

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

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**Form 10-Q**

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(Mark One)

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

For the quarterly period ended June 30, 2022

**OR**

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

**Commission File No. 001-40235**

**Organon & Co.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of incorporation)

**46-4838035**  
(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**

**Not Applicable**

(Former name, former address and former fiscal year, if changed since last report.)

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

Title of each class  
Common Stock (\$0.01 par value)

Trading Symbol(s)  
OGN

Name of each exchange on which registered  
New York Stock Exchange

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☒

Smaller reporting company ☐

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The number of shares of common stock outstanding as of the close of business on August 1, 2022: 254,329,853

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**PART I - FINANCIAL INFORMATION**
**Item 1. Financial Statements**

<b>Organon &amp; Co.</b> <b>Condensed Consolidated Statements of Income</b> (Unaudited, \$ in millions except shares in thousands and per share amounts)				
	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenues	\$ 1,585	\$ 1,595	\$ 3,152	\$ 3,101
Costs, Expenses and Other				
Cost of sales	588	583	1,149	1,174
Selling, general and administrative	423	416	794	798
Research and development	106	76	202	143
Acquired in-process research and development and milestones	97	—	97	—
Restructuring costs	—	1	—	2
Interest expense	98	62	195	62
Other (income) expense, net	(14)	20	(14)	18
	1,298	1,158	2,423	2,197
Income From Continuing Operations Before Income Taxes	287	437	729	904
Taxes on Income	53	6	147	78
Net Income From Continuing Operations	234	431	582	826
Loss From Discontinued Operations - Net of Tax	—	(4)	—	—
Net Income	\$ 234	\$ 427	\$ 582	\$ 826
Earnings (Loss) per Share Attributable to Organon & Co. Stockholders - Basic:				
Continuing operations	\$ 0.92	\$ 1.70	\$ 2.29	\$ 3.26
Discontinued operations	—	(0.02)	—	—
Net Earnings per Share Attributable to Organon & Co. Stockholders	\$ 0.92	\$ 1.68	\$ 2.29	\$ 3.26
Earnings (Loss) per Share Attributable to Organon & Co. Stockholders - Diluted:				
Continuing operations	\$ 0.92	\$ 1.70	\$ 2.28	\$ 3.25
Discontinued operations	—	(0.02)	—	—
Net Earnings per Share Attributable to Organon & Co. Stockholders	\$ 0.92	\$ 1.68	\$ 2.28	\$ 3.25
Weighted Average Shares Outstanding:				
Basic	254,018	253,516	253,802	253,516
Diluted	255,156	253,828	255,105	253,828

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

**Organon & Co.**  
**Condensed Consolidated Statements of Comprehensive Income**  
(Unaudited, \$ in millions)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net Income	\$ 234	\$ 427	\$ 582	\$ 826
Other Comprehensive (Loss) Income, Net of Taxes:				
Benefit plan net income (loss) and prior service credit, net of amortization	1	(6)	—	(8)
Cumulative translation adjustment	(61)	218	(76)	152
	(60)	212	(76)	144
Comprehensive Income	\$ 174	\$ 639	\$ 506	\$ 970

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

**Organon & Co.**  
**Condensed Consolidated Balance Sheets**  
(Unaudited, \$ in millions except shares in thousands)

	June 30, 2022	December 31, 2021
<b>Assets</b>		
Current Assets		
Cash and cash equivalents	\$ 545	\$ 737
Accounts receivable (net of allowance for doubtful accounts of \$9 in 2022 and \$7 in 2021)	1,490	1,382
Inventories (excludes inventories of \$50 in 2022 and \$76 in 2021 classified in Other Assets)	950	915
Other current assets	789	726
Total current assets	3,774	3,760
Property, plant and equipment, net	952	973
Goodwill	4,603	4,603
Other intangibles, net	638	651
Other assets	647	694
	\$ 10,614	\$ 10,681
<b>Liabilities and Equity</b>		
Current Liabilities		
Current portion of long-term debt	\$ 9	\$ 9
Trade accounts payable	1,130	1,382
Accrued and other current liabilities	1,046	1,021
Income taxes payable	211	185
Total current liabilities	2,396	2,597
Long-term debt	8,884	9,125
Deferred income taxes	23	4
Other noncurrent liabilities	448	463
Commitments and Contingencies		
Organon & Co. Equity		
Common stock, \$0.01 par value		
Authorized - 500,000		
Issued and outstanding - 254,321 in 2022	3	3
Accumulated deficit	(551)	(998)
Accumulated other comprehensive loss	(589)	(513)
Total Deficit	(1,137)	(1,508)
	\$ 10,614	\$ 10,681

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

**Organon & Co.**  
**Condensed Consolidated Statements of Equity**  
(Unaudited, \$ in millions, except shares in thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Net Investment from Merck & Co., Inc.	Accumulated Other Comprehensive (Loss) Income	Total
	Shares	Par Value					
Balance at April 1, 2021	—	\$ —	\$ —	\$ —	\$ 5,411	\$ (689)	\$ 4,722
Net income attributable to Organon & Co.	—	—	—	96	331	—	427
Other comprehensive income, net of taxes	—	—	—	—	—	212	212
Stock-based compensation	—	—	—	8	—	—	8
Net transfers from Merck & Co., Inc., including Separation Adjustments	—	—	—	—	1,684	13	1,697
Net consideration paid to Merck & Co., Inc. in connection with Separation	—	—	—	—	(9,000)	—	(9,000)
Issuance of common stock in connection with the Separation and reclassification of Net Investment from Merck & Co., Inc.	253,516	3	—	(1,577)	1,574	—	—
Balance at June 30, 2021	253,516	\$ 3	\$ —	\$ (1,473)	\$ —	\$ (464)	\$ (1,934)
Balance at April 1, 2022	253,637	\$ 3	\$ —	\$ (724)	\$ —	\$ (529)	\$ (1,250)
Net income attributable to Organon & Co.	—	—	—	234	—	—	234
Other comprehensive loss, net of taxes	—	—	—	—	—	(60)	(60)
Cash dividends declared on common stock (\$0.28 per share)	—	—	—	(73)	—	—	(73)
Stock-based compensation plans and other	684	—	—	11	—	—	11
Net transfers from Merck & Co., Inc., including Separation Adjustments	—	—	—	1	—	—	1
Balance at June 30, 2022	254,321	\$ 3	\$ —	\$ (551)	\$ —	\$ (589)	\$ (1,137)

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

**Organon & Co.**  
**Condensed Consolidated Statements of Equity (continued)**  
(Unaudited, \$ in millions, except shares)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Net Investment from Merck & Co., Inc.	Accumulated Other Comprehensive (Loss) Income	Total
	Shares	Par Value					
Balance at January 1, 2021	—	\$ —	\$ —	\$ —	\$ 6,108	\$ (622)	\$ 5,486
Net income attributable to Organon & Co.	—	—	—	96	730	—	826
Other comprehensive income, net of taxes	—	—	—	—	—	144	144
Stock-based compensation	—	—	—	8	—	—	8
Net transfers from Merck & Co., Inc., including Separation Adjustments	—	—	—	—	588	14	602
Net consideration paid to Merck & Co., Inc. in connection with Separation	—	—	—	—	(9,000)	—	(9,000)
Issuance of common stock in connection with the Separation and reclassification of Net investment from Merck & Co., Inc.	253,516	3	—	(1,577)	1,574	—	—
Balance at June 30, 2021	253,516	\$ 3	\$ —	\$ (1,473)	\$ —	\$ (464)	\$ (1,934)
Balance at January 1, 2022	253,550	\$ 3	\$ —	\$ (998)	\$ —	\$ (513)	\$ (1,508)
Net income attributable to Organon	—	—	—	582	—	—	582
Other comprehensive loss, net of taxes	—	—	—	—	—	(76)	(76)
Cash dividends declared on common stock	—	—	—	(144)	—	—	(144)
Stock-based compensation plans and other	771	—	—	26	—	—	26
Net transfers from Merck & Co., Inc., including Separation Adjustments	—	—	—	(17)	—	—	(17)
Balance at June 30, 2022	254,321	\$ 3	\$ —	\$ (551)	\$ —	\$ (589)	\$ (1,137)

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

**Organon & Co.**  
**Condensed Consolidated Statements of Cash Flows**  
(Unaudited, \$ in millions)

	Six Months Ended June 30,	
	2022	2021
<b>Cash Flows from Operating Activities</b>		
Net income from continuing operations	\$ 582	\$ 826
Adjustments to reconcile net income from continuing operations to net cash flows provided by operating activities:		
Depreciation	47	39
Amortization	56	42
Impairment of assets	9	—
Acquired in-process research and development and milestones	97	—
Deferred income taxes	(9)	(171)
Stock-based compensation	34	29
Unrealized foreign exchange (gain) loss	(25)	38
Other	15	3
Net changes in assets and liabilities		
Accounts receivable	(125)	(372)
Inventories	(81)	2
Other current assets	(76)	284
Trade accounts payable	(237)	1,074
Accrued and other current liabilities	(53)	210
Due from/due to related party	—	(164)
Income taxes payable	32	(121)
Other	8	26
Net Cash Flows Provided by Operating Activities from Continuing Operations	274	1,745
<b>Cash Flows from Investing Activities</b>		
Capital expenditures	(78)	(97)
Proceeds from sale of property, plant and equipment	1	2
Purchase of product rights and asset acquisition, net of cash acquired	(69)	(192)
Net Cash Flows Used in Investing Activities from Continuing Operations	(146)	(287)
<b>Cash Flows from Financing Activities</b>		
Proceeds from issuance of long-term debt	—	9,470
Repayments of debt	(106)	—
Payment of long-term debt issuance costs	—	(118)
Repayments of short-term borrowings from Merck & Co., Inc., net	—	(1,512)
Net consideration paid to Merck & Co. Inc. in connection with the Separation	—	(9,000)
Net transfers to Merck & Co., Inc.	(17)	388
Employee withholding taxes related to share-based awards	(8)	—
Dividend payments	(143)	—
Net Cash Flows Used in Financing Activities from Continuing Operations	(274)	(772)
<b>Discontinued Operations</b>		
Net Cash Provided by Operating Activities	—	298
Net Cash Used in Investing Activities	—	—
Net Cash Used in Financing Activities	—	(356)
Net Cash Flows Used in Discontinued Operations	—	(58)
Effect of Exchange Rate Changes on Cash and Cash Equivalents from Continuing Operations	(46)	32
Effect of Exchange Rate Changes on Cash and Cash Equivalents from Discontinued Operations	—	—
Net (Decrease) Increase in Cash and Cash Equivalents	(192)	660
Cash and Cash Equivalents, Beginning of Period	737	12
Cash and Cash Equivalents of Discontinued Operations, Beginning of Period	—	58
Total Cash and Cash Equivalents, End of Period	545	730
Less: Cash and Cash Equivalents of Discontinued Operations, End of Period	—	—
Cash and Cash Equivalents, End of Period	\$ 545	\$ 730

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



## 1. Background and Nature of Operations

Organon & Co. ("Organon" or the "Company") is a global health care company formed through a spinoff from Merck & Co., Inc. ("Merck") to focus on improving the health of women throughout their lives. Organon develops and delivers innovative health solutions through a portfolio of prescription therapies within women's health, biosimilars and established brands (the "Organon Products"). Organon has a portfolio of more than 60 medicines and products across a range of therapeutic areas. The Company sells these products through various channels including drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. The Company operates six manufacturing facilities, which are located in Belgium, Brazil, Indonesia, Mexico, the Netherlands and the United Kingdom ("UK"). 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: the Company has a portfolio of contraception and fertility brands, such as *Nexplanon*® (etonogestrel implant) (sold as *Implanon NXT*™ in some countries outside the US), a long-acting reversible contraceptive, which is a class of contraceptives that are recognized as the most effective type of hormonal contraception available to patients with a lower long-term average cost.
- Biosimilars: the Company's current portfolio spans across immunology and oncology treatments. All five of the biosimilars in Organon's portfolio have launched in certain countries globally, including two biosimilars in the United States.
- Established Brands: the Company has a portfolio of established brands, which generally are beyond market exclusivity, including leading brands in cardiovascular, respiratory, dermatology and non-opioid pain management.

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

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

The Separation was completed pursuant to the Separation and Distribution Agreement and other agreements with Merck related to the Separation, including, but not limited to a tax matters agreement (the "Tax Matters Agreement" or "TMA"), an employee matters agreement (the "Employee Matters Agreement" or "EMA") and a transition services agreement (the "Transition Service Agreement" or "TSA"). Following the Separation, certain functions continue to be provided by Merck under the TSA or are being performed using the Company's own resources or third-party service providers. Under the TSA, Merck is providing Organon various services and, similarly, Organon is providing Merck various services. The provision of services under the TSA generally will terminate within 25 months following the spin-off; however, the provision of certain services has been extended to 31 months. Additionally, under manufacturing and supply agreements, the Company manufactures certain products for Merck, or its applicable affiliate and Merck manufactures certain products for the Company or its applicable affiliate (see Note 14 for additional details). The Company incurred certain costs in its establishment as a standalone public company and expects to incur ongoing additional costs associated with operating as an independent, publicly-traded company.

## 2. Basis of Presentation

The unaudited financial statements for all periods presented, including the historical results of the Company prior to June 2, 2021, are referred to as "Condensed Consolidated Financial Statements," and have been prepared pursuant to the rules and regulations for reporting on Form 10-Q. Accordingly, certain information and disclosures required by U.S. generally accepted accounting principles ("GAAP") for complete consolidated financial statements are not included herein. The results of operations of any interim period are not necessarily indicative of the results of operations for the full year. In the Company's opinion, all adjustments necessary for a fair statement of these interim statements have been included and are of a normal and recurring nature. All intercompany transactions and accounts within Organon have been eliminated. These interim statements should be read in conjunction with the audited financial statements and notes thereto included in Organon's Annual Report on Form 10-K for the year ended December 31, 2021.

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

Prior to the Separation on June 2, 2021, the Company's historical Consolidated Financial Statements were prepared on a standalone basis and were derived from Merck's consolidated financial statements and accounting records. The assets, liabilities, revenue and expenses of the Company were reflected in the Condensed Consolidated Financial Statements on a historical cost basis, as included in the consolidated financial statements of Merck, using the historical accounting policies applied by Merck, following a legal entity approach. For such periods prior to the Separation, certain corporate and shared costs were allocated to the Company based on a specific identification basis or, when specific identification was not practicable, a proportional cost allocation method. Refer to Note 2 of the audited Consolidated Financial Statements in the Company's 2021 Form 10-K for additional details on Organon's basis of presentation during periods prior to the Separation, at Separation and post Separation.

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

For periods prior to the Separation, income tax expense in the Condensed Consolidated Statement of Income was calculated on a separate tax return basis and the Company's operations were included in the tax returns of certain legal entities established to operate the Organon Products business (the "Organon Entities"), Transferred Entities, or the respective Merck entities of which the Company's business was a part. As of June 2, 2021, and in connection with the Separation, the Company adjusted its deferred tax balances and computed its related tax provision to reflect operations as a standalone entity. As a standalone entity, the Company files tax returns on its own behalf, and tax balances and effective income tax rates may differ from the amounts reported in the historical periods.

Certain assets and liabilities, including accounts receivables, inventories and trade payables included on the Condensed Consolidated Balance Sheet prior to the Separation, were retained by Merck post-Separation and therefore were recorded through Net investment from Merck & Co., Inc. in the Company's Condensed Consolidated Financial Statements. As part of the Separation, Net investment from Merck & Co., Inc. was reclassified to Common Stock and Accumulated Deficit.

*Use of Estimates*

The presentation of these Condensed Consolidated Financial Statements and accompanying notes in conformity with U.S. GAAP require management to make estimates and assumptions that affect the amounts reported, as further described in our Form 10-K for the year ended December 31, 2021. Accordingly, actual results could differ materially from management's estimates and assumptions.

Due to the significant uncertainty that exists relative to the duration and overall impact of the COVID-19 pandemic, our future operating performance, particularly in the short-term, may be subject to volatility. The assessment of certain accounting matters and specifically its effect on the Company's results require consideration of forecasted financial information in the context of the information reasonably available to the Company and the unknown future impacts of the COVID-19 pandemic as of June 30, 2022 and through the date of this report.

*Recently Adopted Accounting Standards*

There were no recently issued accounting standards adopted by the Company during the three and six months ended June 30, 2022. Refer to Note 3 of the audited Consolidated Financial Statements in Organon's Form 10-K for the year ended December 31, 2021 for standards adopted in 2021.

*Recently Issued Accounting Standards Not Yet Adopted*

In March 2022, the Financial Accounting Standards Board ("FASB") issued an amendment to the accounting for credit losses on financial instruments. This amendment eliminates the recognition and measurement guidance on troubled debt restructurings for creditors that have adopted the new credit losses guidance in Accounting Standards Codification 326 ("ASC 326") and requires enhanced disclosures about loan modifications for borrowers experiencing financial difficulty. The new guidance also requires public business entities to present gross write-offs by year of origination in their vintage disclosures. The guidance is effective for the Company on January 1, 2023, including interim periods. Early adoption is permitted, and the amendment applied prospectively, except for the recognition and remeasurement of troubled debt restructurings. Entities can elect to adopt the guidance on troubled debt restructurings using either a prospective or modified retrospective transition. If an entity elects to apply a modified retrospective transition, it will record a cumulative effect adjustment to retained earnings in the period of adoption. The Company does not expect the adoption of this guidance to have a material impact on the Consolidated Financial Statements.

# Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

In November 2021, the FASB issued new guidance requiring disclosures about transactions with a government that have been accounted for by analogizing to a grant or contribution accounting model. The guidance increases transparency about the types of transactions, the accounting for the transactions, and the effect of the transactions to the Company's financial statements. The guidance is effective for annual periods in 2022 and can be applied on a prospective or retrospective basis. The Company is currently evaluating the impact of adoption on its Consolidated Financial Statements. The Company does not anticipate a material impact to its Consolidated Financial Statements.

In October 2021, the FASB issued guidance to improve the accounting for contract assets and contract liabilities from acquired revenue contracts with customers in a business combination. The guidance addresses diversity in practice and inconsistency related to the recognition of an acquired contract liability, payment terms and their effect on subsequent revenue recognized by an acquirer. The guidance is effective for the Company on January 1, 2023 and its amendments will be applied prospectively to business combinations occurring on or after the effective date of the guidance. Early adoption is permitted, including adoption in an interim period and subject to different transition requirements. The adoption of this guidance will not have an impact on the Company's Consolidated Financial Statements for prior acquisitions; however, the impact in future periods will be dependent upon the contract assets and contract liabilities acquired in future business combinations.

In March 2020, the FASB issued optional guidance to ease the potential burden in accounting for (or recognizing the effects of) reference rate reform on financial reporting and subsequently issued clarifying amendments. The guidance provides optional expedients and exceptions for applying GAAP to contracts, hedging relationships, and other transactions that reference the London Interbank Offered Rate ("LIBOR") or another reference rate expected to be discontinued because of reference rate reform. The optional guidance is effective upon issuance and can be applied on a prospective basis at any time between January 1, 2020 and December 31, 2022. The Company is currently evaluating the impact of adoption on its Consolidated Financial Statements. The Company does not anticipate a material impact to its Consolidated Financial Statements.

## 3. 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 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 June 30, 2022, potential future regulatory milestone payments of \$25 million remain under the agreement.

Summarized information related to this collaboration is as follows:

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Sales	\$ 118	\$ 85	\$ 217	\$ 166
Cost of sales	70	47	135	100
Selling, general and administrative	24	17	42	32

  

(\$ in millions)	June 30, 2022	December 31, 2021
Receivables from Samsung included in <i>Other current assets</i>	\$ 9	\$ 15
Payables to Samsung included in <i>Trade accounts payable</i>	29	21

#### 4. Acquisitions and Licensing Arrangements

##### Shanghai Henlius Biotech, Inc. ("Henlius")

In June 2022, Organon and Henlius, a global biopharmaceutical company, entered into a definitive agreement whereby Organon will license commercialization rights for biosimilar candidates referencing Perjeta® (pertuzumab, HLX11), (a trademark of Genentech, Inc.), used for the treatment of certain patients with HER2+ breast cancer in combinations with trastuzumab and chemotherapy and Prolia®/Xgeva® (denosumab, HLX14), (trademarks of Amgen Inc.) used for the treatment of certain patients with osteoporosis with high risk of fracture and for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastasis from solid tumors. Organon will acquire exclusive global commercialization rights except for China; including Hong Kong, Macau and Taiwan. The agreement includes an option to negotiate an exclusive license for global commercialization rights for a biosimilar candidate referencing Yervoy® (ipilimumab, HLX13) (a trademark of Bristol-Myers Squibb Company). Ipilimumab is used for the treatment of certain patients with unresectable or metastatic melanoma, as adjuvant treatment of certain patients with cutaneous melanoma, certain patients with Renal Cell Carcinoma, Colorectal Cancer, Hepatocellular Carcinoma, Non-Small Cell Lung Cancer, Malignant Pleural Mesothelioma and Esophageal Cancer.

Under the terms of the license agreement, Organon paid a \$73 million upfront payment during the third quarter of 2022, of which \$3 million was reflected in *Other current assets*. Henlius is eligible to receive potential developmental, regulatory and commercial milestone payments of up to \$468 million. As of June 30, 2022, the Company determined that certain developmental milestones were probable of occurrence and recognized \$97 million reflecting the \$70 million upfront payment and \$27 million related to development milestones as *Acquired in-process research and development and milestones*. The remaining potential milestone payments will be recognized by Organon when achievement of the contractual milestones is probable. Henlius will be responsible for development and, if approved, will supply the products to Organon.

##### Daré Bioscience, Inc. ("Daré")

In March 2022, Organon and Daré, a leader in women's health innovation, entered into an agreement whereby Organon licensed the global commercial rights to *Xaciato*® (clindamycin phosphate vaginal gel, 2%). *Xaciato* is an FDA-approved medication for the treatment of bacterial vaginosis (BV) in females 12 years of age and older. *Xaciato* received both Qualified Infectious Disease Product (QIDP) and Fast Track designations from the FDA for the treatment of bacterial vaginosis.

Under the terms of the license agreement, Organon paid a \$10 million upfront payment during the third quarter of 2022. Daré is eligible to receive potential regulatory and commercial milestone payments of up to \$182.5 million and tiered double-digit royalties based on net sales. *Xaciato* is expected to be available commercially in the U.S. in the fourth quarter of 2022. As of June 30, 2022 management determined that the first commercial milestone was deemed probable of occurring, and recognized an intangible asset of \$12.5 million reflecting the \$10 million upfront payment and \$2.5 million commercial milestone. The intangible asset will be amortized over its useful life of 12 years. The remaining potential milestone payments will be recognized by Organon when achievement of the contractual milestones is probable.

##### Bayer AG

In February 2022, Organon acquired the product rights and related inventory from Bayer AG to *Marvelon*™ (ethinylestradiol, desogestrel) and *Mercilon*™ (ethinylestradiol, desogestrel), combined oral hormonal daily contraceptive pills, in the People's Republic of China, including Hong Kong and Macau, and has entered into an agreement to acquire the rights to these products in Vietnam. *Marvelon* and *Mercilon* are already owned, manufactured, and marketed by Organon as prescription oral contraceptives in 20 other markets. The transaction was accounted for as an asset acquisition. In the first quarter of 2022, Organon paid \$30 million to acquire the product rights and inventory in China and accrued an additional \$35 million related to these rights which was paid during the second quarter of 2022. This resulted in Organon recognizing an intangible asset of \$42 million related to the product rights with the remainder of the consideration recorded to *Inventories* for the fair value of acquired inventory during the first quarter of 2022. The intangible assets related to currently marketed products will be amortized over their estimated useful lives of 10 years.

The transaction to acquire the rights to these products in Vietnam closed in the third quarter of 2022.

For details regarding Organon's 2021 acquisitions and licensing agreements, See Note 5 to the audited Consolidated Financial Statements in the Company's 2021 Form 10-K.

#### 5. Financial Instruments

##### Foreign Currency Risk Management

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

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

The Company uses a balance sheet risk management program to 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 offset the effects of exchange on exposures denominated in developed country currencies, primarily the euro, Swiss franc and Japanese yen. For exposures in developing country currencies, the Company enters into forward contracts to partially offset the effects of exchange on exposures when it is deemed economical to do so based on a cost-benefit analysis that considers the magnitude of the exposure, the volatility of the exchange rate and the cost of the hedging instrument.

Monetary assets and liabilities denominated in a currency other than the functional currency of a given subsidiary are remeasured at spot rates in effect on the balance sheet date with the effects of changes in spot rates reported in *Other (income) expense, net*. The forward contracts are not designated as hedges and are marked to market through *Other (income) expense, net*. 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. As of June 30, 2022 and December 31, 2021, the fair value of these contracts was recorded as an asset of \$28 million and \$19 million, respectively, in *Other current assets* and a liability of \$7 million and \$5 million, respectively, in *Accrued and other current liabilities*. The notional amount of forward contracts was \$1.4 billion as of June 30, 2022 and \$2.1 billion as of December 31, 2021. The cash flows from these contracts are reported as operating activities in the Condensed Consolidated Statements of Cash Flows.

Foreign exchange risk is also managed through the use of economic hedges on foreign currency debt (see Note 7). In each quarter subsequent to the Separation, €1.75 billion in the aggregate of both the euro-denominated term loan (€750 million) and of the 2.875% euro-denominated secured notes (€1.25 billion) has been designated and is effective as an economic hedge of the net investment in euro-denominated subsidiaries. As a result, \$90 million, \$127 million, \$56 million and \$56 million of foreign currency gains due to spot rate fluctuations on the euro-denominated debt instruments are included in foreign currency translation adjustments in *Other Comprehensive Income* for the three and six months ended June 30, 2022 and 2021, respectively.

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

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Allocated net (gains) loss in <i>Revenues</i>	\$ —	\$ 23	\$ —	\$ 55
Foreign exchange (gains) loss in <i>Other (income) expense, net</i>	(21)	9	(25)	5

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

Organon has established accounts receivable factoring agreements with financial institutions in certain countries to sell accounts receivable. Under these agreements, Organon factored \$78 million and \$87 million of accounts receivable during the three months ended June 30, 2022 and December 31, 2021, respectively, which reduced outstanding accounts receivable. The cash received from the financial institutions is reported within operating activities in the Condensed Consolidated Statements of Cash Flows.

## Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

### 6. Inventories

Inventories consisted of:

(\$ in millions)	June 30, 2022	December 31, 2021
Finished goods	\$ 377	\$ 377
Raw materials	75	95
Work in process	527	490
Supplies	39	40
Total (approximates current cost)	\$ 1,018	\$ 1,002
Decrease to LIFO costs	(18)	(11)
	\$ 1,000	\$ 991
Recognized as:		
Inventories	\$ 950	\$ 915
Other assets	50	76

Inventories valued under the last in, first out ("LIFO") method comprised \$83 million and \$52 million as of June 30, 2022 and December 31, 2021, respectively. Amounts recognized as *Other assets* are comprised primarily of raw materials and work in process inventories and are not expected to be converted to finished goods that will be sold within one year. The Company has a long-term vendor supply contract conveyed as part of the Separation that includes certain annual minimum purchase commitments.

### 7. Long-Term Debt

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

(\$ in millions)	June 30, 2022	December 31, 2021
Term Loan B Facility:		
LIBOR plus 300 bps term loan due 2028	\$ 2,793	\$ 2,893
LIBOR plus 300 bps euro-denominated term loan due 2028 (€750 million)	783	843
4.125% secured notes due 2028	2,100	2,100
2.875% euro-denominated secured notes due 2028 (€1.25 billion)	1,321	1,412
5.125% notes due 2031	2,000	2,000
Other borrowings	9	10
Other (discounts and debt issuance costs)	(113)	(124)
Total principal long-term debt	\$ 8,893	\$ 9,134
Less: Current portion of long-term debt	9	9
Total Long-term debt, net of current portion	\$ 8,884	\$ 9,125

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

In June 2021, the Company entered into a credit agreement (the "Senior Credit Agreement") providing for a Term Loan B Facility, consisting of (i) a U.S. Dollar-denominated senior secured "tranche B" term loan in the amount of \$3.0 billion due 2028 (ii) a euro-denominated senior secured "tranche B" term loan in the amount of €750 million due 2028; and a Revolving Credit Facility ("Revolving Credit Facility"), in an aggregate principal amount of up to \$1 billion, with a five-year term that matures in 2026.

The interest rate on revolving loans under the Revolving Credit Facility is subject to a step-down based on meeting a leverage ratio target. A commitment fee applies to the unused portion of the Revolving Credit Facility, initially equal to 0.50% and subject to a step-down to 0.375% based on meeting a leverage ratio target. There were no outstanding balances under the Revolving Credit Facility as of June 30, 2022 or December 31, 2021.

The estimated fair value of long-term debt (including current portion) as of June 30, 2022 was \$8.1 billion compared with a carrying value (which includes a reduction for amortized debt issuance costs) of \$8.9 billion and, at December 31, 2021, was \$9.4 billion compared with a carrying value of \$9.1 billion. Fair value was estimated using inputs other than quoted prices

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

in active markets for identical assets and liabilities that are observable either directly or indirectly for substantially the full term of the asset or liability and would be considered Level 2 in the fair value hierarchy.

The Company made interest payments of \$179 million for the six months ended June 30, 2022 related to its debt instruments. The average maturity of the Company's long-term debt as of June 30, 2022 is approximately 6.5 years and the weighted-average interest rate on total borrowings as of June 30, 2022 is 4.0%.

On June 6, 2022, the Company made a discretionary prepayment of \$100 million on the U.S. Dollar-denominated term loan. The schedule of principal payments required on long-term debt for the next five years and thereafter is as follows:

*(\$ in millions)*

2022	\$	2
2023		9
2024		9
2025		9
2026		12
Thereafter		8,965

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 June 30, 2022, the Company is in compliance with all financial covenants and no default or event of default has occurred.

## 8. 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. In the opinion of Organon as of June 30, 2022, it is unlikely that the resolution of these matters will be material to Organon's financial condition, results of operations or cash flows.

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

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

Organon's decision to obtain insurance coverage is dependent on market conditions, including cost and availability, existing at the time such decisions are made. Organon has evaluated its risks and has determined that the cost of obtaining product liability insurance outweighs the likely benefits of the coverage that is available and, as such, has no insurance for most product liabilities.

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

**Product Liability Litigation***Fosamax*

Merck is a defendant in product liability lawsuits in the United States involving *Fosamax*® (alendronate sodium) (the "Fosamax Litigation"). As of June 30, 2022, approximately 3,450 cases comprising the Fosamax Litigation are pending against Merck in either federal or state court. Plaintiffs in the vast majority of these cases generally allege that they sustained femur fractures and/or other bone injuries ("Femur Fractures") in association with the use of *Fosamax*.

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

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

Accordingly, as of June 30, 2022, approximately 975 cases were actively pending in the Femur Fracture MDL.

As of June 30, 2022, approximately 2,195 cases alleging Femur Fractures have been filed in New Jersey state court and are pending in Middlesex County. The parties selected an initial group of cases to be reviewed through fact discovery, and Merck has continued to select additional cases to be reviewed.

As of June 30, 2022, approximately 275 cases alleging Femur Fractures have been filed and are pending in California state court. All of the Femur Fracture cases filed in California state court have been coordinated before a single judge in Orange County, California.

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

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

*Nexplanon/Implanon*

Merck is a defendant in lawsuits brought by individuals relating to the use of *Nexplanon* and *Implanon*™ (etonogestrel implant). In the United States, as of June 30, 2022, there was one filed product liability action involving *Nexplanon* pending in the Western District of Arkansas (in which Organon is also named as a defendant). The court's schedule for the matter provides for a trial date in the fourth quarter of 2023, should it be necessary. In addition, there were two filed product liability actions involving *Implanon*, both of which are pending in the Northern District of Ohio as well as 56 unfiled cases involving *Implanon* alleging similar injuries, which have been tolled under a written tolling agreement. As of June 30, 2022, Merck had 18 cases pending outside the United States, of which 14 relate to *Implanon* and four relate to *Nexplanon*.



Notes to Condensed Consolidated Financial Statements (unaudited) (continued)*Propecia/Proscar*

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

As of June 30, 2022, only three cases remain pending in the United States, (1) a case currently pending in the MDL; (2) a matter involving *Propecia* in state court in Los Angeles, California in which Merck's motion for summary judgment was granted and subsequently appealed; and (3) a matter involving *Proscar* in the United States District Court for the Eastern District of California in which Merck's motion to dismiss was granted by the District Court. In this case, the plaintiff can appeal the decision. The Company is also defending 17 product liability cases outside the United States, two of which are class actions and four of which are putative class actions.

**Governmental Proceedings**

From time to time, Organon's subsidiaries may receive inquiries and may be the subject of preliminary investigation activities from competition and/or other governmental authorities, including in markets outside the United States. These authorities may include regulators, administrative authorities, and law enforcement and other similar officials, and these preliminary investigation activities may include site visits, formal or informal requests or demands for documents or materials, inquiries or interviews and similar matters. Certain of these preliminary inquiries or activities may lead to the commencement of formal proceedings. Should those proceedings be determined adversely to Organon, monetary fines and/or remedial undertakings may be required. Subject to certain exceptions specified in the Separation and Distribution Agreement, Organon assumed liability for all pending and threatened legal matters related to products transferred to Organon, including competition investigations resulting from enforcement activity concerning Merck's conduct involving Organon's products. Organon could be obligated to indemnify Merck for fines or penalties, or a portion thereof, resulting from such investigations. Organon is aware of one such enforcement activity pending in Europe.

*Hadlima*™ (adalimumab-bwvd)

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

**Patent Litigation**

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

*Nexplanon*

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

## Other Litigation

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 June 30, 2022, either the likelihood of loss is remote or any reasonably possible loss associated with the resolution of such proceedings is not expected to be material to Organon's financial condition, results of operations or cash flows either individually or in the aggregate.

## Legal Defense Reserves

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by Organon; the development of Organon's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against Organon; and the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The legal defense reserve as of June 30, 2022 and December 31, 2021 was \$13 million and \$9 million, respectively, and represented Organon's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by Organon. Organon will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

## 9. Stock-Based Compensation Plans

The Company grants stock option awards, performance share units ("PSUs") and restricted share units ("RSUs") pursuant to its 2021 Incentive Stock Plan. Employee stock options are granted to purchase shares of Company stock at the fair market value at the time of grant. Generally, stock options have a contractual term of ten years and vest one-third each year over a three-year period, subject to limited exceptions. RSUs are stock awards that are granted to employees and entitle the holder to shares of common stock as the awards vest. RSU awards generally vest one-third each year over a three-year period. The fair value of the stock option and RSU awards is determined and fixed on the grant date based on the Company's stock price. The terms of the Company's PSU awards allow the recipients of such awards to earn a variable number of shares based on total stockholder return of the Company relative to an index of peer companies ("relative TSR") specified in the awards. For PSUs with a market-based relative TSR goal, stock-based compensation expense is recognized based on the estimated fair value of the award at the grant date regardless of the actual number of shares earned. PSU awards generally vest after three years. For RSUs and PSUs, dividends declared during the vesting period are payable to the employees only upon vesting. RSU and PSU distributions will be in shares of Company stock after the end of the vesting or performance period, subject to the terms applicable to such awards.

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

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Stock-based compensation expense recognized in:				
Cost of sales	\$ 3	\$ 3	\$ 6	\$ 5
Selling, general and administrative	13	11	23	16
Research and development	3	4	5	8
Income tax benefits	4	4	7	6

# Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

The Company used the Black-Scholes model to determine the fair value of the stock options as of the grant date using the following assumptions:

	Six Months Ended June 30, 2022
Expected dividend yield	3.12 %
Risk-free interest rate	2.47 %
Expected volatility	43.43 %
Expected life (years)	5.89

A summary of the equity award transactions for the six months ended June 30, 2022 are as follows:

	Stock Options			Restricted Share Units		Performance Share Units	
	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
<i>(shares in thousands)</i>							
<b>Outstanding as of January 1, 2022</b>	4,394	\$ 34.35	\$ 8.63	3,280	\$ 36.69	120	\$ 51.63
Granted	556	\$ 34.93	\$ 11.34	2,273	\$ 34.91	—	\$ —
Vested/Exercised	(15)	\$ 37.39	\$ 9.72	(1,196)	\$ 37.49	—	\$ —
Forfeited/Cancelled	—	\$ —	\$ —	(86)	\$ 35.82	—	\$ —
<b>Outstanding as of June 30, 2022</b>	4,935	\$ 34.40	\$ 8.93	4,271	\$ 35.54	120	\$ 51.63

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 June 30, 2022:

	Equity Awards Vested and Expected to Vest				Equity Awards That are Exercisable			
	Awards	Weighted Average Exercise Price	Aggregate Intrinsic Value	Remaining Term	Awards	Weighted Average Exercise Price	Aggregate Intrinsic Value	Remaining Term
<i>(shares in thousands; aggregate intrinsic value in millions)</i>								
Stock Options	4,693	\$ 34.40	\$ 6	7.78	2,429	\$ 32.98	\$ 6	6.49
Restricted Share Units	3,913		145	2.24				
Performance Share Units	211		8	2.13				

The amount of unrecognized compensation costs as of June 30, 2022 was \$157 million, which will be recognized in operating expense ratably over the weighted average vesting period of 2.21 years.

## 10. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
<i>(\$ in millions)</i>				
Exchange (gains) losses	\$ (21)	\$ 9	\$ (25)	\$ 5
Other, net	7	11	11	13
	\$ (14)	\$ 20	\$ (14)	\$ 18

# Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

## 11. Taxes on Income

The effective income tax rates were 18.5% and 1.4% for the three months ended June 30, 2022 and 2021, respectively, and 20.2% and 8.6% for the six months ended June 30, 2022 and 2021, respectively. These effective income tax rates reflect the beneficial impact of foreign earnings, offset by the impact of U.S. inclusions under the Global Intangible Low-Taxed Income regime. During the second quarter of 2021 the Company recorded a \$70 million tax benefit relating to a portion of the non- U.S. step-up of tax basis associated with the Company's Separation from Merck. The effective income tax rate for the six months ended June 30, 2021, also reflects the Internal Revenue Service ("IRS") conclusion of its examinations of Merck's 2015-2016 U.S. federal income tax returns. As a result, the Company reflected an allocation from Merck of \$18 million representing the Company's portion of the payment made to the IRS in the Condensed Consolidated Financial Statements. The Company's portion of reserves for unrecognized tax benefits for the years under examination exceeded the allocated adjustments relating to this examination period and therefore the Company included a \$29 million net tax benefit also included in the six months ended June 30, 2021. This net benefit reflects reductions in reserves for unrecognized tax benefits and other related liabilities for tax positions relating to the years that were under examination.

## 12. Other Comprehensive Income (Loss)

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

(\$ in millions)	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance at April 1, 2021, net of taxes	\$ (33)	\$ (656)	\$ (689)
Other comprehensive income, pretax	—	218	218
Tax	(6)	—	(6)
Other comprehensive (loss) income, net of taxes	(6)	218	212
Transfer of benefit plans from Merck affiliates	13	—	13
Balance at June 30, 2021, net of taxes	\$ (26)	\$ (438)	\$ (464)
Balance at April 1, 2022, net of taxes	\$ (14)	\$ (515)	\$ (529)
Other comprehensive loss, pretax	—	(61)	(61)
Tax	1	—	1
Other comprehensive income (loss), net of taxes	1	(61)	(60)
Balance at June 30, 2022, net of taxes	\$ (13)	\$ (576)	\$ (589)

  

(\$ in millions)	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance at January 1, 2021, net of taxes	\$ (32)	\$ (590)	\$ (622)
Other comprehensive income, pretax	2	152	154
Tax	(10)	—	(10)
Other comprehensive (loss) income, net of taxes	(8)	152	144
Transfer of benefit plans to/from Merck affiliates	14	—	14
Balance at June 30, 2021, net of taxes	\$ (26)	\$ (438)	\$ (464)
Balance at January 1, 2022, net of taxes	\$ (13)	\$ (500)	\$ (513)
Other comprehensive loss, pretax	(1)	(76)	(77)
Tax	1	—	1
Other comprehensive loss, net of taxes	—	(76)	(76)
Transfer of benefit plans to/from Merck affiliates	—	—	—
Balance at June 30, 2022, net of taxes	\$ (13)	\$ (576)	\$ (589)

# Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

## 13. Product and Geographic Information

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

Revenues of the Company's products were as follows:

(\$ in millions)	Three Months Ended June 30,						Six Months Ended June 30,					
	2022			2021			2022			2021		
	U.S.	Int'l	Total	U.S.	Int'l	Total	U.S.	Int'l	Total	U.S.	Int'l	Total
<b>Women's Health</b>												
<i>Nexplanon/Implanon NXT</i>	\$ 134	\$ 61	\$ 195	\$ 129	\$ 56	\$ 184	\$ 250	\$ 116	\$ 366	\$ 269	\$ 98	\$ 368
<i>Follistim AQ</i>	23	35	58	27	38	65	52	66	119	52	65	117
<i>NuvaRing</i>	22	20	42	26	28	53	38	45	83	47	52	98
Ganirelix Acetate Injection	6	25	32	5	25	31	14	47	61	14	46	60
<i>Cerazette</i>	—	15	15	—	18	18	—	32	32	—	34	34
Other Women's Health <sup>(1)</sup>	29	38	67	23	43	66	56	69	125	63	76	139
<b>Biosimilars</b>												
<i>Renflexis</i>	51	8	59	36	7	43	93	12	105	70	11	81
<i>Ontruzant</i>	12	23	35	7	15	22	19	38	57	11	34	45
<i>Brenzys</i>	—	14	14	—	11	11	—	28	28	—	21	21
<i>Aybintio</i>	—	9	9	—	8	8	—	19	19	—	16	16
<i>Hadlima</i>	—	2	2	—	2	2	—	8	8	—	4	4
<b>Established Brands</b>												
<b>Cardiovascular</b>												
<i>Zetia</i>	2	99	101	2	97	99	5	195	200	4	186	190
<i>Vytarin</i>	3	32	35	2	42	45	5	68	73	5	81	86
<i>Atozet</i>	—	122	122	—	121	121	—	240	240	—	233	233
<i>Rosuzet</i>	—	16	16	—	18	18	—	38	38	—	33	33
<i>Cozaar/Hyzaar</i>	2	91	92	2	84	86	10	176	186	6	171	177
Other Cardiovascular <sup>(1)</sup>	1	45	46	1	60	61	2	83	85	2	98	100
<b>Respiratory</b>												
<i>Singulair</i>	3	89	92	3	89	92	5	216	222	8	191	199
<i>Nasonex</i>	—	58	58	1	51	52	9	123	133	3	92	95
<i>Dulera</i>	36	12	47	42	10	52	67	21	88	73	18	91
<i>Clarinox</i>	1	34	35	2	29	30	2	70	73	3	52	55
Other Respiratory <sup>(1)</sup>	11	11	22	13	9	22	23	22	45	29	15	44
<b>Non-Opioid Pain, Bone and Dermatology</b>												
<i>Arcoxia</i>	—	61	61	—	62	62	—	121	121	—	119	119
<i>Fosamax</i>	1	39	40	1	48	49	2	79	81	2	85	86
<i>Diprosan</i>	—	31	31	—	32	32	—	63	63	—	57	57
Other Non-Opioid Pain, Bone and Dermatology <sup>(1)</sup>	5	71	76	4	72	75	8	137	145	3	133	136
<b>Other</b>												
<i>Proscar</i>	—	26	26	—	31	32	1	50	50	1	63	64
<i>Propecia</i>	2	33	35	2	34	36	3	63	66	4	63	67
Other <sup>(1)</sup>	7	74	82	13	68	81	15	149	164	24	146	169
Other <sup>(2)</sup>	—	40	40	(2)	49	47	1	78	76	(3)	119	117
<b>Revenues</b>	<b>\$ 351</b>	<b>\$ 1,234</b>	<b>\$ 1,585</b>	<b>\$ 339</b>	<b>\$ 1,257</b>	<b>\$ 1,595</b>	<b>\$ 680</b>	<b>\$ 2,472</b>	<b>\$ 3,152</b>	<b>\$ 690</b>	<b>\$ 2,412</b>	<b>\$ 3,101</b>

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.

<sup>(1)</sup> Includes sales of products not listed separately. Revenue from an arrangement for the sale of generic etonogestrel/ethinyl estradiol vaginal ring is included in Other Women's Health.

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

# Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

Revenues by geographic area where derived are as follows:

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Europe and Canada	\$ 443	\$ 470	\$ 880	\$ 904
United States	351	339	680	690
Asia Pacific and Japan	291	309	604	587
China	244	236	480	442
Latin America, Middle East, Russia and Africa	216	190	425	357
Other <sup>(1)</sup>	40	51	83	121
Revenues	\$ 1,585	\$ 1,595	\$ 3,152	\$ 3,101

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

## 14. Third Party Arrangements and Related Party Disclosures

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

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

Organon entered into other agreements with Merck that govern aspects of Organon's relationship with Merck following the Separation, including the Transition Services Agreement, Interim Operating Model Agreements ("IOM") agreements, Manufacturing and Supply Agreement, Tax Matters Agreement, Employee Matters Agreement as well as Intellectual Property License Agreements and Regulatory Agreements. For the three and six months ended June 30, 2022, material transactions occurred in connection with the IOM agreements. For details on the rights and responsibilities of the parties under the IOM agreements, refer below; for all other agreements refer to Note 19 to the audited Consolidated Financial Statements in the Company's 2021 Form 10-K.

- IOM agreements - Merck and Organon entered into a series of IOM agreements pursuant to which Merck and certain of its affiliates that held licenses, permits and other rights in connection with marketing, import and/or distribution of Organon products in various jurisdictions prior to the Separation, will continue to market, import and distribute such products until such time as the relevant licenses and permits are transferred to Organon or its affiliates, while permitting Organon (or Merck, as applicable) to recognize revenue relating to the sale of its respective products, to the extent practicable. Under such IOM agreements and in accordance with the Separation and Distribution Agreement, the relevant Merck entity will continue operations in the affected market on behalf of Organon, with Organon receiving all of the economic benefits and burdens of such activities. Organon began receiving these economic benefits as of June 2, 2021. Based on the terms of the IOM agreements, the Company determined it is the Principal under these arrangements. Organon holds all risks and rewards of ownership inclusive of risk of loss, market risk and benefits related to the inventory. Additionally, Organon has latitude in pricing, has the ability to direct Merck regarding decisions over inventory, and is responsible for all credit and collections risks and losses associated with the related receivables. As such, Organon recognizes these sales on a gross basis.

The amount due from Merck under such agreements was \$434 million and \$403 million as of June 30, 2022 and December 31, 2021, respectively, and is reflected in accounts receivable. The amount due to Merck under these agreements was \$702 million and \$928 million as of June 30, 2022 and December 31, 2021, respectively, and is included in accounts payable.

For the three months ended June 30, 2022, sales and cost of sales resulting from the manufacturing and supply agreements with Merck were \$33 million and \$31 million, respectively. For the six months ended June 30, 2022 sales and cost

# Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

of sales resulting from the manufacturing and supply agreements with Merck were \$66 million and \$60 million, respectively. For the period from June 2, 2021 to June 30, 2021, sales and cost of sales resulting from the manufacturing and supply agreements with Merck were \$14 million and \$13 million, respectively.

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

## Cost allocations from Merck

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

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Cost of sales	\$ —	\$ 13	\$ —	\$ 69
Selling, general and administrative	—	46	—	134
Research and development	—	10	—	35
	\$ —	\$ 69	\$ —	\$ 238

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

## Related party transactions

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

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
<i>Included in continuing operations</i>				
Supply sales to Merck affiliates	\$ —	\$ 58	\$ —	\$ 143
Purchases from Merck affiliates	—	28	—	65
Cost reimbursements and fees from Merck affiliates	—	—	—	1
<i>Included in discontinued operations</i>				
Supply sales to Merck affiliates	\$ —	\$ —	\$ —	\$ 12
Purchases from Merck affiliates	—	3	—	53

# Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

## Net transfers to Merck & Co., Inc.

Prior to the Separation, net transfers to Merck were included within *Net investment from Merck & Co., Inc.* on the Condensed Consolidated Statement of Equity and represent the net effect of transactions between the Company and Merck. The components of *Net transfers to Merck & Co., Inc.* for the six months ended June 30, 2021 were as follows:

(\$ in millions)	Six Months Ended June 30, 2021 <sup>(1)</sup>
Cash pooling and general financing activities	\$ 168
Cost allocations, excluding non-cash stock-based compensation	(209)
Taxes deemed settled with Merck	(259)
Allocated derivative and hedging (losses) gains	(88)
<i>Net transfers (from) to Merck &amp; Co., Inc.</i> as reflected in the Condensed Consolidated Statement of Cash Flows for Continuing Operations <sup>(2)</sup>	\$ (388)
Net transfers to (from) Merck included in Net Cash Provided by (Used in) Discontinued Operations	597
Total net transfers to Merck as included in the Condensed Consolidated Statement of Cash Flows	\$ 209
Stock-based compensation expense (includes \$3 of discontinued operations for the six months ended June 30, 2021)	(32)
Net assets contributed by Merck affiliates	(778)
Derecognition of amounts in <i>Accumulated other comprehensive loss</i> related to employee benefit plan transfers to Merck affiliates	13
<i>Net transfers (from) to Merck &amp; Co., Inc.</i> as reflected in the Condensed Consolidated Statement of Equity	\$ (588)

<sup>(1)</sup> Amounts represent activity through the date of the Separation.

The components of Net transfers to Merck & Co., Inc. for the three months ended June 30, 2021 were as follows:

(\$ in millions)	Three Months Ended June 30, 2021
Cash pooling and general financing activities	\$ (585)
Net assets distributed to (contributed by) Merck Affiliates	(838)
Cost allocations	(72)
Income taxes deemed settled with Merck	(136)
Allocated derivative and hedging gains (losses)	(53)
<i>Net transfers (from) to Merck &amp; Co., Inc.</i> as reflected in the Condensed Consolidated Statement of Equity	\$ (1,684)

Prior to the Separation, transfers between the Organon Entities, the Transferring Entities and Merck affiliates were recognized in Net transfers to Merck & Co., Inc. in the Condensed Consolidated Statement of Equity at Merck's historical cost. Additionally, in connection with the Separation, certain assets and liabilities included in the pre-Separation balance sheet were retained by Merck and certain assets and liabilities not included in the pre-Separation balance sheet were transferred to Organon. Adjustments for transfers are reflected in the Company's Condensed Consolidated Financial Statements for the three and six months ended June 30, 2021.

## 15. Discontinued Operations

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



# Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

The components of Income (loss) from discontinued operations, net of tax for the Merck Retained Products business are as follows:

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Sales	\$ —	\$ 4	\$ —	\$ 93
Costs, Expenses and Other				
Cost of Sales	—	13	—	65
Selling, general and administrative	—	1	—	15
Research and development	—	—	—	4
Other (income) expense, net	—	(6)	—	4
Income from discontinued operations before taxes	\$ —	\$ (4)	\$ —	\$ 5
Taxes on income	—	—	—	5
Income from discontinued operations, net of taxes	\$ —	\$ (4)	\$ —	\$ —

Discontinued operations includes related party sales of \$12 million for the six months ended June 30, 2021. Costs for inventory purchases from related parties was \$3 million and \$53 million for the three and six months ended June 30, 2021, respectively.

## 16. Earnings per Share

On June 2, 2021, the date of the Separation, 253,516,000 shares of the Common Stock were distributed to Merck stockholders of record as of the Record Date. This share amount is utilized for the calculation of basic and diluted earnings per share for all periods presented prior to the Separation. For the three and six months ended June 30, 2021, these shares are treated as issued and outstanding as of January 1, 2021 for purposes of calculating historical basic and diluted earnings per share.

Prior to the Separation, certain of the Company's employees participated in stock-based compensation plans sponsored by Merck. Under these plans employees were granted stock options, PSU's, and RSU's. On June 2, 2021, and in accordance with the Employee Matters Agreement, all Merck stock options, PSUs and RSUs were converted using the conversion ratios set forth in the Employee Matters Agreement. Merck stock options, PSUs and RSUs were converted into Organon stock option awards and RSUs. Awards were equitably adjusted to reflect the spin-off and to preserve the same intrinsic value and general terms and conditions (including vesting) as were in place immediately prior to the adjustments.

# Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

The calculation of basic and diluted earnings per common share for the three and six months ended June 30, 2022 and 2021 was as follows:

(\$ in millions and shares in thousands, except per share amounts)	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net income attributable to Organon:				
Income from continuing operations	\$ 234	\$ 431	\$ 582	\$ 826
Income from discontinued operations	—	(4)	—	—
Net income attributable to Organon	\$ 234	\$ 427	\$ 582	\$ 826
Basic weighted average number of shares outstanding	254,018	253,516	253,802	253,516
Stock awards and equity units (share equivalent)	1,138	312	1,303	312
Diluted weighted average common shares outstanding	255,156	253,828	255,105	253,828
Earnings Per Share Attributable to Organon common stockholders - Basic				
Income from continuing operations	\$ 0.92	\$ 1.70	\$ 2.29	\$ 3.26
Income from discontinued operations	—	(0.02)	—	—
Basic earnings per common share attributable to Organon common stockholders	\$ 0.92	\$ 1.68	\$ 2.29	\$ 3.26
Earnings Per Share Attributable to Organon common stockholders - Diluted				
Income from continuing operations	0.92	1.70	2.28	3.25
Income from discontinued operations	—	(0.02)	—	—
Diluted earnings per common share attributable to Organon common stockholders	\$ 0.92	\$ 1.68	\$ 2.28	\$ 3.25

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

For periods subsequent to the Separation and the Distribution, diluted earnings per share is computed by giving effect to all potentially dilutive stock awards that are outstanding. The computation of diluted earnings per share excludes the effect of the potential exercise of stock-based awards, when the effect of the potential exercise would be anti-dilutive. The weighted-average number of common shares outstanding for basic and diluted earnings per share for the three and six months ended June 30, 2022 was based on the weighted-average number of common shares outstanding for the period beginning after June 2, 2021 (the "Distribution date").

For the three and six months ended June 30, 2022 and 2021, 4.5 million, 5.2 million, 4.5 million and 5.2 million, respectively, of common shares issuable under stock-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been anti-dilutive.

## Dividend Program

During the second quarter of 2022, the Board of Directors declared a quarterly dividend of \$0.28 per share on Organon's stock that was paid on June 16, 2022 to stockholders of record at the close of business on May 16, 2022. During each of the first quarter of 2022 and the second quarter of 2021, the Company's Board of Directors also declared a quarterly cash dividend of \$0.28 per share on Organon's Common Stock.

## 17. Subsequent Events

In July 2022, the Company entered into a research collaboration and license agreement with Cirql Biomedical ("Cirql") for a novel investigational non-hormonal, on-demand contraceptive candidate. Under the terms of the agreement, Cirql will be responsible for conducting preclinical studies according to the mutually agreed research plan. Organon will obtain exclusive worldwide rights to develop and commercialize the asset. Cirql is entitled to receive a \$10 million upfront payment, additional potential payments upon achievement of specific milestones of up to \$360 million and royalties based on net sales.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

**CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION**

Some statements and disclosures in this document are forward-looking statements. Forward-looking statements include all statements that do not relate solely to historical or current facts and can be identified by the use of words such as "may," "believe," "will," "expect," "project," "estimate," "anticipate," "plan" or "continue." These forward-looking statements are based on our current plans and expectations and are subject to a number of risks and uncertainties that could cause our plans and expectations, including actual results, to differ materially from the forward-looking statements. Risks and uncertainties that may affect our future results include, but are not limited to, expanded brand and class competition in the markets in which Organon operates; difficulties with performance of third parties Organon relies on for its business growth; the failure of any supplier to provide substances, materials, or services as agreed; the increased cost of supply, manufacturing, packaging, and operations; difficulties developing and sustaining relationships with commercial counterparties; competition from generic products as Organon's products lose patent protection; expiration of current patents or loss of patent protection for Organon's products; difficulties and uncertainties inherent in the implementation of Organon's acquisition strategy or failure to recognize the benefits of such acquisitions; pricing pressures globally, including rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and health care reform, pharmaceutical reimbursement and pricing in general; and other factors discussed in Organon's most recently filed Annual Report on Form 10-K and subsequently filed Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, including those discussed in the "Business," "Risk Factors," "Cautionary Factors that May Affect Future Results" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of those reports.

**General**

The following Management's Discussion and Analysis of Financial Condition and Results of Operations is intended to assist in understanding the Company's financial condition and results of operations. The following discussion and analysis should be read in conjunction with the Company's Condensed Consolidated Financial Statements included in Part I, Item 1 of this report and with our audited financial statements, including the accompanying notes, and Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K. Operating results discussed herein are not necessarily indicative of the results of any future period.

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

**Separation from Merck**

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

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

The Separation was completed pursuant to the Separation and Distribution Agreement and other agreements with Merck related to the Separation, including, but not limited to, a Tax Matters Agreement, an Employee Matters Agreement and a Transition Services Agreement (See Note 14 for additional details).

## **Recent Developments**

### **Business Development**

#### **Shanghai Henlius Biotech, Inc. ("Henlius")**

In June 2022, Organon and Henlius, a global biopharmaceutical company, entered into a definitive agreement whereby Organon will license commercialization rights for biosimilar candidates referencing Perjeta® (pertuzumab, HLX11), (a trademark of Genentech, Inc.), used for the treatment of certain patients with HER2+ breast cancer in combinations with trastuzumab and chemotherapy and Prolia®/Xgeva® (denosumab, HLX14), (trademarks of Amgen Inc.) used for the treatment of certain patients with osteoporosis with high risk of fracture and for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastasis from solid tumors. Organon will acquire exclusive global commercialization rights except for China; including Hong Kong, Macau and Taiwan. The agreement includes an option to negotiate an exclusive license for global commercialization rights for a biosimilar candidate referencing Yervoy® (ipilimumab, HLX13) (a trademark of Bristol-Myers Squibb Company). Ipilimumab is used for the treatment of certain patients with unresectable or metastatic melanoma, as adjuvant treatment of certain patients with cutaneous melanoma, certain patients with Renal Cell Carcinoma, Colorectal Cancer, Hepatocellular Carcinoma, Non-Small Cell Lung Cancer, Malignant Pleural Mesothelioma and Esophageal Cancer.

Under the terms of the license agreement, Organon paid a \$73 million upfront payment during the third quarter of 2022, of which \$3 million was reflected in *Other current assets*. Henlius is eligible to receive potential developmental, regulatory and commercial milestone payments of up to \$468 million. As of June 30, 2022, the Company determined that certain developmental milestones were probable of occurrence and recognized \$97 million reflecting the \$70 million upfront payment and \$27 million related to development milestones as *Acquired in-process research and development and milestones*. The remaining potential milestone payments will be recognized by Organon when achievement of the contractual milestones is probable. Henlius will be responsible for development and, if approved, will supply the products to Organon.

#### **Daré Bioscience, Inc. ("Daré")**

In March 2022, Organon and Daré, a leader in women's health innovation, entered into an agreement whereby Organon licensed the global commercial rights to *Xaciatto*® (clindamycin phosphate vaginal gel, 2%). *Xaciatto* is an FDA-approved medication for the treatment of bacterial vaginosis (BV) in females 12 years of age and older. *Xaciatto* received both Qualified Infectious Disease Product (QIDP) and Fast Track designations from the FDA for the treatment of bacterial vaginosis.

Under the terms of the license agreement, Organon paid a \$10 million upfront payment during the third quarter of 2022. Daré is eligible to receive potential regulatory and commercial milestone payments of up to \$182.5 million and tiered double-digit royalties based on net sales. *Xaciatto* is expected to be available commercially in the U.S. in the fourth quarter of 2022. As of June 30, 2022 management determined that the first commercial milestone was deemed probable of occurring, and recognized an intangible asset of \$12.5 million reflecting the \$10 million upfront payment and \$2.5 million commercial milestone. The intangible asset will be amortized over its useful life of 12 years. The remaining potential milestone payments will be recognized by Organon when achievement of the contractual milestones is probable.

### **Bayer AG**

In February 2022, Organon acquired the product rights and related inventory from Bayer AG to *Marvelon*™ (ethinylestradiol, desogestrel) and *Mercilon*™ (ethinylestradiol, desogestrel), combined oral hormonal daily contraceptive pills, in the People's Republic of China, including Hong Kong and Macau, and has entered into an agreement to acquire the rights to these products in Vietnam. *Marvelon* and *Mercilon* are already owned, manufactured, and marketed by Organon as prescription oral contraceptives in 20 other markets. The transaction was accounted for as an asset acquisition. In the first quarter of 2022, Organon paid \$30 million to acquire the product rights and inventory in China and accrued an additional \$35 million related to these rights which was paid during the second quarter of 2022. This resulted in Organon recognizing an intangible asset of \$42 million related to the product rights with the remainder of the consideration recorded to *Inventories* for the fair value of acquired inventory during the first quarter of 2022. The intangible assets related to currently marketed products will be amortized over their estimated useful lives of 10 years.

The transaction to acquire the rights to these products in Vietnam closed in the third quarter of 2022.

## COVID-19 Update

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

Our product portfolio is comprised of physician prescribed products, mainly in established brands, which have been affected by social distancing measures and fewer medical visits. Additionally, our portfolio in women's health includes products that are physician administered, which have been affected by limited access to physicians and healthcare centers. These impacts, as well as the prioritization of COVID-19 patients at health care providers, resulted in reduced administration of many products within established brands particularly for respiratory and cardiovascular products and women's health product *Nexplanon*® (etonogestrel implant) (sold as *Implanon NXT*™ in some countries outside the US), throughout the prior year. During the second quarter of 2022, our business was impacted by lockdowns in selective cities across the People's Republic of China, across our portfolio in Fertility and Established Brands.

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

## Operating Results

### Sales Overview

(\$ in millions)	Three Months Ended June 30,		% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30,		% Change	% Change Excluding Foreign Exchange
	2022	2021			2021	2020		
United States	\$ 351	\$ 339	4 %	4 %	\$ 680	\$ 690	(1)%	(1)%
International	1,234	1,257	(2)%	5 %	2,472	2,412	2 %	9 %
Total	\$ 1,585	\$ 1,595	(1)%	5 %	\$ 3,152	\$ 3,101	2 %	6 %

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

Worldwide sales were \$1.6 billion for the three months ended June 30, 2022, a decrease of 1% compared with 2021. The decrease is primarily due to the unfavorable impact of foreign exchange of \$83 million and the impact of discount rates in the United States. Offsetting these declines are increases primarily due to strong performance of women's health product *Nexplanon*® (etonogestrel implant) (sold as *Implanon NXT*™ in some countries outside the US), primarily due to the impact of favorable pricing and demand uptake in the United States as well as volume growth across Latin America and the institutional business in Africa. Worldwide sales also reflect strong performance in biosimilar products mainly in the United States resulting from the continued uptake of *Renflexis*® (infliximab-abda) and strong performance for *Ontruzant*® (trastuzumab-dttb).

Worldwide sales were \$3.2 billion for the six months ended June 30, 2022, an increase of 2% compared with 2021. The sales increase is primarily due to strong volume growth for products within the established brands business, particularly for respiratory products *Nasonex*® (mometasone) and *Singulair*® (montelukast sodium) primarily in Japan and China. Worldwide sales also reflect strong performance in biosimilar products mainly in the United States and Canada, resulting from the continued uptake of *Renflexis*® in the United States, as well as strong performance of *Ontruzant*®, primarily in the United States. These increases were offset by generic competition for women's health product *NuvaRing*® (etonogestrel/ethinyl estradiol vaginal ring) and the authorized generic etonogestrel/ethinyl estradiol vaginal ring in the United States and the unfavorable impact of foreign exchange.

The loss of exclusivity ("LOE") negatively impacted sales by approximately \$10 million and \$40 million during the three and six months ended June 30, 2022, respectively, compared to the three and six months ended June 30, 2021, based on the decrease in volume period over period, mainly impacting *NuvaRing* in the United States. Volume-based procurement ("VBP") had a de minimis impact on sales during the three and six months ended June 30, 2022 compared to the prior periods.

Organon's operations include a portfolio of products. Highlights of the sales of Organon's products for the three and six months ended June 30, 2022 and 2021 are provided below. See Note 13 to the Condensed Consolidated Financial Statements for further details on sales of our products.

## Women's Health

(\$ in millions)	Three Months Ended June 30,		% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30,		% Change	% Change Excluding Foreign Exchange
	2022	2021			2022	2021		
<i>Nexplanon/Implanon NXT</i>	\$ 195	\$ 184	6 %	8 %	\$ 366	\$ 368	— %	1 %
<i>NuvaRing</i>	42	53	(21)%	(18)%	83	98	(16)%	(12)%
<i>Follistim AQ</i>	58	65	(11)%	(9)%	119	117	2 %	4 %
<i>Ganirelix Acetate Injection</i>	32	31	3 %	9 %	61	60	3 %	7 %

## Contraception

Worldwide sales of *Nexplanon*, a single-rod subdermal contraceptive implant, increased 6% for the three months ended June 30, 2022 compared to 2021, primarily due to the impact of favorable pricing in the United States and demand uptake in the United States, Latin America and volume growth from the institutional business in Africa, offset by unfavorable discount rates in the United States. Sales of *Nexplanon* for the six months ended June 30, 2022, were consistent with the prior year period reflecting lower volume in the United States in the beginning of the year, resulting from distributors' buying patterns in prior periods, offset by a favorable impact from the timing of tenders in Latin America and volume growth from the institutional business in Africa.

Worldwide sales of *NuvaRing*, a vaginal contraceptive product, declined 21% and 16% for the three and six months ended June 30, 2022 compared to 2021, respectively, primarily due to ongoing generic competition in the United States. We expect a continued decline in *NuvaRing* sales as a result of generic competition. In addition to sales of branded *NuvaRing*, we have an agreement with a generic manufacturer that authorizes the sale of a generic etonogestrel/ethinyl estradiol vaginal ring in the United States. Under the terms of the agreement, we are reimbursed on a cost-plus basis by the generic manufacturer for supplying finished goods and receive a share of the net profits recorded by the generic manufacturer. Under the terms of the agreement, our share in the profits declines over time as new participants enter the market. Revenues from this arrangement were \$14 million and \$19 million for the three months ended June 30, 2022 and 2021, respectively, and \$25 million and \$51 million for the six months ended June 30, 2022 and 2021, respectively. The decline in revenue for the three and six months ended June 30, 2022 is due to the entry of a new market participant. Given the nature of this arrangement, we expect revenues under this arrangement to continue to decline significantly for the remainder of 2022.

## Fertility

Worldwide sales of *Follistim AQ*® (marketed in most countries outside the United States as *Puregon*™), a fertility treatment, decreased 11% for the three months ended June 30, 2022 primarily due to an unfavorable shift in customer mix in the United States and the negative impact from the COVID related lockdowns in certain territories in China. Sales of *Follistim AQ*® increased 2% for the six months ended June 30, 2022 compared to 2021, primarily due to higher demand in China during the first quarter of 2022 and continuous demand growth in the United States, partly offset by an unfavorable shift in customer mix in the United States.

## Biosimilars

(\$ in millions)	Three Months Ended June 30,		% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30,		% Change	% Change Excluding Foreign Exchange
	2022	2021			2022	2021		
<i>Renflexis</i>	\$ 59	\$ 43	38 %	39 %	\$ 105	\$ 81	30 %	30 %
<i>Ontruzant</i>	35	22	57 %	61 %	57	45	28 %	33 %
<i>Brenzys</i>	14	11	28 %	34 %	28	21	34 %	39 %
<i>Hadlima</i>	2	2	5 %	3 %	8	4	99 %	101 %

The following biosimilar products are part of a development and commercialization agreement between Organon and Samsung Bioepis entered into in 2013. See Note 3 to the Condensed Consolidated Financial Statements. Our commercialization territories under the agreement vary by product as noted below.

*Renflexis*® (infliximab-abda) is a biosimilar to *Remicade*® (infliximab) (a trademark of Janssen Biotech, Inc.) for the treatment of certain inflammatory diseases. Sales growth for the three and six months ended June 30, 2022 was driven primarily by continued demand growth, favorable channel mix and favorable discount rates in the United States. We have commercialization rights to *Renflexis* in countries outside Europe, Korea, China, Turkey and Russia.

*Ontruzant*® (trastuzumab-dttb) is a biosimilar to *Herceptin*® (trastuzumab) (a trademark of Genentech, Inc.) for the treatment of HER2-overexpressing breast cancer and HER2-overexpressing metastatic gastric or gastroesophageal junction

adenocarcinoma. Sales in the three and six months ended June 30, 2022 increased driven by the phasing and timing of tenders in Brazil and the continued uptake in the United States since its launch in July 2020, partially offset by competitive pressures in Europe. We have commercialization rights to *Ontruzant* in countries outside of Korea and China.

*Brenzys*<sup>TM</sup> (etanercept) is a biosimilar to *Enbrel*<sup>®</sup> (etanercept) (a trademark of Immunex Corporation) for the treatment of certain inflammatory diseases. Sales in the three and six months ended June 30, 2022 increased 28% and 34%, respectively, primarily due to volume growth in Canada. We have commercialization rights to *Brenzys* in countries outside of the United States, Europe, Korea, China and Japan.

*Hadlima*<sup>TM</sup> (adalimumab-bwvd) is a biosimilar to *Humira*<sup>®</sup> (adalimumab) (a trademark of AbbVie Technology Ltd.) for the treatment of certain inflammatory diseases. We have worldwide commercialization rights to *Hadlima* in countries outside of the EU, Korea, China, Turkey and Russia. Samsung Bioepis reached a global settlement with AbbVie permitting us to launch *Hadlima* outside of the United States starting in 2021 and in the United States in June 2023. *Hadlima* is currently approved in the United States, Australia, Canada, and Israel. *Hadlima* was launched in Australia and Canada in February 2021. Following these launches, we recorded sales of \$2 million and \$8 million during the three and six months ended June 30, 2022, respectively, reflecting an increase from modest sales during the six months ended June 30, 2021.

#### 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)	Three Months Ended June 30,		% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30,		% Change	% Change Excluding Foreign Exchange
	2022	2021			2022	2021		
<i>Zetia/Vytorin</i>	\$ 136	\$ 144	(5)%	— %	\$ 273	\$ 276	(1)%	4 %
<i>Atozet</i>	122	121	— %	11 %	240	233	3 %	12 %
<i>Rosuzet</i>	16	18	(10)%	3 %	38	33	15 %	29 %
<i>Cozaar/Hyzaar</i>	92	86	7 %	12 %	186	177	5 %	9 %

Combined global sales of *Zetia*<sup>®</sup> (ezetimibe) (marketed in most countries outside of the United States as *Ezetrol*<sup>TM</sup>) and *Vytorin*<sup>®</sup> (ezetimibe/simvastatin) (marketed outside of the United States as *Inegy*<sup>TM</sup>), medicines for lowering LDL cholesterol, declined 5% and 1% for the three and six months ended June 30, 2022, compared to 2021, respectively, primarily driven by increased competition and lower performance in Europe and Asia Pacific, partly offset by volume growth in China.

Sales of *Atozet*<sup>TM</sup> (ezetimibe and atorvastatin calcium) (marketed outside of the United States), a medicine for lowering LDL cholesterol, remained consistent for the three months ended June 30, 2022 and increased 3% for the six months ended June 30, 2022, compared to 2021, primarily due to increased demand in France and Spain.

Sales of *Rosuzet*<sup>TM</sup> (ezetimibe and rosuvastatin calcium) (marketed outside of the United States), a medicine for lowering LDL cholesterol, decreased 10% for the three months ended June 30, 2022 compared to 2021, primarily due to the effect of foreign exchange and increased 15% for the six months ended June 30, 2022 compared to 2021, primarily due to higher demand in Japan.

Combined global sales of *Cozaar*<sup>®</sup> (losartan potassium), and *Hyzaar*<sup>®</sup> (losartan potassium and hydrochlorothiazide) (a combination of *Cozaar* and hydrochlorothiazide that is marketed in Japan as *Preminent*<sup>TM</sup>), a medicine for the treatment of hypertension, increased 7% and 5% for the three and six months ended June 30, 2022, compared to 2021, respectively, primarily due to favorable volume demand resulting from competitors' supply disruptions in various markets.

## Respiratory

(\$ in millions)	Three Months Ended June 30,		% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30,		% Change	% Change Excluding Foreign Exchange
	2022	2021			2022	2021		
<i>Singular</i>	\$ 92	\$ 92	— %	8 %	\$ 222	\$ 199	11 %	18 %
<i>Nasonex</i>	58	52	12 %	16 %	133	95	40 %	45 %
<i>Dulera</i>	47	52	(9)%	(8)%	88	91	(3)%	(3)%

Worldwide sales of *Singular*, a once-a-day oral medicine for the chronic treatment of asthma and for the relief of symptoms of allergic rhinitis, remained consistent for the three months ended June 30, 2022 compared to 2021, and increased 11% for the six months ended June 30, 2022 compared to 2021. The increase in sales during the six months ended June 30, 2022 was primarily attributable to volume recovery from the COVID-19 pandemic and demand resulting from competitors supply disruptions in Japan.

Global sales of *Nasonex*, an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, increased 12% for the three months ended June 30, 2022 compared to 2021, primarily driven by increased demand in Europe, Canada and the Middle East region as well as higher demand resulting from competitors' supply disruptions in Japan. *Nasonex* sales increased 40% during the six months ended June 30, 2022 primarily driven by higher demand resulting from competitors' supply disruptions in Japan, recovery from the COVID-19 pandemic in China, and increased demand across several markets. In addition, sales during the six months ended June 30, 2022 included a \$10 million milestone payment related to a regulatory approval in the United States.

Global sales of *Dulera*® (formoterol/fumarate dihydrate), a combination medicine for the treatment of asthma, decreased 9% and 3% for the three and six months ended June 30, 2022 compared to 2021, respectively, primarily due to unfavorable discount rates and lower volume growth in the United States.

### Non-Opioid Pain, Bone and Dermatology

(\$ in millions)	Three Months Ended June 30,		% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30,		% Change	% Change Excluding Foreign Exchange
	2022	2021			2022	2021		
<i>Arcoxia</i>	\$ 61	\$ 62	(2)%	2 %	\$ 121	\$ 119	2 %	7 %

Sales of *Arcoxia*™ (etoricoxib) (marketed outside of the United States), a medicine for the treatment of arthritis and pain, were slightly lower for the three months ended June 30, 2022 compared to 2021, primarily due to the impact of foreign exchange. Sales of *Arcoxia* increased 2% during the six months ended June 30, 2022 compared to 2021, primarily due to the higher demand in China and the South East Asia region.

## Other

(\$ in millions)	Three Months Ended June 30,		% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30,		% Change	% Change Excluding Foreign Exchange
	2022	2021			2022	2021		
<i>Proscar</i>	\$ 26	\$ 32	(18)%	(16)%	\$ 50	\$ 64	(21)%	(20)%

Worldwide sales of *Proscar*, a medicine for the treatment of symptomatic benign prostate enlargement, declined 18% and 21% for the three and six months ended June 30, 2022 compared to 2021, respectively, primarily due to lower demand in China.



## Costs, Expenses and Other

(\$ in millions)	Three Months Ended June 30,		% Change	Six Months Ended June 30,		% Change
	2022	2021		2022	2021	
Cost of sales	\$ 588	\$ 583	1 %	\$ 1,149	\$ 1,174	(2)%
Selling, general and administrative	423	416	2 %	794	798	(1)%
Research and development	106	76	39 %	202	143	41 %
Acquired in-process research and development and milestones	97	—	*	97	—	*
Restructuring costs	—	1	*	—	2	*
Interest expense	98	62	58 %	195	62	215%
Other (income) expense, net	(14)	20	*	(14)	18	*
	\$ 1,298	\$ 1,158	12 %	\$ 2,423	\$ 2,197	10 %

\* Calculation not meaningful.

### Cost of Sales

Cost of sales increased 1% for the three months ended June 30, 2022 compared to 2021 primarily due to product mix offset by favorable foreign exchange. For the six months ended June 30, 2022, cost of sales decreased 2% compared to the same period in 2021, primarily reflecting lower supply sales compared to the prior year, as well as pre-spin allocated costs related to the Separation incurred during the prior year which were not incurred during the six months ended June 30, 2022 and favorable foreign exchange. During the three and six months ended June 30, 2022, the Company recorded an impairment charge of \$9 million related to a product right for a biosimilar product.

Gross margin was 63% for the three months ended June 30, 2022 compared with 63% for the same period in 2021. Gross margin was 64% for the six months ended June 30, 2022 compared with 62% for the same period in 2021. The gross margin increase compared to the prior year reflects lower margin supply sales as well as pre-spin allocated costs related to the Separation incurred during the prior year which were not incurred during the three and six months ended June 30, 2022.

### Selling, General and Administrative

Selling, general and administrative expenses increased 2% for the three months ended June 30, 2022 due to higher selling and promotional costs offset by pre-spin allocated costs related to the Separation incurred during the prior year which were not incurred during the three months ended June 30, 2022. For the six months ended June 30, 2022, selling, general and administrative expenses decreased 1% reflecting pre-spin allocated costs related to the Separation incurred during the prior year which were not incurred during the six months ended June 30, 2022, partially offset by higher selling and promotional costs.

### Research and Development

Research and development expenses increased 39% and 41% for the three and six months ended June 30, 2022, primarily due to higher costs associated with the Company's recent acquisitions of clinical stage assets and higher employee-related costs.

### Acquired In-Process Research and Development and Milestones

Acquired in-process research and development and milestones for the three and six months ended June 30, 2022 represent the upfront and development milestones related to the Henlius transaction.

### Interest Expense

For the three and six months ended June 30, 2022, interest expense increased, due to the \$9.5 billion of debt which was assumed by the Company during the second quarter of 2021.

### Other (Income) Expense, Net

For the three and six months ended June 30, 2022, other (income) expense, net decreased 170% and 178%, primarily attributable to fluctuations in foreign exchange.

### Taxes on Income

The effective income tax rates were 18.5% and 1.4% for the second quarter of 2022 and 2021, respectively. These effective income tax rates reflect the beneficial impact of foreign earnings, offset by the impact of U.S. inclusions under the Global Intangible Low-Taxed Income regime. The effective income tax rate for the first six months of 2021 reflects the beneficial impact of foreign earnings, the \$70 million tax benefit relating to a portion of the non-U.S. step-up of tax basis as

well as the income tax benefit recognized in connection with the conclusion of the Internal Revenue Service (IRS) examination of Merck's 2015-2016 U.S. federal income tax returns. As a result of that examination conclusion, we reflected an allocation from Merck of \$18 million in the Condensed Consolidated Financial Statements representing our portion of the payment made to the IRS. Our portion of reserves for unrecognized tax benefits for the years under examination exceeded the allocated adjustments relating to this examination period. Therefore, for the six months ended June 30, 2021, we reflected a \$29 million net tax benefit. This net benefit reflects reductions in reserves for unrecognized tax benefits and other related liabilities for tax positions relating to the years that were under examination.

#### *Income/Loss from Discontinued Operations*

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

There was no income or loss from discontinued operations, net of taxes for the three and six months ended June 30, 2022 and the six months ended June 30, 2021. Loss from discontinued operations, net of taxes, was \$4 million for the three months ended June 30, 2021.

### **Analysis of Liquidity and Capital Resources**

#### *Liquidity and Capital Resources*

As of June 30, 2022, Organon had cash and cash equivalents of \$545 million. On June 6, 2022, the Company made a discretionary prepayment of \$100 million on the U.S. Dollar-denominated term loan. The Company has historically generated and expects to continue to generate positive cash flow from operations. We plan to continue to fund our ongoing operating, investing and financing requirements mainly through cash flows from operations, available liquidity through cash on hand, available capacity under our Revolving Credit Facility and access to capital markets.

Working capital of continuing operations was \$1.4 billion as of June 30, 2022 and \$1.2 billion as of December 31, 2021. The increase in working capital of continuing operations was primarily driven by a decrease in trade accounts payable and an increase in accounts receivable.

Net cash provided by operating activities was \$274 million for the six months ended June 30, 2022 compared to \$1.7 billion for the same period in the prior year. The decrease in cash provided by operating activities in 2022 was primarily attributable to the decrease in trade payables, including balances with Merck.

Net cash used in investing activities was \$146 million for the six months ended June 30, 2022 compared to \$287 million for the same period in the prior year, primarily reflecting the asset acquisition of Marvelon and Mercilon in the six months ended June 30, 2022 and the asset acquisition of Alydia Health in the six months ended June 30, 2021.

Net cash used in financing activities was \$274 million for the six months ended June 30, 2022 compared to \$772 million for the same period in the prior year. The change in cash used in financing activities reflects the settlement of the transactions with Merck in connection with the Separation in 2021, partially offset by the payment of dividends in the current year (see Note 14 to our Condensed Consolidated Financial Statements).

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.

In February 2022, the armed conflict between Ukraine and Russia escalated, which may adversely impact Organon's business. Specifically, trade sanctions, travel bans and asset and financial freezes announced by the United States, European Union and other countries against Russian entities and designated individuals, as well as counter-measures announced by Russia, have impacted and may continue to impact many global businesses in direct and indirect ways (including, but not limited to, product shipping delays, supply shortages, delays in regulatory approvals and audits, constraints in energy supply, currency exchange rates and exchange controls). Such actions may negatively impact the financial institutions, vendors, manufacturers, suppliers, partners and other third parties with whom Organon conducts business. Organon will continue to monitor the impacts of the conflict, which may negatively impact Organon's operations, financial position or cash flows. For the six months ended June 30, 2022 and the year ended December 31, 2021, Organon's combined revenues from Ukraine and Russia were approximately 2% of total revenues. As of June 30, 2022, the Company's assets in Ukraine and Russia are not material.

Our contractual obligations as of December 31, 2021, which require material cash requirements in the future, consist of purchase obligations and lease obligations. In addition, Organon is responsible for settlement of certain tax matters, of which the Company expects to pay during 2022. Refer to "Management's Discussion and Analysis of Financial Condition and Results of Operations in our 2021 Form 10-K for further details. As of June 30, 2022, there have been no material changes to our contractual obligations, or settlements of tax matters outside the ordinary course of business.

During the first and second quarter of 2022, Organon paid cash dividends of \$0.28 per share. On August 4, 2022, the Board of Directors declared a quarterly dividend of \$0.28 for each issued and outstanding share of the Company's common stock. The dividend is payable on September 15, 2022 to stockholders of record at the close of business on August 15, 2022.

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

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

### **Critical Accounting Estimates**

Our significant accounting policies, which include management's best estimates and judgments, are included in Note 3 to the Consolidated Financial Statements included in our Form 10-K for the year ended December 31, 2021. See Note 2 to the Condensed Consolidated Financial Statements for information on the adoption of new accounting standards during 2022. There have been no changes to our accounting policies as of June 30, 2022. 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 in the Critical Accounting Estimates section of Management's Discussion and Analysis of Financial Condition and Results of Operations included in Organon's Form 10-K for the year ended December 31, 2021.

### **Recently Issued Accounting Standards**

For a discussion of recently issued accounting standards, see Note 2 to the Condensed Consolidated Financial Statements.

### **Item 3. 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 had historically managed our foreign currency risk through Merck foreign currency programs. We are primarily exposed to foreign exchange risk with respect to forecasted transactions and net assets denominated in the euro, Swiss franc, and Japanese yen. Upon Separation, we established a balance sheet risk management program and a net investment hedge to mitigate against volatility of changes in foreign exchange rates. Each quarter subsequent to Separation, €1.75 billion of our euro-denominated debt has been designated as a hedge of the net investment of euro-denominated subsidiaries. See Note 5 to the Condensed Consolidated Financial Statements included elsewhere in this report for further information on Organon's risk management.

#### *Interest Rate Risk*

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

There have been no changes to Organon's market risk during the quarter ended June 30, 2022. For a discussion of our exposure to market risk, refer to our market risk disclosures set forth under Item 7A.—Quantitative and Qualitative Disclosures About Market Risk in our Annual Report on Form 10-K for the year ended December 31, 2021.

**Item 4. Controls and Procedures**

Management of the Company, with the participation of its Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), evaluated the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the period ending June 30, 2022. Based upon that evaluation, our CEO and our CFO concluded that, as of the period ending June 30, 2022, the Company's disclosure controls and procedures were effective and provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the applicable rules and forms, and that it is accumulated and communicated to our management, including our CEO and our CFO, as appropriate, to allow timely decisions regarding required disclosure.

Our Annual Report on Form 10-K for the year ended December 31, 2021 did not include a report of management's assessment regarding internal control over financial reporting or an attestation of the Company's independent registered public accounting firm due to the transition period established by the rules of the SEC for newly created public companies.

No changes in our internal controls over financial reporting during the quarter ended June 30, 2022 have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

**PART II - OTHER INFORMATION**

**Item 1. Legal Proceedings**

The information called for by this Item is incorporated herein by reference to Note 8 included in Part I, Item. 1.

**Item 1A. Risk Factors**

There have been no material changes in the Company's risk factors from those disclosed in Item 1A, Risk Factors, in our Form 10-K for the year ended December 31, 2021.

Items	6.	Exhibits
Number	Description	
*31.1	—	<a href="#">Certification of Principal Executive Officer (CEO) pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>
*31.2	—	<a href="#">Certification of Principal Financial Officer (CFO) pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>
**32.1	—	<a href="#">Section 1350 Certification of Principal Executive Officer (CEO) pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>
**32.2	—	<a href="#">Section 1350 Certification of Principal Financial Officer (CFO) pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>
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.

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: August 5, 2022

/s/ Kathryn DiMarco

Kathryn DiMarco

Senior Vice President Finance - Corporate Controller

Date: August 5, 2022

/s/ Matthew Walsh

Matthew Walsh

Chief Financial Officer

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Kevin Ali certify that:

1. I have reviewed this Form 10-Q of Organon & Co;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. the registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 5, 2022

By /s/ Kevin Ali  
Kevin Ali  
Chief Executive Officer

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

**Exhibit 31.2**

I, Matthew Walsh certify that:

1. I have reviewed this Form 10-Q of Organon & Co;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. the registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 5, 2022

By /s/ Matthew Walsh  
Matthew Walsh  
Chief Financial Officer



**Exhibit 32.1**

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. § 1350,  
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to 18 U.S.C. § 1350, the undersigned certifies that, to the best of my knowledge, the Quarterly Report on Form 10-Q for the period ended June 30, 2022 of Organon & Co. fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. § 78m or 78o(d)) and that the information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of Organon & Co.

August 5, 2022

/s/ Kevin Ali

Kevin Ali

Chief Executive Officer

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**Exhibit 32.2**

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. § 1350,  
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to 18 U.S.C. § 1350, the undersigned certifies that, to the best of my knowledge, the Quarterly Report on Form 10-Q for the period ended June 30, 2022 of Organon & Co. fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. § 78m or 78o(d)) and that the information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of Organon & Co.

Dated: August 5, 2022

/s/ Matthew Walsh

Matthew Walsh

Chief Financial Officer