benign prostatic hyperplasia in men with an enlarged prostate and *Propecia*® (finasteride), used for the treatment of male pattern hair loss. In 2024, *Proscar* and *Propecia*, accounted for $95 million and $111 million of our revenues, respectively.

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 supports these products through global registration, pharmacovigilance, medical affairs and health economics and outcomes research activities. Our science spans the full research and development lifecycle, from Discovery through Phase IV studies, and is driven by seasoned researchers, scientists, regulatory, pharmacovigilance, and medical affairs experts. OB/GYNs, PhDs, nurses and pharmacists are an invaluable part of our team, helping us to better understand women's needs from the perspectives of clinicians, physicians and patients.

As of December 31, 2024, we have licenses to commercialize the following development stage products:

Regulatory Development:

- HLX14, a biosimilar candidate to Amgen's *Prolia²/Xgeva²* (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 is responsible for development of this product and, if approved, will supply the products to us.

- HLX11, a biosimilar candidate to Roche's *Perjeta²* (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 is responsible for development and, if approved, will supply the products to us.

- SJ02, a long-acting recombinant human follicle-stimulating hormone carboxyl-terminal peptide FSH-CTP. SJ02 is designed for COS in combination with a GnRH antagonist to facilitate the development of multiple follicles in women undergoing ART programs. SJ02 is designed to initiate and maintain follicular growth in the ovaries for one week. If approved, a single-dose injection of SJ02 has the potential to offer an alternative to the current treatment regimen. We have exclusive commercialization rights in China. Centergene is responsible for the development of this product and, if approved, will supply the product to us.

Clinical Pharmaceutical Development:

- OG-6219, a HSD17β1 inhibitor, is an investigational agent being evaluated as a potential treatment for endometriosis. Endometriosis is a common and chronic condition that affects up to one in 10 women of reproductive age, causes abdominal pain and is associated with infertility. Approximately 10% of premenopausal women are diagnosed with endometriosis, and diagnosis occurs an average of seven years after the development of symptoms. Current therapies are predominantly hormonal treatments, which are not generally suitable for long-term use, and frequent surgical interventions may be required. OG-6219 is a non-hormonal treatment with a novel mechanism of action. As there are currently limited treatment options for women with endometriosis, this represents a priority disease area for us.

- OG-7191, a HSD17β5 inhibitor, 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. PCOS is a life-long chronic disorder and is associated with infertility as a result of menstrual cycle disruption. Approximately 10-13% of women worldwide suffer from PCOS. Our OG-7191 program aims to directly target the root cause of PCOS and the underlying pathophysiology of this condition. As there are currently no approved therapies for PCOS, this represents another priority disease area for us.

- OG-9489 is an investigational non-hormonal, on-demand contraceptive candidate. In the United States, approximately 65% of women 15–49 of age use some form of contraception, with a growing proportion of these women seeking non-hormonal reliable contraception. 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 is responsible for conducting preclinical studies according to the mutually agreed research plan, and if successful, we will have exclusive worldwide rights to develop and commercialize the product.

MedTech Development:

- The Claria System is an investigational medical device being studied for use during minimally invasive laparoscopic hysterectomy. In 2023, we made a strategic investment in Claria Medical, Inc. ("Claria"). Under the terms of that agreement, Claria is responsible for conducting clinical studies according to the mutually agreed research plan. With approximately 600,000 hysterectomies performed annually in the United States alone, hysterectomy is one of the most performed surgeries for women. Claria's investigational device uses a uterine containment and extraction system that aims to improve the hysterectomy procedure for both patients and physicians by providing a faster, simpler and safer procedure. This technology has been granted Safer Technology designation by FDA. The Safer Technologies designation does not confer FDA marketing clearance or approval, but is given to devices that are, among other things, reasonably expected to significantly improve the safety of currently available treatments or diagnostics that target an underlying disease or condition. Our agreement with Claria also gives us the option to acquire Claria.

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, 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 be likely to 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 worldwide distribution and supply capabilities.

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 portfolios. We also manufacture a range of products for third parties including Merck & Co., Inc. ("Merck") products at each of our six manufacturing sites pursuant to third-party contract manufacturing agreements.

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, 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 some of 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 keep 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 align employee incentives directly with our future performance.

As of December 31, 2024, we had over 10,000 employees worldwide with approximately 1,800 (17%) employees in the United States, including Puerto Rico. Approximately 8,900 of our employees work in key functional areas (Commercial, Research & Development, and Manufacturing/Supply) and approximately 1,600 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 31% 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 have additionally founded ten Employee Resource Groups. We also regularly assess 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 half of our employees are female, and women comprise nearly half of our senior leadership.

Intellectual Property

We actively seek to secure and maintain patents that protect our products, product candidates and other investors or improvements that we consider important to our business. 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.

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. We are also party to a separate licensing agreement with Merck that provides a limited expansion of the fields for which we may use the underlying technology of *Nexplanon / Implanon NXT* beyond contraception in exchange for milestone payments.

We consider the patents that cover Nexplanon to be material to our business. The relevant Nexplanon rod patents will expire in 2027 in the United States and in 2025 in other countries around the world. Key aspects of the Nexplanon applicator are patented until 2030 in the United States and 2026 in certain other countries. There are currently no material contested proceedings or third-party claims that involve the patents that cover Nexplanon. As described above, an application for a five-year duration period of use was submitted to the FDA in December 2024, and is currently undergoing regulatory review, and if approved, we could receive an additional three years of market exclusivity for Nexplanon in the United States. We currently plan to make a similar application for review by EU regulators in 2025. However, there can be no assurance that the additional periods of market exclusivity referred to above will be granted. See Note 18 "Contingencies" to the Consolidated Financial Statements in this report.

Primary patent exclusivity for *Vtama* is provided by patents on topical formulations of tapinarof. These patents expire in May 2036 in the United States and other countries around the world. Additional patents on other aspects of *Vtama* expire later, and related patent applications are pending.

While the expiration of a product patent normally results in generic competition 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 may be available under relevant law. The effect of product patent expiration on pharmaceutical products also depends upon many other factors, such as the nature of the market and the position of the product in it, the growth of the market, the complexities and economics of the process for manufacture of the active ingredient of the product and the requirements of new drug provisions of the Federal Food, Drug and Cosmetic Act or similar laws and regulations in other countries.

Additions to market or data exclusivity are sought in the United States and other countries through all relevant laws, including laws increasing patent life. 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 18 “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 2024 on patent and know-how licenses and other rights amounted to $8 million. We also incurred royalty expenses totaling $5 million in 2024 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 including healthcare provider information and clinical trial data. 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 and imposes penalties of up to 4% of global revenue, and China's Personal Information Protection Law (“PIPL”) and US state privacy laws. The data protection regulatory environment in China has been evolving quickly, including regulations regarding cross-border transfers of personal data. 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.

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, government authorities are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. There have been several Congressional inquiries, and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer-sponsored patient assistance programs, and reform government program reimbursement methodologies for drugs.

For example, effective January 1, 2024, the American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacture price, for single source and innovator multiple source drugs. In addition, the Inflation Reduction Act of 2022 ("IRA"), among other things, allows Medicare to penalize drug companies that raise prices for products covered under Medicare Parts B and D faster than inflation; and beginning in 2025, implement changes to the Medicare Part D benefit that will cap benefit annual out-of-pocket spending at $2,000, with new discount obligations for pharmaceutical manufacturers. The Centers for Medicare & Medicaid Services ("CMS") has taken steps to implement the IRA, including on December 20, 2024, releasing a list of 64 Medicare Part B products that had an adjusted coinsurance rate based on the inflationary rebate provisions of the IRA for the time period of January 1, 2025 to March 31, 2025. It remains to be seen how the drug pricing provisions imposed by the IRA will affect the broader pharmaceutical industry, and Organon cannot predict how future regulatory actions to implement the IRA could result in further pricing pressures.

Other proposed administrative actions may affect Organon's government pricing responsibilities. For example, CMS has issued proposals to amend the existing Medicaid Drug Rebate Program regulations. In addition, we may also be affected by developments relating to the federal 340B Drug Pricing 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. Courts of Appeals for the District of Columbia Circuit and the Third Circuit recently ruled in favor of several manufacturers. To date, other challenges are still pending. At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing. We believe that our policy complies with the 340B statute, yet it is unclear how this pending litigation, recent and proposed legislation, or future administrative actions relating to the 340B Drug Pricing Program will impact our business.

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 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

Despite going through multiple loss of exclusivity ("LOE") events in our portfolio, our performance in China has remained consistent, largely due to the strength of our underlying business. As used in this report, LOE refers to a loss of regulatory, data, or other marketing exclusivity that can, in the absence of patent protection, result in direct competition for the product in a given market. 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 minimization 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 updates the National reimbursement Drug List ("NRDL") for the government-administered insurance plans on a yearly basis; a drug's initial access to the NRDL is coupled with significant price reductions and is subject to further price reviews after two years.

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 roughly a 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 approximately 450 molecules included under the first ten rounds of VBP. After the expiration of the national VBP period, the VBP products may be subject to further price reductions in the provincial-level VBP programs implemented by individual provinces or province alliances; such provincial-level VBP programs may also target molecules that are not qualified for national VBP. 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.

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 continue 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 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.

In the future, we will likely become subject to new laws and regulations. For additional information, please see "Risk Factors — 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."

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 $14 million in the aggregate for the years 2025 through 2029. For additional information, please see "Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Estimates" and Note 18 "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. For additional information, please see "Risk Factors — 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."

Third-Party Collaboration

We are party to an agreement with Samsung Bioepis (the "Samsung Bioepis Agreement") that 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' 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, 2024, 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 16 "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.

Additional Information

We are a Delaware corporation incorporated on March 11, 2020. 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 documents are furnished or filed 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. In addition, we may also use social media to disclose material information to the public. Accordingly, investors should monitor these channels in addition to our press releases, SEC filings, and public conference calls and webcasts. 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 report.

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 rely on third parties for activities related to preclinical and clinical testing.
- We may experience difficulties identifying future acquisition opportunities or completing such transactions. Even if we complete such transactions, we may have difficulty integrating or otherwise realizing the benefits of such acquisitions.
- We may be unable to market our pharmaceutical products or medical devices if we do not obtain and maintain required regulatory approvals or marketing authorizations.
- We and/or our partners may fail to demonstrate the safety and efficacy of any of our product candidates in pre-clinical and clinical trials, which would prevent or delay development, regulatory approval or clearance, and commercialization of our product candidates.
- Developments following regulatory approval or marketing authorization may adversely affect sales of our pharmaceutical products or medical devices.
- Disruptions at the FDA, the SEC and other comparable foreign government agencies caused by funding shortages or other events could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions, which could negatively impact our business.
- Issues with product quality could have an adverse effect on our business or cause a loss of customer confidence in us or our products, among other negative consequences.
- Certain of our products currently benefit from patent protection and market exclusivity. When the patent protection and market exclusivity periods for such products expire, a significant and rapid loss of sales from those products is generally experienced. Expiry of patent protection and market exclusivity for products that contribute significantly to our sales will adversely affect our business.
- We depend on our patent rights for the marketing of certain of our products, and invalidation or circumvention of our patent rights would adversely affect our business.
- We have incurred substantial indebtedness, which could adversely affect our financial condition and results of operations.
- We are subject to minimum purchase obligations under certain supply agreements, and if we fail to meet those minimum purchase requirements, our financial results may be unfavorably impacted.
- The health care industry in the United States has been, and will continue to be, subject to judicial decisions and increasing laws, regulation, executive orders and political action.
- We are subject to a variety of laws and regulations, and we may face serious consequences for violations if we fail to meet the applicable legal and regulatory requirements.
- We or our third-party suppliers, logistics, and manufacturers may not comply with ethical business practices or with related laws and regulations, including relating to AI use.
- Our business and operations are subject to risks related to climate change and natural disasters.
- Our business could be negatively impacted by corporate citizenship and sustainability matters.

- Our corporate restructuring and the associated headcount reduction may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

Risks Related to Our Common Stock

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

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*, *Arcoxia*, *Singulair* and the ezetimibe family of products. As a result of our dependence on key products, any event that adversely affects any of these products or the markets for any of these products could adversely affect our sales, results of operations or cash flows. These adverse events could include increased costs associated with manufacturing, product shortages, increased generic or over-the-counter availability of our products or competitive products, the discovery of previously unknown side effects, results of post-approval trials, increased competition from the introduction of new, more effective treatments and discontinuation or removal from the market of these products for any reason. We also expect that competition will continue to adversely affect the sales of these products (including generic competition as a result of LOE in 2024 for *Atozet* and, if we are unable to obtain an additional period of market exclusivity for *Nexplanon*).

We face continued pricing pressure with respect to our products.

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

Changes to the health care system due to 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, such as the EU, the United Kingdom, China and Japan, have active government involvement including extensive pricing and reimbursement mechanisms and processes for pharmaceutical products affecting 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 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' products or our failure to maintain the competitive position of our products 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 with regulations, and other systems to conduct clinical trials, prepare regulatory application submissions and required post-approval reports, manufacture or distribute product, or other activities.

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, our ability to do so could be limited by the scope of our limited intellectual property licenses for certain women's health products. 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, 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 future acquisition opportunities or completing such transactions. Even if we complete such transactions, we may have difficulty integrating or otherwise realizing the benefits of such acquisitions.

As part of our business strategy to expand our product offerings and geographic presence, we intend to continue pursuing acquisitions of complementary businesses, licensing arrangements and strategic partnerships such as our acquisition of Dermavant and our agreements with Centergene and Lilly to promote *Emgality* and *Rayvow* in Europe. However, we may experience difficulties identifying future acquisition opportunities or completing such transactions. Many of our competitors for these opportunities are well established and have extensive experience identifying and effecting these types of strategic acquisitions. Moreover, some of these competitors may possess greater financial, technical, human and other resources than we do.

Further, any future transactions may not be completed in a timely manner, on a cost-effective basis, or at all, and we may not realize the expected benefits of any acquisition, license arrangement or strategic partnerships. For example, there are risks associated with regulatory approval of any product we may acquire, and even if approved, such approvals may not be secured in the timeframes we anticipate. See "We may be unable to market our pharmaceutical products or medical devices if we do not obtain and maintain required regulatory approvals or marketing authorizations" below. In addition, such acquisition opportunities may relate to products, technologies or operations with which we have limited or no historical experience.

Even if we are successful in making acquisitions or entering into other business development arrangements, the products and technologies we acquire may not be successful or may require significantly greater resources and investments than we originally anticipate, including due to material issues that we fail to identify in connection with our due diligence of the counterparty and its products or product candidates. We could experience negative effects on our results of operations and financial condition from acquisition-related charges, amortization of intangible assets and asset impairment charges. Integrating acquired businesses could lead us to experience numerous risks related to combining geographically separated organizations, systems and facilities and personnel with diverse backgrounds, as well as encountering unforeseen cybersecurity risks and breaches from the businesses acquired or their manufacturers and vendors and unforeseen product liability matters. Any of the foregoing could materially and adversely affect our business, financial condition, results of operations or cash flows.

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 governmental authorities in the United States, including the FDA, and by regulatory authorities 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 product safety and effectiveness and, in many cases, reduction in product cost. In addition, regulatory authorities have increased their focus on safety when assessing the benefit/risk balance of pharmaceutical products.

These regulatory authorities, including in China and Japan, also have substantial discretion to require additional testing in local populations, to delay or withhold registration and marketing approval and to otherwise preclude distribution and sale of a product. We cannot market or sell our pharmaceutical products or medical devices or new indications or modifications to our existing products unless and until we have obtained all required regulatory approvals or marketing authorizations in each relevant jurisdiction. Our applications or submissions for regulatory approval or marketing authorization may be rejected or otherwise delayed by the FDA or other regulatory authorities.

It is possible that the FDA could issue complete response letters indicating that any of our applications for our pharmaceutical products are not ready for approval. Even if the requisite approvals are obtained, we must maintain such approvals or marketing authorizations as long as we plan to market products in each jurisdiction where approval or marketing authorization is required. For instance, we currently market one product in the United States regulated as a medical device, *Jada*. We currently market *Jada* outside of the United States in a number of international markets and it is subject to the regulatory requirements imposed in those jurisdictions. In the future, we also plan to continue to sell *Jada* in additional major international markets and it will be subject to the regulatory requirements imposed in those jurisdictions. For example, in order to sell medical devices in the EU, we will need to comply with the EU's Medical Device Regulation.

The FDA or other regulators may also change their policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay regulatory approval or marketing authorization of our future products or impact our ability to modify our currently marketed products on a timely basis. Our failure to obtain approval or marketing authorization, significant delays in the approval or marketing authorization process or our failure to maintain approval or marketing authorization in any jurisdiction will prevent us from selling the products in that jurisdiction. We would not be able to realize revenues for our pharmaceutical products or medical devices in any jurisdiction where we do not have required approval or marketing authorization.

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

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

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, it may be more limited or restrictive than anticipated or be subject to additional post-marketing testing requirements.

Developments following regulatory approval or marketing authorization may adversely affect sales of 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. For example, in January 2023, 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. It is possible that future recalls or similar developments could materially and adversely impact our business, result of operations, and financial condition. Although to date, any market actions to which we have been subject have not had a material impact on our business, such actions could in the future have a materially adverse impact on our business, results of operations, and financial condition.

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

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

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

Disruptions at the FDA, the SEC and other comparable foreign government agencies caused by funding shortages or other events could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely is subject to the impacts of political events, which are inherently fluid and unpredictable. Disruptions at the FDA and other agencies may increase the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which could adversely affect our business. For example, over the last few years, the U.S. government has faced threats of a prolonged shut down several times and certain regulatory agencies, such as the FDA and the SEC, faced the possibility of furloughing critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA and the SEC to timely review and process our submissions, which could have a material adverse effect on our business. Further, future government shutdowns and agency operational disruptions in comparable foreign governments could impact our ability to continue our operations in other markets.

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, when possible, improve product quality and our quality management program. Quality management plays an essential role in meeting customer requirements, preventing defects, improving our products and services and assuring the safety and efficacy of our products. While we have a quality system that covers the lifecycle of our products, quality and safety issues have and may in the future occur with respect to our products. A quality or safety issue may result in adverse inspection reports, voluntary or official action indicated, warning letters, import bans, product recalls (either voluntary or required by FDA or similar governmental authorities in other countries) or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions (which may include corporate integrity agreements), costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses. An inability to address a quality or safety issue in an effective and timely manner may also cause negative publicity or a loss of customer confidence in us or our current or future products, which may result in the loss of sales and difficulty in successfully launching new products.

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 products that contribute significantly to our sales, LOE could materially adversely affect our business, cash flow, results of operations, financial condition or prospects. In the United States, we expect patent expiry for the Nexplanon implant in 2027 and patent expiry for the Nexplanon applicator in 2030. We expect market exclusivity for the majority of countries where *Nexplanon* is commercialized outside the United States will expire in 2026. In addition, in February 2025, we received a Paragraph IV Certification Letter notifying us that Xiromed Pharma Espana, S.L. filed an abbreviated new drug application to the FDA seeking approval to market a generic version of *Nexplanon*. See Note 18 “Contingencies—Other Matters” to the Consolidated Financial Statements in this report for additional information.

In the past, our business and results of operations have been adversely impacted by the LOE of our second largest product, *Atozet*, and if we do not obtain an additional period of new clinical investigation exclusivity for *Nexplanon* for the proposed five-year indication upon FDA approval of this indication, our business could also suffer negative financial impacts. See “Business—Products” and “—Intellectual Property” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Key Trends Affecting Our Results of Operations” for details, including the patent protection for certain of our marketed products.

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 and sale of certain of our products, particularly certain of our women's health products, as such protection provides market exclusivity.

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, court decisions relating to other companies' patents, potential legislation in both the United States and certain other markets relating to patents, as well as regulatory initiatives, may result in a more general weakening of intellectual property protection.

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

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

As of December 31, 2024, we had outstanding indebtedness of approximately $8.9 billion, as described more fully in the Notes to our financial statements. In addition, we may incur additional debt from time to time to finance acquisitions or for other purposes, subject to the restrictions contained in the documents that govern our indebtedness. Current or future levels of indebtedness may increase the possibility that we will be unable to generate cash sufficient to pay amounts due in respect of such indebtedness.

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

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 2022, we recognized $5 million in Cost of Sales pertaining to estimated unavoidable losses associated with a long-term vendor supply contract conveyed as part of the spinoff. We also have 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 judicial decisions and increasing laws, regulation, executive orders and political action.

We believe that the health care industry will continue to be impacted by judicial decisions, increasing regulation, political and legal action at both the federal and state/local levels in the United States and internationally, and US executive orders. While it is uncertain how such developments will affect our business, they could, at a minimum, introduce additional uncertainty into the regulatory process, result in legal challenges to actions taken by regulatory agencies, and subject us to additional pricing pressures.

For instance, changes to the health care system enacted as part of health care reform in the United States and increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid and private sector beneficiaries could result in further pricing pressures. Health care reform has already contributed to an increase in the number of patients in the Medicaid program under which sales of pharmaceutical products are subject to substantial rebates. There are pending legal and legislative developments relating to the 340B Drug 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 laws and regulations and, in the future, we will likely become subject to new laws and regulations. The costs of compliance with such laws and regulations, or the negative results of non-compliance, could adversely affect our business, cash flow, results of operations, financial condition or prospects. The compliance-related costs and penalties may be particularly significant with respect to health care reform and related initiatives, including: additional mandatory discounts or fees; new laws, regulations and judicial 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 United Kingdom, the United States and China; legislative mandates or preferences for local manufacturing of our products; and emerging and new global regulatory requirements for reporting payments and other value transfers to health care professionals and health care organizations. In addition, we are and may in the future become subject to changing environmental regulations (such as the EU's new Urban Wastewater Treatment Directive and other waste and packaging regulations); new laws and regulations addressing human rights and environmental matters in direct operations as well as in the supply chain and in some downstream users; and importation restrictions, embargoes and trade sanctions. Any of the foregoing may, individually or in the aggregate, have a material impact on our business.

Due to our global operations, we are subject to anti-corruption laws and regulations, in the United States and internationally, including but not limited to the US Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"), and other applicable anti-bribery and corruption laws. Recent years have seen a substantial increase in the global enforcement of anti-corruption laws. Our operations outside the United States could increase the risk of such violations. Our business is also heavily regulated and involves significant interaction with foreign officials. In many countries excluding the United States, prescribers of our products are employed by government entities, and purchasers are themselves government entities, such as government-affiliated hospitals, universities and other organizations. As such, our interactions with such prescribers and purchasers are subject to regulation under the FCPA, as well as other similar under anti-corruption laws and/or regulations enacted by other countries. The failure to comply with the FCPA and similar such laws could result in material civil or criminal sanctions or other adverse consequences.

We engage third parties outside the United States, to sell our products and to obtain necessary permits, licenses, patent registrations and other regulatory approvals of jurisdictions. We can be held liable for the corrupt or other illegal activities of our third-party contractors, even if we do not explicitly authorize or have actual knowledge of such activities.

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

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 2024, we generated $4.8 billion in revenues outside the United States, representing approximately 75% of our total revenues. Risks inherent in conducting a global business include:

- changes in medical reimbursement policies and programs and pricing restrictions in key markets;
- multiple regulatory requirements that could restrict our ability to manufacture and sell our products in key markets;
- multiple, conflicting and changing laws, executive orders and directives, and regulations such as privacy regulations, tax laws, tariffs, employment laws, regulatory requirements, government funding allocation processes, and other governmental approvals, permits and licenses;
- trade protection measures and import or export licensing requirements, including the imposition of tariffs, trade sanctions or similar restrictions by the United States or other governments;
- financial risks, such as foreign currency exchange fluctuations, longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products;
- volatility of commodity prices, fuel, shipping rates that impact the costs and/or ability to supply our products;
- diminished protection of intellectual property in some countries; and
- possible nationalization and expropriation.

Our business, financial condition, results of operations, and reputation could be materially and adversely impacted if we (or third parties upon which we rely) do not comply with applicable requirements and restrictions globally. In addition, our operations depend, in part, on our relationships and business arrangements with third parties that receive government funding. As the U.S. and foreign federal or local governments shift their pharmaceutical approval and regulatory priorities, including funding allocations, we may encounter challenges receiving key regulatory approvals or maintaining business relationships with third parties that depend on government funding, which could materially adversely affect our business, financial condition, results of operations, and reputation.

In addition, there may be changes to our business and strategic position if there is instability, disruption or destruction in a significant geographic region, regardless of cause, including health epidemics or pandemics, riot, civil insurrection or social unrest, and natural or man-made disasters, including famine, flood, fire, earthquake, storm or disease. In addition, our operations and performance may be affected by political or civil unrest or military action. As a result of global economic conditions, some parties may delay or be unable to satisfy their payment or reimbursement obligations. In addition, patients' ability to afford health care may also be affected by job losses or other economic hardships, increased co-pay or deductible obligations, greater cost sensitivity to existing co-pay or deductible obligations, and lost health care insurance coverage. Further, with rising international trade tensions or sanctions, our business may be adversely affected following new or increased tariffs, as well as increased costs of materials, products, and commodities upon which we rely. As a result, changes in international trade policy, changes in trade agreements and the imposition of tariffs or sanctions by the United States 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, the EU and other countries against Russian entities and designated individuals. Such restrictions have impacted, and may continue to impact, many global businesses in direct and indirect ways (including, but not limited to, product shipping delays, supply shortages, delays in regulatory approvals and audits and currency exchange rates). Such actions may negatively impact the financial institutions, vendors, manufacturers, suppliers, partners and other third parties with whom we conduct business and therefore may negatively impact us. In addition, although we do not expect the recent Israel-Hamas war and ongoing conflicts in the Middle East region to have a direct material impact on our business, the war and escalating tensions in the region may impact global markets or affect our supply chain.

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, data protection and artificial intelligence ("AI") continues to evolve.

The GDPR and related implementing laws in individual EU or the Member States of the European Economic Area (the "EEA"), as well as similar legislation in the United Kingdom, govern the collection and use of personal health data and other personal data in the EU. The GDPR increased responsibility and liability in relation to personal data that we process. It also imposes several obligations and restrictions on the ability to process (which includes collection, storage and access, analysis, and transfer of) personal data, including health data from clinical trials and adverse event reporting. The GDPR also includes requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the

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, Canada, the United Kingdom, Australia, Asia and Latin America have increased enforcement and litigation activity in the United States and other developed markets, as well as increased regulatory cooperation among privacy authorities globally. The data protection regulatory environment in China has been evolving quickly, including regulations regarding cross-border transfers of personal data ("CBDT"). These laws, including the PIPL, regulate the processing of personal information and increase obligations on companies to protect and safeguard personal information. These regulations also require organizations to evaluate CBDTs and may require localization of certain data. If we fail to effectively adjust to the changing regulatory landscape and comply with applicable laws and regulations in our operating regions, our business, prospects, financial condition and operating results would be materially and adversely affected.

In addition to the foregoing, AI-based solutions, including generative AI, are increasingly being used in the pharmaceutical industry, including by us, and we expect to use other systems and tools that incorporate AI-based technologies in the future. The use of AI solutions by our employees or third parties on which we rely could lead to the public disclosure of confidential information (including personal data or proprietary information) in contravention of our internal policies, data protection or other applicable laws, or contractual requirements. The misuse of AI solutions could also result in unauthorized access and use of personal data of our employees, clinical trial participants, collaborators, or other third parties. In addition, the legal and regulatory landscape surrounding AI technologies is rapidly evolving and uncertain, including in the areas of intellectual property, cybersecurity, and privacy and data protection. Compliance with these new or changing laws, regulations or industry standards relating to AI may impose significant operational costs or otherwise negatively impact our business.

We have adopted a comprehensive global privacy program to help manage these evolving risks, adjust to the changing regulatory landscape and facilitate CBDTs. Any failure by us, or our third-party vendors, to comply with applicable data privacy and security laws may lead to government enforcement actions and private litigation, which could result in financial, legal, business, and reputational harm to us and could have a material adverse effect on our business, results of operations, and financial condition.

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

We depend on sophisticated software applications (including AI), 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, to assist in conducting our business. Disruption, degradation, destruction or manipulation of these IT systems through intentional or accidental means by our employees, third parties with authorized access or cyber threat actors could adversely affect key business processes. The size and complexity of our IT systems, and those of our third-party providers with whom we contract, make such systems potentially vulnerable to service interruptions. In addition, we and our third-party providers have experienced and expect to continue to experience phishing attempts, scanning attempts of our network, and other attempts of unauthorized access to our computer environment. Such attacks are increasingly sophisticated and are made by groups and individuals with a wide range of motives and expertise, including state and quasi-state actors, criminal groups, "hackers" and others. These attacks could lead to loss of confidentiality, integrity and/or availability of our data, applications or systems.

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

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 consumers and employees, or the modification of critical data, could result in financial, legal, business, and reputational harm to us, including loss of revenue, loss of critical or sensitive information from our or our third-party providers' databases or IT systems and substantial remediation and recovery costs.

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

We or our suppliers and other manufacturing partners may experience difficulties or delays in connection with manufacturing our products that may lead to increased costs, such as: failure to comply with applicable regulations and quality assurance guidelines; delays related to the construction of new facilities or the expansion of existing facilities; delays related to the supply of key ingredients or other components of our products; increased costs of key materials, packaging or operational procedures; difficulties obtaining materials of adequate quality and quantity and other manufacturing or distribution problems, including, but not limited to, changes in manufacturing production sites and limits to manufacturing capacity resulting from regulatory requirements and changes in types of products produced and physical limitations that could impact supply. In addition, we could experience difficulties or delays in manufacturing our products caused by natural disasters, such as hurricanes and wildfires, and public health crises and epidemics/pandemics (including those like the recent COVID-19 global pandemic). Any of the foregoing could result in product shortages, lost sales, government agency actions, and reputational harm to us, which could have a material adverse effect on our business, results of operations, and financial condition.

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. 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 choose to seek recovery or damages from such supplier for any supply shortages or disruptions, such recovery or damages may be limited and not include indirect or consequential losses or any loss of revenue or lost profits. Our ability to achieve continuity of our supply may also be affected by public health crises and epidemics/pandemics. A reduction or interruption in supply and an inability to quickly develop acceptable alternative sources for such supply could adversely affect our ability to complete clinical trials, manufacture and distribute our products in a timely or cost-effective manner, negatively impacting our ability to sell our products.

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

We continue to take steps to increase our sales in China and emerging markets; however, our efforts to expand sales in these markets may not succeed. Some countries may be especially vulnerable to periods of global financial instability or may have 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 pharmaceutical products to patients a key priority and has implemented reimbursement and procurement programs to achieve these goals, such as VBP and URPS. For example, the VBP program regularly reduces the prices for affected products by over 50%. These and other such programs could adversely affect our business in China.

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

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

Adverse developments in the global economy or in one or more of our local markets could impact our ability to grow our business.

Any negative impact on economic conditions and international markets, such as volatility or deterioration in the capital markets, recession, inflation, deflation or other adverse economic conditions, may negatively impact our business. For instance, we may be unable to replace maturing liabilities and to access the capital markets to meet liquidity needs. An inflationary environment has led, and may continue to lead, to increased raw material and other costs, negatively impacting our margins and operating results. In addition, ongoing uncertain economic and financial market conditions may also adversely affect the financial condition of our customers, suppliers and other business partners. If our customers' financial conditions are adversely affected, those customers may reduce their purchases of our products or we may not be able to collect accounts receivable, each of which

could have a material adverse impact on our business operations or financial results, and we may not be able to fully absorb any such additional costs or revenue declines in the prices for our products and services. Any of the foregoing could have a material adverse effect on our financial condition and results of operations.

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

Counterfeit pharmaceutical products pose a significant risk to patient health and safety because of the conditions under which they are manufactured—often in unregulated, unlicensed, uninspected and unsanitary sites—as well as the lack of regulation of their contents. Failure to mitigate this threat could adversely impact our customers, potentially causing them harm. This, in turn, may result in the loss of confidence in our products' 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 conflicts in Ukraine and the Middle East, steps taken by governments and central banks, as well as other stimulus and spending programs, have led to higher inflation, which is likely to lead to an increase in costs and may cause changes in fiscal and monetary policy, including increased interest rates. In a higher inflationary environment, we may be unable to raise the prices of our products sufficiently to keep up with the rate of inflation.

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

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

In order to mitigate the adverse impact of these market fluctuations, we enter into hedging agreements from time to time. While hedging agreements, such as currency options and forwards and interest rate swaps, may limit some of the exposure to exchange rate and interest rate fluctuations, such attempts to mitigate these risks may be costly and not always successful. As a result, currency fluctuations among our reporting currency, the US 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, and third-party service providers, for key aspects of our business, including development, manufacture and commercialization of our products (including supplying our products or key ingredients of our products) and support for our IT systems. Reliance on third parties and their systems poses risks, including that the third parties will not comply with applicable legal or regulatory requirements for activities conducted on our behalf or for our benefit and we may be adversely affected if we have indemnification obligations or tax liabilities to Merck under our Separation and Distribution Agreement. We could be subject to penalties that flow to us, require us to undertake costly corrective measures such as recalling product, interrupt our business plans such as by rendering clinical data not usable for regulatory submissions, or other adverse consequences on our business. We may also learn of certain issues after entering into an agreement that were not identified during diligence and may impact the ability to realize the projected business goals of the agreement. We may enter into agreements with third parties in certain jurisdictions, including China, to continue our business operations in compliance with local regulatory requirements. Failure of these third parties to meet their contractual, regulatory and other obligations to us or the development of factors that materially disrupt the relationships between us and these third parties could adversely affect our business. Please see the risk factor above entitled, "We 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.

If we or our third-party suppliers, logistics, and manufacturers do not comply with ethical business practices or with related laws and regulations, including relating to AI use, our reputation, business, financial condition, results of operations and prospects could be harmed. Our third-party suppliers use of AI that does not comply with ethical standards, industry recognized AI frameworks or related laws and regulations will expose us to various risks including those relating to privacy, cybersecurity, intellectual property, inaccuracy of data, exposure of our confidential information, producing bias outcomes and overreliance on AI by those third-party suppliers without human oversight.

Our reputation and our clients' and customer' willingness to purchase our products depend in part on our and our suppliers', packagers', manufacturers, and formulators' compliance with ethical employment practices, such as with respect to child labor, wages and benefits, forced labor, discrimination, safe and healthy working conditions, and with all legal and regulatory requirements relating to the conduct of their businesses. We do not exercise control over our suppliers, packagers, shippers, manufacturers, and formulators and cannot guarantee their compliance with ethical and lawful business practices. If our suppliers, packagers, shippers, manufacturers, or formulators fail to comply with applicable laws, regulations, safety codes, employment practices, human rights standards, quality standards, environmental standards, production practices, or other obligations, norms, or ethical standards, our reputation and brand image could be harmed, and we could be exposed to litigation, investigations, enforcement actions, monetary liability, and additional costs that would harm our reputation, business, financial condition, results of operations and prospects.

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

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

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

If we are unable to successfully commercialize 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 and natural disasters.

We believe that global climate change will present a degree of risk to our business. Natural disasters, extreme weather and other conditions caused by or related to climate change could adversely impact our supply chain, including manufacturing and distribution networks, the availability and cost of raw materials and components, energy supply, transportation, or other inputs necessary for the operation of our business. Climate change and natural disasters could also result in physical damage to our facilities as well as those of our suppliers, customers, and other business partners, which could cause disruption in our business and operations or increase costs to operate our business. For instance, California and Florida are two of our top five states in terms of annual U.S. Organon revenues. The geographic location of our healthcare professional and patient customers in these states subjects them to earthquake, drought, wildfire, and hurricane risks, respectively. The recent Hurricanes Milton and Helene and wildfires in California disrupted critical infrastructure and damaged many point-of-care facilities, which displaced or reduced interactions between healthcare professionals and patients that generate demand for our products.

Additionally, increased environmental, social and governance regulations, including to address climate change, may result in increases in our costs to operate our business or restrict certain aspects of our activities. Additional potential effects of climate change to our business could include increased operating costs due to additional regulatory requirements, changes in supply and suppliers due to regulatory requirements, water limitations and disruptions to our supply chain. For example, concern over climate change continues to result in new legal or regulatory requirements designed to address the effects of climate change on the environment, such as the EU's CSRD and CSDDD, California's Climate Corporate Data Accountability Act and Climate

Related Financial Risk Act, and similar regulations adopted or under consideration by the regulators globally. While certain potential risks are integrated into our business planning, including investment in reducing energy, water use and greenhouse gas emissions, the extent and severity of future natural disasters and/or other climate change impacts are unknown, and therefore, the scope of potential impact on our business is difficult to predict, and it may be difficult to adequately prepare for such impact.

Our business could be negatively impacted by corporate citizenship and sustainability matters.

We are proud of our corporate citizenship and sustainability efforts. We have disclosed a number of initiatives, including initiatives relating to environmental matters, social investments and diversity, equity and inclusion (often referred to as "ESG" initiatives and programs). In recent years, investor advocacy groups and certain institutional investors have placed increasing importance on sustainability, and we may not succeed in our achievement of our initiatives or goals. At the same time, there also exists "anti-ESG" sentiment in certain of our markets, and we may face reduced revenue, reputational harm, market restrictions or legal actions if we are targeted by groups or influential individuals who disagree with our public positions on social or environmental issues.

Increasing focus on sustainability matters has resulted in, and is expected to continue to result in, evolving legal and regulatory requirements, including mandatory due diligence, disclosure and reporting requirements, as well as a variety of voluntary disclosure frameworks and standards. We have incurred, and are likely to continue to incur, increased costs complying with such standards and regulations, particularly given the lack of convergence among standards. In addition, our processes and controls may not always comply with evolving standards and regulations for identifying, measuring and reporting sustainability metrics, or our interpretation of reporting standards and regulations may differ from those of others; and such standards and regulations may change over time, any of which could result in significant revisions to our goals or reported progress in achieving such goals. Further, methodologies for reporting our data may be updated and previously reported data may be adjusted to reflect improvement in availability and quality of third-party data, changing assumptions, changes in the nature and scope of our operations (including from acquisitions and divestitures), and other changes in circumstances. Any failure or perceived failure (whether or not valid) to pursue or fulfill our sustainability goals and aspirations or to satisfy various sustainability reporting standards or regulatory requirements within the timelines we announce, or at all, could increase the risk of litigation or result in regulatory actions.

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

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

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

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

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, such as the adoption by the EU and the enactment by additional countries of a global minimum tax, to negatively impact our effective tax rate and results of operations. Other changes in tax laws or regulations around the world, including in the United States, could negatively impact our cash tax liability, and will likely have a negative impact on our effective tax rate, and results of operations and lead to greater audit scrutiny.

Social media and mobile messaging platforms present risks and challenges.

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

Our corporate restructuring and the associated headcount reduction may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

Beginning in 2023, we have implemented restructuring activities related to the ongoing optimization of our internal operations by reducing headcount in certain markets and functions. We expect to continue these restructuring activities in 2025. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition could be adversely affected. Furthermore, such restructuring efforts may be disruptive to our operations. For example, our headcount reductions could yield

unanticipated consequences, such as increased difficulties in implementing our business strategy, including retention of our remaining employees.

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

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;
- prohibit stockholder action by written consent;
- provide that special meetings of stockholders can be called only by the Board of Directors;
- provide that vacancies on the Board of Directors could be filled only by a majority vote of directors then in office, even if less than a quorum, or by a sole remaining director; and
- establish advance notice requirements for stockholder proposals and nominations of candidates for election as directors.

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

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

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

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

These exclusive provisions may limit a stockholder's ability to bring a claim in a judicial forum that they 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.

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 controls to protect such information, and aim to ensure that the third-party providers on which we rely have taken steps to protect such information, such controls may not be adequate. 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 consumers and employees, or the modification of critical data, could result in financial, legal, business, and reputational harm to us, including loss of revenue, loss of critical or sensitive information from our or our third-party providers' 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 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 leverage third parties to test and assess our cyber capabilities. 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 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. 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.

Our information security program is managed by our Chief Information Security Officer ("CISO"), who leads our enterprise-wide cybersecurity risk management, strategy, policy, standards, architecture, and processes. Our CISO has over 30 years of experience in information technology, including over 10 years in information security. She holds a B.S. in Computer Science and a Master of Management. Additionally, she served as an executive committee member of the Health Sector Coordinating Council Cybersecurity Working Group and is a Certified Information Systems Security Professional ("CISSP").

Supporting our CISO is our Deputy CISO, who serves as the primary backup to the CISO and helps oversee our information security program. Our Deputy CISO has over 20 years of experience in information technology, including over 10 years in information security. He holds a BS in Electronics Engineering and has served as the chair of the risk and vulnerability working groups at the Health Information Sharing and Analysis Center.

For additional information, see "Risk Factors — 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"; "— 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"; "— Reliance on third-party relationships and outsourcing arrangements could materially adversely affect our business" and "— 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."

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. We believe that our facilities are suitable and adequate for our operations and we anticipate that additional suitable space will be available when needed.

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, 2024, please See Note 18 "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 25, 2025, there were 64,928 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.

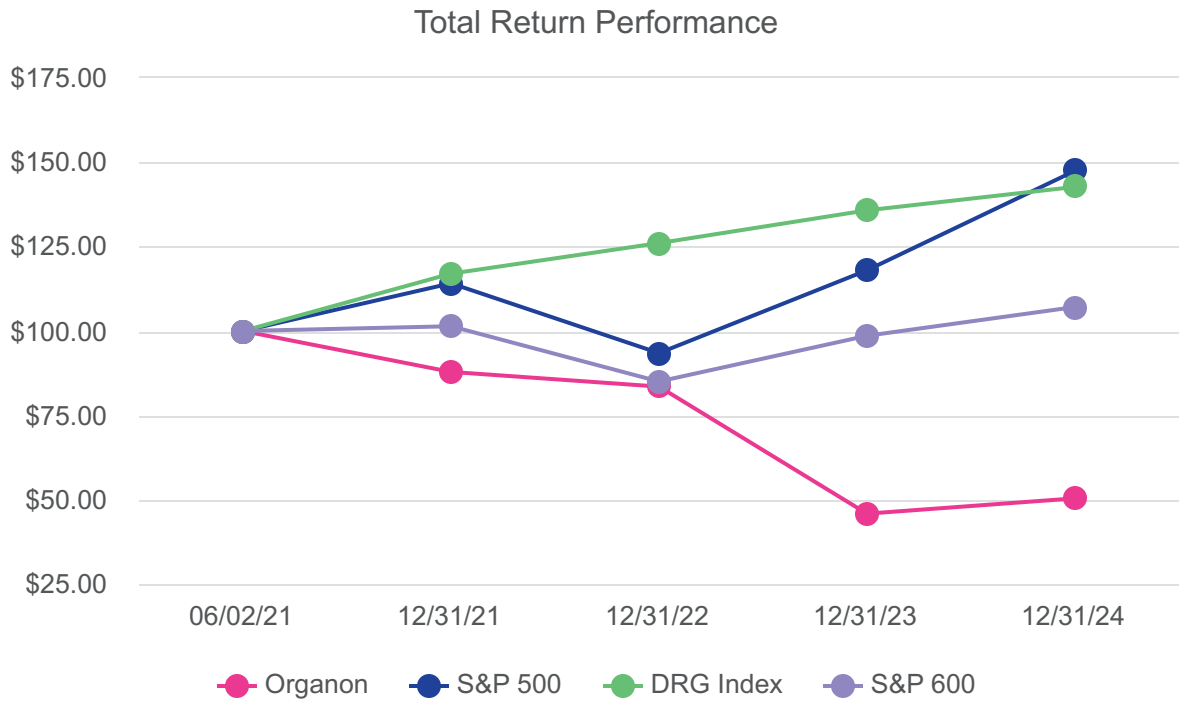
Dividends

During the fourth quarter of 2024, we paid cash dividends of $0.28 per share. On February 13, 2025, 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 13, 2025, to stockholders of record at the close of business on February 24, 2025.

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, 2024 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 2024. 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," "future," "might," "likely," "target," "predict," "continue," "should," 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 retain market exclusivity to *Nexplanon* or to obtain an additional period of exclusivity in the United States for Nexplanon subsequent to the expiration of the rod patents in 2027;
- the continued impact of the September 2024 LOE for *Atozet*;
- disruptions at the FDA, the SEC and other U.S. and comparable government agencies;
- 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 US FDA and other regulatory authorities;
- the failure by us or our third party collaborators and/or their suppliers to fulfill our or their regulatory or quality obligations, which could lead to a delay in regulatory approval or commercial marketing of our products;
- cyberattacks on, or other failures, accidents, or security breaches of, our or third-party providers' information technology systems, which could disrupt our operations and those of third parties upon which we rely;
- 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, 2024 and 2023 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, 2023, 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, 2023 and 2022.

We are a global healthcare company with a primary 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 70 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*: Except for *Emgality*, *Rayvow* and *Vtama*, our established brands products are beyond market exclusivity. Although these products continue to represent a valuable opportunity to generate significant operating profit relative to low promotional and development expenses, they are subject to competition from generic versions of these products. For instance, we have been negatively impacted by the September 2024 LOE for *Atozet*, and we expect those negative impacts to continue or intensify in 2025. In addition, *Nexplanon* is an important Organon brand that continues to have good market exclusivity, especially in the United States. This complex drug-device combination has different components with different patent exclusivities. In the United States, patents claiming key aspects of the *Nexplanon* applicator will expire in 2030 and patents for the *Nexplanon* rod will expire in late 2027. Patents for the majority of countries where *Nexplanon* is commercialized outside the United States will expire between 2025 and 2026. See Note 18 "Contingencies—Other Matters" to the Consolidated Financial Statements in this report.
- *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, including *Nexplanon*, is expected to continue to be an important and large segment of the overall contraceptive market. Despite an increasingly diverse market of contraception methods (including the over-the-counter birth control pill), payors, providers, and patients continue to believe in the benefits of long-acting and highly effective options such as *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*: The market for biologics continues 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

Dermavant Sciences Ltd. ("Dermavant")

On October 28, 2024, we acquired Dermavant, a company dedicated to developing and commercializing innovative therapeutics in immuno-dermatology. Dermavant's novel product, *Vtama*, for the topical treatment of mild, moderate, and severe plaque psoriasis in adults, was approved by the U.S. Food and Drug Administration (the "FDA") in May 2022. In December 2024, the FDA approved *Vtama* for the treatment of atopic dermatitis, also known as eczema, in adults and children two years of age and older. Atopic dermatitis is one of the most common inflammatory dermatological conditions in adults, presenting a higher disease burden for women compared to men. The acquisition allows us to further expand our existing portfolio of established brands and biosimilar dermatology treatments.

Consideration for Dermavant consists of the upfront payment of $175 million and a $75 million milestone payment upon regulatory approval, as well as payments of up to $950 million for the achievements of certain commercial milestones, tiered royalties on net sales, and the assumption of liabilities, including certain debt obligations, which were accounted for at fair value on the acquisition date.

During the fourth quarter of 2024, the regulatory milestone related to *Vtama's* atopic dermatitis indication, which was recorded as part of contingent consideration at fair value, was achieved and recorded in *Accrued and other current liabilities.* In January 2025, we paid $75 million related to the milestone.

In the fourth quarter of 2024, we recognized an additional intangible asset of $24 million, related to a sales-based milestone that was deemed probable and was related to an assumed licensing agreement. The intangible asset will be amortized over 11 years.

Suzhou Centergene Pharmaceuticals ("Centergene")

In September 2024, we entered into license and supply agreements with Centergene, pursuant to which we acquired the exclusive commercialization rights to Centergene's investigational asset, SJ02, in China. SJ02 is a long-acting recombinant human follicle-stimulating hormone carboxyl-terminal peptide fusion protein (FSH-CTP) designed for controlled ovarian stimulation ("COS") in combination with a GnRH antagonist. It is used to facilitate the development of multiple follicles in women undergoing ART programs. Under the terms of the agreement, we will pay $12 million, of which $6 million was paid in the fourth quarter of 2024. In addition, the remaining $6 million is payable upon obtaining the manufacturing license, which is refundable if thereafter either the regulatory approval is not obtained or marketing authorization cannot be transferred. We may owe additional regulatory and sales-based milestones to Centergene of up to $170 million under the terms of the license and supply agreements. We will recognize regulatory and sales-based milestones when the achievement is probable.

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 recognize sales-based milestones when the achievement is deemed probable. In the first quarter of 2024, we recognized an intangible asset of $220 million, comprised of the $50 million upfront payment and $170 million of sales-based milestones that were deemed probable. The intangible asset will be amortized over 10 years.

In August of 2024, we expanded our agreement with Lilly to become the sole distributor and promoter for *Emgality* in the following additional markets: Canada, Colombia, Israel, South Korea, Kuwait, Mexico, Qatar, Saudi Arabia, Taiwan, Turkey, and the United Arab Emirates. We paid an upfront payment of $23 million for the expansion of territory upon closing of the transaction in August 2024, and will recognize sales-based milestones when the achievement is deemed probable. In the third quarter of 2024, we recognized an additional intangible asset of $113 million, comprised of the $23 million upfront payment and $90 million related to the sales-based milestones that were deemed probable. The intangible asset will be amortized over 10 years.

As of December 31, 2024, we had accrued $20 million in *Accrued and Other current liabilities* and $240 million in *Other noncurrent liabilities* in total related to the probable sales-based milestones. In January 2025, we paid $20 million related to the milestones.

Operating Results

Sales Overview

($ in millions)	Year Ended December 31, 2024	2023	2022	% Change 2024 vs. 2023	% Change Excluding Foreign Exchange 2024 vs. 2023	% Change 2023 vs. 2022	% Change Excluding Foreign Exchange 2023 vs. 2022
United States	$ 1,572	$ 1,478	$ 1,437	6 %	6 %	3 %	3 %
International	4,831	4,785	4,737	1	3	1	4
Total	$ 6,403	$ 6,263	$ 6,174	2 %	3 %	1 %	3 %

Worldwide sales were $6.4 billion for the year ended December 31, 2024, an increase of 2%, compared to 2023. Worldwide sales during the year ended December 31, 2024 were negatively impacted by approximately 1%, or $77 million, due to unfavorable foreign exchange.

Excluding foreign exchange, sales increases for the year ended December 31, 2024, primarily reflect the performance of:

- *Nexplanon,* due to increased demand, favorable price and discount rates in the United States, increased demand and favorable price in international markets and an increase in demand in our institutional business in Africa;
- *Emgality* and *Rayvow,* due to the acquisition of the distribution and promotion rights from Lilly in 2024 in certain markets outside of the United States;
- *Hadlima,* due to the launch in the United States in July 2023 and a modest increase in international markets; and
- *Diprospan*, due to recovery from the manufacturing issues resulting from the 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").

This performance was offset by decreases for the year ended December 31, 2024 in:

- *NuvaRing,* due to ongoing generic competition and the negative impact of increased government discount rates in the United States;
- *Atozet,* primarily due to LOE in France, Spain and Japan and the timing of tenders in the Latin America region, partially offset by increased demand in certain markets in Europe, prior to LOE in September 2024;
- *Singulair* due to decreased demand in China and Japan and price decreases in Japan; and
- *Cozaar* and *Hyzaar,* driven by the negative impact of volume-based procurement ("VBP") in China and unfavorable pricing in Japan.

LOE negatively impacted sales of certain of our products by approximately $57 million during the year ended December 31, 2024, based on the decrease in volume period over period, which was primarily driven by the LOE of *Atozet* in France, Spain, and Japan. VBP in China had a $13 million negative impact on our sales during the year ended December 31, 2024. We expect VBP to continue 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, 2024 and 2023 are provided below. See Note 5 "Product and Geographic Information" to the Consolidated Financial Statements for further details on sales of our products.

Women's Health

($ in millions)	Year Ended December 31, 2024	2023	2022	% Change 2024 vs. 2023	% Change Excluding Foreign Exchange 2024 vs. 2023	% Change 2023 vs. 2022	% Change Excluding Foreign Exchange 2023 vs. 2022
Nexplanon/Implanon NXT	$ 963	$ 830	$ 834	16 %	17 %	(1)%	1 %
NuvaRing [(1)]	115	176	219	(35)	(33)	(19)	(18)
Marvelon/Mercilon	134	134	110	—	2	22	24
Follistim AQ	237	262	229	(10)	(9)	14	16
Ganirelix Acetate Injection	109	110	123	(1)	1	(10)	(8)
Jada	61	43	20	40	40	113	113

(1) Sales of the authorized generic version of ***NuvaRing*** *were previously included in Other Women's Health.*

Contraception

Worldwide sales of *Nexplanon,* a single-rod subdermal contraceptive implant, increased 16% for the year ended December 31, 2024, compared to 2023, primarily due to increased demand, favorable price and discount rates in the United States, increased demand and favorable price in international markets and an increase in demand in our institutional business in Africa.

Worldwide sales of *NuvaRing*, a vaginal contraceptive product, declined 35% for the year ended December 31, 2024, compared to 2023, due to ongoing generic competition and the negative impact of increased government discount rates 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, remained consistent for the year ended December 31, 2024, compared to 2023, as a result of increased demand in various international markets offset by slight declines in China and Japan.

Fertility

Worldwide sales of *Follistim AQ*, a fertility treatment, declined 10% for the year ended December 31, 2024, compared to 2023, due to a one-time buy-in as a result of our exit from our interim operating model agreement in the United States with Merck, during the fourth quarter of 2023, and unfavorable discount rates in the United States, partially offset by increased demand in the United States and launches in various international markets.

Worldwide sales of ganirelix acetate injection, a fertility treatment, declined 1% for the year ended December 31, 2024, compared to 2023, primarily due to generic competition, partially offset by increased demand in the United States and various international markets.

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 40% for the year ended December 31, 2024, compared to 2023. The sales increase is due to continued uptake in the United States following the *Jada* launch in early 2022.

Biosimilars

($ in millions)	Year Ended December 31, 2024	2023	2022	% Change 2024 vs. 2023	% Change Excluding Foreign Exchange 2024 vs. 2023	% Change 2023 vs. 2022	% Change Excluding Foreign Exchange 2023 vs. 2022
Renflexis	$ 274	$ 278	$ 226	(1)%	(1)%	23 %	24 %
Ontruzant	141	155	122	(9)	(9)	28	27
Brenzys	77	73	75	6	6	(2)	1
Hadlima	142	44	19	224	225	125	130

Renflexis is a biosimilar to *Remicade*[2] (infliximab) for the treatment of certain autoimmune conditions. Sales declined 1% for the year ended December 31, 2024, compared to 2023, primarily due to unfavorable discount rates in the United States partially offset by demand growth in the United States and Canada. We have commercialization rights to *Renflexis* in countries outside of Europe, Korea, China, Turkey, and Russia.

Ontruzant is a biosimilar to *Herceptin*[2] (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, 2024, compared to 2023, declined 9%, driven by lower demand in the United States and Europe partially offset by increased demand as a result of tenders in Brazil. We have commercialization rights to *Ontruzant* in all countries except in Korea and China.

Brenzys is a biosimilar to *Enbrel*[2] (etanercept) for the treatment of certain inflammatory diseases. Sales for the year ended December 31, 2024, compared to 2023, increased 6%, driven by increased demand in Canada. We have commercialization rights to *Brenzys* in countries outside of the United States, Europe, Korea, China, and Japan.

Hadlima is a biosimilar to *Humira*[2] (adalimumab) for the treatment of certain autoimmune and autoinflammatory conditions. We have commercialization rights to *Hadlima* in countries outside of the EU, Korea, China, Turkey, and Russia. We recorded sales of $142 million during the year ended December 31, 2024, reflecting an increase due to the launch in the United States in July 2023 and a modest increase in international markets. *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

($ in millions)	Year Ended December 31, 2024	2023	2022	% Change 2024 vs. 2023	% Change Excluding Foreign Exchange 2024 vs. 2023	% Change 2023 vs. 2022	% Change Excluding Foreign Exchange 2023 vs. 2022
Zetia/Vytorin [(1)]	$ 425	$ 451	$ 500	(6)%	(4)%	(10)%	(8)%
Atozet	473	519	457	(9)	(8)	14	13
Cozaar/Hyzaar	243	281	323	(14)	(11)	(13)	(9)

*(1) Sales of the authorized generic version of **Zetia** were previously included in Other Cardiovascular.*

Combined global sales of *Zetia* and *Vytorin*, medicines for lowering LDL cholesterol, declined 6% for the year ended December 31, 2024, compared to 2023, primarily driven by the decrease in demand and mandatory annual price reductions in Japan, partially offset by increased demand in China.

Sales of *Atozet*, a medicine for lowering LDL cholesterol, declined 9% for the year ended December 31, 2024, compared to 2023, primarily due to LOE in France, Spain, and Japan and the timing of tenders in the Latin America region partially offset by increased demand in certain markets in Europe. We anticipate a continued significant decline in sales of *Atozet* in 2025 due to LOE, which occurred late in the third quarter of 2024, in certain markets in Europe.

Combined global sales of *Cozaar* and *Hyzaar*, medicines for the treatment of hypertension, declined 14% for the year ended December 31, 2024, compared to 2023, driven by the negative impact of VBP in China and mandatory annual price reductions in Japan.

Respiratory

	Year Ended December 31,			% Change	% Change Excluding Foreign Exchange	% Change	% Change Excluding Foreign Exchange
($ in millions)	2024	2023	2022	2024 vs. 2023		2023 vs. 2022	
Singulair	$ 359	$ 404	$ 411	(11)%	(8)%	(2)%	3 %
Nasonex [(1)]	276	266	260	4	6	2	6
Dulera	203	194	180	5	5	8	9

(1) Sales of the authorized generic version of ***Nasonex*** *were previously included in Other Respiratory.*

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, decreased 11% for the year ended December 31, 2024, compared to 2023, due to decreased demand in China and Japan and mandatory annual price reductions in Japan.

Global sales of *Nasonex*, an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, increased 4% for the year ended December 31, 2024, compared to 2023, respectively, due to increased demand across international markets.

Global sales of *Dulera*, which is also marketed as *Zenhale* in certain markets outside of the United States, a combination medicine for the treatment of asthma, increased 5% for the year ended December 31, 2024, compared to 2023, primarily due to the favorable impact of increased demand in the United States and Canada.

Non-Opioid Pain, Bone and Dermatology

	Year Ended December 31,			% Change	% Change Excluding Foreign Exchange	% Change	% Change Excluding Foreign Exchange
($ in millions)	2024	2023	2022	2024 vs. 2023		2023 vs. 2022	
Arcoxia	$ 270	$ 257	$ 241	5 %	7 %	7 %	12 %
Diprospan	139	91	122	52	55	(25)%	(22)%
Vtama	12	—	—	*	*	— %	— %

** Calculation not meaningful.*

Sales of *Arcoxia*, a medicine for the treatment of arthritis and pain, increased 5% for the year ended December 31, 2024, compared to 2023, primarily due to increased demand in China and favorable pricing in the Asia Pacific region partially offset by a decrease in demand in various international markets.

Sales of *Diprospan*, a corticosteroid approved for treatment of a wide range of inflammatory conditions, increased 52% for the year ended December 31, 2024, compared to 2023, due to recovery from the manufacturing issues resulting from the Market Action. In the first quarter of 2023, we resolved the regulatory inspection findings.

Sales of *Vtama* a cream for the topical treatment of mild, moderate, and severe plaque psoriasis in adults were $12 million for the year ended December 31, 2024, reflecting the acquisition of Dermavant in the fourth quarter of 2024.

Other

($ in millions)	Year Ended December 31, 2024	2023	2022	% Change 2024 vs. 2023	% Change Excluding Foreign Exchange 2024 vs. 2023	% Change 2023 vs. 2022	% Change Excluding Foreign Exchange 2023 vs. 2022
Emgality/Rayvow	$ 107	$ —	$ —	*	*	— %	— %
Proscar	95	97	101	(2)	—	(3)	1

** Calculation not meaningful.*

Sales of *Emgality* and *Rayvow* were $107 million for the year ended December 31, 2024, reflecting the acquisition of the distribution and promotion rights from Lilly in 2024, in certain markets outside of the United States.

Worldwide sales of *Proscar*, a medicine for the treatment of symptomatic benign prostate enlargement, declined 2% for the year ended December 31, 2024, compared to 2023, due to decreased demand in China.

Gross Profit, Expenses and Other

($ in millions)	Year Ended December 31, 2024	2023	2022	% Change 2024 vs. 2023	% Change 2023 vs. 2022
Cost of sales	$ 2,688	$ 2,515	$ 2,294	7 %	10 %
Gross profit	3,715	3,748	3,880	(1)	(3)
Selling, general and administrative	1,760	1,893	1,704	(7)	11
Research and development	469	528	471	(11)	12
Acquired in-process research and development and milestones	81	8	107	*	(93)
Restructuring costs	31	62	28	(50)	*
Interest expense	520	527	422	(1)	25
Exchange losses	26	42	11	(38)	*
Other expense, net	21	15	15	40	—

** Calculation not meaningful.*

Cost of Sales

Cost of sales increased 7% for the year ended December 31, 2024, compared to 2023, primarily due to higher sales volume, higher inflation impacts to material and distribution costs and amortization of $7 million associated with the inventory fair value adjustment related to the Dermavant acquisition purchase accounting, partially offset by foreign exchange translation. Cost of sales includes amortization of intangible assets which totaled $145 million in 2024, $116 million in 2023 and $116 million in 2022. Amortization for 2024, includes $6 million related to the Dermavant acquired intangibles.

Gross Profit

Gross profit decreased 1% for the year ended December 31, 2024, compared to 2023, due to the impact of unfavorable price, foreign exchange translation and higher inflation impacts to material and distribution costs partially offset by increased sales due to volume.

Selling, General and Administrative

Selling, general and administrative expenses decreased 7% for the year ended December 31, 2024, compared to 2023, due to the $80 million charge in 2023 related to the Microspherix legal matter (as discussed in Note 18 “Contingencies” to the Consolidated Financial Statements in this report) and lower costs associated with the implementation of our Enterprise Resource Planning (“ERP”) system, partially offset by increased expenses related to the Dermavant acquisition, including transaction costs of $12 million.

Research and Development

Research and development expenses decreased 11% for the year ended December 31, 2024, compared to 2023, primarily due to a decrease in clinical study activity and lower personnel costs due to a reduction in headcount related to our restructuring initiatives.

Acquired In-Process Research and Development and Milestones

For the year ended December 31, 2024, acquired in-process research and development and milestones of $81 million primarily represent the research and development milestones of $70 million for our agreement with Henlius and $10 million for our agreement with Cirqle, which were determined to be probable of being achieved. For the year ended December 31, 2023 acquired in-process research and development and milestones of $8 million represent the upfront and development milestones related to the Claria transaction. See Note 3 "Acquisitions and Licensing Arrangements" to the Consolidated Financial Statements included elsewhere in this report for further information regarding our agreements with Henlius and Cirqle.

Restructuring Costs

For the year ended December 31, 2024, we incurred $31 million of headcount-related restructuring expense related to the ongoing optimization of our internal operations, primarily the research and development function. During the first quarter of 2025, we implemented additional restructuring initiatives that will drive operational efficiencies in 2025, and will result in an approximate 5% headcount reduction.

Interest Expense

Interest expense decreased 1% for the year ended December 31, 2024, compared to 2023, reflecting lower interest rates as a result of refinancing a portion of our long-term debt and the impact of our cross-currency swaps, partially offset by interest related to the debt acquired as part of the Dermavant acquisition and approximately $6 million in debt issuance costs related to the refinancing of our long-term debt. Beginning in May 2024, the difference between the interest rate received of 7.3125% and paid of 5.8330% under the cross-currency swap agreements is recorded in *Interest expense.*

Exchange Losses

Exchange losses decreased 38% for the year ended December 31, 2024, compared to 2023, driven by less volatility in foreign exchange compared to the prior year and the favorable changes in spot rates of our forward contracts.

Other Expense, net

Other expense increased 40% for the year ended December 31, 2024, compared to 2023, due to the fair value adjustment of contingent consideration related to the Dermavant acquisition.

Taxes on Income

The effective income tax rate was (7.1)% and (52.2)% for the year ended December 31, 2024 and 2023, respectively. The effective income tax rate reflects 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. There was a favorable impact to the 2024 effective tax rate, which was driven by the favorable closure of two non-U.S. tax audits and a return to provision adjustment for the Switzerland entity.

In the third quarter of 2024, the Swiss tax authority confirmed to us the applicable useful life of an existing tax asset. As a result, we have now concluded it is more likely than not we will utilize the entirety of the tax asset. As such, we released a $210 million related valuation allowance.

Effective January 1, 2024, multiple jurisdictions, most notably, a majority of the European Union member states, implemented the Organization for Economic Co-operation and Development's Pillar 2 global corporate minimum tax rate of 15% on companies with revenues of at least €750 million. We have evaluated the impact of this for 2024 and it does not have a material effect on a full year basis.

Liquidity and Capital Resources

As of December 31, 2024, we had cash and cash equivalents of $675 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.

During the second and fourth quarters of 2024, we refinanced a portion of our long-term debt. These transactions extended certain maturity dates, resulted in lower interest rates for certain of our long-term debt and increased the capacity of our revolving credit facility. See Note 12 "Long-Term Debt and Leases" to the Consolidated Financial Statements included elsewhere in this report for further information on our long-term debt transactions.

Working capital is defined as current assets less current liabilities and was $1.6 billion as of December 31, 2024 and December 31, 2023, respectively. Working capital was impacted by our active cash cycle management, including the factoring of receivables and timing of vendor payments.

We have accounts receivable factoring agreements with financial institutions in certain countries. Under these agreements, we have factored $186 million of our accounts receivable as of December 31, 2024.

Net cash provided by operating activities was $939 million for the year ended December 31, 2024, compared to $799 million for the same period in the prior year. The increase in cash provided by operating activities was primarily attributable to our favorable operating performance and cash cycle working capital, partially offset by higher cash taxes paid and higher severance-related payments.

Net cash used in investing activities was $513 million for the year ended December 31, 2024, compared to $260 million for the same period in the prior year, primarily due to the Dermavant acquisition, the $73 million upfront payments related to the agreement with Lilly and the additional $71 million payments related to milestones, partially offset by lower capital spending as a result of the completion of the implementation of our ERP system.

Net cash used in financing activities was $368 million for the year ended December 31, 2024, compared to $569 million for the same period in the prior year. The decrease in cash used in financing activities was driven by the $250 million voluntary prepayment on the U.S. dollar-denominated term loan in the year ended December 31, 2023, compared to a $7.5 million discretionary prepayment on the U.S. dollar-denominated term loan and $38 million of debt issuance costs related to the long-term debt refinancing in the year ended December 31, 2024.

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, 2024 and 2023, 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 conflict, as of December 31, 2024, our assets in Ukraine, Russia and Israel are not material.

Contractual Obligations

Our contractual obligations as of December 31, 2024, which require material cash requirements in the future, consist of contractual milestones, purchase obligations and lease obligations.

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 are uncertain and the likelihood of achieving

the milestones cannot be determined. As of December 31, 2024, total potential payments for contractual milestones are $3.4 billion. Potential amounts to be paid within the next twelve months are $218 million.

Purchase obligations are enforceable and legally binding obligations for purchases of goods and services which include inventory purchase commitments. As of December 31, 2024, total payments due for purchase obligations are $850 million and extend through 2032. Amounts due within the next twelve months are $356 million.

Long-term debt consists of both fixed and variable-rate instruments. As of December 31, 2024, total payments due for debt obligations are $9.0 billion and extend through 2034. Amounts due within the next twelve months are $8 million.

Lease obligations exclude reasonably certain lease renewals that have not yet been executed. As of December 31, 2024, total payments due for lease obligations are $177 million and extend through 2041. Amounts due within the next twelve months are $49 million.

During 2024, we paid cash dividends of $1.12 per share. On February 13, 2025, 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 13, 2025, to stockholders of record at the close of business on February 24, 2025.

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 2024, 2023, or 2022.

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)	2024	2023	2022
Balance January 1	$ 504	$ 385	$ 329
Provision	3,024	2,640	2,221
Payments [1]	(3,048)	(2,521)	(2,165)
Balance December 31	$ 480	$ 504	$ 385

(1) Includes $48 million of liabilities assumed as part of the Dermavant acquisition.

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 $100 million and $380 million, respectively, at December 31, 2024, $87 million and $417 million, respectively, at December 31, 2023 and $78 million and $307 million, respectively, at December 31, 2022. The increase in accrued rebates in 2023 is attributable to a wholesaler buy-in in conjunction with the exit of the interim operating model 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 2 "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 18 "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 $3 million in 2024, and are estimated at $14 million in the aggregate for the years 2025 through 2029. Liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $16 million and $19 million at December 31, 2024 and 2023, 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 13 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 $23 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, 2024 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.

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 LOE 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, 2024 and 2023. We recorded impairment charges of $9 million as of December 31, 2022. See Note 11 "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.

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 in-process research and development ("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. No goodwill is recorded in an asset acquisition.

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 identifiable intangible assets related to currently marketed products are primarily determined by using an income approach through which fair value is estimated based on each asset's discounted projected net cash flows. Our estimates of market participant net cash flows consider historical and projected pricing, margins and expense levels; the performance of competing products and the current and expected competition environment where applicable; relevant industry and product growth drivers and factors; product life cycles; the ability to obtain additional marketing and regulatory approvals; the ability to manufacture and commercialize the products; and the life of each asset's underlying patent and related patent term extension, if any. The net cash flows are then discounted to present value utilizing an appropriate discount rate.

The fair values of identifiable intangible assets related to IPR&D are also determined using an income approach, through which fair value is estimated based on each asset's probability-adjusted future net cash flows, which reflect the different stages of development of each product and the associated probability of successful completion. The net cash flows are then discounted to present value using an appropriate discount rate. Amounts allocated to acquired IPR&D are capitalized and accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each IPR&D project, we 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.

Certain of our business combinations involve the potential for future payment of consideration that is contingent upon the achievement of performance milestones, including product development milestones and royalty payments on future product sales. The fair value of contingent consideration liabilities is determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability-weighted cash flows. Subsequent to the acquisition date, at each reporting period until the contingency is resolved, the contingent consideration liability is remeasured at current fair value with changes (either expense or income) recorded in earnings in Other expense, net. Changes in any of the inputs may result in a significantly different fair value adjustment.

Pension

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

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 2 "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, Brazilian real, Japanese yen, and Swiss franc. 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 13 "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, 2024 and 2023, 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, 2024, 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, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024 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, 2024, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

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

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

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

Definition and Limitations of Internal Control over Financial Reporting

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

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

Critical Audit Matters

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

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

As described in Note 2 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, 2024 in the United States was $380 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 28, 2025
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,		
	2024	2023	2022
Revenues	$ 6,403	$ 6,263	$ 6,174
Cost of sales	2,688	2,515	2,294
Gross profit	3,715	3,748	3,880
Selling, general and administrative	1,760	1,893	1,704
Research and development	469	528	471
Acquired in-process research and development and milestones	81	8	107
Restructuring costs	31	62	28
Interest expense	520	527	422
Exchange losses	26	42	11
Other expense, net	21	15	15
Income before income taxes	807	673	1,122
Income tax (benefit) expense	(57)	(350)	205
Net income	$ 864	$ 1,023	$ 917
Earnings per share:			
Basic	$ 3.36	$ 4.01	$ 3.61
Diluted	$ 3.33	$ 3.99	$ 3.59
Weighted average shares outstanding:			
Basic	257,046	255,239	254,082
Diluted	259,152	256,270	255,169

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,		
	2024	2023	2022
Net income	$ 864	$ 1,023	$ 917
Other Comprehensive (Loss) Income, Net of Taxes:			
Benefit plan net (loss) gain and prior service credit, net of amortization	(2)	(25)	23
Cumulative translation adjustment	(106)	48	(74)
	(108)	23	(51)
Comprehensive income	$ 756	$ 1,046	$ 866

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, 2024	December 31, 2023
Assets		
Current Assets:		
Cash and cash equivalents	$ 675	$ 693
Accounts receivable (net of allowance for doubtful accounts of $14 in 2024 and $9 in 2023)	1,358	1,744
Inventories (excludes inventories of $215 in 2024 and $110 in 2023 classified in Other assets)	1,321	1,315
Other current assets	994	756
Total Current Assets	4,348	4,508
Property, plant and equipment, net	1,168	1,183
Goodwill	4,680	4,603
Intangibles, net	1,414	533
Other assets	1,491	1,231
Total Assets	$ 13,101	$ 12,058
Liabilities and Equity		
Current Liabilities:		
Current portion of long-term debt	$ 20	$ 9
Trade accounts payable	1,153	1,314
Accrued and other current liabilities	1,411	1,389
Income taxes payable	134	206
Total Current Liabilities	2,718	2,918
Long-term debt	8,860	8,751
Deferred income taxes	74	47
Other noncurrent liabilities	977	412
Total Liabilities	12,629	12,128
Contingencies (Note 18)		
Organon & Co. Stockholders' Equity (Deficit):		
Common stock, $0.01 par value Authorized - 500,000 Issued and outstanding - 257,799 in 2024 and 255,626 in 2023	3	3
Additional paid-in capital	108	25
Retained earnings	1,010	443
Accumulated other comprehensive loss	(649)	(541)
Total Stockholders' Equity (Deficit)	472	(70)
Total Liabilities and Stockholders' Equity (Deficit)	$ 13,101	$ 12,058

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)	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Par Value				
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)
Net income	—	—	—	864	—	864
Other comprehensive loss, net of taxes	—	—	—	—	(108)	(108)
Cash dividends declared on common stock ($1.12 per share)	—	—	—	(297)	—	(297)
Stock-based compensation plans and other	2,173	—	83	—	—	83
Balance at December 31, 2024	257,799	$ 3	$ 108	$ 1,010	$ (649)	$ 472

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,		
	2024	2023	2022
Cash Flows from Operating Activities			
Net income	$ 864	$ 1,023	$ 917
Adjustments to reconcile net income to net cash flows provided by operating activities:			
Depreciation	132	120	96
Amortization	145	116	116
Impairment of assets	—	—	9
Acquired in-process research and development and milestones	81	8	107
Fair value changes in contingent consideration	11	—	—
Deferred income tax benefit	(160)	(485)	(18)
Stock-based compensation	105	101	75
Unrealized foreign exchange (gain) loss	(2)	40	(18)
Other	41	31	26
Net changes in assets and liabilities, net of assets acquired			
Accounts receivable	383	(212)	(123)
Inventories	(131)	(230)	(220)
Other current assets	(236)	(10)	(43)
Trade accounts payable	(157)	163	(237)
Accrued and other current liabilities	(101)	102	172
Income taxes payable	(65)	16	7
Other	29	16	(8)
Net Cash Flows Provided by Operating Activities	939	799	858
Cash Flows from Investing Activities			
Capital expenditures	(175)	(251)	(196)
Proceeds from sale of property, plant and equipment	4	1	7
Acquired in-process research and development and milestones	(71)	(8)	(107)
Dermavant acquisition, net of cash acquired	(166)	—	—
Purchase of product rights and asset acquisition	(105)	(2)	(124)
Net Cash Flows Used in Investing Activities	(513)	(260)	(420)
Cash Flows from Financing Activities			
Proceeds from debt	1,186	80	—
Repayments of debt	(1,197)	(338)	(108)
Payment of long-term debt issuance costs	(38)	—	—
Net transfers to Merck & Co., Inc.	—	—	(24)
Employee withholding taxes related to stock-based awards	(22)	(17)	(11)
Dividend payments	(297)	(294)	(290)
Net Cash Flows Used in Financing Activities	(368)	(569)	(433)
Effect of Exchange Rate Changes on Cash and Cash Equivalents	(76)	17	(36)
Net Decrease in Cash and Cash Equivalents	(18)	(13)	(31)
Cash and Cash Equivalents, Beginning of Period	693	706	737
Cash and Cash Equivalents, End of Period	$ 675	$ 693	$ 706

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 healthcare company with a primary 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 70 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 portfolio of 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.

- *Biosimilars*: Organon's current biosimilars 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, Organon's immunology biosimilars, *Brenzys*™ [1] (etanercept), *Renflexis*® (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 launched in the United States.

- *Established Brands*: Organon has a portfolio of established brands, which includes leading brands in cardiovascular, respiratory, dermatology and non-opioid pain management. Most brands in the established brands portfolio (with the exception of *Emgality*® [2] (galcanezumab-gnlm), *Rayvow*™ [2] (lasmiditan) and *Vtama*® (tapinarof)) lost exclusivity years ago and have faced generic competition for some time.

2. 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 2024, 2023, or 2022.

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)	2024	2023	2022
Balance January 1	$ 504	$ 385	$ 329
Provision	3,024	2,640	2,221
Payments [1]	(3,048)	(2,521)	(2,165)
Balance December 31	$ 480	$ 504	$ 385

(1) Includes $48 million of liabilities assumed as part of the Dermavant acquisition.

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 $100 million and $380 million, respectively, at December 31, 2024 and $87 million and $417 million, respectively, at December 31, 2023.

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, 2024 and 2023, the accrued balances related to the provision for rebates and discounts included in other current liabilities were approximately $155 million and $126 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 5 "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 $103 million and $113 million as of December 31, 2024 and 2023, respectively. VAT payables included in *Accrued and other current liabilities* were $11 million and $18 million as of December 31, 2024 and 2023, 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 $132 million in 2024, $120 million in 2023, and $96 million in 2022. 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 $206 million, $209 million, and $255 million in 2024, 2023 and 2022, 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, 2024 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.

Intangibles — 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. Licenses include milestone payments made to collaborative partners upon or subsequent to regulatory approval. The estimated useful lives of intangibles range from 5 to 15 years. The Company periodically evaluates whether current facts or circumstances indicate that the carrying values of its 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 11 "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. See Note 11 "Intangibles" for additional details.

Contingent Consideration — For transactions accounted for as a business combination, contingent consideration liabilities are recognized at the estimated fair value on the acquisition date. Subsequent changes to the fair value of contingent consideration liabilities are recognized in *Other expense, net* in the *Consolidated Statements of Income*. Contingent consideration liabilities that are payable prior to regulatory approval are recognized in *Research and development* in the C*onsolidated Statements of Income* when achievement of the milestone is deemed probable. Contingent consideration liabilities that are payable on or after regulatory approval are capitalized as intangible assets when the payments have become probable and amortized to *Cost of sales* over the remaining useful life of the related intangible assets. Contingent consideration payments made or received soon after the acquisition date are classified as *Investing activities i*n the *Consolidated Statements of Cash Flows.* Contingent consideration payments not made or received soon after the acquisition date that are related to the acquisition date fair value are reported as *Financing activities* in the *Consolidated Statements of Cash Flows*, and amounts paid or received in excess of the original acquisition date fair value are reported as *Operating activities* in the *Consolidated Statements of Cash Flows.*

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.

Stock-Based Compensation — 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 6 "Stock-Based Compensation Plans" for additional details.

Pension and Other Postretirement Benefit Plans — For certain defined benefit plans, the over funded or underfunded status of the plan was recognized as an asset or liability on the consolidated balance sheet. Organon sponsors certain non-U.S. defined benefit pension plans. See Note 14 "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 — 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 17 "Third-Party Arrangements" for additional details and defined terms.

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 12 "Long-Term Debt and Leases" for additional details.

Principles of Consolidation — The consolidated financial statements include the accounts of the Company and all of its subsidiaries. All intercompany transactions and accounts have been eliminated.

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.

Segments — The Company's operations includes three 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. The Company's chief operating decision-maker ("CODM") is the Chief Executive Officer. The CODM assesses performance and decides how to allocate resources for our one operating segment based on consolidated net income that is reported on the consolidated statements of income. The Company has also evaluated the significant segment expenses incurred by our single segment and regularly provided to the CODM. The significant segment expenses provided to the CODM are consistent with those reported on the consolidated statements of income and include cost of sales, selling, general and administrative, research and development, interest expense and income taxes. The CODM uses these metrics to make key operating decisions such as: approving a new product launch strategy, making significant capital expenditures, approving the design of key commercialization strategies, decisions about key personnel, and approving annual operating and capital budgets. Our CODM considers budget-to-actual variances and year over year performance when making decisions supporting capital resource allocation. The Company manages assets on a consolidated basis as reported on the consolidated balance sheets.

Recently Adopted Accounting Standards

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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. The Company adopted this ASU for the fiscal year beginning on January 1, 2024 on a retrospective basis for all periods presented. The adoption of the ASU did not have an impact on the Company's consolidated financial condition or results of operations, see Note 2 "Summary of Accounting Policies— Segments".

Recently Issued Accounting Standards Not Yet Adopted

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures,* Additionally, in January 2025, the FASB issued ASU 2025-01 to clarify the effective date of ASU

2024-03. The standard requires entities to disaggregate operating expenses into specific categories to provide enhanced transparency into the nature and function of expenses. This guidance is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. This guidance should be applied either prospectively to financial statements issued for reporting periods after the effective date or retrospectively to any or all prior periods presented in the financial statements. This ASU will have no impact on the Company's consolidated financial condition or results of operations. The Company is currently in the process of evaluating the effects of this guidance on its related disclosures.

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.

3. Acquisitions and Licensing Arrangements

2024 Transactions

Dermavant Sciences Ltd. ("Dermavant")

On October 28, 2024, Organon acquired Dermavant, a company dedicated to developing and commercializing innovative therapeutics in immuno-dermatology. Dermavant's novel product, *Vtama*, for the topical treatment of mild, moderate, and severe plaque psoriasis in adults, was approved by the U.S. Food and Drug Administration (the "FDA") in May 2022. In December 2024, the FDA approved *Vtama* for the treatment of atopic dermatitis, also known as eczema, in adults and children two years of age and older. Atopic dermatitis is one of the most common inflammatory dermatological conditions in adults, presenting a higher disease burden for women compared to men. The acquisition allows Organon to further expand its existing portfolio of established brands and biosimilar dermatology treatments.

Consideration for Dermavant consists of the upfront payment of $175 million and a $75 million milestone payment upon regulatory approval, as well as payments of up to $950 million for the achievements of certain commercial milestones, tiered royalties on net sales, and the assumption of liabilities, including certain debt obligations, which were accounted for at fair value on the acquisition date.

The transaction was accounted for as a business combination. The estimated aggregate consideration is calculated as follows:

(in millions)		
Cash consideration paid to Dermavant at closing	$	198
Fair value of contingent consideration		383
Aggregate purchase price consideration		581

Contingent consideration included as part of the consideration relates to potential future milestone obligations of up to $1.025 billion, including: (i) up to $75 million in cash payable upon regulatory approval, and (ii) up to $950 million for the achievements of certain commercial milestones. The fair value of the contingent consideration recognized on the acquisition date was estimated by using the inputs disclosed in Note 13. "Financial Instruments." The Company reassesses its acquisition-related contingent consideration liabilities each quarter for changes in fair value.

The valuation of assets acquired and liabilities assumed has not yet been finalized as of December 31, 2024. As a result, Organon recorded preliminary estimates for the fair value of assets acquired and liabilities assumed as of the acquisition date. Finalization of the valuation during the measurement period could result in a change in the amounts recorded for the acquisition date fair value of intangible assets, goodwill, inventories, debts assumed, contingent considerations and income taxes among other items. The completion of the valuation will occur no later than one year from the acquisition date.

The following table summarizes the preliminary fair values of the assets acquired and liabilities assumed related to the Dermavant acquisition as of the acquisition date:

($ in millions)		
Cash and cash equivalents	$	31
Accounts receivable		46
Inventories		97
Other assets		36
Intangibles		672
Long-term debt		(258)
Other liabilities		(108)
Deferred income taxes		(12)
Total identifiable net assets		504
Goodwill		77
Purchase Consideration	$	581

The carrying values of cash and cash equivalents, account receivables, raw materials inventory, other assets and other liabilities represented their fair values at the date of acquisition.

The fair value of finished goods inventory was determined based on its net realizable based on the estimated selling price adjusted for cost of the selling effort and a reasonable profit allowance for the selling effort.

The fair value of the identifiable intangible assets was determined primarily using the "income approach," which requires a forecast of the expected future cash flows (including net revenue, cost of sales, operating expenses) and the appropriate discount rate.

The intangible assets acquired, as well as their fair values and estimated useful life consist of the following:

($ in millions)	Fair Value	Estimated Useful Life (in years)
Currently marketed products - products and product rights:		
Vtama - Psoriasis	$ 216	11
Indefinite life - acquired IPR&D:		
Vtama - Atopic Dermatitis [(1)]	395	N/A
Vtama - International	61	N/A
	$ 672	

(1) In December 2024, the FDA approved *Vtama* for the treatment of atopic dermatitis, also known as eczema, in adults and children two years of age and older. As a result, the Company reclassified the *Vtama* - Atopic Dermatitis acquired IPR&D intangible asset to product and product rights.

The fair value of the assumed debt was determined using the option-pricing model which is determined using expected payments and timing of payments, and a discount rate.

The fair value measurement of contingent consideration arising from business combinations is determined via a probability-weighted cash flows using a Monte Carlo simulation model which are then discounted to present value. These inputs may include: (i) the estimated amount and timing of projected cash flows, (ii) the probability of the achievement of the factor(s) on which the contingency is based and (iii) the risk-adjusted discount rate used to present value the probability-weighted cash flows.

The excess of the consideration paid over the fair value of the net assets acquired was recorded as goodwill. The goodwill recognized upon acquisition is not deductible for income tax purposes.

In December 2024, the FDA approved *Vtama* for atopic dermatitis. As a result, the Company transferred the IPR&D amount of 395 million to Currently marketed products – products and product rights and will amortize the asset over 11 years.

During the fourth quarter of 2024, the regulatory milestone related to *Vtama's* atopic dermatitis indication, which was recorded as part of contingent consideration at fair value, was achieved and recorded in *Accrued and other current liabilities.* In January 2025, the Company paid $75 million related to the milestone.

During the fourth quarter of 2024, Organon recognized an additional intangible asset of $24 million, related to a sales-based milestone that was deemed probable and was related to an assumed licensing agreement. The intangible asset will be amortized over 11 years.

Unaudited Pro forma Information

The unaudited pro forma combined financial information was prepared using the acquisition method of accounting and was based on the historical financial information of Organon and Dermavant. The unaudited pro forma financial information includes adjustments to reflect incremental amortization expense to be incurred based on the current preliminary fair values of the identifiable intangible assets acquired; the incremental cost of sales related to the fair value adjustments associated with acquisition date inventory; and the reclassification of acquisition-related costs incurred during the year ended December 31, 2024 to the year ended December 31, 2023. The unaudited pro forma financial information is not necessarily indicative of what the consolidated results of operations would have been had the acquisition been completed on January 1, 2023. In addition, the unaudited pro forma financial information is not a projection of future results of operations of the combined company nor does it reflect the expected realization of any synergies or cost savings associated with the acquisition.

The following unaudited pro forma summary presents consolidated information as if the business combination had occurred on January 1, 2023:

	Pro forma Year Ended December 31,	
	2024	2023
	(unaudited)	(unaudited)
Revenues	$ 6,499	$ 6,349
Net income	788	640

Transactions Costs

Organon incurred costs associated with the Dermavant transaction of approximately $12 million, comprised of transaction fees and legal costs and were recognized in *Selling, general and administrative* expenses for the year ended December 31, 2024.

Suzhou Centergene Pharmaceuticals ("Centergene")

In September 2024, Organon entered into license and supply agreements with Centergene, pursuant to which Organon acquired the exclusive commercialization rights to Centergene's investigational asset, SJ02, in China. SJ02 is a long-acting recombinant human follicle-stimulating hormone carboxyl-terminal peptide fusion protein (FSH-CTP) designed for controlled ovarian stimulation ("COS") in combination with a gonadotropin-releasing hormone ("GnRH") antagonist. It is used to facilitate the development of multiple follicles in women undergoing assisted reproductive technology ("ART") programs. Under the terms of the agreement, Organon will pay $12 million, of which $6 million was paid in the fourth quarter of 2024. In addition, the remaining $6 million is payable upon Organon obtaining the manufacturing license, which is refundable if thereafter either the regulatory approval is not obtained or marketing authorization cannot be transferred. Organon may owe additional regulatory and sales-based milestones to Centergene of up to $170 million under the terms of the license and supply agreements. Organon will recognize regulatory and sales-based milestones when the achievement is probable.

Eli Lilly ("Lilly")

In December 2023, Organon 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, Organon paid an upfront payment of $50 million upon closing of the transaction in January 2024, and will recognize sales-based milestones when the achievement is deemed probable. In the first quarter of 2024, the Company recognized an intangible asset of $220 million, comprised of the $50 million upfront payment and $170 million of sales-based milestones that were deemed probable. The intangible asset will be amortized over 10 years.

In August of 2024, Organon expanded its agreement with Lilly to become the sole distributor and promoter for *Emgality* in the following additional markets: Canada, Colombia, Israel, South Korea, Kuwait, Mexico, Qatar, Saudi Arabia, Taiwan, Turkey, and the United Arab Emirates. Organon paid an upfront payment of $23 million for the expansion of territory upon closing of the transaction in August 2024, and will recognize sales-based milestones when the achievement is deemed probable. In the third quarter of 2024, Organon recognized an additional intangible asset of $113 million, comprised of the $23 million upfront payment and $90 million related to the sales-based milestones that were deemed probable. The intangible asset will be amortized over 10 years.

As of December 31, 2024, Organon had accrued $20 million in *Accrued and Other current liabilities* and $240 million in *Other noncurrent liabilities* in total related to the probable sales-based milestones. In January 2025, the Company paid $20 million related to the milestones.

Shanghai Henlius Biotech, Inc. ("Henlius")

For the year ended December 31, 2024 research and development milestones related to the Henlius agreement were determined to be probable of being achieved and the Company expensed $70 million, in *Acquired in-process research and development and milestones* expense related to the development of HLX11, an investigational biosimilar of *Perjeta* [2] (pertuzumab), and HLX14, an investigational biosimilar of *Prolia*[2] and *Xgeva*[2] (denosumab). As of December 31, 2024, $60 million of these milestones have been paid. On May 24, 2024, the European Medicines Agency validated the marketing authorization applications for HLX14. On October 30, 2024, the U.S. Food and Drug Administration accepted the biologic license application for HLX14.

Cirqle Biomedical ("Cirqle")

For the year ended December 31, 2024, research and development milestones related to the Cirqle agreement were determined to be probable of being achieved and the Company expensed and paid $10 million in *Acquired in-process research and development and milestones* expense.

Oss Biotech Site

Organon has entered into an agreement with Merck to acquire the Oss Bio-Tech manufacturing facility in the Netherlands. This agreement covers Organon's fertility drug substance production and associated support functions. Organon will pay aggregate consideration of $25 million, of which $15 million will be paid upon closing in the third quarter of 2025 and the remaining $10 million will be paid in the first half of 2026.

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.

4. Earnings per Share ("EPS")

The calculations of basic and diluted EPS are as follows:

($ in millions and shares in thousands, except per share amounts)	Year Ended December 31, 2024	2023	2022
Net income	$ 864	$ 1,023	$ 917
Basic weighted average number of shares outstanding	257,046	255,239	254,082
Stock awards and equity units (share equivalent)	2,106	1,031	1,087
Diluted weighted average common shares outstanding	259,152	256,270	255,169
EPS:			
Basic	$ 3.36	$ 4.01	$ 3.61
Diluted	$ 3.33	$ 3.99	$ 3.59
Anti-dilutive shares excluded from the calculation of EPS	8,363	9,025	4,375

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.

5. Product and Geographic Information

Revenues of the Company's products were as follows:

	Year Ended December 31,								
	2024			2023			2022		
($ in millions)	U.S.	Int'l	Total	U.S.	Int'l	Total	U.S.	Int'l	Total
Women's Health									
Nexplanon/Implanon NXT	$ 672	$ 291	$ 963	$ 572	$ 257	$ 830	$ 573	$ 261	$ 834
Follistim AQ	84	152	237	125	136	262	105	124	229
NuvaRing [1]	39	75	115	90	86	176	131	88	219
Ganirelix Acetate Injection	20	89	109	19	91	110	26	97	123
Marvelon/Mercilon	—	134	134	—	134	134	—	110	110
Jada	60	1	61	43	—	43	20	—	20
Other Women's Health [1] [2]	56	104	158	48	101	147	44	94	138
Biosimilars									
Renflexis	219	55	274	234	43	278	196	30	226
Ontruzant	29	112	141	46	109	155	48	74	122
Brenzys	—	77	77	—	73	73	—	75	75
Aybintio	—	28	28	—	43	43	—	39	39
Hadlima	104	38	142	17	26	44	—	19	19
Established Brands									
Cardiovascular									
Zetia [1]	7	310	317	8	314	322	8	363	370
Vytorin	6	102	108	6	124	129	8	123	130
Atozet	—	473	473	—	519	519	—	457	457
Rosuzet	—	49	49	—	70	70	—	71	71
Cozaar/Hyzaar	9	234	243	10	272	281	13	310	323
Other Cardiovascular [1] [2]	2	130	133	2	136	139	3	143	146
Respiratory									
Singulair	9	350	359	11	393	404	11	400	411
Nasonex [1]	—	276	276	—	266	266	10	251	260
Dulera	162	42	203	156	38	194	140	40	180
Clarinex	3	125	127	5	132	136	4	121	125
Other Respiratory [1] [2]	38	13	53	49	14	64	46	14	61
Non-Opioid Pain, Bone and Dermatology									
Arcoxia	—	270	270	—	257	257	—	241	241
Fosamax	3	147	151	3	156	159	4	148	152
Diprospan	—	139	139	—	91	91	—	122	122
Vtama	10	1	12	—	—	—	—	—	—
Other Non-Opioid Pain, Bone and Dermatology [2]	19	279	295	14	261	275	15	257	273
Other									
Emgality/Rayvow	—	107	107	—	—	—	—	—	—
Proscar	1	94	95	1	96	97	1	99	101
Propecia	6	105	111	7	118	125	7	118	125
Other [2]	14	314	328	13	308	319	24	302	326
Other [3]	—	115	115	(1)	121	121	—	146	146
Revenues	$ 1,572	$ 4,831	$ 6,403	$ 1,478	$ 4,785	$ 6,263	$ 1,437	$ 4,737	$ 6,174

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) Sales of the authorized generic versions of **NuvaRing, Zetia** and **Nasonex** were previously included in other and have been reclassified to their respective brand name product.*

(2) Includes sales of products not listed separately.

(3) Includes manufacturing sales to third parties.

Revenues by geographic area where derived are as follows:

($ in millions)	Year Ended December 31, 2024	2023	2022
Europe and Canada	$ 1,763	$ 1,673	$ 1,631
United States	1,572	1,478	1,437
Asia Pacific and Japan	1,050	1,129	1,143
China	847	864	917
Latin America, Middle East, Russia, and Africa	1,034	965	895
Other [(1)]	137	154	151
Revenues	$ 6,403	$ 6,263	$ 6,174

(1) Includes manufacturing sales to third parties.

As of December 31, 2024, approximately 71% of the Company's long-lived fixed assets are located in Europe and Canada, and 20% are in the United States. The Company does not disaggregate assets on a products and services basis for internal management reporting and, therefore, such information is not presented.

6. Stock-Based Compensation Plans

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

Employee stock options are granted to purchase shares of Company common 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 ("TSR") of the Company relative to an index of peer companies specified in the awards; and
- the results of cumulative free cash flow ("FCF") and revenue metrics of the Company.

PSUs include awards issued where the service inception date precedes the grant date. The grant date for the performance conditions is the date grantees have a mutual understanding of the key terms and conditions of the award, which will occur when the performance condition is objectively determinable and measurable. Recognition of stock-based compensation occurs at the service inception date. Measurement of stock-based compensation attributed to the PSU's will be based on the fair value once the grant date is determined.

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 Common Stock after the end of the vesting or performance period, subject to the terms applicable to such awards.

Cash awards will be recognized and expensed over their vesting period at the fair market value of the shares on the date they are awarded and will be remeasured on a quarterly basis until the award vests or is otherwise settled.

Stock-based compensation expenses incurred by the Company were as follows:

	Year Ended December 31,		
($ in millions)	2024	2023	2022
Stock-based compensation expense recognized in:			
Cost of sales	$ 17	$ 17	$ 13
Selling, general and administrative	70	68	51
Research and development	18	16	11
Total	$ 105	$ 101	$ 75
Income tax benefits	$ 22	$ 21	$ 16

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.

In 2024, the historical component of expected volatility is based on the historical monthly price changes of Organon and implied volatility of Organon. 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, 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 fair value of options granted was determined using the following assumptions:

	Year Ended December 31,		
	2024	2023	2022
Expected dividend yield	6.00 %	4.82 %	3.12 %
Risk-free interest rate	4.12	3.56	2.47
Expected volatility	41.02	42.30	43.43
Expected life (years)	5.89	5.89	5.89

A summary of the equity award transactions for the year ended December 31, 2024 is as follows:

	Stock Options			RSUs		PSUs	
(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, 2024	5,758	$ 32.20	$ 8.51	7,511	$ 25.05	1,122	$ 30.16
Granted/Issued	1,503	18.80	4.59	5,509	18.46	184	31.25
Vested/Exercised	—	—	—	(3,351)	27.51	(56)	51.63
Forfeited/Cancelled	(313)	29.11	7.66	(1,079)	21.44	(129)	37.44
Outstanding as of December 31, 2024	6,948	$ 29.44	$ 7.70	8,590	$ 20.28	1,121	$ 28.44

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, 2024:

	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	6,795	$ 29.44	$ —	6.58	4,645	$ 33.54	$ —	5.46
RSUs	8,037		128	1.91				
PSUs	867		14	1.45				

The amount of unrecognized compensation costs as of December 31, 2024 was $141 million, which will be recognized in operating expense ratably over the weighted average vesting period of 1.88 years.

7. Restructuring

In the first quarter of 2024, Organon implemented additional restructuring activities related to the ongoing optimization of its internal operations by reducing headcount, primarily in the research and development function. In the fourth quarter of 2023, Organon implemented restructuring activities related to the ongoing optimization of its internal operations by reducing headcount in certain markets and functions. As a result of these combined activities, the Company's headcount was reduced by approximately 5% by the end of 2024. Organon expects the remaining severance payments associated with the restructuring activities to be within the next twelve months.

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

	December 31, 2024	December 31, 2023
Beginning balance	$ 61	$ 20
Severance & severance related costs	31	62
Cash payments and other	(78)	(21)
Ending Balance	$ 14	$ 61

During the first quarter of 2025, we implemented additional restructuring initiatives that will drive operational efficiencies in 2025, and will result in an approximate 5% headcount reduction.

8. Taxes on Income

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

	Year Ended December 31,					
	2024		2023		2022	
($ in millions)	Amount	Tax Rate	Amount	Tax Rate	Amount	Tax Rate
U.S. statutory rate applied to income before taxes	$ 169	21.0 %	$ 141	21.0 %	$ 236	21.0 %
Differential arising from:						
Foreign earnings	(79)	(9.7)	(91)	(13.6)	(113)	(10.1)
Tax settlements	(14)	(1.8)	(13)	(1.9)	(2)	(0.1)
Amortization of intangible assets	—	—	(686)	(102.0)	—	—
State taxes	—	—	(5)	(0.8)	(2)	(0.2)
Global Intangible Low-Taxed Income	62	7.7	54	8.0	57	5.1
Interest expense disallowance	11	1.3	46	6.8	13	1.2
Valuation allowance	(208)	(25.8)	208	30.9	4	0.4
Other	2	0.2	(4)	(0.6)	12	1.0
	$ (57)	(7.1)%	$ (350)	(52.2)%	$ 205	18.3 %

As a result of the Tax Cuts and Jobs Act ("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, 2024 and 2022, the deferred tax balance on undistributed earnings for certain subsidiaries that are deemed indefinitely reinvested was not material. At December 31, 2023 the deferred tax balance was $4 million.

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 (7.1)%, (52.2)% and 18.3% for 2024, 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 third quarter of 2024, the Swiss tax authority confirmed to the Company the applicable useful life of an existing tax asset. As a result, the Company has now concluded it is more likely than not it will utilize the entirety of the tax asset. As such, the Company released a $210 million related valuation allowance. In the fourth quarter of 2023, $476 million tax benefit was recorded, 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.

Income before taxes consisted of:

	Year Ended December 31,		
($ in millions)	2024	2023	2022
Domestic	$ (479)	$ (554)	$ (451)
Foreign	1,286	1,227	1,573
	$ 807	$ 673	$ 1,122

Taxes on income consisted of:

($ in millions)	Year Ended December 31, 2024	2023	2022
Current provision			
Federal	$ 32	$ 47	$ 51
Foreign	71	87	172
State	—	1	—
	$ 103	$ 135	$ 223
Deferred provision			
Federal	$ (58)	$ (52)	$ (38)
Foreign	(102)	(428)	22
State	—	(5)	(2)
	$ (160)	$ (485)	$ (18)
	$ (57)	$ (350)	$ 205

Deferred income taxes at December 31 consisted of:

($ in millions)	December 31, 2024 Assets	2024 Liabilities	2023 Assets	2023 Liabilities
Product intangibles and licenses	$ 841	$ —	$ 927	$ —
Inventory related	—	18	3	—
Reserves and allowances	43	—	38	—
Accrued expenses	6	—	5	—
Accelerated depreciation	—	34	—	18
Unremitted foreign earnings	—	5	—	5
Right of use asset	33	—	38	—
Lease liability	—	33	—	38
Interest expense limitation carryforward	102	—	72	—
Compensation related	20	—	17	—
Hedging	—	74	—	41
Net operating losses and other tax credit carryforwards	224	—	35	—
Other	28	—	37	—
Subtotal	$ 1,297	$ 164	$ 1,172	$ 102
Valuation allowance	(261)	—	(309)	—
Total deferred taxes	$ 1,036	$ 164	$ 863	$ 102
Net deferred income taxes	$ 872		$ 761	
Recognized as:				
Other Assets	$ 946		$ 808	
Deferred Income Taxes		$ 74		$ 47

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

	Year Ended December 31,		
	2024	2023	2022
Beginning balance	$ (309)	$ (52)	$ (35)
Additions charged to expense	(24)	(257)	(17)
Reductions charged to expense	211	—	—
Foreign currency translation	8	—	—
Acquisition related	(147)	—	—
Ending balance	$ (261)	$ (309)	$ (52)

The Company has recognized $224 million and $35 million of deferred taxes on net operating loss ("NOL") carryforwards in multiple jurisdictions as of December 31, 2024 and 2023, respectively. Valuation allowances of $261 million have been established on $180 million of foreign deferred tax assets and $82 million of U.S. deferred tax assets. The additions charged to expense are related to the U.S. disallowed interest expense carryforward. The reduction and other adjustments of $211 million is primarily due to the $210 million reversal of a prior year valuation allowance recorded in connection with the future benefit of a Swiss tax asset. The acquisition related valuation allowance activity of $147 million is for the valuation allowance established as part of purchase accounting in connection with the acquisition of Dermavant.

Income taxes paid in 2024, 2023 and 2022, were $293 million, $135 million and $214 million, respectively.

As of December 31, 2024 and 2023, the Company deferred the income tax consequences resulting from intra-entity transfers of inventory totaling $509 million and $396 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)	2024	2023	2022
Balance January 1	$ 115	$ 93	$ 78
Additions related to current year tax positions	31	32	30
Additions related to prior year tax positions	7	7	3
Reductions for tax positions of prior years	(5)	(8)	(3)
Settlements	(27)	(7)	(12)
Lapse of statute of limitations	—	(2)	(3)
Balance December 31	$ 121	$ 115	$ 93

If the Company were to recognize the unrecognized tax benefits of $121 million, at December 31, 2024, the income tax provision would reflect a favorable net impact of $121 million.

In 2024, 2023 and 2022, foreign tax authorities concluded their examinations of certain foreign income tax returns. As a result, the Company reflected a payment of $27 million, $7 million and $12 million in the consolidated financial statements in 2024, 2023 and 2022, respectively. A corresponding reduction in reserves of $27 million, $15 million and $11 million were also reflected in 2024, 2023 and 2022, respectively, for unrecognized tax benefits for tax positions relating to the years that were under examination.

The Company does not anticipate any events in the next 12 months that would result in a material change to the uncertain tax positions. 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 a benefit of $15 million in 2024, an expense of $3 million in 2023 and were not material in 2022. These amounts reflect the beneficial impacts of various tax settlements. Liabilities for accrued interest and penalties were $20 million and $40 million as of December 31, 2024 and 2023, respectively.

Various foreign tax examinations are in progress and for these jurisdictions, income tax returns are open for examination for the period 2006 through 2024.

9. Inventories

Inventories consisted of:

($ in millions)	December 31, 2024	December 31, 2023
Finished goods	$ 764	$ 566
Raw materials	25	110
Work in process	675	684
Supplies	79	65
Total (approximates current cost)	$ 1,543	$ 1,425
Decrease to last in, first out ("LIFO") costs	(7)	—
	$ 1,536	$ 1,425
Recognized as:		
Inventories	$ 1,321	$ 1,315
Other assets	215	110
Inventories valued under the LIFO method	133	105

As part of the Dermavant acquisition the Company acquired 97 million of inventory, which includes a $63 million purchase accounting inventory fair value adjustment. As of December 31, 2024 $56 million related to the fair value adjustment is included in inventory.

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 long-term vendor supply contracts that include certain annual minimum purchase commitments.

As of December 31, 2024, total inventory purchase obligations are $738 million and extend through 2032. Inventory purchase obligations due within the next twelve months amount to $320 million.

10. Property, Plant and Equipment

($ in millions)	December 31, 2024	December 31, 2023
Land	$ 12	$ 14
Buildings	721	721
Machinery, equipment and office furnishings	1,209	1,191
Construction in progress	286	274
Less: accumulated depreciation	(1,060)	(1,017)
Property, Plant and Equipment, net	$ 1,168	$ 1,183

11. Intangibles

Intangibles consists of:

($ in millions)	December 31, 2024 Gross Carrying Amount	December 31, 2024 Accumulated Amortization	December 31, 2024 Net	December 31, 2023 Gross Carrying Amount	December 31, 2023 Accumulated Amortization	December 31, 2023 Net
Products and product rights	$ 24,917	$ 23,936	$ 981	$ 24,290	$ 23,845	$ 445
Licenses	564	192	372	231	143	88
Acquired IPR&D	61	—	61	—	—	—
	$ 25,542	$ 24,128	$ 1,414	$ 24,521	$ 23,988	$ 533

As of December 31, 2024, net intangibles include $629 million of *Vtama* intangibles that will be amortized over 11 years and $61 million of indefinite lived Acquired IPR&D related to *Vtama*. See Note 3 “Acquisitions and Licensing Arrangements” for further information.

The Company did not have impairment charges in 2024 and 2023.

Aggregate amortization expense recorded within *Cost of sales* was $145 million in 2024, $116 million in 2023 and $116 million in 2022.

The estimated aggregate future amortization expense is as follows:

($ in millions)	
2025	$ 202
2026	196
2027	139
2028	131
2029	126
Thereafter	559

The following table summarizes the changes in goodwill:

($ in millions)	December 31, 2024	December 31, 2023
Beginning balance	$ 4,603	$ 4,603
Additions [1]	77	—
Ending balance	$ 4,680	$ 4,603

[1] Relates to the Dermavant acquisition. See Note 3 “Acquisitions and Licensing Arrangements” for further information.

12. Long-Term Debt and Leases

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

($ in millions)	December 31, 2024	December 31, 2023
Term Loan B Facility:		
SOFR plus 225 bps term loan due 2031 [1]	$ 1,543	$ 2,543
EURIBOR plus 275 bps euro-denominated term loan due 2031 (€724 million in 2024 and €731 million in 2023) [2]	755	809
4.125% secured notes due 2028	2,100	2,100
2.875% euro-denominated secured notes due 2028 (€1.25 billion)	1,304	1,384
5.125% notes due 2031	2,000	2,000
6.750% secured notes due 2034	500	—
7.875% notes due 2034	500	—
Revenue Interest Purchase and Sale Agreement [3]	165	—
NovaQuest Funding Agreement [3]	103	—
Other borrowings	7	8
Other (discounts and debt issuance costs)	(97)	(84)
Total principal long-term debt	$ 8,880	$ 8,760
Less: Current portion of long-term debt	20	9
Total Long-term debt, net of current portion	$ 8,860	$ 8,751

(1) Prior to entering into Amendment No. 2 to the Senior Credit Agreement on May 17, 2024, the maturity date was 2028.
(2) Prior to entering into Amendment No. 3 to the Senior Credit Agreement on December 20, 2024, the maturity date was 2028.
(3) Recognized at the amortized cost basis. The remaining principal is determined as the initial fair value less principal payments. As of December 31, 2024, the remaining principal of the RIPSA and NovaQuest debt is 156 million and 102 million, respectively.

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 ("U.S. Dollar Term Loan Facility") in the amount of $3.0 billion, and (ii) a euro denominated senior secured "tranche B" term loan ("Euro Term Loan Facility") 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 May 17, 2024, Organon entered into Amendment No. 2 to the Senior Credit Agreement ("Amendment No. 2") which, among other things, (i) extended the maturity of the U.S. Dollar Term Loan Facility to May 17, 2031, (ii) extended the maturity of the revolving credit loans made under the Revolving Credit Facility to December 2, 2027, (iii) increased the maximum amount of the Revolving Credit Facility by $300 million and decreased the commitment fee payable in respect of the Revolving Credit Facility to 0.375%, (iv) removed the credit spread adjustment applicable to SOFR loans, and (v) reduced the interest rate in respect of the remaining $1.55 billion of loans under the U.S. Dollar Term Loan Facility (the "U.S. Dollar Term Loans") from Term SOFR plus 3.0% to Term SOFR plus 2.50%.

On December 20, 2024, Organon entered into Amendment No. 3 to the Senior Credit Agreement ("Amendment No. 3") which, among other things, (i) reduced the interest rate of the outstanding U.S. Dollar Term Loans from Term SOFR plus 2.50% to Term SOFR plus 2.25%, (ii) reduced the interest rate of the loans outstanding under the Euro Term Loan Facility (the "EUR Term Loans" and, together with the U.S. Dollar Term Loans, the "Term Loans") from EURIBOR plus 3.0% to EURIBOR plus 2.75%, (iii) extended the maturity of the Euro Term Loan Facility to December 20, 2031, (iv) reduced the interest rate under the Revolving Credit Facility from Term SOFR plus 2.00% to Term SOFR plus 1.50%.

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 2.25% in excess of Term SOFR (subject to a floor of 0.50%), or 1.25% in excess of an alternate base rate ("ABR"), at Organon's option and (ii) denominated in euros, at 2.75% in excess of EURIBOR (subject to a floor of 0.00%); and
- revolving loans under the Revolving Credit Facility (i) in U.S. Dollars, at 1.50% in excess of Term SOFR (subject to a floor of 0.00%), or 0.50% in excess of ABR, at Organon's option and (ii) in euros, at 1.50% in excess of EURIBOR.

Interest payments on the Term Loans are due monthly or quarterly, depending on the interest period selected. Principal payments on the Term Loans were based on 0.25% of the original principal amount outstanding on the closing date of the Senior Credit Agreement 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 Term Loans are no longer required. Effective as of the December 20, 2024 closing date of Amendment No. 3, Principal Payments on the Euro Term Loans are based on the principal amount outstanding on the Amendment No. 3 effective date.

On June 26, 2024, the Company made a discretionary prepayment of $7.5 million on the U.S. Dollar Term Loans. On March 30, 2023, the Company made a discretionary prepayment of $250 million on the U.S. Dollar Term Loans. In the second quarter of 2022, the Company made a discretionary prepayment of $100 million on the U.S. Dollar Term Loans.

During the second quarter of 2024, the Company borrowed $36 million on the Revolving Credit Facility and subsequently repaid the amount on June 17, 2024. The Company borrowed $100 million on the Revolving Credit Facility in October 2024 and an additional $50 million in November 2024 and repaid the amounts in December 2024. There were no outstanding balances under the Revolving Credit Facility as of December 31, 2024 or December 31, 2023. The Company borrowed $90 million on the Revolving Credit Facility in January 2025.

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, 2024, the Company is in compliance with all financial covenants and no default or event of default has occurred.

Notes

In April 2021, 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.

During the second quarter of 2024, Organon issued $500 million of 6.750% senior secured notes due 2034 (the "2034 Secured Notes") and $500 million of 7.875% senior unsecured notes due 2034 (the "2034 Unsecured Notes" and, together with the Secured Notes the "2034 Notes"). Each series of notes is guaranteed by each of the entities that guarantees the Companies' existing senior secured credit facilities (the "Credit Facilities"). Organon used the net proceeds from the sale of the 2034 Notes to repay a portion of its borrowings under the Credit Facilities' U.S. dollar-denominated "tranche B" term loan and to pay the fees and expenses incurred in connection with the foregoing.

As of December 31, 2024, the Company recorded approximately $38 million of deferred debt issuance costs and discounts related to the 2034 Notes, Amendment No. 2 and Amendment No. 3. Debt issuance costs and discounts are presented as a reduction of debt on the Condensed Consolidated Balance Sheets and are amortized as a component of interest expense over the term on the related debt using the effective interest method.

Revenue Interest Purchase and Sale Agreement

In connection with the Dermavant acquisition, Organon assumed a revenue interest purchase and sale agreement (the "RIPSA") with XYQ Luxco, NovaQuest Co-Investment Fund XVII, L.P., an affiliate of NovaQuest Capital Management, LLC, and MAM Tapir Lender, LLC, an affiliate of Marathon Asset Management, L.P., together with U.S. Bank National Association, as collateral agent. Under the terms of the RIPSA, Organon is obligated to pay quarterly royalties equal to $1.5 million through 2026. After 2026, the royalties are based on a capped single-digit revenue interest in net sales of *Vtama* for all dermatological indications in the United States, up to a cap of $344 million.

The RIPSA is accounted for as debt and was initially recognized at fair value of 156 million. Over the term of the arrangement, the effective interest rate will be updated prospectively each reporting period based on the carrying amount of the debt, and the estimated timing and remaining cash flows related to the debt. As of December 31, 2024 the effective interest rate of the RIPSA is 7.3.

Funding Agreement with NovaQuest

In connection with the Dermavant acquisition, Organon assumed the funding agreement with NovaQuest Co-Investment Fund VIII, L.P. ("NovaQuest"). Organon will make quarterly payments due totaling $118 million in aggregate, to be paid through 2028, with payments due totaling $6 million in 2025, $21 million in 2026, $57 million in 2027 and $34 million in 2028. The debt was initially recognized at fair value of 102 million and will be subsequently recognized at the amortized cost basis.

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)	Fair Value Measurement Level	December 31, 2024	December 31, 2023
Long-term debt	2	$ 8,354	$ 8,253
Long-term debt (RIPSA & NovaQuest)	3	268	—

Level 2 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 liability. Level 3 was estimated using unobservable inputs.

The Company made interest payments related to its debt instruments of $487 million for the year ended December 31, 2024. The average maturity of the Company's long-term debt as of December 31, 2024 is approximately 5.6 years and the weighted-average interest rate on total borrowings as of December 31, 2024 is 5.1%.

The schedule of principal payments required on long-term debt for the next five years, exclusive of $12 million of accrued interest related to the RIPSA and NovaQuest debt, and thereafter are as follows:

($ in millions)	
2025	$ 8
2026	25
2027	62
2028	3,445
2029	9
Thereafter	5,418

Leases

Operating lease costs were $63 million, $67 million and $61 million for the year ended December 31, 2024, 2023, and 2022, 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 $52 million, $56 million and $55 million for the year ended December 31, 2024, 2023 and 2022, respectively. Operating lease assets obtained in exchange for new operating lease liabilities were $25 million, $25 million and $28 million for the year ended December 31, 2024, 2023 and 2022, respectively, and primarily consists of real estate operating leases.

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

($ in millions)	December 31, 2024	December 31, 2023
Assets		
Other Assets	$ 157	$ 173
Liabilities		
Accrued and other current liabilities	44	46
Other Noncurrent Liabilities	112	125
	$ 156	$ 171
Weighted-average remaining lease term (years)	5.2	5.0
Weighted-average discount rate	5.1%	4.8%

Maturities of operating lease liabilities as of December 31, 2024 are as follows ($ in millions):

2025	$ 49
2026	34
2027	28
2028	18
2029	16
Thereafter	32
Total lease payments	$ 177
Less: Imputed interest	21
	$ 156

13. Financial Instruments

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 was as follows:

($ in millions)	Fair Value Measurement Level	December 31, 2024	December 31, 2023
Other current assets:			
Forward contracts	2	$ 29	$ 9
Other assets:			
Cross-currency swap	2	27	—
Accrued and other current liabilities:			
Contingent consideration	3	75	—
Forward contracts	2	13	16
Other noncurrent liabilities:			
Contingent consideration	3	319	—
Long-term debt	2	8,354	8,253
Long-term debt (RIPSA & NovaQuest)	3	268	—

Foreign Currency Risk Management

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.

Forward Contracts

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* in the Consolidated Statements of Income. The forward contracts are not designated as hedges and are marked to market through *Exchange losses* in the Consolidated Statements of Income. 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 as of December 31, 2024 and December 31, 2023, 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.

Net Investment Hedge

Euro-denominated debt instruments

Foreign exchange risk is also managed through the use of economic hedges on foreign currency balances. €724 million of the euro-denominated term loan and €1.25 billion of the 2.875% euro-denominated secured notes have been designated and are effective as a hedge of the net investment in euro-denominated subsidiaries. See Note 12 "Long-Term Debt and Leases" for additional details.

Cross-Currency Swaps

In conjunction with the issuance of the 2034 Notes, the Company entered into cross-currency swaps that mature in 2029. The Company elected to designate the fixed-for-fixed swaps as a hedge of the net investment in euro-denominated subsidiaries balance and the change in the fair value attributable to the changes in the spot rate is recorded in *Other Comprehensive Income (Loss), Net of Taxes.* Throughout the term of the swaps, the Company will pay a fixed interest rate of 5.8330% based on the Euro notional amount of €922 million and receive a fixed interest rate of 7.3125% based on the U.S. dollar notional amount of $1 billion. The notional amount based on the Euro leg of the cross-currency swaps has been designated and is effective as a

hedge of the net investment in euro-denominated subsidiaries. The difference between the interest rate received and paid under the cross-currency swap agreements is recorded in *Interest expense* in the Consolidated Statements of Income. The cash flows and the related gains and losses from the periodic settlements of the cross-currency swaps are reported as *Operating Activities* in the Consolidated Statements of Cash Flows.

Foreign currency gain (loss) due to spot rate fluctuations on the euro-denominated debt instruments and the change in fair value of the cross-currency swaps resulting from hedge designation were included within *Cumulative translation adjustment* in *Other comprehensive income (loss):*

	Year Ended December 31,		
($ in millions)	2024	2023	2022
Euro-denominated debt instruments gain (loss)	$ 126	$ (84)	$ 111
Cross-currency swaps gain	27	—	—

The Consolidated Statements of Income include the impact of net (gains) losses of Organon's derivative financial instruments:

	Year Ended December 31,		
($ in millions)	2024	2023	2022
Derivative (gain) loss in *Exchange losses*	$ (22)	$ (22)	15
Derivative gain in *Interest expense*	(9)	—	—

Contingent Consideration

The fair value measurement of contingent consideration arising from business combinations is determined via a probability-weighted cash flows using a Monte Carlo simulation model which are then discounted to present value. These inputs may include: (i) the estimated amount and timing of projected cash flows, (ii) the probability of the achievement of the factor(s) on which the contingency is based and (iii) the risk-adjusted discount rate used to present value the probability-weighted cash flows. Significant increases or decreases in any of those inputs in isolation could result in a significantly higher or lower fair value measurement. At December 31, 2024, the fair value measurements of acquisition-related contingent consideration were determined using discount rates ranging from 6.26% to 8.05%.

The following table presents a reconciliation of contingent consideration measured on a recurring basis using significant unobservable inputs (Level 3):

($ in millions)	December 31, 2024
Beginning balance	$ —
Additions	383
Fair value adjustment	11
Ending balance	$ 394

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 $186 million and $66 million of accounts receivable as of December 31, 2024 and December 31, 2023, 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 cost of factoring such accounts receivable were not material for the year ended December 31, 2024, 2023, and 2022.

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, Cardinal Health and Cencora, Inc. which represented approximately 12%, 7% and 6%, respectively, of total gross account receivable at December 31, 2024. Bad debts have been minimal. The Company does not normally require collateral or other security to support credit sales.

14. Pension and Other Postretirement Benefit 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)	2024	2023	2022
Service cost	$ 23	$ 17	$ 22
Interest cost	5	5	2
Expected return on plan assets	(7)	(6)	(4)
Net loss amortization	—	(1)	—
Curtailments	2	—	—
Settlements	1	—	—
Net periodic benefit cost	$ 24	$ 15	$ 20

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, 2024	December 31, 2023
Fair value of plan assets January 1	$ 149	$ 114
Actual return on plan assets	14	10
Company contributions	22	16
Effects of exchange rate changes	(9)	9
Benefits paid	(7)	(5)
Other	(2)	2
Net transfer of plan assets from Merck affiliates	—	3
Fair value of plan assets December 31	$ 167	$ 149
Benefit obligation January 1	$ 226	$ 161
Service cost	23	17
Interest cost	5	5
Actuarial gains	11	31
Benefits paid	(7)	(5)
Effects of exchange rate changes	(16)	12
Other	1	2
Net transfer of benefit obligations from Merck affiliates	—	3
Benefit obligation December 31	$ 243	$ 226
Funded status December 31	$ (76)	$ (77)
Recognized as:		
Other assets	$ 1	$ —
Accrued and other current liabilities	—	(1)
Other Noncurrent liabilities	(77)	(76)

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

($ in millions)	December 31, 2024	December 31, 2023
Pension plans with a projected benefit obligation in excess of plan assets		
Projected benefit obligation	$ 233	$ 218
Fair value of plan assets	156	141
Pension plans with an accumulated benefit obligation in excess of plan assets		
Accumulated benefit obligation	$ 179	$ 171
Fair value of plan assets	120	107

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)	2024				2023			
Cash and cash equivalents	$ 5	$ —	$ —	$ 5	$ 5	$ —	$ —	$ 5
Investment funds								
Developed markets equities	60	3	—	63	51	3	—	54
Government and agency obligations	39	1	—	40	35	1	—	36
Emerging markets equities	7	—	—	7	7	—	—	7
Other	4	—	—	4	4	—	—	4
Equity income securities								
Developed markets equities	—	—	—	—	—	—	—	—
Fixed income securities								
Government and agency obligations	—	2	—	2	—	2	—	2
Corporate Obligations	—	1	—	1	—	1	—	1
Other investments								
Insurance contracts	—	43	—	43	—	38	—	38
Other	1	1	—	2	1	1	—	2
Plan assets at fair value	$ 116	$ 51	$ —	$ 167	$ 103	$ 46	$ —	$ 149

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 2025 are approximately $15 million for the Company's pension plans.

Expected Benefit Payments

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

2025	2026	2027	2028	2029	Thereafter
$ 8	$ 9	$ 9	$ 11	$ 11	$ 68

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)	2024	2023	2022
Net (loss) gain arising during the period	$ (4)	$ (28)	$ 28
Net loss amortization or (settlement) included in benefit cost	1	(1)	—

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)	2024	2023	2022
Net periodic benefit cost			
Discount rate	2.77 %	3.82 %	1.49 %
Expected rate of return on plan assets	4.48	4.44	4.05
Salary growth rate	2.83	2.98	2.75
Benefit obligation			
Discount rate	2.41	2.77	3.82
Salary growth rate	2.77	2.83	2.98

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.

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 $27 million as of December 31, 2024, of which $21 million is reflected in *Other Assets* and $6 million is reflected in *Other current assets.* See Note 17 "Third-Party Arrangements" for additional details and defined terms.

Savings Plan

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. 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 2024, 2023 and 2022 were $36 million and $39 million and $32 million, respectively.

As of December 31, 2024 and 2023, the Company had $187 million and $149 million, respectively, in *Accrued and other current liabilities* of the consolidated Balance Sheets related to annual compensation.

15. Accumulated Other Comprehensive Income (Loss)

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

($ in millions)	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive (Loss) Income
Balance at January 1, 2022, 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)
Balance at January 1, 2023, 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)
Balance at January 1, 2024, net of taxes	$ (15)	$ (526)	$ (541)
Other comprehensive loss, pretax	(3)	(106)	(109)
Tax	1	—	1
Other comprehensive loss, net of taxes	(2)	(106)	(108)
Balance at December 31, 2024, net of taxes	$ (17)	$ (632)	$ (649)

16. 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, 2024, potential future regulatory milestone payments of $25 million remain under the agreement.

Summarized information related to this collaboration is as follows:

($ in millions)	Year Ended December 31, 2024	2023	2022
Sales	$ 662	$ 593	$ 481
Cost of sales	437	406	315
Selling, general and administrative	78	72	86

($ in millions)	December 31, 2024	December 31, 2023
Receivables from Samsung included in *Other current assets*	$ 30	$ —
Payables to Samsung included in *Trade accounts payable*	143	104

17. Third-Party Arrangements

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

The Separation and Distribution Agreement, 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 provided Organon and certain of its affiliates, on an interim, transitional basis, various services, and (ii) Organon and certain of its affiliates provided Merck and certain of its affiliates, on an interim, transitional basis, various services. The services provided by Merck included, among others, information technology, human resources, finance, quality, regulatory, supply chain management, promotional services, distribution services and certain other services, and were provided on a cost or, where applicable, a cost-plus basis. The services provided by Organon included quality, regulatory, supply chain management, promotional services, distribution services and certain other services and were provided 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 on July 2, 2023, however, certain services were extended to at least 35 months following the Separation. As of December 31, 2024 there were no material TSAs between the two companies.
- Interim Operating Agreements - Merck and Organon entered into a series of interim operating model ("IOM") agreements, pursuant to which Merck and certain of its affiliates that held licenses, permits and other rights in connection with marketing, import and/or distribution of Organon products in various jurisdictions prior to the Separation, 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, 2024, only one jurisdiction remains under an IOM agreement.
- 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.

The amounts due under such agreements were:

($ in millions)	December 31, 2024	December 31, 2023
Due from Merck in *Accounts receivable*	$ 148	$ 583
Due to Merck in *Accounts payable*	362	619

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

	Year Ended December 31,		
($ in millions)	2024	2023	2022
Sales	$ 108	$ 122	$ 127
Cost of sales	101	114	116

18. 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, 2024, the Fosamax Litigation comprises approximately 975 cases in Federal court, approximately 1,740 cases in New Jersey state court in Middlesex County, and approximately 275 cases in California 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 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. The Femur Facture MDL court then dismissed with prejudice approximately 650 cases on these same preemption grounds. Following a series of appeals, including a U.S. Supreme Court decision in 2019, the Third Circuit ruled in September 2024 that plaintiffs' failure-to-warn claims are not preempted by federal law. Consequently, 975 cases are now before the Femur Fracture MDL court for further litigation.

In New Jersey state court, the parties selected an initial group of cases to be reviewed through fact discovery, and Merck continues to select additional cases to be reviewed. In California state court, the cases have been consolidated before a single judge in Orange County, California, and discovery is presently stayed.

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, 2024, Merck had 20 cases pending outside the United States, of which 11 relate to *Implanon* and nine relate to *Nexplanon*.

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.

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. In December 2023, the parties executed a settlement agreement and the district court dismissed the case. Organon made its first payment of $35 million in December 2023, its second payment of $25 million in August 2024, and its final payment of $20 million in January 2025.

Other Matters

On February 24, 2025, Organon received a Paragraph IV Certification Letter notifying the Company that Xiromed Pharma Espana, S.L. filed an abbreviated new drug application to the FDA seeking approval to market a generic version of *Nexplanon* in the United States prior to the expiration of U.S. Patent Nos. 8,722,037 and 9,757,552, in 2027 and 2030, respectively. Organon is reviewing the matter and intends to defend and enforce its intellectual property rights protecting *Nexplanon*.

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, 2024, 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, 2024 and December 31, 2023 was $7 million and $20 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 $16 million and $19 million at December 31, 2024 and 2023, 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 13 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.

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

During the fourth quarter of 2024, there have been no changes in our internal control over financial reporting that have materially affected, or are 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, 2024 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, 2024.

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.

PricewaterhouseCoopers LLP, an independent registered public accounting firm, which has audited the consolidated financial statements as of and for the year ended December 31, 2024 included in the Annual Report, has issued its report on the effectiveness of the Company’s internal control over financial reporting as of December 31, 2024, as stated in their attestation report which appears under Item 8 of this Annual Report.

Item 9B. Other Information

During the three months ended December 31, 2024, 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 2025 Proxy Statement and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this item will be included in the 2025 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 2025 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 2025 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 2025 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 97, 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)
4.3	—	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)
4.4	—	Form of 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)
4.5	—	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)
4.6	—	Form of 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)
4.7	—	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)
4.8	—	Form of 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)
4.9	—	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 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)
4.10	—	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 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)
4.11	—	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)
4.12	—	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 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)

4.13	—	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 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)
4.14	—	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)
*4.15	—	Third Supplemental Indenture, dated as of July 30, 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
*4.16	—	Third Supplemental Indenture, dated as of July 30, 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
*4.17	—	Third Supplemental Indenture, dated as of July 30, 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
*4.18	—	Fourth Supplemental Indenture, dated as of December 31, 2024, among Organon & Co., Organon 2 LLC, Organon Pharma Holdings II LLC, Organon Finance LLC, and (v) Organon International LLC, the subsidiary guarantors party thereto, Dermavant Sciences, Inc., and U.S. Bank Trust Company, National Association, as trustee and collateral agent, with respect to 2.875% Senior Secured Notes due 2028
*4.19	—	Fourth Supplemental Indenture, dated as of December 31, 2024, among Organon & Co., Organon 2 LLC, Organon Pharma Holdings II LLC, Organon Finance LLC, and (v) Organon International LLC, the subsidiary guarantors party thereto, Dermavant Sciences, Inc., and U.S. Bank Trust Company, National Association, as trustee and collateral agent, with respect to 4.125% Senior Secured Notes due 2028
*4.20	—	Fourth Supplemental Indenture, dated as of December 31, 2024, among Organon & Co., Organon 2 LLC, Organon Pharma Holdings II LLC, Organon Finance LLC, and (v) Organon International LLC, the subsidiary guarantors party thereto, Dermavant Sciences, Inc., and U.S. Bank Trust Company, National Association, as trustee, with respect to 5.125% Senior Notes due 2031
4.21	—	Indenture, dated as of May 17, 2024, by and among Organon & Co., Organon Foreign Debt Co-Issuer B.V., the subsidiary guarantors party thereto, and U.S. Bank Trust Company, National Association, as trustee and collateral agent, with respect to 6.750% Senior Secured Notes Due 2034 (incorporated herein by reference to Exhibit 4.1 to the Company's Form 8-K (File No. 001-40235) filed on May 17, 2024)
4.22	—	Form of 6.750% Senior Secured Notes due 2034 (incorporated herein by reference to Exhibit 4.1 to the Company's Form 8-K (File No. 001-40235) filed on May 17, 2024)
4.23	—	Indenture, dated as of May 17, 2024, by and among Organon & Co., Organon Foreign Debt Co-Issuer B.V., the subsidiary guarantors party thereto, and U.S. Bank Trust Company, National Association, as trustee, with respect to 7.875% Senior Notes Due 2034 (incorporated herein by reference to Exhibit 4.3 to the Company's Form 8-K (File No. 001-40235) filed on May 17, 2024)
4.24	—	Form of 7.875% Senior Notes due 2034 (incorporated herein by reference to Exhibit 4.3 to the Company's Form 8-K (File No. 001-40235) filed on May 17, 2024)
*4.25	—	First Supplemental Indenture, dated as of December 31, 2024, among Organon & Co., Organon 2 LLC, Organon Pharma Holdings II LLC, Organon Finance LLC, and (v) Organon International LLC, the subsidiary guarantors party thereto, Dermavant Sciences, Inc., and U.S. Bank Trust Company, National Association, as trustee and collateral agent, with respect to 6.750% Senior Secured Notes due 2034

*4.26	—	First Supplemental Indenture, dated as of December 31, 2024, among Organon & Co., Organon 2 LLC, Organon Pharma Holdings II LLC, Organon Finance LLC, and (v) Organon International LLC, the subsidiary guarantors party thereto, Dermavant Sciences, Inc., and U.S. Bank Trust Company, National Association, as trustee, with respect to 7.875% Senior Notes due 2034
†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	—	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)
†10.6	—	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).
†10.7	—	Amendment No. 2 to Senior Secured Credit Agreement, dated as of May 17, 2024, by and among Organon & Co., Organon Foreign Debt Co-Issuer B.V., the lenders party thereto and JPMorgan Chase Bank, N.A., as administrative agent and collateral agent (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-40235) filed on May 17, 2024)
*†10.8	—	Amendment No. 3 to Senior Secured Credit Agreement, dated as of December 20, 2024, Organon & Co., Organon Foreign Debt Co-Issuer B.V., the lenders party thereto and JPMorgan Chase Bank, N.A., as administrative agent and collateral agent
+10.9	—	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)
+10.10	—	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)
+10.11	—	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)
+10.12	—	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)
+10.13	—	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)
+10.14	—	Organon & Co. Executive Severance Program, as amended and restated on February 8, 2024. (incorporated by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K (File No. 001-40235) filed on February 26, 2024)
*+10.15	—	Organon Non-Employee Director Savings Plan, as amended and restated on January 1, 2025
+10.16	—	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)
+10.17	—	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)

+10.18	—	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)
+10.19	—	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)
+10.20	—	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)
+10.21	—	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)
+10.22	—	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)
+10.23	—	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)
+10.24	—	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)
+10.25	—	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)
+10.26	—	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)
+10.27	—	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 (incorporated by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K (File No. 001-4023) filed on March 21, 2022)
+10.28	—	Form of Executive Separation Agreement (incorporated by reference to Exhibit 10.38 to the Company's Annual Report on Form 10-K (File No. 001-40235) filed on February 26, 2024)
+10.29	—	Form of Global Terms for 2024 Non-Qualified Stock Option Grants Under the Organon & Co. 2021 Incentive Stock Plan (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q (File No. 001-40235) filed on August 7, 2024)
+10.30	—	Form of Global Terms for 2024 Performance Stock Unit Award Under the Organon & Co. 2021 Incentive Stock Plan (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q (File No. 001-40235) filed on August 7, 2024)
+10.31	—	Form of Global Terms for 2024 Restricted Stock Unit Award Under the Organon & Co. 2021 Incentive Stock Plan (Stock Default) (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q (File No. 001-40235) filed on August 7, 2024)
+10.32	—	Form of Global Terms for 2024 Restricted Stock Unit Award Under the Organon & Co. 2021 Incentive Stock Plan (Cash Default) (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q (File No. 001-40235) filed on August 7, 2024)
*+10.33	—	Form of Global Terms for 2025 Non-Qualified Stock Option Grants Under the Organon & Co. 2021 Incentive Stock Plan
*+10.34	—	Form of Global Terms for 2025 Performance Stock Unit Award Under the Organon & Co. 2021 Incentive Stock Plan

*+10.35	—	Form of Global Terms for 2025 Restricted Stock Unit Award Under the Organon & Co. 2021 Incentive Stock Plan (Stock Default)
*+10.36	—	Form of Global Terms for 2025 Restricted Stock Unit Award Under the Organon & Co. 2021 Incentive Stock Plan (Cash Default)
+10.37	—	Agreement and Plan of Merger, dated September 17, 2024, by and among Organon & Co., Organon Bermuda Ltd., Dermavant Sciences Ltd. and Roivant Sciences Ltd. (incorporated herein by reference to Exhibit 10.1 to the Company's Form 8-K (File No. 00140235) filed on September 23, 2024)
*19.1		Insider Trading Policy
*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 (incorporated by reference to Exhibit 97.1 to the Company's Annual Report on Form 10-K (File No. 001-40235) filed on February 26, 2024)
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 2024 Form 10-K, brand names of products, which are not available in the United States.

[2] Indicates, in this 2024 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.; *Clarinex* is a trademark registered in the U.S. in the name of Bayer Healthcare LLC (used under license); *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 28, 2025

/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 *(Principal Executive Officer)*		February 28, 2025
/s/ Matthew Walsh		Chief Financial Officer *(Principal Financial and Accounting Officer)*		February 28, 2025
/s/ Kathryn DiMarco		SVP Finance – Corporate Controller		February 28, 2025
/s/ Carrie Cox		Chairman of the Board of Directors		February 28, 2025
/s/ Robert Essner		Director		February 28, 2025
/s/ Alan Ezekowitz		Director		February 28, 2025
/s/ Helene Gayle		Director		February 28, 2025
/s/ Rochelle Lazarus		Director		February 28, 2025
/s/ Deborah Leone		Director		February 28, 2025
/s/ Philip Ozuah		Director		February 28, 2025
/s/ Cynthia Patton		Director		February 28, 2025
/s/ Grace Puma		Director		February 28, 2025
/s/ Shalini Sharp		Director		February 28, 2025