

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

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

OR

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

For the transition period from _____ to _____

Commission File No. 001-40235

Organon & Co.

(Exact name of registrant as specified in its charter)

Delaware
(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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 October 27, 2023: 255,606,461

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PART I - FINANCIAL INFORMATION
Item 1. Financial Statements

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues	\$ 1,519	\$ 1,537	\$ 4,665	\$ 4,689
Costs, Expenses and Other				
Cost of sales	612	551	1,832	1,700
Selling, general and administrative	538	440	1,424	1,234
Research and development	137	127	394	329
Acquired in-process research and development and milestones	—	10	8	107
Restructuring costs	—	11	4	11
Interest expense	134	108	398	303
Exchange losses (gains)	14	4	25	(21)
Other expense, net	4	4	11	15
	1,439	1,255	4,096	3,678
Income Before Income Taxes	80	282	569	1,011
Taxes on income	22	55	92	202
Net Income	\$ 58	\$ 227	\$ 477	\$ 809
Earnings per Share:				
Basic	\$ 0.23	\$ 0.89	\$ 1.87	\$ 3.19
Diluted	\$ 0.23	\$ 0.89	\$ 1.86	\$ 3.17
Weighted Average Shares Outstanding:				
Basic	255,588	254,348	255,112	253,986
Diluted	256,349	255,067	256,162	255,094

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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net income	\$ 58	\$ 227	\$ 477	\$ 809
Other Comprehensive Income, Net of Taxes:				
Benefit plan net loss and prior service cost, net of amortization	—	—	(1)	—
Cumulative translation adjustment	(43)	(97)	(11)	(173)
	(43)	(97)	(12)	(173)
Comprehensive income	\$ 15	\$ 130	\$ 465	\$ 636

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 and per share amounts)

	September 30, 2023	December 31, 2022
Assets		
Current Assets:		
Cash and cash equivalents	\$ 414	\$ 706
Accounts receivable (net of allowance for doubtful accounts of \$9 in 2023 and \$9 in 2022)	1,648	1,475
Inventories (excludes inventories of \$95 in 2023 and \$148 in 2022 classified in Other assets)	1,186	1,003
Other current assets	802	747
Total Current Assets	4,050	3,931
Property, plant and equipment, net	1,096	1,018
Goodwill	4,603	4,603
Intangibles, net	561	649
Other assets	702	754
Total Assets	\$ 11,012	\$ 10,955
Liabilities and Equity		
Current Liabilities:		
Current portion of long-term debt	\$ 8	\$ 8
Trade accounts payable	1,067	1,132
Accrued and other current liabilities	1,255	1,188
Income taxes payable	161	184
Total Current Liabilities	2,491	2,512
Long-term debt	8,646	8,905
Deferred income taxes	43	19
Other noncurrent liabilities	421	411
Total Liabilities	11,601	11,847
Contingencies (Note 15)		
Organon & Co. Stockholders' Deficit:		
Common stock, \$0.01 par value		
Authorized - 500,000		
Issued and outstanding - 255,606 in 2023 and 254,370 in 2022	3	3
Accumulated deficit	(16)	(331)
Accumulated other comprehensive loss	(576)	(564)
Total Stockholders' Deficit	(589)	(892)
Total Liabilities and Stockholders' Deficit	\$ 11,012	\$ 10,955

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

Organon & Co.
Condensed Consolidated Statements of Stockholders' Equity (Deficit)
(Unaudited, \$ in millions, except shares in thousands and per share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Par Value				
Balance at July 1, 2022	254,321	\$ 3	\$ —	\$ (551)	\$ (589)	\$ (1,137)
Net income	—	—	—	227	—	227
Other comprehensive loss, net of taxes	—	—	—	—	(97)	(97)
Cash dividends declared on common stock (\$0.28 per share)	—	—	—	(74)	—	(74)
Stock-based compensation plans and other	43	—	—	15	—	15
Net transfers from Merck & Co., Inc., including Separation Adjustments	—	—	—	—	—	—
Balance at September 30, 2022	254,364	\$ 3	\$ —	\$ (383)	\$ (686)	\$ (1,066)
Balance at July 1, 2023	255,568	\$ 3	\$ —	\$ (25)	\$ (533)	\$ (555)
Net income	—	—	—	58	—	58
Other comprehensive loss, net of taxes	—	—	—	—	(43)	(43)
Cash dividends declared on common stock (\$0.28 per share)	—	—	—	(74)	—	(74)
Stock-based compensation plans and other	38	—	—	25	—	25
Balance at September 30, 2023	255,606	\$ 3	\$ —	\$ (16)	\$ (576)	\$ (589)
Balance at January 1, 2022	253,550	\$ 3	\$ —	\$ (998)	\$ (513)	\$ (1,508)
Net income	—	—	—	809	—	809
Other comprehensive loss, net of taxes	—	—	—	—	(173)	(173)
Cash dividends declared on common stock (\$0.84 per share)	—	—	—	(218)	—	(218)
Stock-based compensation plans and other	814	—	—	41	—	41
Net transfers to Merck & Co., Inc. including Separation Adjustments	—	—	—	(17)	—	(17)
Balance at September 30, 2022	254,364	\$ 3	\$ —	\$ (383)	\$ (686)	\$ (1,066)
Balance at January 1, 2023	254,370	\$ 3	\$ —	\$ (331)	\$ (564)	\$ (892)
Net income	—	—	—	477	—	477
Other comprehensive loss, net of taxes	—	—	—	—	(12)	(12)
Cash dividends declared on common stock (\$0.84 per share)	—	—	—	(221)	—	(221)
Stock-based compensation plans and other	1,236	—	—	59	—	59
Balance at September 30, 2023	255,606	\$ 3	\$ —	\$ (16)	\$ (576)	\$ (589)

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)

	Nine Months Ended September 30,	
	2023	2022
Cash Flows from Operating Activities		
Net income	\$ 477	\$ 809
Adjustments to reconcile net income to net cash flows provided by operating activities:		
Depreciation	88	72
Amortization	88	88
Impairment of assets	—	9
Acquired in-process research and development and milestones	8	107
Deferred income taxes	4	(18)
Stock-based compensation	74	52
Unrealized foreign exchange loss (gain)	19	(45)
Other	24	24
Net changes in assets and liabilities		
Accounts receivable	(185)	(119)
Inventories	(137)	(134)
Other current assets	(56)	(76)
Trade accounts payable	(68)	(323)
Accrued and other current liabilities	34	108
Income taxes payable	(21)	45
Other	53	(8)
Net Cash Flows Provided by Operating Activities	402	591
Cash Flows from Investing Activities		
Capital expenditures	(172)	(133)
Proceeds from sale of property, plant and equipment	1	3
Acquired in-process research and development and milestones	(8)	(105)
Purchase of product rights and asset acquisition, net of cash acquired	—	(124)
Net Cash Flows Used in Investing Activities	(179)	(359)
Cash Flows from Financing Activities		
Proceeds from debt	80	—
Repayments of debt	(336)	(106)
Net transfers to Merck & Co., Inc.	—	(17)
Employee withholding taxes related to stock-based awards	(15)	(11)
Dividend payments	(221)	(217)
Net Cash Flows Used in Financing Activities	(492)	(351)
Effect of Exchange Rate Changes on Cash and Cash Equivalents	(23)	(119)
Net Decrease in Cash and Cash Equivalents	(292)	(238)
Cash and Cash Equivalents, Beginning of Period	706	737
Cash and Cash Equivalents, End of Period	\$ 414	\$ 499

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

Notes to Condensed Consolidated Financial Statements (unaudited)**1. Background and Nature of Operations**

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

The Company's operations include the following product portfolios:

- *Women's Health*: Organon's women's health products are sold by prescription primarily in two therapeutic areas, contraception, with key brands such as *Nexplanon*® (etonogestrel implant) (sold as *Implanon NXT*™ in some countries outside the United States) and *NuvaRing*® (etonogestrel / ethinyl estradiol vaginal ring), and fertility, with key brands such as *Follistim AQ*® (follitropin beta injection) (marketed in most countries outside the United States as *Puregon*™). *Nexplanon* is a long-acting reversible contraceptive, which is a class of contraceptives that is recognized as one of the most effective types of hormonal contraception available to patients with a low long-term average cost. Other women's health products include the *Jada*® System, which is intended to provide control and treatment of abnormal postpartum uterine bleeding or hemorrhage when conservative management is warranted and a license from Daré Biosciences for the global commercial rights to *Xaciat*™ (clindamycin phosphate vaginal gel, 2%), an FDA-approved medication for the treatment of bacterial vaginosis ("BV") in females 12 years of age and older. In October 2023, *Xaciat* was launched in the United States.
- *Biosimilars*: Organon's current portfolio spans across immunology and oncology treatments. Organon's oncology biosimilars have been launched in more than 20 countries and Organon's immunology biosimilars have been launched in five countries. All five biosimilars in Organon's portfolio have launched in Canada, and three biosimilars; *Ontruzant*® (trastuzumab-dttb), *Renflexis*® (infliximab-abda) and *Hadlima*™ (adalimumab-bwvd) have been launched in the United States.
- *Established Brands*: Organon has a portfolio of established brands, which generally are beyond market exclusivity, including leading brands in cardiovascular, respiratory, dermatology and non-opioid pain management. A number of Organon's established brands lost exclusivity years ago and have faced generic competition for some time.

2. Basis of Presentation

The accompanying unaudited financial statements have been prepared in accordance with U.S. Generally Accepted Accounting Principles ("GAAP") and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, certain information and disclosures required by 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, 2022.

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 the Annual Report on Form 10-K for the year ended December 31, 2022. Accordingly, actual results could differ materially from management's estimates and assumptions.

The Company was impacted by COVID-19 during the first half of 2023, specifically, in the Company's operations in China. The Company does not anticipate a continued impact from COVID-19. 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

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

information reasonably available to the Company as of September 30, 2023 and through the date of this report which are difficult to predict.

Recently Adopted Accounting Standards

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*, optional guidance to ease the potential burden in accounting for (or recognizing the effects of) reference rate reform on financial reporting and subsequently issued clarifying amendments. The guidance provides optional expedients and exceptions for applying GAAP to contracts, hedging relationships, and other transactions that reference the London Interbank Offered Rate ("LIBOR") or another reference rate expected to be discontinued because of reference rate reform. The optional guidance is effective upon issuance and can be applied on a prospective basis at any time between January 1, 2020 and December 31, 2022; the sunset date was subsequently deferred to December 31, 2024 based on the amendment issued in December 2022 under ASU 2022-06, *Reference Rate Reform (Topic 848)*. The Company applied this guidance to our Senior Credit Agreement, as amended on June 30, 2023. The impact to the Consolidated Financial Statements as a result of the application of the reference rate reform guidance is not material. See Note 11 "Long-Term Debt" for additional details.

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

3. Acquisitions and Licensing Arrangements

Claria Medical, Inc. ("Claria")

In January 2023, the Company made a strategic investment in Claria, a privately-held company developing an investigational medical device being studied for use during minimally invasive laparoscopic hysterectomy. Under the terms of the agreement, Organon paid \$8 million upfront and has the option to acquire Claria for an additional \$47 million, payable if and when the option is exercised. The \$8 million was expensed as *Acquired in-process research and development and milestones* in our Condensed Consolidated Statement of Income for the nine months ended September 30, 2023.

4. Earnings per Share ("EPS")

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

(\$ in millions and shares in thousands, except per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net income	\$ 58	\$ 227	\$ 477	\$ 809
Basic weighted average number of shares outstanding	255,588	254,348	255,112	253,986
Stock awards and equity units (share equivalent)	761	719	1,050	1,108
Diluted weighted average common shares outstanding	256,349	255,067	256,162	255,094
EPS:				
Basic	\$ 0.23	\$ 0.89	\$ 1.87	\$ 3.19
Diluted	\$ 0.23	\$ 0.89	\$ 1.86	\$ 3.17
Anti-dilutive shares excluded from the calculation of EPS	10,390	6,313	9,833	4,432

Diluted EPS was computed using the treasury stock method for stock option awards, performance share units and restricted share units. The computation of diluted EPS excludes the effect of the potential exercise of stock-based awards when the effect of the potential exercise would be anti-dilutive.

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

5. 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 September 30,						Nine Months Ended September 30,					
	2023			2022			2023			2022		
	U.S.	Int'l	Total	U.S.	Int'l	Total	U.S.	Int'l	Total	U.S.	Int'l	Total
Women's Health												
<i>Nexplanon/Implanon NXT</i>	\$ 146	\$ 74	\$ 220	\$ 151	\$ 78	\$ 229	\$ 418	\$ 181	\$ 599	\$ 401	\$ 194	\$ 595
<i>Follistim AQ</i>	22	32	54	27	33	60	74	105	179	79	100	179
<i>NuvaRing</i>	18	20	37	27	23	50	50	67	117	65	68	133
Ganirelix Acetate Injection	4	21	25	6	30	36	15	74	88	20	77	97
<i>Marvelon/Mercilon</i>	—	30	30	—	31	31	—	97	97	—	85	85
<i>Jada</i>	12	—	13	5	—	5	30	—	31	12	—	12
Other Women's Health ⁽¹⁾	16	22	39	19	23	42	52	74	126	68	70	138
Biosimilars												
<i>Renflexis</i>	57	12	69	54	7	60	172	29	201	145	20	166
<i>Ontruzant</i>	11	28	40	15	14	29	36	57	93	35	52	87
<i>Brenzys</i>	—	13	13	—	24	24	—	45	45	—	52	52
<i>Aybintio</i>	—	12	12	—	10	10	—	34	34	—	29	29
<i>Hadlima</i>	2	6	8	—	6	6	2	18	20	—	14	14
Established Brands												
Cardiovascular												
<i>Zetia</i>	2	65	66	2	85	87	5	234	239	7	280	287
<i>Vytarin</i>	2	31	33	1	30	31	5	95	100	6	98	104
<i>Atozet</i>	—	126	126	—	109	109	—	397	397	—	350	350
<i>Rosuzet</i>	—	17	17	—	17	17	—	52	52	—	55	55
<i>Cozaar/Hyzaar</i>	3	65	68	2	68	70	8	217	225	11	244	256
Other Cardiovascular ⁽¹⁾	1	42	44	1	34	35	2	124	126	3	117	120
Respiratory												
<i>Singulair</i>	3	88	91	3	92	94	8	282	290	8	308	316
<i>Nasonex</i>	—	54	55	—	49	49	—	187	188	9	173	182
<i>Dulera</i>	40	9	49	31	9	40	116	28	144	98	30	127
<i>Clarinx</i>	2	26	28	—	25	26	4	103	107	3	96	99
Other Respiratory ⁽¹⁾	17	9	25	11	10	21	42	20	61	34	32	66
Non-Opioid Pain, Bone and Dermatology												
<i>Arcoxia</i>	—	64	64	—	64	64	—	207	207	—	185	185
<i>Fosamax</i>	1	40	41	1	35	36	2	121	123	2	115	117
<i>Diprosan</i>	—	31	31	—	28	28	—	58	58	—	91	91
Other Non-Opioid Pain, Bone and Dermatology ⁽¹⁾	4	70	74	2	63	65	11	196	207	10	200	210
Other												
<i>Proscar</i>	—	25	25	—	26	27	1	76	77	1	76	77
<i>Propecia</i>	2	21	22	2	28	30	5	86	92	5	90	95
Other ⁽¹⁾	5	72	76	6	81	87	10	231	240	21	230	251
Other ⁽²⁾	—	24	24	—	39	39	(1)	103	102	—	115	116
Revenues	\$ 370	\$ 1,149	\$ 1,519	\$ 366	\$ 1,171	\$ 1,537	\$ 1,067	\$ 3,598	\$ 4,665	\$ 1,043	\$ 3,646	\$ 4,689

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

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

⁽²⁾ Includes manufacturing sales to Merck & Co., Inc. ("Merck") and third parties for current and prior periods.

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

Revenues by geographic area where derived are as follows:

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Europe and Canada	\$ 392	\$ 363	\$ 1,259	\$ 1,243
United States	370	366	1,067	1,043
Asia Pacific and Japan	284	283	869	888
China	202	241	661	721
Latin America, Middle East, Russia, and Africa	239	236	687	665
Other ⁽¹⁾	32	48	122	129
Revenues	\$ 1,519	\$ 1,537	\$ 4,665	\$ 4,689

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

6. 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.

The PSU awards are based on the following performance factors:

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

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

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Stock-based compensation expense recognized in:				
Cost of sales	\$ 5	\$ 3	\$ 13	\$ 9
Selling, general and administrative	18	12	50	35
Research and development	4	3	11	8
Total	\$ 27	\$ 18	\$ 74	\$ 52
Income tax benefits	\$ 6	\$ 3	\$ 16	\$ 11

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

	Nine Months Ended September 30,	
	2023	2022
Expected dividend yield	4.82 %	3.12 %
Risk-free interest rate	3.56	2.47
Expected volatility	42.30	43.43
Expected life (years)	5.89	5.89

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

A summary of the equity award transactions for the nine months ended September 30, 2023 is 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>							
Outstanding as of January 1, 2023	4,729	\$ 34.34	\$ 8.91	5,048	\$ 33.27	486	\$ 46.72
Granted	1,124	23.52	6.55	3,867	23.51	636	23.30
Vested/Exercised	—	—	—	(1,930)	33.93	—	—
Forfeited/Cancelled	(89)	36.12	8.70	(459)	30.79	—	—
Outstanding as of September 30, 2023	5,764	\$ 32.21	\$ 8.45	6,526	\$ 27.47	1,122	\$ 33.44

The following table summarizes information about equity awards outstanding that are vested and expected to vest and equity awards outstanding that are exercisable as of September 30, 2023:

	Equity Awards Vested and Expected to Vest				Equity Awards That are Exercisable			
	Awards	Weighted Average Exercise Price	Aggregate Intrinsic Value	Remaining Term (in years)	Awards	Weighted Average Exercise Price	Aggregate Intrinsic Value	Remaining Term (in years)
<i>(awards in thousands; aggregate intrinsic value in millions)</i>								
Stock Options	5,591	\$ 32.21	\$ —	7.04	3,311	\$ 33.79	\$ —	5.87
Restricted Share Units	6,071		114	1.98				
Performance Share Units	629		12	1.82				

The amount of unrecognized compensation costs as of September 30, 2023 was \$170 million, which will be recognized in operating expense ratably over the weighted average vesting period of 1.93 years.

7. Restructuring

In 2022, Organon initiated restructuring activities to optimize its internal operations by reducing headcount through selected markets and functions. As a result of this program, the Company restructured approximately 130 positions, with the majority of the position eliminations occurring in selected markets outside of the United States in our commercial organizations. During the nine months ended September 30, 2023, \$15 million of restructuring charges have been paid, with the remaining severance payments to be paid by the end of the 2023 fiscal year. For the nine months ended September 30, 2023, the Company recorded restructuring charges of \$4 million, which relate to severance costs for eliminated positions.

Liabilities for costs associated with restructuring activities were \$10 million and \$20 million at September 30, 2023 and December 31, 2022, respectively, and are included primarily in *Accrued and other current liabilities*.

In the fourth quarter of 2023, Organon will implement additional restructuring activities to optimize its internal operations by reducing headcount in certain markets and functions. As a result of these activities, the Company expects to restructure approximately 3% of the Company's headcount, which is expected to result in a charge of approximately \$60 million to \$70 million primarily representing severance and severance related costs in the fourth of quarter of 2023. These amounts will be paid over the next twelve months.

8. Taxes on Income

The effective income tax rates were 27.0% and 19.6% for the three months ended September 30, 2023 and 2022, respectively, and 16.1% and 20.0% for the nine months ended September 30, 2023 and 2022, respectively. These effective income tax rates reflect the beneficial impact of foreign earnings, offset by the impact of U.S. inclusions under the Global Intangible Low-Taxed Income regime and a partial valuation allowance recorded against non-deductible U.S. interest expense. The 2023 year-to-date effective tax rate favorable impact is primarily attributable to a reduced tax rate arrangement that was agreed to in Switzerland for an active entity.

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

On August 16, 2022, the United States enacted the Inflation Reduction Act of 2022. Provisions of the bill that relate to tax include the minimum tax on book income, a 1% excise tax on stock buybacks and certain tax incentives to promote clean energy. There are no impacts of the legislation to the third quarter 2023 results. The Company will continue to assess future impacts of this legislation.

9. Inventories

Inventories consisted of:

(\$ in millions)	September 30, 2023	December 31, 2022
Finished goods	\$ 496	\$ 482
Raw materials	128	44
Work in process	606	601
Supplies	57	44
Total (approximates current cost)	\$ 1,287	\$ 1,171
Decrease to LIFO costs	(6)	(20)
	\$ 1,281	\$ 1,151
Recognized as:		
Inventories	\$ 1,186	\$ 1,003
Other assets	95	148
Inventories valued under the last in, first out ("LIFO") method	85	77

Amounts recognized as *Other assets* are comprised primarily of raw materials and work in process inventories and are not expected to be converted to finished goods that will be sold within one year. The Company has a long-term vendor supply contract that includes certain annual minimum purchase commitments.

10. Financial Instruments

Foreign Currency Risk Management

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

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

Monetary assets and liabilities denominated in a currency other than the functional currency of a given subsidiary are remeasured at spot rates in effect on the balance sheet date with the effects of changes in spot rates reported in *Exchange losses (gains)*. The forward contracts are not designated as hedges and are marked to market through *Exchange losses (gains)*. Accordingly, fair value changes in the forward contracts help mitigate the changes in the value of the remeasured assets and liabilities attributable to changes in foreign currency exchange rates, except to the extent of the spot-forward differences. These differences are not significant due to the short-term nature of the contracts, which typically have average maturities at inception of less than one year. The notional amount of forward contracts was \$1.0 billion and \$1.5 billion as of September 30, 2023 and December 31, 2022, respectively. The cash flows and the related gains and losses from these contracts are reported as operating activities in the Condensed Consolidated Statements of Cash Flows.

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

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

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

(\$ in millions)	Fair Value Measurement Level	September 30, 2023	December 31, 2022
Forward contracts in <i>Other current assets</i>	2	\$ 17	\$ 6
Forward contracts in <i>Accrued and other current liabilities</i>	2	12	24

Foreign exchange risk is also managed through the use of economic hedges on foreign currency balances. See Note 11 "Long-Term Debt" for additional details. €1.983 billion in the aggregate of both the euro-denominated term loan (€733 million) and the 2.875% euro-denominated secured notes (€1.25 billion) has been designated and is effective as an economic hedge of the net investment in euro-denominated subsidiaries.

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

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Foreign currency gains in <i>Other comprehensive income</i>	\$ 79	\$ 176	\$ 21	\$ 303

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

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Foreign exchange loss (gain) in <i>Exchange losses (gains)</i>	\$ 14	\$ 4	\$ 25	\$ (21)

Organon has established accounts receivable factoring agreements with financial institutions in certain countries to sell accounts receivable. Under these agreements, Organon factored \$55 million and \$43 million of accounts receivable as of September 30, 2023 and December 31, 2022, respectively, which reduced outstanding accounts receivable. The cash received from the financial institutions is reported within operating activities in the Condensed Consolidated Statements of Cash Flows.

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

11. Long-Term Debt

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

(\$ in millions)	September 30, 2023	December 31, 2022
Term Loan B Facility:		
SOFR plus 300 bps plus SOFR adjustment ¹ term loan due 2028	\$ 2,543	\$ 2,793
EURIBOR plus 300 bps euro-denominated term loan due 2028 (€750 million)	773	787
4.125% secured notes due 2028	2,100	2,100
2.875% euro-denominated secured notes due 2028 (€1.25 billion)	1,318	1,331
5.125% notes due 2031	2,000	2,000
Other borrowings	7	7
Other (discounts and debt issuance costs)	(87)	(105)
Total principal long-term debt	\$ 8,654	\$ 8,913
Less: Current portion of long-term debt	8	8
Total Long-term debt, net of current portion	\$ 8,646	\$ 8,905

¹. The SOFR adjustment is an additional interest amount per annum of 11.448 bps for a one-month interest period, 26.161 bps for a three-month interest period, or 42.826 bps for a six-month interest period, at our option.

The nature and terms of our Senior Credit Agreement, Notes and Other borrowings are described in detail in Note 11 "Long-Term Debt and Leases" in the 2022 Annual Report on Form 10-K for the year ended December 31, 2022.

On June 30, 2023, the Company entered into Amendment No. 1 to the Senior Credit Agreement. Amendment No. 1 replaces LIBOR-based rates with Adjusted Term Secured Overnight Financing Rate ("SOFR")-based rates and updates certain other provisions of the Senior Credit Agreement to reflect the transition from LIBOR to the Adjusted Term SOFR. The impact of the rate transition was not material to the Condensed Consolidated Financial Statements.

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

(\$ in millions)	September 30, 2023	December 31, 2022
Long-term debt	\$ 7,853	\$ 8,294

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

The Company made interest payments related to its debt instruments of \$311 million for the nine months ended September 30, 2023. The average maturity of the Company's long-term debt as of September 30, 2023 is approximately 5.3 years and the weighted-average interest rate on total borrowings as of September 30, 2023 is 5.7%.

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

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

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

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

(\$ in millions)

2023	\$	2
2024		9
2025		9
2026		9
2027		9
Thereafter		8,703

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 September 30, 2023, the Company is in compliance with all financial covenants and no default or event of default has occurred.

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

12. Accumulated Other Comprehensive Income (Loss)

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

(\$ in millions)	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Loss
Balance at July 1, 2022, net of taxes	\$ (13)	\$ (576)	\$ (589)
Other comprehensive loss, pretax	—	(97)	(97)
Tax	—	—	—
Other comprehensive loss, net of taxes	—	(97)	(97)
Balance at September 30, 2022, net of taxes	\$ (13)	\$ (673)	\$ (686)
Balance at July 1, 2023, net of taxes	\$ 9	\$ (542)	\$ (533)
Other comprehensive loss, pretax	—	(43)	(43)
Tax	—	—	—
Other comprehensive loss, net of taxes	—	(43)	(43)
Balance at September 30, 2023, net of taxes	\$ 9	\$ (585)	\$ (576)
Balance at January 1, 2022, net of taxes	\$ (13)	\$ (500)	\$ (513)
Other comprehensive loss, pretax	(1)	(173)	(174)
Tax	1	—	1
Other comprehensive loss, net of taxes	—	(173)	(173)
Balance at September 30, 2022, net of taxes	\$ (13)	\$ (673)	\$ (686)
Balance at January 1, 2023, net of taxes	\$ 10	\$ (574)	\$ (564)
Other comprehensive loss, pretax	(1)	(11)	(12)
Tax	—	—	—
Other comprehensive loss, net of taxes	(1)	(11)	(12)
Balance at September 30, 2023, net of taxes	\$ 9	\$ (585)	\$ (576)

13. Samsung Collaboration

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

Samsung Bioepis is eligible for additional payments associated with pre-specified clinical and regulatory milestones. As of September 30, 2023, potential future regulatory milestone payments of \$25 million remain under the agreement.

In July 2023, the Company began selling *Hadlima*, a biosimilar referencing *Humira*¹ (adalimumab), in the United States.

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

Summarized information related to this collaboration is as follows:

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Sales	\$ 143	\$ 129	\$ 394	\$ 346
Cost of sales	98	86	272	221
Selling, general and administrative	17	18	53	60

(\$ in millions)	September 30, 2023	December 31, 2022
Receivables from Samsung included in <i>Other current assets</i>	\$ 8	\$ 21
Payables to Samsung included in <i>Trade accounts payable</i>	62	72

14. Third-Party Arrangements

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 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, Interim Operating Model Agreements ("IOM Agreements"), Manufacturing and Supply Agreements, Intellectual Property License Agreements, Regulatory Agreements 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 certain services under the TSA expired as of July 2, 2023, however, certain services have been extended to at least 35 months. Additionally, under manufacturing and supply agreements, the Company manufactures certain products for Merck, or its applicable affiliate, and Merck manufactures certain products for the Company, or its applicable affiliate. For details on the rights and responsibilities of the parties under the agreements, refer to Note 18 "Third-Party Arrangements and Related Party Disclosures" to the audited Consolidated Financial Statements in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

For the three and nine months ended September 30, 2023, material transactions occurred in connection with the IOM Agreements.

The amounts due under such agreements were:

(\$ in millions)	September 30, 2023	December 31, 2022
Due from Merck in <i>Accounts receivable</i>	\$ 467	\$ 374
Due to Merck in <i>Accounts payable</i>	601	543

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

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Sales	\$ 28	\$ 38	\$ 95	\$ 104
Cost of sales	25	31	88	91

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

15. Contingencies

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

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

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

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

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

Product Liability Litigation

Fosamax

Merck is a defendant in product liability lawsuits in the United States involving *Fosamax*® (alendronate sodium) (the "Fosamax Litigation"). As of September 30, 2023, approximately 3,130 cases comprising the Fosamax Litigation are pending against Merck in either federal or state court. Plaintiffs in the vast majority of these cases generally allege that they sustained femur fractures and/or other bone injuries ("Femur Fractures") in association with the use of *Fosamax*.

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

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

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

December 16, 2022, those plaintiffs filed their Notice of Appeal to the Third Circuit challenging the District Court's preemption ruling. 974 of the 975 cases previously pending in the Femur Fracture MDL have either been dismissed or are on appeal to the Third Circuit. Plaintiff's motion to remand one case back to its transferor court is pending.

As of September 30, 2023, approximately 1,880 cases alleging Femur Fractures have been filed in New Jersey state court and are pending in Middlesex County. The parties selected an initial group of cases to be reviewed through fact discovery, and Merck continued to select additional cases to be reviewed.

As of September 30, 2023, approximately 275 cases alleging Femur Fractures have been filed and are pending in California state court. All of the Femur Fracture cases filed in California state court have been consolidated before a single judge in Orange County, California.

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

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

Nexplanon/Implanon

Merck is a defendant in lawsuits brought by individuals relating to the use of *Nexplanon* and *Implanon*TM (etonogestrel implant). There are two filed product liability actions involving *Implanon*, both of which are pending in the Northern District of Ohio as well as 56 unfiled cases involving *Implanon* alleging similar injuries, which have been tolled under a written tolling agreement. As of September 30, 2023, Merck had 18 cases pending outside the United States, of which 12 relate to *Implanon* and six relate to *Nexplanon*.

Propecia/Proscar

As of September 30, 2023, one case involving *Proscar*[®] (finasteride) remains pending in the United States in the United States District Court for the Eastern District of California in which Merck's motion to dismiss was granted by the District Court, but the plaintiff can appeal the decision. The Company is also defending 14 product liability cases involving *Propecia*[®] (finasteride) outside the United States, two of which are class actions and three of which are putative class actions.

Governmental Proceedings

From time to time, Organon's subsidiaries may receive inquiries and may be the subject of preliminary investigation activities from competition and/or other governmental authorities, including in markets outside the United States. These authorities may include regulators, administrative authorities, and law enforcement and other similar officials, and these preliminary investigation activities may include site visits, formal or informal requests or demands for documents or materials, inquiries or interviews and similar matters. Certain of these preliminary inquiries or activities may lead to the commencement of formal proceedings. Should those proceedings be determined adversely to Organon, monetary fines and/or remedial undertakings may be required. Subject to certain exceptions specified in the Separation and Distribution Agreement, Organon assumed liability for all pending and threatened legal matters related to products transferred to Organon, including competition investigations resulting from enforcement activity concerning Merck's conduct involving Organon's products. Organon could be obligated to indemnify Merck for fines or penalties, or a portion thereof, resulting from such investigations. In one such enforcement matter in Spain concerning *NuvaRing*, in October 2022, the National Commission on Markets and Competition ("CNMC") imposed a fine on Merck in the amount of €39 million for abuse of a dominant position in the market for contraceptive vaginal rings from June 2017 to April 2018. The CNMC decision to impose the fine has been appealed to the National High Court in Spain. If the fine ultimately stands, Organon could be obligated to indemnify Merck for a portion thereof.

Hadlima

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

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)**Patent Litigation**

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

Nexplanon

In June 2017, Microspherix LLC ("Microspherix") sued Organon in the U.S. District Court for the District of New Jersey asserting that the manufacturing, use, sale and importation of Nexplanon infringed several of Microspherix's patents that claim radio-opaque, implantable drug delivery devices. Microspherix is claiming damages from September 2014 until the patents expired in May 2021. Organon brought Inter Partes Review proceedings in the United States Patent and Trademark Office ("USPTO") and successfully stayed the district court action. The USPTO invalidated some, but not all, of the claims asserted against Organon. Organon appealed the decisions that found claims valid, and the Court of Appeals for the Federal Circuit affirmed the USPTO's decisions. 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 a claim construction order issued on February 27, 2023. This case was scheduled for trial before a jury in Camden, New Jersey starting on October 16, 2023; however, on October 13, 2023, a status conference was held during which the parties informed the district court that an agreement in principle of the key terms of a settlement was reached. The proceedings were stayed for 60 days to allow time for the parties to execute a settlement agreement. Organon reserved \$80 million to cover the settlement.

Other Litigation

In addition to the matters described above, there are various other pending legal proceedings involving Organon, principally product liability and intellectual property lawsuits. While it is not feasible to predict the outcome of such proceedings, in the opinion of Organon as of September 30, 2023, either the likelihood of loss is remote or any reasonably possible loss associated with the resolution of such proceedings is not expected to be material to Organon's financial condition, results of operations or cash flows either individually or in the aggregate.

Legal Defense Reserves

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by Organon; the development of Organon's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against Organon; and the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The legal defense reserve as of September 30, 2023 and December 31, 2022 was \$23 million and \$17 million, respectively, and represented Organon's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by Organon. Organon will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

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, 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; an inability to fully execute on our product development and commercialization plans in the United States, Europe, and elsewhere internationally; an inability to adapt to the industry-wide trend toward highly discounted channels; changes in tax laws or other tax guidance which could adversely affect our cash tax liability, effective tax rates, and results of operations and lead to greater audit scrutiny; expanded brand and class competition in the markets in which Organon operates; global tensions, which may result in disruptions in the broader global economic environment; uncertainty regarding the U.S. federal budget and debt ceiling, and the impact of a potential U.S. federal government shutdown; governmental initiatives that adversely impact our marketing activities, particularly in China; volatility in Organon's stock price; political and social pressures, or regulatory developments, that adversely impact demand for, availability of, or patient access to contraception or fertility products; 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 implementing or executing on Organon's acquisition strategy or failure to recognize the benefits of such acquisitions; 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 for the year ended December 31, 2022. Operating results discussed herein are not necessarily indicative of the results of any future period.

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

Recent Developments

Business Development

Claria Medical, Inc. ("Claria")

In January 2023, the Company made a strategic investment in Claria, a privately-held company developing an investigational medical device being studied for use during minimally invasive laparoscopic hysterectomy. Under the terms of the agreement, Organon paid \$8 million upfront and has the option to acquire Claria for an additional \$47 million, payable if and when the option is exercised. The \$8 million was expensed as *Acquired in-process research and development and milestones* in our Condensed Consolidated Statement of Income for the nine months ended September 30, 2023.

COVID-19 Update

COVID-19 related disruptions, including patients' inability to access health care providers, prioritization of COVID-19 patients, as well as social distancing measures, negatively affected our results during 2022 and the first half of 2023, specifically, in China. During 2022 and to a lesser extent in the first half of 2023, our business was impacted by previous lockdowns in selective cities across China. The China economy has had a slower recovery post-COVID which has impacted the retail business.

Operating Results

Sales Overview

(\$ in millions)	Three Months Ended September 30,			% Change Excluding Foreign Exchange	Nine Months Ended September 30,			% Change Excluding Foreign Exchange
	2023	2022	% Change		2023	2022	% Change	
United States	\$ 370	\$ 366	1 %	1 %	\$ 1,067	\$ 1,043	2 %	2 %
International	1,149	1,171	(2)	(1)	3,598	3,646	(1)	2
Total	\$ 1,519	\$ 1,537	(1)%	(1)%	\$ 4,665	\$ 4,689	(1)%	2 %

Worldwide sales were \$1.5 billion for the three months ended September 30, 2023, a decrease of 1% compared with the same period in 2022. Worldwide sales were negatively impacted by approximately \$10 million, due to unfavorable foreign exchange. Excluding foreign exchange, sales decreases primarily reflect *Zetia*® (ezetimibe) (marketed in most countries outside of the United States as *Ezetrol*™) and *Vytorin*® (ezetimibe/simvastatin) (marketed outside of the United States as *Inegy*™) driven by the impact of volume-based procurement ("VBP") in China, the Fertility portfolio mainly due to the negative impact of unfavorable discount rates in the United States, *NuvaRing* due to ongoing generic competition in the United States, *Brenzys*™ (etanercept) primarily driven by the timing of tenders in Brazil and *Nexplanon* due to unfavorable discount rates in the United States and decreased volume from the tender process in Mexico. This was offset by sales increases in *Atozet*™ (ezetimibe and atorvastatin calcium) (marketed outside of the United States) due to increased demand in France, *Ontruzant* driven by increased demand and the timing of tenders in Brazil and *Renflexis* driven primarily by continued demand growth in the United States and Canada.

Worldwide sales were \$4.7 billion for the nine months ended September 30, 2023, consistent with 2022. Worldwide sales were negatively impacted by approximately 3%, or \$119 million, due to unfavorable foreign exchange. Excluding foreign exchange, sales increases primarily reflect the performance of *Atozet*, due to increased demand in France and the timing of customers' buying patterns in the Middle East, Korea and Mexico, *Renflexis* driven primarily by continued demand growth in the United States and Canada, *Arcoxia*™ (etoricoxib) (marketed outside of the United States) primarily due to customers buying patterns in various international regions and higher demand in China, *Jada* due to continued uptake in the United States following the launch in February 2022, *Dulera*® (formoterol/fumarate dihydrate) primarily due to the favorable impact from discount rates and price in the United States and *Marvelon*™ (desogestrel and ethinyl estradiol pill) and *Mercilon*™ (desogestrel and ethinyl estradiol pill), resulting from the transaction with Bayer Healthcare where Organon gained full rights in selected territories in Southeast Asia and China during 2022. This performance was offset by *Zetia* and *Vytorin* driven by the impact of VBP in China, the impact of the *Diprospan*™ (betamethasone) regulatory inspection finding at the Heist manufacturing location that impacted the manufacturing of selected injectable steroid brands (the "Market Action") and decreased sales of *Cozaar*® (losartan potassium) and *Hyzaar*® (a combination of losartan potassium and hydrochlorothiazide that is marketed in Japan as *Preminent*™), primarily due to ongoing generic competition.

The loss of exclusivity negatively impacted sales by approximately \$7 million and \$9 million during the three and nine months ended September 30, 2023, compared to the three and nine months ended September 30, 2022, based on the decrease in volume period over period, mainly impacting *NuvaRing* in the United States. VBP in China had a \$31 million and \$83 million negative impact on sales during the three and nine months ended September 30, 2023, compared to the three and nine months ended September 30, 2022. Organon expects VBP to impact the Company's established brands product portfolio for the next several quarters.

Organon's operations include a portfolio of products. Highlights of the sales of Organon's products for the three and nine months ended September 30, 2023 and 2022 are provided below. See Note 5 "Product and Geographic Information" to the Condensed Consolidated Financial Statements for further details on sales of our products.

Women's Health

(\$ in millions)	Three Months Ended September 30,		% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30,		% Change	% Change Excluding Foreign Exchange
	2023	2022			2023	2022		
<i>Nexplanon/Implanon NXT</i>	\$ 220	\$ 229	(4)%	(3)%	\$ 599	\$ 595	1 %	2 %
<i>NuvaRing</i>	37	50	(26)	(23)	117	133	(12)	(10)
<i>Marvelon/Mercilon</i>	30	31	(3)	(2)	97	85	13	17
<i>Follistim AQ</i>	54	60	(10)	(8)	179	179	—	3
<i>Ganirelix Acetate Injection</i>	25	36	(30)	(29)	88	97	(9)	(7)
<i>Jada</i>	13	5	134	134	31	12	150	150

Contraception

Worldwide sales of *Nexplanon*, a single-rod subdermal contraceptive implant, decreased 4% for the three months ended September 30, 2023, compared to 2022 due to unfavorable discount rates in the United States and decreased volume from the tender process in Mexico. Sales of *Nexplanon* increased 1% for the nine months ended September 30, 2023, compared to 2022, primarily due to price increases, the impact of the timing of tenders in various international markets and the impact of distributors' buying patterns in prior periods in the United States, offset by unfavorable discount rates in the United States.

Worldwide sales of *NuvaRing*, a vaginal contraceptive product, declined 26% and 12% for the three and nine months ended September 30, 2023, respectively, compared to 2022, due to ongoing generic competition in the United States. We expect a continued decline in *NuvaRing* sales as a result of generic competition.

Worldwide sales of *Marvelon* and *Mercilon*, combined oral hormonal daily contraceptive pills not approved or marketed in the United States but available in certain countries outside the United States, remained consistent for the three months ended September 30, 2023, compared to 2022. Sales of *Marvelon* and *Mercilon* increased 13% for the nine months ended September 30, 2023, compared to 2022, as a result of the transaction with Bayer Healthcare where Organon gained full rights in selected territories in Southeast Asia and China during 2022.

Fertility

Worldwide sales of *Follistim AQ*, a fertility treatment, declined 10% for the three months ended September 30, 2023, compared to 2022, due to the negative impact of unfavorable discount rates in the United States offset by increased demand. Sales of *Follistim AQ* remained consistent for the nine months ended September 30, 2023, compared to 2022, due to volume recovery in China related to the COVID-19 negative impact during the first half of the year, offset by the negative impact of unfavorable discount rates in the United States.

Worldwide sales of Ganirelix Acetate Injection (marketed in certain countries outside the United States as *Orgalutran*TM), a fertility treatment, declined 30% and 9% for the three and nine months ended September 30, 2023, respectively, compared to 2022, primarily due to unfavorable discount rates in the United States and the impact of distributors' buying patterns in several markets.

Other Women's Health

Worldwide sales of *Jada*, a device intended to provide control and treatment of abnormal postpartum uterine bleeding or hemorrhage when conservative management is warranted, increased 134% and 150% for the three and nine months ended September 30, 2023, respectively, compared to 2022. The sales increase in both periods is due to continued uptake in the United States following the *Jada* launch.

Biosimilars

(\$ in millions)	Three Months Ended September 30,		% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30,		% Change	% Change Excluding Foreign Exchange
	2023	2022			2023	2022		
<i>Renflexis</i>	\$ 69	\$ 60	15 %	15 %	\$ 201	\$ 166	22 %	22 %
<i>Ontruzant</i>	40	29	36	34	93	87	8	7
<i>Brenzys</i>	13	24	(43)	(41)	45	52	(13)	(8)
<i>Hadlima</i>	8	6	38	42	20	14	48	55

Renflexis is a biosimilar to *Remicade*¹ (infliximab) for the treatment of certain inflammatory diseases. Sales growth of 15% and 22% for the three and nine months ended September 30, 2023, respectively, compared to 2022, was driven primarily by continued demand growth in the United States and Canada. We have commercialization rights to *Renflexis* in countries outside Europe, Korea, China, Turkey, and Russia.

Ontruzant is a biosimilar to *Herceptin*¹ (trastuzumab) for the treatment of HER2-overexpressing breast cancer and HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. Sales in the three and nine months ended September 30, 2023, compared to 2022, increased 36% and 8%, respectively, driven by increased demand and the timing of tenders in Brazil partially offset by the competitive pressures in Europe. We have commercialization rights to *Ontruzant* in countries outside of Korea and China.

Brenzys is a biosimilar to *Enbrel*¹ (etanercept) for the treatment of certain inflammatory diseases. Sales in the three and nine months ended September 30, 2023, compared to 2022, declined 43% and 13%, respectively, primarily driven by the timing of tenders in Brazil. We have commercialization rights to *Brenzys* in countries outside of the United States, Europe, Korea, China, and Japan.

Hadlima is a biosimilar to *Humira*¹ (adalimumab) for the treatment of certain inflammatory diseases. We have commercialization rights to *Hadlima* in countries outside of the EU, Korea, China, Turkey, and Russia. *Hadlima* is currently approved in the United States, Australia, Canada, and Israel. We recorded sales of \$8 million and \$20 million during the three and nine months ended September 30, 2023, respectively, reflecting an increase from modest sales during 2022 in markets outside of the United States and the launch in the United States in July 2023.

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 September 30,		% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30,		% Change	% Change Excluding Foreign Exchange
	2023	2022			2023	2022		
<i>Zetia/Vytorin</i>	\$ 99	\$ 118	(16)%	(16)%	\$ 339	\$ 390	(13)%	(11)%
<i>Atozet</i>	126	109	16	10	397	350	14	14
<i>Cozaar/Hyzaar</i>	68	70	(2)	2	225	256	(12)	(7)

Combined global sales of *Zetia* and *Vytorin*, medicines for lowering LDL cholesterol, declined 16% and 13% for the three and nine months ended September 30, 2023, respectively, compared to 2022, primarily driven by the impact of VBP in China.

Sales of *Atozet*, a medicine for lowering LDL cholesterol, increased 16% and 14% for the three and nine months ended September 30, 2023, respectively, compared to 2022, primarily due to increased demand in France and the timing of customers' buying patterns in the Middle East, Korea, and Mexico.

Combined global sales of *Cozaar* and *Hyzaar*, medicines for the treatment of hypertension, declined 2% and 12% for the three and nine months ended September 30, 2023, respectively, compared to 2022, primarily due to ongoing generic competition.

Respiratory

(\$ in millions)	Three Months Ended September 30,		% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30,		% Change	% Change Excluding Foreign Exchange
	2023	2022			2023	2022		
<i>Singulair</i>	\$ 91	\$ 94	(4)%	— %	\$ 290	\$ 316	(8)%	(3)%
<i>Nasonex</i>	55	49	10	16	188	182	3	7
<i>Dulera</i>	49	40	24	24	144	127	13	14

Worldwide sales of *Singulair*® (montelukast sodium), a once-a-day oral medicine for the chronic treatment of asthma and for the relief of symptoms of allergic rhinitis, remained consistent during the three months ended September 30, 2023 compared to 2022. Sales of *Singulair* declined 8% during the nine months ended September 30, 2023, compared to 2022, due to increased pricing pressures in China related to renewal contracts for hospital tenders and the alleviation of our competitors' supply disruptions in Japan during 2022, which had positively impacted demand for *Singulair* in 2022.

Global sales of *Nasonex*® (mometasone), an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, increased 10% and 3% during the three and nine months ended September 30, 2023, compared to 2022, due to increased demand across several markets partially offset by a \$10 million milestone payment related to a regulatory approval received during the first quarter of 2022.

Global sales of *Dulera*, a combination medicine for the treatment of asthma, increased 24% and 13% for the three and nine months ended September 30, 2023, respectively, compared to 2022, primarily due to the favorable impact from discount rates and price in the United States.

Non-Opioid Pain, Bone and Dermatology

(\$ in millions)	Three Months Ended September 30,		% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30,		% Change	% Change Excluding Foreign Exchange
	2023	2022			2023	2022		
<i>Arcoxia</i>	\$ 64	\$ 64	— %	5 %	\$ 207	\$ 185	12 %	16 %
<i>Diprosopan</i>	31	28	10	11	58	91	(37)	(36)

Sales of *Arcoxia*, a medicine for the treatment of arthritis and pain, remained consistent during the three months ended September 30, 2023 compared to 2022. Sales of *Arcoxia* increased 12% during the nine months ended September 30, 2023, compared to 2022, primarily due to customers buying patterns in various international regions and higher demand in China.

Sales of *Diprosopan*, a corticosteroid approved for treatment of wide range of inflammatory conditions, increased 10% during the three months ended September 30, 2023 compared to 2022 as the Company replenishes supply from the Market Action. Sales of *Diprosopan* declined 37% during the nine months ended September 30, 2023, compared to 2022, due to the Market Action. In the first quarter of 2022

3, we resolved the regulatory inspection findings. The Company expects sales recovery to continue to occur over the next twelve months.

Other

(\$ in millions)	Three Months Ended September 30,		% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30,		% Change	% Change Excluding Foreign Exchange
	2023	2022			2023	2022		
<i>Proscar</i>	\$ 25	\$ 27	(6)%	(2)%	\$ 77	\$ 77	— %	6 %

Worldwide sales of *Proscar*, a medicine for the treatment of symptomatic benign prostate enlargement, for the three and nine months ended September 30, 2023 were substantially consistent with sales for the corresponding periods in 2022.

Costs, Expenses and Other

(\$ in millions)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2023	2022	% Change	2023	2022	% Change
Cost of sales	\$ 612	\$ 551	11 %	\$ 1,832	\$ 1,700	8 %
Selling, general and administrative	538	440	22	1,424	1,234	15
Research and development	137	127	8	394	329	20
Acquired in-process research and development and milestones	—	10	(100)	8	107	(93)
Restructuring costs	—	11	(100)	4	11	(64)
Interest expense	134	108	24	398	303	31
Exchange losses (gains)	14	4	*	25	(21)	*
Other expense, net	4	4	—	11	15	(27)
	\$ 1,439	\$ 1,255	15 %	\$ 4,096	\$ 3,678	11 %

* Calculation not meaningful.

Cost of Sales

Cost of sales increased 11% and 8% for the three and nine months ended September 30, 2023, respectively, compared to the same periods in 2022, primarily due to foreign exchange translation, higher employee-related costs and distribution related costs, which increased as a result of inflationary pressures, and product mix. During the nine months ended September 30, 2022, the Company recorded an impairment charge of \$9 million related to a product right for a biosimilar product.

Selling, General and Administrative

Selling, general and administrative expenses increased 22% and 15% for the three and nine months ended September 30, 2023, respectively, compared to the same period in 2022, due to higher employee-related costs, costs incurred in connection with the separation from Merck, which includes the implementation of the enterprise resource planning system, and the \$80 million charge related to the Microspherix legal matter as discussed in Note 15. "Contingencies" to the Condensed Consolidated Financial Statements.

Research and Development

Research and development expenses increased 8% and 20% for the three and nine months ended September 30, 2023, respectively, compared to the same period in 2022, primarily due to higher costs associated with the Company's recent acquisitions of clinical stage assets, increased clinical study activity and higher employee-related costs.

Acquired In-Process Research and Development and Milestones

For the nine months ended September 30, 2023, acquired in-process research and development and milestones of \$8 million related to the Claria transaction. For the three months ended September 30, 2022, acquired in-process research and development and milestones represents the upfront milestones related to the Cirle transaction. For the nine months ended September 30, 2022 acquired in-process research and development and milestones represents the upfront and development milestones related to both the Cirle and Henlius transactions.

Restructuring Costs

For the nine months ended September 30, 2023, the Company incurred \$4 million of headcount related restructuring expense as part of the restructuring activities which were initiated during 2022 to optimize its internal operations.

Interest Expense

For the three months ended September 30, 2023, interest expense increased due to increased interest rates on our term loans. For the nine months ended September 30, 2023, interest expense increased due to increased interest rates, unamortized debt fees and discounts expensed as part of the prepayment on the U.S. Dollar-denominated term loan and the impact of exchange rates.

Exchange Losses (Gains)

For the three and nine months ended September 30, 2023, the change in exchanges losses (gains) was driven by foreign currency translation losses as well as the impact of the portion of Euro-denominated debt not designated as a net investment hedge in the prior year period.

Other Expense, net

For the three and nine months ended September 30, 2023, other expense, net, remained relatively consistent with the prior year.

Taxes on Income

The effective income tax rates were 27.0% and 19.6% for the three months ended September 30, 2023 and 2022, respectively, and 16.1% and 20.0% for the nine months ended September 30, 2023 and 2022, respectively. These effective income tax rates reflect the beneficial impact of foreign earnings, offset by the impact of U.S. inclusions under the Global Intangible Low-Taxed Income regime and a partial valuation allowance recorded against non-deductible U.S. interest expense. The 2023 quarter-to-date and year-to-date effective tax rate favorable impact is primarily attributable to a reduced tax rate arrangement that was agreed to in Switzerland for an active entity.

On August 16, 2022, the United States enacted the Inflation Reduction Act of 2022. Provisions of the bill that relate to tax include the minimum tax on book income, a 1% excise tax on stock buybacks and certain tax incentives to promote clean energy. There are no impacts of the legislation to the third quarter 2023 results. The Company will continue to assess future impacts of this legislation.

Liquidity and Capital Resources

As of September 30, 2023, Organon had cash and cash equivalents of \$414 million.

Working capital was \$1.6 billion and \$1.4 billion as of September 30, 2023 and December 31, 2022, respectively. The increase in working capital was primarily driven by an increase in inventory and the timing of collection of receivables.

Net cash provided by operating activities was \$402 million for the nine months ended September 30, 2023 compared to \$591 million for the same period in the prior year. The decrease in cash provided by operating activities was primarily attributable to lower net income partially offset by the changes in working capital balances.

Net cash used in investing activities was \$179 million for the nine months ended September 30, 2023 compared to \$359 million for the same period in the prior year, primarily reflecting lower investment in business development transactions in the nine months ended September 30, 2023 compared to the same period in the prior year, partially offset by an increase in capital expenditures.

Net cash used in financing activities was \$492 million for the nine months ended September 30, 2023 compared to \$351 million for the same period in the prior year. The increase in cash used in financing activities was driven by the \$250 million voluntary prepayment on the U.S. Dollar-denominated term loan in the first quarter of 2023.

Organon will continue to monitor the impacts of the Ukraine-Russia war and the Hamas-Israel war, which may negatively impact Organon's operations, financial position, or cash flows. For the three and nine months ended September 30, 2023 and 2022, Organon's combined revenues from Ukraine, Russia and Israel were approximately 2% of total revenues. As of September 30, 2023, the Company's assets in Ukraine, Russia and Israel are not material.

Our contractual obligations as of September 30, 2023, which require material cash requirements in the future, consist of contractual milestones, purchase obligations and lease obligations. In addition, Organon is responsible for settlement of certain tax matters that the Company expects to pay during 2023. Refer to "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2022 for further details. The Company has terminated the ebopiprant license agreement and development program; as a result, the Company will not owe the previously disclosed \$25 million milestone payment or other milestone payments under the ebopiprant license agreement. As of September 30, 2023, there have been no material changes to our contractual obligations, or settlements of tax matters outside the ordinary course of business.

During the third quarter of 2023, Organon paid cash dividends of \$0.28 per share. On November 2, 2023, the Board of Directors declared a quarterly dividend of \$0.28 for each issued and outstanding share of the Company's common stock. The dividend is payable on December 14, 2023, to stockholders of record at the close of business on November 13, 2023.

The Company has historically generated and expects to continue to generate positive cash flow from operations. Our ability to fund our operations and anticipated capital needs is reliant upon the generation of cash from operations, supplemented as necessary by periodic utilization of our Revolving Credit Facility. Our principal uses of cash in the future will be primarily to fund our operations, working capital needs, capital expenditures, repayment of borrowings, payment of dividends and strategic business development transactions. We believe that our financing arrangements, future cash from operations, and access to capital markets will provide adequate resources to fund our future cash flow needs.

Critical Accounting Estimates

Our significant accounting policies, which include management's best estimates and judgments, are included in Note 3 "Summary of Accounting Policies" to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2022. See Note 2 "Basis of Presentation" to the Condensed Consolidated Financial Statements for information on the adoption of new accounting standards during 2023. There have been no changes to our accounting policies as of September 30, 2023. 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 Annual Report on Form 10-K for the year ended December 31, 2022.

Recently Issued Accounting Standards

For a discussion of recently issued accounting standards, see Note 2 "Basis of Presentation" 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 are primarily exposed to foreign exchange risk with respect to forecasted transactions and net assets denominated in the euro, Swiss franc, and Japanese yen. We established a balance sheet risk management program and a net investment hedge to mitigate against volatility of changes in foreign exchange rates. See Note 10 "Financial Instruments" 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 September 30, 2023. 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, 2022.

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 September 30, 2023. Based upon that evaluation, our CEO and our CFO concluded that, as of September 30, 2023, the end of the period covered by this report, 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.

The Company began an implementation of an enterprise resource planning ("ERP") system, which will replace the existing core financial system. The ERP system is designed to accurately maintain the Company's financial records used to report operating results. The implementation of the consolidated financial reporting module will be completed during Q4 of the 2023 fiscal year. The implementation of the general ledger modules is in progress and occurring in phases and is expected to be completed by the first half of 2024. The changes in process under the new ERP will continue to be subject to our evaluation of the operating effectiveness of internal control over financial reporting.

Except for the implementation of an ERP system, there was no change in our internal control over financial reporting that occurred during the quarter ended September 30, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control 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 15 "Contingencies" 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 Annual Report on Form 10-K for the year ended December 31, 2022 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2023.

Item 5. Other Information

During the three months ended September 30, 2023, no director or officer of the company adopted or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement, as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

Number	Description
10.1	Amendment No. 1 to Senior Secured Credit Agreement, dated as of June 30, 2023, to the Credit Agreement by and among Organon & Co., Organon Foreign Debt Co-Issuer B.V., JPMorgan Chase Bank, N.A., as Administrative Agent, Collateral Agent, and the L/C Issuers and Lenders party thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-40235) filed on July 7, 2023).
*31.1	— Certification of Principal Executive Officer (CEO) pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
*31.2	— Certification of Principal Financial Officer (CFO) pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
**32.1	— Section 1350 Certification of Principal Executive Officer (CEO) pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
**32.2	— Section 1350 Certification of Principal Financial Officer (CFO) pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
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).
	* Filed herewith
	** Furnished herewith

¹ Indicates, in this Form 10-Q for Quarter Ending September 30, 2023, brand names of products, which are trademarks not owned by the Company or its subsidiaries. *Humira* is a trademark registered in the United States in the name of AbbVie Biotechnology Ltd.; *Enbrel* is a trademark registered in the United States in the name of Immunex Corporation; *Remicade* is a trademark registered in the United States in the name of Janssen Biotech, Inc.; and *Herceptin* is a trademark registered in the United States in the name of Genentech, Inc. Brand names of products that are in all italicized letters, without the footnote, are trademarks of, or are otherwise licensed by, Organon and/or one of its subsidiaries.

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: November 3, 2023

/s/ Kathryn DiMarco

Kathryn DiMarco

Senior Vice President Finance - Corporate Controller

Date: November 3, 2023

/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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) 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
 - (d) 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.

November 3, 2023

/s/ Kevin Ali

Kevin Ali

Chief Executive Officer

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

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) 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

(d) 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.

November 3, 2023

/s/ Matthew Walsh

Matthew Walsh

Chief Financial Officer

**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 September 30, 2023 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.

November 3, 2023

/s/ Kevin Ali

Kevin Ali

Chief Executive Officer

**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 September 30, 2023 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.

November 3, 2023

/s/ Matthew Walsh

Matthew Walsh

Chief Financial Officer