

**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 June 30, 2026

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

Trading Symbol(s)

Name of each exchange on which registered

Common Stock (\$0.01 par value)

OGN

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

Indicate by check mark whether the registrant 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 July 24, 2026: 262,609,433

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The following notations in this Quarterly Report on Form 10-Q for the quarter ended June 30, 2026 (this "Form 10-Q") have the meanings as set forth below:

"1" Indicates, in this Form 10-Q, brand names of products, that are not available in the United States.

"2" Indicates, in this Form 10-Q, brand names of products that are trademarks not owned by Organon & Co. 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.; *Herceptin* and *Perjeta* are trademarks registered in the United States in the name of Genentech, Inc.; *Emgality* is a trademark registered in the United States in the name of Eli Lilly and Company (used under license); *Prolia* and *Xgeva* are trademarks registered in the U.S. in the name of Amgen Inc.; *Jada* is a trademark registered in the US in the name of Alydia Health, Inc.; and *Pyzchiva* and *Epyztek* are trademarks registered in the United States, Canada and Australia in the name of Samsung Bioepis Co., Ltd. (used under license). Brand names of products that are in all italicized letters, without the footnote, are trademarks of, or are otherwise licensed by, Organon & Co. and/or one of its subsidiaries.

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 June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Revenues	\$ 1,558	\$ 1,594	\$ 3,018	\$ 3,107
Cost of sales	711	720	1,388	1,392
Gross profit	847	874	1,630	1,715
Selling, general and administrative	434	453	858	873
Research and development	90	95	183	191
Acquired in-process research and development and milestones	1	—	1	6
Restructuring costs	—	2	31	88
Interest expense	108	131	219	255
Exchange losses (gains)	2	(1)	9	(5)
Other expense (income), net	29	(35)	(67)	(23)
Income before income taxes	183	229	396	330
Income tax expense	75	84	142	98
Net income	\$ 108	\$ 145	\$ 254	\$ 232
Earnings per share:				
Basic	\$ 0.41	\$ 0.56	\$ 0.97	\$ 0.90
Diluted	\$ 0.40	\$ 0.56	\$ 0.95	\$ 0.89
Weighted average shares outstanding:				
Basic	262,611	259,939	261,497	258,906
Diluted	270,449	260,156	266,679	260,584

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Net income	\$ 108	\$ 145	\$ 254	\$ 232
Other Comprehensive (Loss) Income, Net of Taxes:				
Benefit plan net gain and prior service credit, net of amortization	—	—	1	—
Cumulative translation adjustment	(9)	45	(22)	77
	(9)	45	(21)	77
Comprehensive income	\$ 99	\$ 190	\$ 233	\$ 309

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)

	June 30, 2026	December 31, 2025
Assets		
Current Assets:		
Cash and cash equivalents	\$ 1,132	\$ 574
Accounts receivable (net of allowance for doubtful accounts of \$13 in 2026 and \$12 in 2025)	1,492	1,331
Inventories (excludes inventories of \$273 in 2026 and \$236 in 2025 classified in Other assets)	1,351	1,406
Other current assets	1,136	1,033
Assets held for sale	—	8
Total Current Assets	5,111	4,352
Property, plant and equipment, net	1,281	1,303
Goodwill	4,153	4,153
Intangibles, net	1,112	1,130
Other assets	1,521	1,539
Noncurrent assets held for sale	—	390
Total Assets	\$ 13,178	\$ 12,867
Liabilities and Equity		
Current Liabilities:		
Current portion of long-term debt and short-term borrowings	\$ 74	\$ 16
Trade accounts payable	1,051	952
Accrued and other current liabilities	1,407	1,335
Income taxes payable	84	85
Liabilities held for sale	—	2
Total Current Liabilities	2,616	2,390
Long-term debt	8,479	8,628
Deferred income taxes	51	57
Other noncurrent liabilities	1,026	1,008
Noncurrent liabilities held for sale	—	32
Total Liabilities	12,172	12,115
Contingencies (Note 15)		
Organon & Co. Stockholders' Equity:		
Common stock, \$0.01 par value Authorized - 500,000 Issued and outstanding - 262,609 in 2026 and 260,316 in 2025	3	3
Additional paid-in capital	199	167
Retained earnings	1,352	1,109
Accumulated other comprehensive loss	(548)	(527)
Total Stockholders' Equity	1,006	752
Total Liabilities and Stockholders' Equity	\$ 13,178	\$ 12,867

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

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

	Common Stock		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive (Loss) Income	Total
	Shares	Par Value				
Balance at April 1, 2025	257,950	\$ 3	\$ 130	\$ 1,026	\$ (617)	\$ 542
Net income	—	—	—	145	—	145
Other comprehensive income, net of taxes	—	—	—	—	45	45
Cash dividends declared on common stock (\$0.02 per share)	—	—	—	(8)	—	(8)
Stock-based compensation plans and other	2,015	—	9	—	—	9
Balance at June 30, 2025	259,965	\$ 3	\$ 139	\$ 1,163	\$ (572)	\$ 733
Balance at April 1, 2026	262,649	\$ 3	\$ 186	\$ 1,253	\$ (539)	\$ 903
Net income	—	—	—	108	—	108
Other comprehensive loss, net of taxes	—	—	—	—	(9)	(9)
Cash dividends declared on common stock (\$0.02 per share)	—	—	—	(9)	—	(9)
Stock-based compensation plans and other	(40)	—	13	—	—	13
Balance at June 30, 2026	262,609	\$ 3	\$ 199	\$ 1,352	\$ (548)	\$ 1,006
Balance at January 1, 2025	257,799	\$ 3	\$ 108	\$ 1,010	\$ (649)	\$ 472
Net income	—	—	—	232	—	232
Other comprehensive income, net of taxes	—	—	—	—	77	77
Cash dividends declared on common stock (\$0.30 per share)	—	—	—	(79)	—	(79)
Stock-based compensation plans and other	2,166	—	31	—	—	31
Balance at June 30, 2025	259,965	\$ 3	\$ 139	\$ 1,163	\$ (572)	\$ 733
Balance at January 1, 2026	260,316	\$ 3	\$ 167	\$ 1,109	\$ (527)	\$ 752
Net income	—	—	—	254	—	254
Other comprehensive loss, net of taxes	—	—	—	—	(21)	(21)
Cash dividends declared on common stock (\$0.04 per share)	—	—	—	(11)	—	(11)
Stock-based compensation plans and other	2,293	—	32	—	—	32
Balance at June 30, 2026	262,609	\$ 3	\$ 199	\$ 1,352	\$ (548)	\$ 1,006

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

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

	Six Months Ended June 30,	
	2026	2025
Cash Flows from Operating Activities		
Net income	\$ 254	\$ 232
Adjustments to reconcile net income to net cash flows provided by operating activities:		
Depreciation	73	70
Amortization	93	103
Impairment of assets	—	9
Acquired in-process research and development and milestones	1	6
Accretion and changes in fair value in contingent consideration	4	23
Deferred income tax expense (benefit)	19	(7)
Stock-based compensation	44	46
Unrealized foreign exchange (gain) loss	(9)	1
Gain on sale of <i>Jada</i>	(81)	—
Gain on debt repurchase	—	(46)
Other	17	44
Net changes in assets and liabilities, net of assets acquired		
Accounts receivable	(176)	(76)
Inventories	(24)	(31)
Other current assets	(91)	(78)
Trade accounts payable	106	(109)
Accrued and other current liabilities	75	(59)
Income taxes payable	3	46
Other	24	121
Net Cash Flows Provided by Operating Activities	332	295
Cash Flows from Investing Activities		
Capital expenditures	(79)	(71)
Proceeds from sale of property, plant and equipment	—	1
Acquired in-process research and development and milestones	(10)	(10)
Proceeds from sale of <i>Jada</i>	433	—
Dermavant acquisition, net of cash acquired	—	(75)
Purchase of product rights and asset acquisition	(34)	(55)
Net Cash Flows Provided by (Used) in Investing Activities	310	(210)
Cash Flows from Financing Activities		
Proceeds from debt	—	430
Repayments of debt	(32)	(634)
Employee withholding taxes related to stock-based awards	(7)	(13)
Dividend payments	(11)	(81)
Net Cash Flows Used in Financing Activities	(50)	(298)
Effect of Exchange Rate Changes on Cash and Cash Equivalents	(34)	137
Net Increase (Decrease) in Cash and Cash Equivalents	558	(76)
Cash and Cash Equivalents, Beginning of Period	574	675
Cash and Cash Equivalents, End of Period	\$ 1,132	\$ 599

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

1. Background and Nature of Operations

Organon & Co. (“Organon” or the “Company”) is a global healthcare company with a mission to deliver impactful medicines and solutions for a healthier every day. With a portfolio of over 70 products across women’s health and general medicines, which includes biosimilars, Organon focuses on addressing health needs that uniquely, disproportionately or differently affect women, while expanding access to essential treatments in over 140 countries and territories. The Company sells these products through various channels including drug wholesalers and retailers, hospitals, government agencies and managed healthcare providers such as health maintenance organizations, pharmacy benefit managers and other institutions. The Company operates six manufacturing facilities, which are located in Belgium, Brazil, Indonesia, Mexico, the Netherlands and the United Kingdom (“UK”). Unless otherwise indicated, trademarks appearing in italics throughout this document are trademarks of, or are used under license by, the Organon group of companies.

Organon’s operations include the following product portfolios:

- *Women’s Health*: Organon’s health portfolio of products is 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 in a class recognized as one of the most effective types of hormonal contraception available to patients with a low long-term average cost. The *Jada*®² device is intended to provide control and treatment of abnormal postpartum uterine bleeding or hemorrhage when conservative management is warranted. In January 2026, the Company divested the *Jada*® System to Laborie Medical Technologies Corporation (“Laborie”).
- *General Medicines*: Organon’s general medicines portfolio includes biosimilars and established brands.
 - *Biosimilars*: Organon’s current biosimilars portfolio spans across immunology and oncology related treatments. Organon’s oncology biosimilars: *Ontruzant*® (trastuzumab-dttb), *Aybintio*™¹ (bevacizumab), *Bildyos*® (denosumab-nxxp) and *Bilprevda*® (denosumab-nxxp) have been launched in more than 20 countries. Organon’s immunology biosimilars consist of: *Brenzys*™¹ (etanercept), *Renflexis*® (infliximab-abda), *Hadlima*® (adalimumab-bwwd) and *Tofidence*® (tocilizumab-bavi). *Brenzys*, *Renflexis*, and *Hadlima* have been launched in five countries. In 2025, Organon launched *Bildyos* injection 60 mg/mL and *Bilprevda* injection 120 mg/1.7 mL, biosimilars to *Prolia*² (denosumab) and *Xgeva*² (denosumab), respectively, in the United States. In 2025, *Poherdy*® (pertuzumab-dpzb) was approved by the U.S. Food and Drug Administration (“FDA”), and the Company is assessing the future commercial launch of this product.
 - *Established Brands*: Organon has a portfolio of established brands, which includes brands in cardiovascular, respiratory, dermatology and non-opioid pain management, including *Emgality*®² (galcanezumab-gnlm) and *Vtama*® (tapinarof) cream 1%. Many brands in the established brands portfolio lost exclusivity years ago and have faced generic competition for some time.

On April 26, 2026, the Company entered into a definitive agreement with Sun Pharmaceutical Industries Limited (“Sun Pharma”) under which Sun Pharma will acquire all of the Company’s outstanding shares of common stock for \$14.00 per share in cash. Completion of the transaction is subject to customary closing conditions, including receipt of required regulatory approvals and approval by the Company’s stockholders. On July 23, 2026, the Company received stockholder approval at its special meeting of stockholders. The transaction is expected to close in early 2027.

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 for 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, 2025.

Use of Estimates

The presentation of these Condensed Consolidated Financial Statements and accompanying notes in conformity with 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, 2025. Accordingly, actual results could differ materially from management's estimates and assumptions.

Recently Issued Accounting Standards Not Yet Adopted

In October 2025, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2025-07, *Derivatives and Hedging (Topic 815) and Revenue from Contracts with Customers (Topic 606): Derivatives Scope Refinements and Scope Clarification for Share-Based Noncash Consideration from a Customer in a Revenue Contract*. Among other things, the ASU adds the scope exception from derivative accounting for contracts that are not exchange-traded and have features based on operations or activities specific to one of the parties involved, reducing complexity and diversity in practice. The amendments in this ASU are effective for annual periods beginning on January 1, 2027, and should be applied on a prospective basis, with the option to apply the amendments on a modified retrospective basis; early adoption is permitted. The Company is currently assessing the impact of this ASU on its consolidated financial statements and related disclosures.

In September 2025, the FASB issued ASU No. 2025-06, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software*. The amendments modernize the accounting for internal-use software to better reflect contemporary development practices, such as agile and iterative methodologies. Key changes include revised cost capitalization thresholds, enhanced guidance for assessing development uncertainty, and new disclosure requirements intended to improve transparency and consistency across entities. The amendments in this ASU are effective for annual periods beginning on January 1, 2028 and interim reporting periods within those periods, and may be applied either prospectively, retrospectively or on a modified retrospective basis; early adoption is permitted. The Company is currently assessing the impact of this ASU on its consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures*. Additionally, in January 2025, the FASB issued ASU 2025-01 to clarify the effective date of ASU 2024-03. The standard requires entities to disaggregate operating expenses into specific categories to provide enhanced transparency into the nature and function of expenses. This guidance is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. This guidance should be applied either prospectively to financial statements issued for reporting periods after the effective date or retrospectively to any or all prior periods presented in the consolidated financial statements. This ASU will have no impact on the Company's consolidated financial condition or results of operations. The Company is currently evaluating the effects of this guidance on its related disclosures.

3. Acquisitions and Licensing Arrangements

Shanghai Henlius Biotech, Inc. ("Henlius")

In the first quarter of 2026, in anticipation of the expected launch of HLX-11 in the United States, the Company entered into an agreement with Henlius that amended the terms of the existing license agreement to modify the previous commercial milestone payments. Under the amended agreement, the Company will make payments of \$17 million total, with \$10 million payable in December 2026, and \$7 million, payable in February 2028. The Company capitalized the \$17 million as an intangible asset.

In April 2026, the European Commission granted marketing authorization for *Poherdy*® (pertuzumab) 420 mg/14 mL injection for intravenous use, the first and only approved biosimilar to *Perjeta*® (pertuzumab) in Europe, for all indications of the product. As a result, sales-based milestones related to the Henlius agreement were determined to be probable of being achieved and the Company recognized intangible assets of \$10 million related to these milestones.

Sebela Pharmaceuticals ("Sebela")

On February 19, 2026, Organon entered into an exclusive license agreement with Sebela for the global rights to *Miudella*®, a hormone-free copper intrauterine device ("IUD") that was approved by the FDA on February 24, 2025. Under the terms of the agreement, Organon paid \$27.5 million in June 2026, with potential sales-based milestone payments of up to \$505 million, and tiered double-digit royalties based on net sales. In the second quarter of 2026, the Company recognized an intangible asset of \$27.5 million. The intangible assets will be amortized over 8 years.

Laborie Medical Technologies Corporation (“Laborie”)

In January 2026, the Company divested the *Jada* System to Laborie for an aggregate payment of up to \$465 million, comprised of consideration of \$440 million, subject to certain customary closing adjustments, including inventory value, plus potential contingent consideration payments of up to \$25 million based on the achievement of certain 2026 net sales targets. Approximately 100 Company employees transferred to Laborie as part of this transaction.

Upon the closing of the divestiture, the Company recognized a net gain on the sale of the *Jada* System of \$81 million recognized in *Other expense (income), net* in the Condensed Consolidated Statement of Income for the six months ended June 30, 2026.

As part of the divestiture of the *Jada* System in January 2026, the Company is eligible to receive potential contingent consideration of up to \$25 million based on the achievement of certain net sales targets for the *Jada* System during 2026. This contingent consideration is recorded as a financial asset at fair value. The fair value of the contingent consideration was estimated using the projected future net sales of the *Jada* System and the probability of various achievement scenarios for the sales targets. See Note 11. “Financial Instruments” for further information.

In connection with the *Jada* divestiture, certain related assets and liabilities met the criteria for held for sale classification as of December 31, 2025. The disposal group is measured at the lower of carrying amount or fair value less cost to sell. No impairment was recognized.

Details of assets and liabilities held for sale as of December 31, 2025 are as follows:

Inventory	\$	8
Assets held for sale	\$	8
Goodwill	\$	226
Intangible assets, net		164
Noncurrent assets held for sale	\$	390
Accrued and other current liabilities	\$	2
Liabilities held for sale	\$	2
Deferred taxes	\$	32
Noncurrent liabilities held for sale	\$	32

Oss Biotech Site

In July 2025, Organon acquired the Oss Biotech manufacturing facility in the Netherlands from Merck & Co., Inc., Rahway, NJ, U.S. (“Merck”). This agreement covers Organon’s fertility drug substance production and associated support functions. Organon paid aggregate consideration of \$25 million for the facility, of which \$15 million was paid in July 2025, with the remainder paid during the second quarter of 2026. In addition to the purchase of the facility, the Company also paid \$71 million for the purchase of the remaining inventory at the site.

4. Earnings per Share (“EPS”)

The calculations of basic and diluted EPS are as follows:

(\$ in millions and shares in thousands, except per share amounts)	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Net income	\$ 108	\$ 145	\$ 254	\$ 232
Basic weighted average number of shares outstanding	262,611	259,939	261,497	258,906
Stock awards and equity units (share equivalent)	7,838	217	5,182	1,678
Diluted weighted average common shares outstanding	270,449	260,156	266,679	260,584
EPS:				
Basic	\$ 0.41	\$ 0.56	\$ 0.97	\$ 0.90
Diluted	\$ 0.40	\$ 0.56	\$ 0.95	\$ 0.89
Anti-dilutive shares excluded from the calculation of EPS	9,337	18,568	9,029	17,761

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

5. Product and Geographic Information

Revenues of the Company's products were as follows:

(\$ in millions)	Three Months Ended June 30,						Six Months Ended June 30,					
	2026			2025			2026			2025		
	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>	\$ 129	\$ 101	\$ 230	\$ 163	\$ 77	\$ 240	\$ 256	\$ 175	\$ 431	\$ 339	\$ 148	\$ 488
<i>Follistim AQ</i>	17	43	59	30	43	74	38	82	120	65	77	142
<i>NuvaRing</i>	9	18	27	7	21	28	14	37	51	13	37	50
<i>Ganirelix Acetate Injection</i>	2	24	26	3	25	27	4	48	52	7	47	54
<i>Marvelon/Mercilon</i>	—	32	32	—	33	33	—	58	58	—	72	72
<i>Jada</i> ⁽³⁾	—	—	—	18	—	18	5	—	5	33	—	33
Other Women's Health ⁽¹⁾	15	29	45	14	27	42	33	58	90	30	57	86
General Medicines												
<u>Biosimilars</u>												
<i>Renflexis</i>	44	21	65	46	17	63	87	36	122	90	30	120
<i>Hadlima</i>	55	24	79	36	14	50	106	40	146	69	27	96
<i>Ontruzant</i>	5	1	6	5	26	31	9	2	11	8	41	49
<i>Brenzys</i>	—	14	14	—	22	22	—	34	34	—	36	36
<i>Bildyos/Bilprevda</i>	14	5	19	—	—	—	20	15	35	—	—	—
Other Biosimilars ⁽¹⁾	10	2	12	3	4	7	15	5	20	3	10	13
<u>Established Brands</u>												
Cardiovascular												
<i>Atozet</i>	—	80	80	—	86	86	—	165	165	—	162	162
<i>Zetia</i>	2	95	96	1	72	74	3	181	183	3	156	159
<i>Cozaar/Hyzaar</i>	2	48	50	2	54	56	5	103	107	4	107	111
<i>Vytarin</i>	1	20	21	1	26	27	2	40	42	2	48	50
<i>Rosuzet</i>	—	5	5	—	6	6	—	11	11	—	10	10
Other Cardiovascular ⁽¹⁾	1	23	25	1	33	34	1	50	53	1	64	65
Respiratory												
<i>Singulair</i>	2	46	48	2	64	66	4	84	88	4	136	140
<i>Nasonex</i>	—	58	58	—	66	66	—	123	123	—	137	137
<i>Dulera</i>	30	11	41	32	9	41	53	23	76	66	19	84
<i>Clarinox</i>	1	30	30	1	33	34	2	60	61	1	67	68
Other Respiratory ⁽¹⁾	16	1	18	11	3	14	27	3	30	21	6	27
Non-Opioid Pain, Bone and Dermatology												
<i>Arcoxia</i>	—	69	69	—	63	63	—	128	128	—	124	124
<i>Fosamax</i>	1	24	25	—	34	34	1	53	54	2	65	67
<i>Diprosan</i>	—	44	44	—	41	41	—	79	79	—	71	71
<i>Vtama</i>	34	1	35	29	2	31	57	3	60	49	6	54
Other Non-Opioid Pain, Bone and Dermatology ⁽¹⁾	4	75	79	4	76	80	7	140	147	7	143	151
Other												
<i>Propecia</i>	2	34	36	1	30	32	3	62	65	3	55	58
<i>Emgality</i>	—	54	54	—	42	42	—	108	108	—	74	74
<i>Proscar</i>	—	20	20	—	22	22	—	46	46	—	46	46
Other ⁽¹⁾	2	94	96	3	85	87	4	178	184	5	159	164
Other ⁽²⁾	—	14	14	1	24	23	—	32	33	1	44	46
Revenues	\$ 398	\$ 1,160	\$ 1,558	\$ 414	\$ 1,180	\$ 1,594	\$ 756	\$ 2,262	\$ 3,018	\$ 826	\$ 2,281	\$ 3,107

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 unless otherwise indicated.

(1) Includes sales of products not listed separately.

(2) Includes manufacturing sales to third parties.

(3) **Jada** is a trademark registered in the US in the name of Alydia Health, Inc.

Notes to Condensed Consolidated Financial Statements (unaudited)

Revenues by geographic area where derived are as follows:

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Europe and Canada	\$ 432	\$ 419	\$ 845	\$ 795
United States	398	414	756	826
Asia Pacific and Japan	232	250	457	502
China	208	204	402	409
Latin America, Middle East, Russia, and Africa	269	285	516	524
Other ⁽¹⁾	19	22	42	51
Revenues	\$ 1,558	\$ 1,594	\$ 3,018	\$ 3,107

(1) Includes manufacturing sales to third parties.

6. Stock-Based Compensation Plans

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

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

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Stock-based compensation expense recognized in:				
Cost of sales	\$ 4	\$ 4	\$ 7	\$ 8
Selling, general and administrative	16	14	29	30
Research and development	5	4	8	8
Total	\$ 25	\$ 22	\$ 44	\$ 46
Income tax benefits	\$ 5	\$ 5	\$ 9	\$ 10

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

	Six Months Ended June 30, 2025
Expected dividend yield	7.41 %
Risk-free interest rate	4.08
Expected volatility	40.25
Expected life (years) ⁽¹⁾	5.89

⁽¹⁾The expected term was estimated using the historical option-exercise and settlement patterns, supplemented by a midpoint-based assumption applied to awards meeting a one-year post-grant eligibility filter.

Notes to Condensed Consolidated Financial Statements (unaudited)

A summary of the equity award transactions for the six months ended June 30, 2026 is as follows:

	Stock Options			RSUs		PSUs	
	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, 2026	7,519	\$ 27.30	\$ 6.99	9,716	\$ 15.35	589	\$ 23.61
Granted/Issued	—	—	—	13,585	6.02	2,128	8.27
Vested/Exercised	—	—	—	(3,497)	17.81	(193)	23.20
Forfeited/Cancelled	(2,299)	30.78	8.11	(1,053)	9.68	(140)	23.20
Outstanding as of June 30, 2026	5,220	\$ 25.76	\$ 6.50	18,751	\$ 8.45	2,384	\$ 9.98

The following table summarizes information about equity awards outstanding that are vested and expected to vest and equity awards outstanding that are exercisable as of June 30, 2026:

	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	5,126	\$ 25.76	\$ —	6.23	3,949	\$ 29.00	\$ —	5.49
RSUs	17,065		254	2.19				
PSUs	2,328		36	2.22				

The amount of unrecognized compensation costs as of June 30, 2026 was \$162 million, which will be recognized in operating expense ratably over the weighted average vesting period of 2.16 years.

7. Restructuring

During the first quarter of 2026, the Company implemented restructuring initiatives that will result in an approximate 3% headcount reduction, to streamline and optimize the Company's research and development and manufacturing operations, focusing on enhancing efficiency and aligning resources with strategic priorities. The *Restructuring costs* primarily consist of employee termination benefits and other associated expenses.

During the first quarter of 2025, the Company implemented restructuring initiatives to drive an enterprise-wide operating model optimization that resulted in an approximate 6% headcount reduction. The restructuring activities were initiated to streamline and simplify the Company's operating model to create more efficient processes and a simplified structure. *Restructuring costs* include separation costs associated with manufacturing-related headcount reductions.

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

	June 30, 2026	December 31, 2025
Beginning balance	\$ 8	\$ 14
Severance & severance related costs	31	95
Cash payments and other	(23)	(101)
Ending balance	\$ 16	\$ 8

Organon expects the remaining severance payments associated with the restructuring activities to be paid within the next twelve months.

8. Taxes on Income

The effective income tax rates were 41.3% and 37.0% for the three months ended June 30, 2026 and 2025, respectively, and 36.0% and 29.8% for the six months ended June 30, 2026 and 2025, 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 valuation allowance recorded against non-deductible U.S. interest expense. Also included in the six month tax rate is the beneficial impact of the sale of the *Jada* System. There was a favorable impact to the 2025 year-to-date effective tax rate driven by a tax amortization benefit.

On July 4, 2025, U.S. House Resolution 1, referred to as the One Big Beautiful Bill Act (“OBBBA”), was signed into law. The OBBBA includes significant corporate tax provisions such as modifications to interest deductibility, the option to fully expense U.S.-based R&D costs, and changes to the taxation of foreign earnings. For 2026 and beyond, the impacts of the OBBBA are reflected in the Company’s U.S. cash tax liability and income tax provision primarily reflected as an increase in the Company’s interest expense limitation offset by a decrease in the Company’s foreign income inclusions.

9. Inventories

Inventories consisted of:

(\$ in millions)	June 30, 2026	December 31, 2025
Finished goods	\$ 686	\$ 751
Raw materials	12	14
Work in process	845	791
Supplies	78	81
Total (approximates current cost)	\$ 1,621	\$ 1,637
Increase (Decrease) to last in, first out (“LIFO”) costs	3	5
	\$ 1,624	\$ 1,642
Recognized as:		
Inventories	\$ 1,351	\$ 1,406
Other assets	273	236
Inventories valued under the LIFO method	155	114

In connection with the *Jada* divestiture in January 2026, \$8 million of inventory was reclassified to *Assets held for sale* on the Consolidated Balance Sheet as of December 31, 2025.

As part of the Dermavant acquisition in 2024, the Company acquired \$97 million of inventory, which included a \$63 million purchase accounting inventory fair value adjustment. As of June 30, 2026, the amount has been fully expensed. As of December 31, 2025, there was \$7 million remaining in inventory related to the fair value adjustment.

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

Notes to Condensed Consolidated Financial Statements (unaudited)

10. Long-Term Debt and Short-Term Borrowings

Long-term debt and short-term borrowings consist of the following:

(\$ in millions)	June 30, 2026	December 31, 2025
Senior Credit Agreement		
Term Loan B Facility:		
SOFR plus 225 bps term loan due 2031	\$ 1,522	\$ 1,543
EURIBOR plus 275 bps euro-denominated term loan due 2031 (€707 million in 2026 and €717 million in 2025)	806	843
4.125% secured notes due 2028	2,100	2,100
2.875% euro-denominated secured notes due 2028 (€1.25 billion)	1,425	1,470
5.125% notes due 2031	1,582	1,582
6.750% secured notes due 2034	500	500
7.875% notes due 2034	500	500
Revenue Interest Purchase and Sale Agreement ⁽¹⁾	182	179
Other borrowings	8	8
Other (discounts and debt issuance costs)	(72)	(81)
Total principal long-term debt and short-term borrowings	\$ 8,553	\$ 8,644
Less: Current portion of long-term debt and short-term borrowings	74	16
Total Long-term debt, net of current portion	\$ 8,479	\$ 8,628

(1) Recognized at the amortized cost basis. The remaining principal is determined as the initial fair value less principal payments. As of June 30, 2026, the remaining principal of the revenue interest purchase and sale agreement (the "RIPSA") that the Company assumed in connection with its 2024 acquisition of Dermavant is \$156 million.

The nature and terms of Organon's long-term debt are described in detail in Note 12. "Long-Term Debt and Leases" in the Company's Annual Report on Form 10-K for the year ended December 31, 2025.

On February 6, 2026, the Company made mandatory prepayments from the proceeds of the *Jada* System divestiture of \$20.4 million on the U.S. Dollar Term Loans and €9.6 million on the Euro Term Loan Facility. Additional mandatory prepayments totaling \$55 million are required across the Company's senior secured notes within 450 days of the January 2026 closing of the *Jada* System divestiture.

For the six months ended June 30, 2026, the Company had no borrowings or repayments on the Company's Revolving Credit Facility (the "Revolving Credit Facility"). There were no outstanding balances under the Revolving Credit Facility as of June 30, 2026 or December 31, 2025.

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

(\$ in millions)	Fair Value Measurement Level	June 30, 2026	December 31, 2025
Long-term debt	2	\$ 8,438	\$ 7,922
Long-term debt - RIPSA	3	134	136

Level 2 was estimated using inputs other than quoted prices in active markets for identical assets and liabilities that are observable either directly or indirectly for substantially the full term of the liability. Level 3 was estimated using unobservable inputs.

The Company made interest payments related to its debt instruments of \$209 million for the six months ended June 30, 2026. The average maturity of the Company's long-term debt as of June 30, 2026 is approximately 4.1 years and the weighted-average interest rate on total borrowings as of June 30, 2026 is 4.9%.

Notes to Condensed Consolidated Financial Statements (unaudited)

The schedule of principal payments required on long-term debt and short-term borrowings for the next five years, exclusive of \$26 million of accrued interest related to the RIPSAs, and thereafter are as follows:

(\$ in millions)

2026	\$	1
2027		61
2028		3,486
2029		9
2030		21
Thereafter		5,021

The Senior Credit Agreement contains customary financial covenants, including a total leverage ratio covenant, which measures the ratio of (i) consolidated total debt to (ii) consolidated earnings before interest, taxes, depreciation and amortization, and subject to other adjustments, that must meet certain defined limits which are tested on a quarterly basis. In addition, the Senior Credit Agreement contains covenants that limit, among other things, Organon's ability to prepay, redeem or repurchase its subordinated and junior lien debt, incur additional debt, make acquisitions, merge with other entities, pay dividends or distributions, redeem, or repurchase equity interests, and create or become subject to liens. As of June 30, 2026, the Company is in compliance with all financial covenants, and no default or event of default has occurred.

11. Financial Instruments

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

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

(\$ in millions)	Fair Value Measurement Level	June 30, 2026	December 31, 2025
Other current assets:			
Forward contracts	2	\$ 16	\$ 12
Contingent consideration ^(a)	3	9	—
Accrued and other current liabilities:			
Forward contracts	2	18	11
Other noncurrent liabilities:			
Contingent consideration	3	273	269
Cross-currency swap	2	58	82

(a) As part of the divestiture of the **Jada** System in January 2026, the Company is eligible to receive potential contingent consideration based on the achievement of certain net sales targets for the **Jada** System during 2026. See Note 3. "Acquisitions and Licensing Arrangements" for further information.

Foreign Currency Risk Management

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

Forward Contracts

Monetary assets and liabilities denominated in a currency other than the functional currency of a given subsidiary are remeasured at spot rates in effect on the balance sheet date with the effects of changes in spot rates reported in *Exchange losses (gains)* in the Condensed Consolidated Statements of Income. The forward contracts are not designated as hedges and are marked to market through *Exchange losses (gains)* in the Condensed Consolidated Statements of Income. Accordingly, fair value changes in the forward contracts help mitigate the changes in the value of the remeasured assets and liabilities attributable to changes in foreign currency exchange rates, except to the extent of the spot-forward differences. These differences are not significant due to the short-term nature of the contracts, which typically have average maturities at inception of less than one year. The notional amount of forward contracts was \$1.6 billion and \$1.7 billion as of June 30, 2026 and December 31, 2025, 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.

Net Investment Hedge

Euro-denominated debt instruments

Foreign exchange risk is also managed through the use of economic hedges on foreign currency balances. €707 million of the euro-denominated term loan and €1.25 billion of the 2.875% euro-denominated secured notes have been designated and are effective as a hedge of the net investment in euro-denominated subsidiaries. See Note 10 “Long-Term Debt and Short-Term Borrowings” for additional details.

Cross-currency swaps

The Company entered into cross-currency swaps that mature in 2029. The Company elected to designate the fixed-for-fixed swaps as a hedge of the net investment in euro-denominated subsidiaries balance and the change in the fair value attributable to the changes in the spot rate is recorded in *Other Comprehensive Income (Loss), Net of Taxes*. Throughout the term of the swaps, the Company will pay a fixed interest rate of 5.8330% based on the Euro notional amount of €922 million and receive a fixed interest rate of 7.3125% based on the U.S. dollar notional amount of \$1 billion. The notional amount based on the Euro leg of the cross-currency swaps has been designated and is effective as a hedge of the net investment in euro-denominated subsidiaries. The difference between the interest rate received and paid under the cross-currency swap agreements is recorded in *Interest expense* in the Condensed Consolidated Statements of Income. The cash flows and the related gains and losses from the periodic settlements of the cross-currency swaps are reported as *Operating Activities* in the Condensed Consolidated Statements of Cash Flows.

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

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Euro-denominated debt instruments gain (loss)	\$ 22	\$ (179)	\$ 71	\$ (249)
Cross-currency swaps (loss) gain	(3)	(104)	24	(129)

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

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Derivative loss (gain) in <i>Exchange losses (gains)</i>	\$ 13	\$ (17)	\$ 25	\$ (19)
Derivative gain in <i>Interest expense</i>	(3)	(1)	(5)	(5)

Contingent Consideration

The fair value measurement of contingent consideration arising from business combinations is determined via probability-weighted cash flows using a Monte Carlo simulation model, which are then discounted to present value. These inputs may include: (i) the estimated amount and timing of projected cash flows, (ii) the probability of the achievement of the factor(s) on which the contingency is based and (iii) the risk-adjusted discount rate used to present value the probability-weighted cash flows. Significant increases or decreases in any of those inputs in isolation could result in a significantly higher or lower fair value measurement. At June 30, 2026, the fair value measurements of acquisition-related contingent consideration were determined using discount rates ranging from 5.91% to 7.15%.

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

<i>(\$ in millions)</i>	June 30, 2026
Beginning balance	\$ 269
Accretion and changes in fair value in <i>Other expense (income), net</i>	4
Ending balance	\$ 273

In the first quarter of 2026, the Company identified an approximate \$12 million error related to the fair value remeasurement of tax-related contingent consideration, including expected net operating loss utilization. An adjustment was recorded to increase *Other (income) expense, net* during the first quarter of 2026 and relates to amounts that should have been reflected in the fourth quarter of 2025. The contingent consideration liability is appropriately stated as of June 30, 2026. The error was determined not to be material to the current or previously issued financial statements.

Concentrations of Credit Risk

Organon has established accounts receivable factoring agreements with financial institutions in certain countries to sell accounts receivable. Under these agreements, Organon factored \$216 million and \$217 million of accounts receivable as of June 30, 2026 and December 31, 2025, 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. The cost of factoring such accounts receivable was not material for the six months ended June 30, 2026 and 2025.

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 Income (Loss)
Balance at April 1, 2025, net of taxes	\$ (17)	\$ (600)	\$ (617)
Other comprehensive income, pretax	—	45	45
Tax	—	—	—
Other comprehensive income, net of taxes	—	45	45
Balance at June 30, 2025, net of taxes	\$ (17)	\$ (555)	\$ (572)
Balance at April 1, 2026, net of taxes	\$ 5	\$ (544)	\$ (539)
Other comprehensive loss, pretax	—	(9)	(9)
Tax	—	—	—
Other comprehensive loss, net of taxes	—	(9)	(9)
Balance at June 30, 2026, net of taxes	\$ 5	\$ (553)	\$ (548)
Balance at January 1, 2025, net of taxes	\$ (17)	\$ (632)	\$ (649)
Other comprehensive income, pretax	—	77	77
Tax	—	—	—
Other comprehensive income, net of taxes	—	77	77
Balance at June 30, 2025, net of taxes	\$ (17)	\$ (555)	\$ (572)
Balance at January 1, 2026, net of taxes	\$ 4	\$ (531)	\$ (527)
Other comprehensive income (loss), pretax	1	(22)	(21)
Tax	—	—	—
Other comprehensive income (loss), net of taxes	1	(22)	(21)
Balance at June 30, 2026, net of taxes	\$ 5	\$ (553)	\$ (548)

13. Samsung Collaboration

The Company is party to a Development and Commercialization Agreement (the “Samsung 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.

On May 22, 2026, the Samsung Agreement was amended to include commercialization rights for *Pyzchiva*®² (ustekinumab biosimilar) in Canada. Samsung Bioepis retains full development, manufacturing, and regulatory responsibilities (“Amendment No. 8”).

On May 26, 2026, the Samsung Agreement was amended to extend commercialization rights for certain biosimilar products, including *Renflexis* and *Brenzys*, in specified markets for up to seven years beyond the original contract term (“Amendment No. 9”).

In connection with Amendment No. 9, the Company is required to make fixed payments totaling \$30 million over a nine-year period from 2026 through 2034. The Company recorded an intangible asset and corresponding liability of \$20.8 million, the present value of the future payments. The intangible asset will be amortized over nine years.

The liability is accreted to its contractual value over time using the effective interest method, with accretion recognized within *Interest expense* to reflect the nature of the underlying arrangement.

Notes to Condensed Consolidated Financial Statements (unaudited)

Amendment No. 9 also includes the return of commercialization rights to Samsung for certain oncology biosimilars, including *Ontruzant* and *Aybintio*, in specified ex-U.S. markets such as Europe, Canada, and Brazil. These returns of rights are subject to defined, phased transition and cutover periods extending from 2026 through 2029, during which the Company may continue to commercialize products and fulfill contractual obligations.

On June 2, 2026, the Samsung Agreement was amended to include commercialization rights for *Epyztek*®² in Australia. Samsung Bioepis retains full development, manufacturing, and regulatory responsibilities (“Amendment No. 10”).

Under the broader 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).

Summarized information related to this collaboration is as follows:

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Sales	\$ 166	\$ 170	\$ 318	\$ 311
Cost of sales	100	102	191	192
Selling, general and administrative	18	20	36	38

(\$ in millions)	June 30, 2026	December 31, 2025
Payables to Samsung included in <i>Trade accounts payable</i>	161	94

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. As of June 30, 2026, only one jurisdiction remains under an Interim Operating Model Agreement.

Under the 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 17 “Third-Party Arrangements” to the audited Consolidated Financial Statements in the Company’s Annual Report on Form 10-K for the year ended December 31, 2025.

The amounts due under such agreements were:

(\$ in millions)	June 30, 2026	December 31, 2025
Due from Merck in <i>Accounts receivable</i>	\$ 143	\$ 98
Due to Merck in <i>Accounts payable</i>	374	337

Notes to Condensed Consolidated Financial Statements (unaudited)

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

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Sales	\$ 13	\$ 19	\$ 26	\$ 37
Cost of sales	10	16	21	32

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) which 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 available coverage and, as such, has no insurance for most product liabilities.

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

Product Liability Litigation

Fosamax

Merck is a defendant in product liability lawsuits in the United States involving *Fosamax*® (alendronate sodium) (the "Fosamax Litigation"). As of June 30, 2026, the Fosamax Litigation comprises approximately 498 cases in Federal court, approximately 1,478 cases in New Jersey state court, one case in Pennsylvania state court and approximately 149 cases in California state court. Plaintiffs in the vast majority of these cases generally allege that they sustained femur fractures and/or other bone injuries ("Femur Fractures") associated with the use of *Fosamax*.

All federal cases alleging femur fractures have been transferred to a multidistrict litigation in the U.S. District Court for the District of New Jersey (the "Femur Fracture MDL") where the only bellwether case tried to date, *Glynn v. Merck*, resulted in a verdict in Merck's favor. Although many cases were previously dismissed on federal preemption grounds, subsequent appellate rulings — including a September 2024 Third Circuit decision and the U.S. Supreme Court's June 2025 denial of certiorari — resulted in those cases being reinstated and proceeding before the court.

In New Jersey state court, the cases have been consolidated before a single judge in Middlesex County. On July 28, 2025, the Company entered into a Master Settlement Agreement with the New Jersey state and federal plaintiffs' lawyers who represent eligible clients ("NJ MSA Attorneys"), pursuant to which, in exchange for a confidential, but non-material settlement payment, at least 95% of the NJ MSA Attorneys' eligible clients will release the Company and Merck from any liability related to their filed claims.

In California state court, the cases have been consolidated before a single judge in Orange County, California. In the only bellwether case tried to date in California, *Galper v. Merck*, the jury returned a verdict in Merck's favor. On February 18, 2026, the Company entered into a Master Settlement Agreement with the California plaintiffs' lawyers and claimants pursuant to which, in exchange for a confidential, non-material settlement payment, at least 95% of the claimants will release the Company and Merck from any liability related to their claims.

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, all of which have been tolled under a written tolling agreement. There is one matter involving *Nexplanon* pending in California state court. On March 12, 2026, the Company signed a Master Settlement Agreement with the attorneys representing plaintiffs and all but two of the claimants with unfiled cases, pursuant to which, in exchange for a confidential, but non-material settlement payment, 56 plaintiffs and claimants will release the defendant parties from any liability for their filed and unfiled claims. As of June 30, 2026, Merck had 19 of such cases pending outside the United States, of which seven relate to *Implanon* and twelve relate to *Nexplanon*.

Securities and Stockholder Derivative Litigation

On May 27, 2025, a stockholder filed a lawsuit against the Company and certain of its officers on behalf of a putative class of stockholders who acquired Company shares between October 31, 2024 and April 30, 2025. A separate stockholder suit was filed on July 8, 2025 on behalf of a putative class of stockholders who acquired Company shares between November 3, 2022 and April 30, 2025. Both actions allege that the defendants made materially false and misleading statements regarding the Company's capital allocation strategy, including through the use of quarterly dividends, and its debt reduction strategy.

The court consolidated the securities class actions on March 6, 2026 and appointed Teamsters Local 710 Pension Fund (the "Lead Plaintiff") as the lead plaintiff. On May 8, 2026, the Lead Plaintiff filed an amended complaint that contained allegations similar to those raised in the complaints filed in the original, individual actions. The amended complaint also raised allegations relating to the *Nexplanon* matter (defined below). The amended complaint seeks unspecified monetary damages. On May 29, 2026, the Lead Plaintiff informed the defendants that it intended to file a second amended complaint and on June 17, 2026, the court entered an order setting the Company's time to answer, move or otherwise respond as 60 days from the later of the date on which the court denies the Lead Plaintiff's motion to file a second amended complaint or the date on which the Lead Plaintiff files a second amended complaint.

The same alleged misconduct also forms the basis of two stockholder derivative lawsuits filed against the Company, and certain of its officers and directors asserting breach of fiduciary duties arising from purportedly materially false and misleading statements. On July 7, 2025, the court consolidated each of the stockholder derivative lawsuits. Subsequently, on September 8, 2025, the court stayed the proceedings pending the final resolution of all motions to dismiss filed in the securities lawsuits.

All of the foregoing actions were filed in the U.S. District Court for the District of New Jersey and seek unspecified monetary damages and other relief.

Governmental Proceedings

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

On October 26, 2025, Organon made a voluntary self-disclosure to the U.S. Securities and Exchange Commission (the "SEC") to advise it of an investigation conducted by the Audit Committee of the Company's Board of Directors (the "Audit Committee") regarding the Company's *Nexplanon* sales to certain wholesalers in the United States (the "Nexplanon Matter").

The SEC subsequently opened an investigation into the Nexplanon Matter, and the Company intends to cooperate with any inquiries from the SEC or any other regulatory authorities. The Company cannot guarantee that it (or its directors or officers) will not be subject to future inquiries, investigations, claims, actions, or proceedings relating to the Nexplanon Matter, nor can it predict the outcome of any of the foregoing; however, regardless of outcome, any inquiries, investigations, claims, actions, or proceedings relating to the Nexplanon Matter would likely consume a significant amount of Company resources and result in considerable legal and other costs.

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

On February 24, 2025, Organon received a Paragraph IV Certification Letter notifying the Company that Xiromed Pharma Espana, S.L. ("Xiromed") filed an abbreviated new drug application ("ANDA") to the FDA seeking approval to market a generic version of *Nexplanon* in the United States prior to the expiration of U.S. Patent Nos. 8,722,037 (the "'037 patent") and 9,757,552 (the "'552 patent"), in 2027 and 2030, respectively. On April 2, 2025, the Company sued Xiromed in the U.S. District Court for the District of New Jersey asserting that the filing of the ANDA infringed the '037 patent and '552 patent and triggering a stay of regulatory approval of Xiromed's ANDA for up to 30 months.

Vtama

On July 22, 2026, Organon received a Paragraph IV Certification Letter under the Hatch-Waxman Act notifying the Company that Encube Ethical Private Limited (Encube) has filed an abbreviated new drug application to the FDA seeking approval to market a generic version of *Vtama*. Encube's notice letter included a Paragraph IV certification with respect to twelve patents listed in the Orange Book for *Vtama*, expiring between 2036 and 2039. On July 23, 2026, Organon received a Paragraph IV Certification Letter under the Hatch-Waxman Act notifying the Company that Mylan Pharmaceuticals, Inc. (Mylan) has filed an abbreviated new drug application to the FDA seeking approval to market a generic version of *Vtama*. Mylan's notice letter included a Paragraph IV certification with respect to nine patents listed in the Orange Book for *Vtama*, expiring between 2036 and 2039. On July 27, 2026, Organon received a Paragraph IV Certification Letter under the Hatch-Waxman Act notifying the Company that Natco Pharma Limited (Natco) has filed an abbreviated new drug application to the FDA seeking approval to market a generic version of *Vtama*. Natco's notice letter included a Paragraph IV certification with respect to nine patents listed in the Orange Book for *Vtama*, expiring between 2036 and 2039. Organon is reviewing the details of the Paragraph IV Certification Letters and intends to defend and enforce its intellectual property rights protecting *Vtama*.

Other Matters

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 June 30, 2026, either the likelihood of loss is remote or any reasonably possible loss associated with the resolution of such proceedings is not expected to be material to Organon's financial condition, results of operations or cash flows either individually or in the aggregate.

Legal Defense Reserves

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by Organon; the development of Organon's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against Organon; and the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The legal defense reserve as of June 30, 2026 and December 31, 2025 was \$8 million and \$10 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, other events that could arise in the course of pending litigation, or the filing of new matters, 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 above, 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,” “potential,” “possible,” “probable,” “outcome,” “likely,” “could,” “should,” “estimate,” “anticipate,” “plan,” “intend,” “would,” “future,” “target,” “seek,” “continue,” and other words of similar meaning, or negative variations of any of the foregoing. 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, uncertainties as to the timing of the proposed transaction with Sun Pharmaceutical Industries Limited (together with its subsidiaries and/or associated companies, “Sun Pharma”); the risk that the proposed transaction may not be completed on the anticipated terms in a timely manner or at all; the possibility that competing offers or acquisition proposals for Organon will be made; the possibility that any or all of the remaining conditions to the consummation of the proposed transaction may not be satisfied or waived, including the failure to receive any required regulatory approvals from any applicable governmental entities (or any conditions, limitations or restrictions placed on such approvals); the occurrence of any event, change or other circumstance that could give rise to the termination of the definitive agreement, including in circumstances that would require us to pay a termination fee; the effect of the pendency of the proposed transaction on our ability to retain and hire key personnel, our ability to maintain relationships with our customers, suppliers and others with whom we do business, or our operating results and business generally; risks related to diverting management’s attention from our ongoing business operations; the risk that stockholder litigation in connection with the proposed transaction may result in significant costs of defense, indemnification and liability; certain restrictions during the pendency of the proposed transaction that may impact our ability to pursue certain business opportunities or strategic transactions; the risk that any announcements relating to the proposed transaction could have adverse effects on the market price of our common stock, including if the proposed transaction is not consummated; risks that the benefits of the proposed transaction are not realized when and as expected; expanded brand and class competition in the markets in which we operate; trade protection measures and import or export licensing requirements, including the direct and indirect impacts of tariffs (including pharmaceutical sector tariffs), trade sanctions or similar restrictions by the United States or other governments; changes in U.S. and foreign federal, state and local governmental funding allocations including the timing and amounts allocated to our customers and business partners; the impact of global business, political and macroeconomic conditions, including inflation, interest rate fluctuations, recessionary pressures, foreign currency exchange rates, volatile market conditions, and instability in the global banking system; global events, such as regional conflicts in the Middle East and elsewhere; our ability to access the public securities and other capital and credit markets in accordance with our financial plans, the cost of such capital, and overall condition of the capital and credit markets; actions that may be taken by credit rating agencies that could negatively affect either our access to or terms of financing or our financial condition and liquidity; our ability to meet our revenue and growth expectations and outlook; our ability to retain members of our senior management and other key employees; the failure of any supplier to provide substances, materials, or services as agreed, or otherwise meet their obligations to us; the increased cost of supply, manufacturing, packaging, and operations; difficulties developing and sustaining relationships with commercial counterparties; competition from generic products as our products lose patent protection; any failure by us to retain market exclusivity for *Nexplanon* or to obtain an additional period of exclusivity in the United States for *Nexplanon* subsequent to the expiration of the rod patents in 2027; the success of our efforts to adapt our business and sales strategies to address the changing market and regulatory landscape in order to achieve our business objectives and remain competitive; restructurings or other disruptions at the U.S. Food and Drug Administration (“FDA”), the SEC and other U.S. and comparable foreign government agencies; difficulties in connection with future strategic transactions, including as a result of the impact of macroeconomic or geopolitical developments; pricing pressures globally, including rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to or affecting Medicare, Medicaid and healthcare reform, pharmaceutical pricing and reimbursement, access to our products, international reference pricing, including Most-Favored-Nation drug pricing, and other pricing-related initiatives and policy efforts; the impact of higher selling and promotional costs; changes in government laws and regulations in the United States and other jurisdictions, including laws and regulations governing the research, development, approval, clearance, manufacturing, supply, distribution, and/or marketing of our products and related intellectual property, environmental regulations, and the enforcement thereof affecting our business; efficacy, safety or other quality concerns with respect to our marketed products, whether or not scientifically justified, leading to product recalls, withdrawals, labeling changes, or declining sales; delays or failures to demonstrate adequate efficacy and safety of our product candidates in pre-clinical and clinical trials, which may prevent or delay the development, approval, clearance, or commercialization of our product candidates; reduced research and development investment and increased reliance on fewer research and development programs for new products to generate future revenue and replace existing products that come to the end of their market life cycle; future actions of third-parties, including significant changes in customer relationships or changes in the behavior and spending patterns of purchasers of healthcare products and services, including delaying medical procedures, rationing prescription medications, reducing the

frequency of physician visits and forgoing healthcare insurance coverage; legal factors, such as product liability claims, stockholder litigation, governmental investigations, and patent disputes; lost market opportunity resulting from delays and uncertainties in clinical trials and the approval or clearance process of the FDA and other regulatory authorities; the failure by us or our third party collaborators and/or their suppliers to fulfill our or their regulatory or quality obligations, which could lead to a delay in regulatory approval or commercial marketing of our products; cyberattacks on, or other failures, accidents, or security breaches of, our or third-party providers' information technology systems, which could disrupt our operations and those of third parties upon which we rely; increased focus on privacy issues in countries around the world, including the United States, the European Union, and China, and a more difficult legislative and regulatory landscape for privacy and data protection that continues to evolve with the potential to directly affect our business, including recently enacted laws in a majority of states in the United States requiring security breach notification; changes in tax laws including changes related to the taxation of foreign earnings; the impact of any future pandemic, epidemic, or similar public health threat on our business, operations and financial performance; changes in accounting pronouncements promulgated by standard-setting or regulatory bodies, including the Financial Accounting Standards Board and the SEC, that are adverse to us; volatility of commodity prices, fuel, and shipping rates that impact the costs and/or ability to supply our products; and other factors discussed in our most recently filed Annual Report on Form 10-K, Quarterly Report on Form 10-Q, and subsequent filings, including those discussed in the "Business," "Risk Factors," "Cautionary Statement Regarding Forward-Looking Statements" 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 the reader in understanding our financial condition and results of operations. The following discussion and analysis should be read in conjunction with our 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, 2025. Operating results discussed herein are not necessarily indicative of the results of any future period.

We are a global healthcare company with a primary focus on improving the health of women throughout their lives. We develop and deliver innovative health solutions through a portfolio of prescription therapies within our women's health and general medicines portfolios. We have a portfolio of more than 70 medicines and products across a range of therapeutic areas. We sell these products through various channels including drug wholesalers and retailers, hospitals, government agencies and managed healthcare providers such as health maintenance organizations, pharmacy benefit managers and other institutions. We own and operate six manufacturing facilities, which are located in Belgium, Brazil, Indonesia, Mexico, the Netherlands and the United Kingdom. Unless otherwise indicated, trademarks appearing in italics throughout this document are trademarks of, or are used under license by, our group of companies.

Recent Developments

Sun Pharma Transaction

On April 26, 2026, we entered into a definitive agreement with Sun Pharma under which Sun Pharma will acquire all of our outstanding shares of common stock for \$14.00 per share in cash. Completion of the transaction is subject to customary closing conditions, including receipt of required regulatory approvals and approval by the Company's stockholders. On July 23, 2026, the Company received stockholder approval at its special meeting of stockholders. The Company and Sun Pharma are continuing to work to satisfy the other conditions to closing. The transaction is expected to close in early 2027.

Business Development

Samsung Collaboration

On May 22, 2026, the Samsung Agreement was amended to include commercialization rights for *Pyzchiva* (ustekinumab biosimilar) in Canada. Samsung Bioepis retains full development, manufacturing, and regulatory responsibilities ("Amendment No. 8"). *Pyzchiva* is expected to launch in Canada in the second half of 2026.

On May 26, 2026, the Samsung Agreement was amended to extend commercialization rights for certain biosimilar products, including *Renflexis* and *Brenzys*, in specified markets for up to seven years beyond the original contract term ("Amendment No. 9").

In connection with Amendment No. 9, the Company is required to make fixed payments totaling \$30 million over a nine-year period from 2026 through 2034. The Company recorded an intangible asset and corresponding liability of \$20.8 million, the present value of the future payments. The intangible asset will be amortized over nine years.

The liability is accreted to its contractual value over time using the effective interest method, with accretion recognized within *Interest expense* to reflect the nature of the underlying arrangement.

Amendment No. 9 also includes the return of commercialization rights to Samsung for certain oncology biosimilars, including *Ontruzant* and *Aybintio*, in specified ex-U.S. markets such as Europe, Canada, and Brazil. These returns of rights are subject to defined, phased transition and cutover periods extending from 2026 through 2029, during which the Company may continue to commercialize products and fulfill contractual obligations.

On June 2, 2026, the Samsung Agreement was amended to include commercialization rights for *Epyztek* in Australia. Samsung Bioepis retains full development, manufacturing, and regulatory responsibilities ("Amendment No. 10"). *Epyztek* is expected to launch in Australia in the second half of 2026.

Sebela Pharmaceuticals ("Sebela")

On February 19, 2026, we entered into an exclusive license agreement with Sebela for the global rights to *Miudella*®, a hormone-free copper intrauterine device ("IUD") that was approved by the FDA on February 24, 2025 and is estimated to launch commercial sales in the United States in late 2026. Under the terms of the agreement, we paid \$27.5 million in June 2026, with potential sales-based milestone payments of up to \$505 million, and tiered double-digit royalties based on net sales. In the second quarter of 2026, the Company recognized an intangible asset of \$27.5 million.

Laborie Medical Technologies Corporation ("Laborie")

In January 2026, we divested the *Jada* System to Laborie for an aggregate payment of up to \$465 million, comprised of consideration of \$440 million, subject to certain closing adjustments, plus potential contingent consideration payments of up to \$25 million based on the achievement of certain 2026 net sales targets. Approximately 100 Company employees transferred to Laborie as part of this transaction.

Upon the closing of the divestiture, we recognized a net gain on the sale of the *Jada* System of \$81 million recognized in *Other expense (income), net* in the Condensed Consolidated Statement of Income for the six months ended June 30, 2026.

Operating Results

Sales Overview

(\$ in millions)	Three Months Ended June 30,		% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30,		% Change	% Change Excluding Foreign Exchange
	2026	2025			2026	2025		
United States	\$ 398	\$ 414	(4)%	(4)%	\$ 756	\$ 826	(8)%	(8)%
International	1,160	1,180	(2)	(5)	2,262	2,281	(1)	(6)
Total	\$ 1,558	\$ 1,594	(2)%	(5)%	\$ 3,018	\$ 3,107	(3)%	(7)%

Worldwide sales were \$1.6 billion for the three months ended June 30, 2026, a decrease of 2%, compared to 2025. Worldwide sales were positively impacted by approximately \$42 million or 3%, due to favorable foreign exchange rates.

Excluding the impact of foreign exchange rates, sales decreases for the three months ended June 30, 2026 primarily reflect the lower sales of:

- *Ontruzant*, due to lower tendered volume from Brazil's Ministry of Health when compared with the same period in 2025;
- *Singulair*® (montelukast sodium), primarily attributable to decreased demand due to less favorable medical guidelines in certain international markets, most recently in China, as well as temporary supply constraints in Japan and mandatory price reductions in China and Japan; and
- *Jada*, due to no longer having sales following the sale of the Jada System to Laborie in January 2026.

This performance was offset by sales increases for the three months ended June 30, 2026 in:

- *Hadlima*, due to stronger demand in the United States and Puerto Rico;
- *Zetia*® (ezetimibe)/*Vytorin*® (ezetimibe / simvastatin), primarily driven by increased demand in China; and
- *Emgality*, as a result of increased demand in various international markets.

Worldwide sales were \$3.0 billion for the six months ended June 30, 2026, a decrease of 3%, compared to 2025. Worldwide sales during the six months ended June 30, 2026 were positively impacted by approximately \$118 million, or approximately 4%, due to favorable foreign exchange rates.

Excluding the impact of foreign exchange rates, sales decreases for the six months ended June 30, 2026, primarily reflect lower sales of:

- *Nexplanon*, primarily due to decreased physician demand in the United States following the five-year label approval as reinsertions have been delayed and there has been uncertainty around federal funding;
- *Singulair*, primarily attributable to decreased demand due to less favorable medical guidelines in certain international markets, most recently in China, as well as temporary supply constraints in Japan and mandatory price reductions in China and Japan;
- *Ontruzant*, due to lower tendered volume from Brazil's Ministry of Health when compared with the same period in 2025; and
- *Jada*, due to no longer having sales following the sale of the Jada System to Laborie in January 2026.

This performance was offset by sales increases for the six months ended June 30, 2026 in:

- *Hadlima*, due to stronger demand in the United States and Puerto Rico;
- *Emgality*, as a result of increased demand in various international markets; and
- *Zetia*/V*vytorin*, primarily driven by increased demand in China.

Loss of exclusivity ("LOE") negatively impacted sales of certain of our products by approximately \$6 million and \$10 million during the three and six months ended June 30, 2026, respectively, based on the decrease in sales volume of those products compared to 2025. Volume-based procurement ("VBP") in China negatively impacted sales by approximately \$5 million and \$7 million during the three and six months ended June 30, 2026, respectively. We expect VBP to continue to negatively impact our general medicines product portfolio for the next several quarters.

Due to changing market conditions, including ongoing regional conflicts in the Middle East and elsewhere, new and evolving U.S. and international tariffs, U.S. tax law changes and regulatory uncertainty that impact our business, as well as the pharmaceutical industry, we have been and will continue to adapt our business and sales strategies to address this changing

landscape in order to achieve our business objectives and remain competitive. Such strategies may include implementing or continuing to assess product discount programs and wholesaler inventory levels under the relevant agreements or waivers of their terms for certain key products.

Highlights of the sales of our products for the three and six months ended June 30, 2026 and 2025 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 June 30,		% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30,		% Change	% Change Excluding Foreign Exchange
	2026	2025			2026	2025		
<i>Nexplanon/Implanon NXT</i>	\$ 230	\$ 240	(4)%	(6)%	\$ 431	\$ 488	(12)%	(14)%
<i>NuvaRing</i>	27	28	(4)	(8)	51	50	2	(5)
<i>Marvelon/Mercilon</i>	32	33	(4)	(5)	58	72	(20)	(22)
<i>Follistim AQ</i>	59	74	(19)	(21)	120	142	(16)	(18)
<i>Jada</i>	—	18	(100)	(100)	5	33	(84)	(84)

Contraception

Worldwide sales of *Nexplanon*, a single-rod subdermal contraceptive implant, declined 4% and 12% for the three and six months ended June 30, 2026, compared to 2025, respectively, primarily due to decreased physician demand in the United States following the five-year label approval as reinsertions have been delayed and there has been uncertainty around federal funding. We estimate that expanding use from the new label will begin to favorably offset the reinsertion headwind beginning in the second half of 2026. In 2025, we submitted a similar application for a five-year duration period of use to the EU and UK Health Authorities. The application for five-year duration was approved for the UK in April, 2026. The EU application is currently under review, with potential approval in 2027, subject to health authority review and approval. Outside of the U.S., sales were positively impacted by increased demand and access in Brazil, which we expect to continue for the remainder of 2026.

Worldwide sales of *NuvaRing*, a vaginal contraceptive product, declined 4% for the three months ended June 30, 2026, compared to 2025, due to decreased demand in various international markets, partially offset by lower discount rates in the United States. Sales of *NuvaRing*, increased 2% for the six months ended June 30, 2026, compared to 2025, due to the favorable impact of foreign exchange and lower discount rates in the United States, offset by decreased demand in various international markets.

Worldwide sales of *Marvelon*TM (desogestrel and ethinyl estradiol pill) and *Mercilon*TM (desogestrel and ethinyl estradiol pill), combined oral hormonal daily contraceptive pills not approved or marketed in the United States, but available in certain countries outside the United States, declined 4% and 20% for the three and six months ended June 30, 2026, compared to 2025, respectively, as a result of decreased demand and market contraction in China and the timing of shipments in Asia Pacific. In the second quarter of 2026, we received regulatory approval in Japan for *Mercilon* Combination Tablets, a low-dose estrogen-progestin (LEP) product for the treatment of dysmenorrhea.

Fertility

Worldwide sales of *Follistim AQ*, a fertility treatment, declined 19% and 16% for the three and six months ended June 30, 2026, compared to 2025, respectively, as a result of competitive-driven price reduction in the United States. We expect sales to continue to decline compared to 2025 for the remainder of the year, reflecting the material price decrease implemented in February 2025. We anticipate that year-over-year comparisons will stabilize once a full year has elapsed following the price reduction, assuming no additional structural price decreases occur in the interim.

Other Women’s Health

In January 2026, we completed the sale of the *Jada* System to Laborie and, thereafter, we were no longer actively selling the *Jada* System. As a result, worldwide sales of *Jada*, a device intended to provide control and treatment of abnormal postpartum uterine bleeding or hemorrhage when conservative management is warranted, significantly declined for the three and six months ended June 30, 2026, compared to 2025, respectively.

General Medicines

Biosimilars

(\$ in millions)	Three Months Ended June 30,			% Change Excluding Foreign Exchange	Six Months Ended June 30,			% Change Excluding Foreign Exchange
	2026	2025	% Change		2026	2025	% Change	
<i>Renflexis</i>	\$ 65	\$ 63	4 %	3 %	\$ 122	\$ 120	2 %	1 %
<i>Hadlima</i>	79	50	59	58	146	96	51	51
<i>Ontruzant</i>	6	31	(81)	(81)	11	49	(77)	(77)
<i>Brenzys</i>	14	22	(34)	(37)	34	36	(5)	(10)
<i>Bildyos/Bilprevda</i>	19	—	*	*	35	—	*	*

* Calculation not meaningful.

Renflexis is a biosimilar to *Remicade*² (infliximab) for the treatment of certain autoimmune conditions. Sales increased 4% and 2% for the three and six months ended June 30, 2026, compared to 2025, respectively, primarily due to increased demand in Canada, partially offset by competitive pressure and unfavorable discount rates in the United States.

Hadlima is a biosimilar to *Humira*² (adalimumab) for the treatment of certain autoimmune and autoinflammatory conditions. Sales increased 59% and 51% for the three and six months ended June 30, 2026, compared to 2025, respectively, due to stronger demand in the United States and Puerto Rico. We have commercialization rights to *Hadlima* in countries outside of the European Union, South Korea, China, Turkey, and Russia. *Hadlima* is currently approved in the United States, Australia, Canada, and Israel.

Ontruzant is a biosimilar to *Herceptin*² (trastuzumab) for the treatment of HER2-overexpressing breast cancer and HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. Sales for the three and six months ended June 30, 2026, compared to 2025, declined 81% and 77%, respectively, due to lower tendered volume from Brazil's Ministry of Health when compared with the same period in 2025. We have commercialization rights to *Ontruzant* in all countries except in South Korea and China.

Brenzys is a biosimilar to *Enbrel*² (etanercept) for the treatment of certain inflammatory diseases. Sales for the three and six months ended June 30, 2026, compared to 2025, declined 34% and 5%, respectively, as a result of the timing of shipments in Brazil. We have commercialization rights to *Brenzys* in countries outside of the United States, Europe, South Korea, China, and Japan.

Bildyos injection 60 mg/mL and *Bilprevda* injection 120 mg/1.7 mL, are biosimilars to *Prolia* and *Xgeva*, respectively, for all indications of the reference products. Sales were \$19 million and \$35 million for the three and six months ended June 30, 2026, respectively, as a result of the product launch in the third quarter of 2025.

Established Brands

Cardiovascular

(\$ in millions)	Three Months Ended June 30,		% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30,		% Change	% Change Excluding Foreign Exchange
	2026	2025			2026	2025		
<i>Atozet</i>	\$ 80	\$ 86	(7)%	(9)%	\$ 165	\$ 162	1 %	(2)%
<i>Zetia/Vytorin</i>	118	101	16	12	226	209	8	3
<i>Cozaar/Hyzaar</i>	50	56	(10)	(13)	107	111	(3)	(7)

Sales of *Atozet*TM (ezetimibe and atorvastatin), a medicine for lowering LDL cholesterol, decreased 7% for the three months ended June 30, 2026 compared to 2025, due to unfavorable pricing in Europe, partially offset by increased demand in Korea. Sales of *Atozet* increased 1% for the six months ended June 30, 2026, compared to 2025, primarily due to favorable foreign exchange, increased demand in China, due to the product launch in 2025, in Asia Pacific and Korea as well as volume uptake in certain countries in Europe, partially offset by unfavorable pricing in Europe.

Combined global sales of *Zetia*, which is marketed as *Ezetrol*TM in most countries outside the United States; and of *Vytorin*, which is marketed as *Inegy*TM outside the United States, which are medicines for lowering LDL cholesterol, increased 16% and 8% for the three and six months ended June 30, 2026, compared to 2025, respectively, primarily driven by increased demand in China.

Combined global sales of *Cozaar*[®] (losartan) and *Hyzaar*[®] (losartan / hydrochlorothiazide), which are medicines for the treatment of hypertension, declined 10% and 3% for the three and six months ended June 30, 2026, compared to 2025, respectively, driven by decreased demand in various international markets.

Respiratory

(\$ in millions)	Three Months Ended June 30,		% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30,		% Change	% Change Excluding Foreign Exchange
	2026	2025			2026	2025		
<i>Singulair</i>	\$ 48	\$ 66	(27)%	(27)%	\$ 88	\$ 140	(37)%	(39)%
<i>Nasonex</i>	58	66	(12)	(16)	123	137	(10)	(17)
<i>Dulera</i>	41	41	1	—	76	84	(10)	(11)

Worldwide sales of *Singulair*, a once-a-day oral medicine for the chronic treatment of asthma and for the relief of symptoms of allergic rhinitis, declined 27% and 37% for the three and six months ended June 30, 2026, compared to 2025, respectively. This decline during these periods was primarily attributable to decreased demand due to less favorable medical guidelines in certain international markets, most recently in China, as well as temporary supply constraints in Japan and mandatory price reductions in China and Japan.

Global sales of *Nasonex*[®] (mometasone furoate), an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, declined 12% and 10% for the three and six months ended June 30, 2026, compared to 2025, respectively, due to competitive pressure in various international markets.

Global sales of *Dulera*[®] (formoterol/fumarate dihydrate), which is also marketed as *Zenhale*TM in certain markets outside of the United States, a combination medicine for the treatment of asthma, increased 1% for the three months ended June 30, 2026, compared to 2025, primarily due to the favorable impact of foreign exchange, offset by decreased demand in the United States. Global sales of *Dulera* declined 10% for the six months ended June 30, 2026, compared to 2025, primarily due to decreased demand in the United States.

Non-Opioid Pain, Bone and Dermatology

(\$ in millions)	Three Months Ended June 30,		% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30,		% Change	% Change Excluding Foreign Exchange
	2026	2025			2026	2025		
<i>Arcoxia</i>	\$ 69	\$ 63	11 %	6 %	\$ 128	\$ 124	3 %	(4)%
<i>Vtama</i>	35	31	15	15	60	54	11 %	11 %

Sales of *Arcoxia*^{TM 1} (etoricoxib), a medicine for the treatment of arthritis and pain, increased 11% and 3% for the three and six months ended June 30, 2026, compared to 2025, due to increased demand in China and the phasing of shipments in various international regions.

Sales of *Vtama*, a cream for the topical treatment of mild, moderate, and severe plaque psoriasis in adults and atopic dermatitis, also known as eczema, in adults and children two years of age and older, increased 15% and 11% for the three and six months ended June 30, 2026, compared to 2025, respectively, due to increased demand and favorable discount rates in the United States, partially offset by lower demand in Japan. We anticipate launching *Vtama* in certain international markets in 2026 and beyond, subject to health authority reviews and approvals.

Other

(\$ in millions)	Three Months Ended June 30,		% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30,		% Change	% Change Excluding Foreign Exchange
	2026	2025			2026	2025		
<i>Emgality</i>	\$ 54	\$ 42	27%	20	\$ 108	\$ 74	45 %	33 %

Sales of *Emgality*, a medicine for the preventive treatment of migraine, increased 27% and 45% for the three and six months ended June 30, 2026, compared to 2025, respectively, as a result of increased demand in various international markets.

Gross Profit, Expenses and Other

(\$ in millions)	Three Months Ended June 30,			Six Months Ended June 30,		
	2026	2025	% Change	2026	2025	% Change
Cost of sales	\$ 711	\$ 720	(1)%	\$ 1,388	\$ 1,392	— %
Gross profit	847	874	(3)	1,630	1,715	(5)
Selling, general and administrative	434	453	(4)	858	873	(2)
Research and development	90	95	(5)	183	191	(4)
Acquired in-process research and development and milestones	1	—	*	1	6	(83)
Restructuring costs	—	2	(100)	31	88	(65)
Interest expense	108	131	(18)	219	255	(14)
Exchange losses (gains)	2	(1)	*	9	(5)	*
Other expense (income), net	29	(35)	*	(67)	(23)	*

* Calculation not meaningful.

Cost of Sales

Cost of sales decreased 1% and less than 1% for the three and six months ended June 30, 2026, compared to 2025, respectively, driven by our product mix and the impact of unfavorable foreign exchange. Cost of sales for the three and six months ended June 30, 2026 includes amortization associated with the inventory fair value adjustment related to the Dermavant acquisition of \$0 and \$7 million, respectively, and amortization of intangible assets of \$46 million and \$93 million, respectively. Cost of sales for the three and six months ended June 30, 2025, includes amortization associated with the inventory fair value adjustment related to the Dermavant acquisition of \$10 million and \$19 million, respectively, an impairment charge related to a currently marketed women's health product of \$9 million and amortization of intangible assets of \$53 million and \$103 million, respectively.

Gross Profit update

Gross profit decreased 3% and 5% for the three and six months ended June 30, 2026, compared to 2025, respectively, due to the impact of unfavorable volume, pricing and product mix and unfavorable foreign exchange.

Selling, General and Administrative

Selling, general and administrative expenses decreased 4% and 2% for the three and six months ended June 30, 2026, compared to 2025, respectively, due to reduced headcount-related costs and lower spending as part of our cost-saving and restructuring initiatives.

Research and Development

Research and development expenses decreased 5% for each of the three and six months ended June 30, 2026, compared to 2025, primarily due to reduced headcount-related costs related to our restructuring initiatives and a decrease in clinical study activity. During 2025, we discontinued the clinical development programs for investigational candidates OG-6219 and OG-7191.

Acquired In-Process Research and Development and Milestones

For the six months ended June 30, 2025, we recognized \$6 million in acquired in-process research and development and milestones, related to the exit of our agreement with Suzhou Centergene Pharmaceuticals, due to the evolving fertility landscape in China.

Restructuring Costs

For the six months ended June 30, 2026, we incurred restructuring costs of \$31 million related to our 2026 restructuring initiatives to streamline and optimize our research and development and manufacturing operations, focusing on enhancing efficiency and aligning resources with strategic priorities. For the six months ended June 30, 2025, we incurred restructuring costs of \$88 million, comprised primarily of headcount-related restructuring expense associated with restructuring initiatives that were aimed at driving operational efficiencies in 2025.

Interest Expense

Interest expense decreased 18% and 14% for the three and six months ended June 30, 2026, compared to 2025, respectively, due to the repurchase and cancellation of approximately \$419 million of the Company's 5.125% notes due in 2031 (the "2031 Notes") during the second and fourth quarters of 2025, mandatory prepayments to our term loans in the first quarter of 2026 and lower reference rates on our USD-denominated variable rate debt.

Exchange Losses (Gains)

Exchange losses (gains) were unfavorable for the three and six months ended June 30, 2026, compared to 2025, respectively primarily due to unfavorable movements in certain foreign currencies relative to the U.S. dollar.

Other Expense (Income), net

Other expense (income), net was impacted for the three months ended June 30, 2026, by \$17 million due to an unfavorable resolution of a working capital matter related to the Dermavant acquisition and \$9 million related to the fair value adjustments and accretion of the Dermavant acquisition contingent consideration, related to changes in the timing of expected commercial milestones based on updated sales forecasts. Other expense (income), net was impacted for the six months ended June 30, 2026, by an \$81 million net gain related to the divestiture of the Jada System to Laborie in the first quarter of 2026, \$17 million due to an unfavorable resolution of a working capital matter related to the Dermavant acquisition and \$4 million related to the fair value adjustments and accretion of the Dermavant acquisition contingent consideration, related to changes in the timing of expected commercial milestones based on updated sales forecasts.

Taxes on Income

The effective income tax rates were 36.0% and 29.8% for the six months ended June 30, 2026 and 2025, 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 valuation allowance recorded against non-deductible U.S. interest expense. Also included in the six month tax rate is the beneficial impact of the sale of the Jada System. There was a favorable impact to the 2025 year-to-date effective tax rate driven by a tax amortization benefit.

On July 4, 2025, U.S. House Resolution 1, referred to as the One Big Beautiful Bill Act ("OBBBA"), was signed into law. The OBBBA includes significant corporate tax provisions such as modifications to interest deductibility, the option to fully expense U.S.-based R&D costs, and changes to the taxation of foreign earnings. For 2026 and beyond, the impacts of the OBBBA are reflected in our U.S. cash tax liability and income tax provision primarily reflected as an increase in our interest expense limitation offset by a decrease in our foreign income inclusions.

Liquidity and Capital Resources

As of June 30, 2026, we had cash and cash equivalents of \$1.13 billion. We have historically generated and expect to continue to generate positive cash flow from operations. Our ability to fund our operations and anticipated capital needs is reliant upon the generation of cash from operations, supplemented as necessary by periodic utilization of our revolving credit facility. Our principal uses of cash in the future will be primarily to fund our operations, working capital needs, capital expenditures, repayment of borrowings, strategic business development transactions and the payment of dividends. 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. Our ability to raise new capital or refinance our debt, will depend on the capital markets and our financial condition at such times.

Working capital is defined as current assets less current liabilities and was \$2.50 billion and \$1.96 billion as of June 30, 2026 and December 31, 2025, respectively. Working capital was positively impacted by our active cash cycle management, which includes the factoring of receivables and timing of vendor payments and the proceeds from the divestiture of the *Jada* System.

We have accounts receivable factoring agreements with financial institutions in certain countries. Under these agreements, we have factored \$216 million and \$217 million of our accounts receivable as of June 30, 2026 and December 31, 2025, respectively. See Note 11 “Financial Instruments” to the Condensed Consolidated Financial Statements for information on our accounts receivable factoring and related agreements.

Net cash provided by operating activities was \$332 million for the six months ended June 30, 2026, compared to \$295 million for the same period in the prior year due to our active cash cycle management.

Net cash provided by investing activities was \$310 million for the six months ended June 30, 2026, compared to \$210 million used in investing activities for the same period in the prior year, primarily due to proceeds from the divestiture of the *Jada* system and decreased milestone payments.

Net cash used in financing activities was \$50 million for the six months ended June 30, 2026, compared with \$298 million for the same period in the prior year, primarily driven by decreased dividend payments and decreased repayments of debt in the current year.

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

Our contractual obligations as of June 30, 2026, which require material cash requirements in the future, consist of contractual milestones, purchase obligations and lease obligations. 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, 2025 for further details. As of June 30, 2026, there have been no material changes to our contractual obligations outside of the ordinary course of business.

During the second quarter of 2026, we paid cash dividends of \$0.02 per share. On July 31, 2026, the Board of Directors declared a quarterly dividend of \$0.02 for each issued and outstanding share of our common stock. The dividend is payable on September 10, 2026, to stockholders of record at the close of business on August 14, 2026.

We or our affiliates may, at any time and from time to time, seek to retire or purchase our outstanding debt through cash purchases and/or exchanges for equity or debt, in open-market purchases, privately negotiated transactions or otherwise. Such transactions, if any, may be material, and will depend upon such terms and at such prices as we may determine, and will depend on prevailing market conditions, our liquidity requirements, contractual restrictions and other factors.

Critical Accounting Estimates

Our significant accounting policies, which include management's best estimates and judgments, are included in Note 2 "Summary of Accounting Policies" to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2025. See Note 2 "Basis of Presentation" to the Condensed Consolidated Financial Statements for information on the adoption of new accounting standards during 2026. There have been no changes to our accounting policies as of June 30, 2026. A discussion of accounting estimates considered critical because of the potential for a significant impact on the Condensed Consolidated 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, 2025.

Recently Issued Accounting Standards

For a discussion of recently issued accounting standards, see Note 2 "Basis of Presentation" to the Condensed Consolidated Financial Statements included in this report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

There have been no changes to our market risk during the quarter ended June 30, 2026. 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, 2025.

Item 4. Controls and Procedures

Quarterly Evaluation of Disclosure Controls and Procedures

We have established disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Exchange Act) to provide reasonable assurance that information required to be disclosed in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer ("CEO") (our principal executive officer) and Chief Financial Officer ("CFO") (our principal financial officer), as appropriate to allow timely decisions regarding required disclosure, and ensure that information required to be disclosed in the reports we file or submit is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms.

Our management, with the participation of the CEO and the CFO, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2026 in connection with the filing of this report. Based on this evaluation, the CEO and the CFO concluded that our disclosure controls and procedures were effective as of June 30, 2026 at the reasonable assurance level.

Remediation of Material Weaknesses in Internal Control Over Financial Reporting

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

As disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2025, we previously identified the following material weaknesses in our internal control over financial reporting.

- We failed to set an appropriate tone at the top. Specifically, our former CEO and leader of our U.S. commercial organization applied inappropriate pressure to achieve sales targets through sales of *Nexplanon* to two United States wholesalers above demand and engaged in inappropriate business conduct that violated our Code of Conduct.
- The material weakness with respect to our tone at the top contributed to an additional material weakness of not maintaining effective controls related to information and communication. We did not design and maintain effective controls related to the information and communication component of the framework in Internal Control — Integrated Framework issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Specifically, our former CEO and certain senior members of our U.S. commercial organization did not ensure appropriate communication with, or provide complete information to, our Disclosure Committee and the financial reporting group to evaluate disclosures and financial reporting conclusions related to sales practices for wholesalers.

These material weaknesses did not result in misstatements of our previously reported historical financial statements. Each of these material weaknesses could have resulted in a misstatement of substantially all account balances or disclosures that could

have resulted in a material misstatement to our annual or interim consolidated financial statements that would not have been prevented or detected.

During 2026, management executed upon its previously disclosed remediation plan to address the material weaknesses described above. We devoted substantial resources towards the implementation of enhanced procedures and controls and the remediation of material weaknesses in our internal control over financial reporting. We established a Remediation Plan Task Force to serve as a Project Management Office to monitor our remediation efforts and have also engaged external legal, accounting, financial and other consulting and professional services firms to assist in the development and execution of our comprehensive remediation plan. Actions taken include:

- On October 27, 2025, our Board of Directors enacted Company leadership changes with the executive appointments of Joseph Morrissey as our Interim CEO and Carrie S. Cox as our Interim Executive Chair, with Mr. Morrissey and Ms. Cox being appointed to such roles on a permanent basis on April 26, 2026.
- On October 27, 2025, Michael Casia was appointed as Interim Head of US Commercial and Government Affairs, with Mr. Casia being appointed to this role on a permanent basis on May 6, 2026.
- Beginning in November 2025, we held multiple Founders meetings with employees, including Global Founders Forums and U.S. Commercial Town Hall. Senior leadership disseminated Company-wide and team-specific communications to emphasize our commitment to our core values, compliance, integrity and ethics.
- On December 2, 2025, our Board of Directors ratified our enhanced Code of Conduct to clarify responsibilities related to our financial reporting and disclosures, including awareness of the options to raise concerns or questions to our management, human resources, compliance, legal, the technical accounting department and/or through the SpeakUp Tool, which is available globally as an alternate, confidential channel for raising concerns.
- On January 30, 2026, we communicated and launched training on our Code of Conduct, as amended, regarding ethical tone, corporate culture and appropriate business practices.
- During the quarter ended December 31, 2025, we implemented revisions to our Quarterly Financial Certification Questionnaire to include targeted questions that are designed to (i) address areas tied to the material weaknesses we identified in our internal control over financial reporting, (ii) strengthen our disclosures and (iii) reduce the risk of misleading business practices.
- On February 2, 2026, our Audit Committee ratified an enhanced Disclosure Committee charter that was previously approved by our Interim CEO and CFO. These changes to the Disclosure Committee charter included, among other changes, (i) enumerating additional Disclosure Committee meeting requirements and guidelines for Disclosure Committee members and participants, (ii) providing for a Disclosure Committee Chair designated by the CEO and CFO, (iii) expanding the duties and responsibilities of the Disclosure Committee as to the type and scope of disclosure and risks for its review, (iv) requiring the Disclosure Committee to annually review its charter to identify any recommend changes and (v) mandating continuing education and training of the participants in our disclosure process. In addition, we strengthened our Disclosure Committee processes and procedures to facilitate active participation by Disclosure Committee members.
- During the quarter ended December 31, 2025, we implemented additional and enhanced Sarbanes-Oxley (“SOX”) sub-certifications and internal management representation letters to support our public reporting and disclosure. By January 15, 2026, we provided training to our Executive Leadership Team and to other Disclosure Committee members and participants on the purpose and importance of SOX, SOX sub-certifications and the process for evaluating the representations made that support the disclosure contained in our filings.
- On February 25, 2026, an enhancement to the Company’s Annual Ethics and Policy Certification was launched to all of our employees, requiring all founders to review and certify their understanding of ethical responsibilities and compliance with laws, regulations, and Organon policies, including our Code of Conduct.
- On March 31, 2026, we communicated and launched training to relevant commercial and finance employees on revenue-related business practices, emphasizing the importance of revenue recognition and related disclosures. This training reinforced our commitment to ethical conduct, transparency, accuracy and reliability and helped to strengthen credibility and trust in our financial reporting.
- We performed a comprehensive review of the quarterly Distribution Services Agreement payment process. Based on that review, we developed an internal policy to provide oversight and establish guidelines for management fee arrangements with wholesalers. This policy and related procedures were communicated to relevant U.S. Commercial employees on April 24, 2026.
- New internal controls were implemented effective Q1 2026 related to US sales monitoring, as well as enhanced reviews for inventory levels at the wholesaler and days on hand at the wholesaler.

Our management completed testing of the implemented remediation actions described above during the quarter ended June 30, 2026, and found them to be operating effectively. As a result, management has concluded that the material weaknesses in internal control over financial reporting have been remediated as of June 30, 2026.

Quarterly Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the three months ended June 30, 2026 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” to the Condensed Consolidated Financial Statements included in Part I, Item. 1.

Item 1A. Risk Factors

There have been no material changes in our risk factors from those disclosed in Item 1A. Risk Factors, in our Annual Report on Form 10-K for the year ended December 31, 2025 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2026.

Item 5. Other Information

Rule 10b5-1 and Non-Rule 10b5-1 Trading Arrangements

During the three months ended June 30, 2026, none of our directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement, as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

Number	Description
2.1	Agreement and Plan of Merger, dated as of April 26, 2026, by and among Organon & Co., Sun Pharmaceutical Holdings USA, Inc., Sun Pharma America, Inc. and, solely for the purposes of certain Covered Provisions of the Merger Agreement (as defined therein), Sun Pharmaceutical Industries Limited, Sun Pharma Canada Inc. and Sun Pharma (Netherlands) B.V. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on April 27, 2026).
*♦10.1	Amendment No. 8 to Development and Commercialization Agreement, dated May 22, 2026, by and between Samsung Bioepis Co., Ltd. and Organon LLC.
*♦10.2	Amendment No. 9 to Development and Commercialization Agreement, dated May 26, 2026, by and between Samsung Bioepis Co. Ltd. and Organon LLC.
*♦10.3	Amendment No. 10 to Development and Commercialization Agreement, dated June 2, 2026, by and between Samsung Bioepis Co., Ltd. and Organon LLC.
+10.4	Amended and Restated Organon & Co. 2021 Incentive Stock Plan (incorporated by reference to the Company's Definitive Proxy Statement on Schedule 14A filed on April 24, 2026).
*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).
♦	Certain confidential information contained in portions of this exhibit, marked by [***] has been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K because such portions are (i) not material and (ii) are the type of information the registrant customarily and actually treats as private or confidential.
†	Certain schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant agrees to furnish a copy of any omitted schedule or exhibit to the SEC upon request; provided, however, that the registrant may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act for any document so furnished.
+	Management contract or compensatory plan or arrangement.
*	Filed herewith.
**	Furnished herewith.

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: July 31, 2026

/s/ Lynette Holzbaur

Lynette Holzbaur

Senior Vice President Finance - Corporate Controller

Date: July 31, 2026

/s/ Matthew Walsh

Matthew Walsh

Chief Financial Officer

Execution Version

**AMENDMENT NO. 8 TO
DEVELOPMENT AND COMMERCIALIZATION AGREEMENT**

This Amendment No. 8 to Development and Commercialization Agreement (this “**Amendment No. 8**”) is effective as of May 22, 2026 (the “**Amendment No. 8 Effective Date**”) and is entered into by and between **SAMSUNG BIOEPIS CO., LTD.**, a corporation organized and existing under the laws of the Republic of Korea with a place of business at 76, Songdoggyoyuk-ro, Yeonsu-gu, Incheon, 21987, Republic of Korea (hereinafter referred to as “**Samsung**”) and **ORGANON LLC**, a limited liability company organized and existing under the laws of the State of Delaware, USA, with a place of business at 30 Hudson Street, Jersey City, NJ 07302 (hereinafter referred to as “**Organon**”).

Samsung and Organon are hereinafter referred to jointly as the “**Parties**” and individually as a “**Party**”.

RECITALS

WHEREAS

(i) On February 18, 2013, Samsung and Merck Sharp & Dohme Corporation (“**Merck**”) executed the Development and Commercialization Agreement, as amended on July 21, 2014, July 11, 2017, October 1, 2017, September 1, 2018, October 15, 2018, December 19, 2018, and May 15, 2020 (“**DCA**” or “**Agreement**”), for the purpose of, among other things, granting Merck an exclusive license (even as to Samsung) to Commercialize any and all Compounds and Products in the Territory.

(ii) Pursuant to Amendment No. 7 to Development and Commercialization Agreement effective May 15, 2020, Merck assigned all of its rights and obligations under the DCA to Organon.

(iii) The Parties now wish to amend the DCA to grant to Organon the right to commercialize an additional Product in Canada.

NOW THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

I. DEFINITIONS

[* * *]=[CONFIDENTIAL PORTION HAS BEEN OMITTED BECAUSE IT (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.]

The Parties agree that capitalized terms used but not otherwise defined in this Amendment No. 8 shall have the meanings ascribed thereto in the DCA.

II. AMENDMENT

2.1 In Section 1.14, the following clause is added to the definition of “Compound”:

1.14.7 Ustekinumab/Stelara Biosimilar (“**SB17**”).

2.2 New Section 1.39A is added to the DCA as follows:

2.3 “**Primary-Packaged Presentation**” for each Product means the specific dosage and Presentation referred to in Section 6.3.3(a).

2.4 In Section 1.40, the following sentence is added at the end:

2.5 Without limiting the foregoing, SB17 shall be referred to, where applicable, as the “**SB17 Product**”.

2.6 Section 1.41 is deleted in its entirety and replaced with the following:

2.7 “**Product Criteria**” shall mean the criteria with respect to Indications, Presentations, dosage strengths and timing for receipt of Marketing Authorization (or in the case of the [* * *], and timing for filing applications for Marketing Authorization), set forth with respect to each Product on Schedule 1.41 and Schedule 1.41A.

2.8 Section 1.42 is deleted in its entirety and replaced with the following:

“**Region**” shall mean each of (i) the European Union, as a whole, (ii) the USA and its territories and possessions, as a whole, and (iii) the remainder of the Territory excluding the European Union and the USA and its territories and possessions (collectively, the “**ROW Region**”). However, (a) for Bevacizumab/Avastin Biosimilar only, “Region” shall mean (1) United Kingdom, France, Italy, Germany and Spain, as a whole, (2) the USA (including its territories and possessions), (3) Canada, and (4) the respective territories and possessions of United Kingdom, France, Italy, Germany, Spain and Canada that are set forth on Schedule 1.56D and (b) for SB17 Product only, “Region” shall mean Canada.

For purposes of this Agreement, “**European Union**” or “**E.U.**” means, collectively, (a) the economic, scientific, and political organization of member states known as the European Union, as its membership may be altered from time to time, and any successor thereto, and (b) the United Kingdom.

2.9 Section 1.53 is deleted in its entirety and replaced with the following:

2.10 “**Supply Price**” of each unit of a Product in a particular Presentation supplied by Samsung to Organon for sale in a Region shall mean (i) with respect to Products other than SB17 Product, the Target Supply Price determined under the Supply Price True-up Mechanism for such Product in such Presentation in such Region and (ii) with respect to SB17 Product, the Actual Supply Price determined in accordance with Schedule 1.54A.

2.11 In Section 1.54, the following sentence is added at the end:

2.12 For clarity, notwithstanding the foregoing, the Supply Price True-up Mechanism is not applicable to SB17 Product. With respect to SB17 Product, the Actual Supply Price will be determined in accordance with Schedule 1.54A.

2.13 In Section 1.56, the following clause is added to the definition of “Territory”:

2.14 1.56.5 With respect to Ustekinumab/Stelara Biosimilar, Canada.

2.15 Section 1.58 is deleted in its entirety and replaced with the following:

2.16 “**Trademarks**” shall mean any trademark, whether or not registered, (including but not limited to product names, word marks, logos, colors, packaging designs, slogans, trade dress, domain names, and other indicia of origin) under which Compounds or Products are Commercialized under this Agreement.

2.17 In Section 2A.1, the following sentences are added to the end of the Section:

Notwithstanding the foregoing, with respect to the SB17 Product, no later than October 31 of each Calendar Year, Organon will prepare and present to Samsung a Commercialization Plan for the SB17 Product for the following Calendar Year (each, a “**Commercialization Plan for the SB17 Product**”). For the Calendar Year of 2026, Organon will prepare and present to Samsung a Commercialization Plan no later than [* * *] after the Effective Date. The Commercialization Plan for the SB17 Product will include sales estimates (both units and Net Sales) by Calendar Quarter. Organon

will present the Commercialization Plan for the SB17 Product to Samsung for discussion, and Organon shall reasonably consider Samsung's comments in making any adjustments to the Commercialization Plan for the SB17 Product.

2.18 Section 3.7 is deleted in its entirety and replaced with the following:

3.7. Trademarks.

3.7.1. Trademarks for Products Other Than SB17 Product. The Trademarks under which the Products (other than the SB17 Product) are Commercialized in the Territory shall be created, developed, selected and approved by Organon. Organon shall be responsible for filing, prosecuting, registering, maintaining and protecting the Trademarks (other than Trademarks for the SB17 Product) in all countries in the Territory at its own expense. Samsung recognizes that the Trademarks (other than the Trademarks for the SB17 Product) are trademarks of Organon and that Samsung has no right or interest in the Trademarks (other than the Trademarks for the SB17 Product) other than those rights explicitly granted in this Agreement. Organon shall own all copyright in any promotional materials or other works created in support of the Commercialization of the Products (other than the SB17 Product). Notwithstanding the foregoing, subject to Section 10.6.2, (i) upon the expiration or termination of this Agreement with respect to a Product (other than an SB17 Product) in less than all of its Presentations and/or in less than all Regions, Organon shall promptly grant to Samsung an exclusive (even as to Organon), non-transferable, royalty-free license, with the right to grant and authorize sublicenses, to use, solely for and in support of the Commercialization of such Product in such Presentation(s) and in such Region(s) for which this Agreement has expired or been terminated, (a) the Trademarks for such Product registered or used in such Region(s) and (b) all promotional materials and other works created by, for or on behalf of, or used by, Organon or its Related Parties in support of the Commercialization of such Product in such Region(s) (which license shall remain in effect until all of Organon's rights, title and interests in and to such Trademarks, promotional materials and other works are assigned to Samsung pursuant to clause (ii) below); and (ii) upon the expiration or termination of this Agreement with respect to a Product (other than an SB17 Product) in all of its Presentations and in all Regions, Organon shall promptly assign to Samsung for no consideration all of its rights, title and interests in and to all such Trademarks (other than Trademarks for SB17 Product), promotional materials and other works; provided, however, that Samsung shall bear all recordation costs and other incidental expenses associated with such license or assignment. No license or

assignment granted under this Section 3.7.1 shall include the right to use any Organon corporate name, corporate logo or other indicia of Organon's corporate identity.

3.7.2. Trademarks for SB17 Product.

(a) The Trademarks for the SB17 Product are set forth on Schedule 3.7.2.

(b) Samsung shall own and upon registration maintain the Trademarks for the SB17 Product. Subject to Section 9.7 and Section 9.8, Samsung shall be responsible for filing, prosecuting, registering, maintaining, enforcing and protecting the Trademarks for the SB17 Product, at Samsung's own expense. Organon recognizes that the Trademarks for the SB17 Product are trademarks of Samsung and that Organon has no right or interest in the Trademarks for the SB17 Product other than those rights explicitly granted in this Agreement. Samsung will inform Organon of any action it may take with respect to the Trademarks for the SB17 Product to the extent such action may impact Organon's rights, benefits and obligations hereunder. Samsung hereby grants to Organon an exclusive (even as to Samsung), non-transferable, royalty-free license to reproduce and use the Trademarks for the SB17 Product solely to Commercialize the SB17 Product in Canada during the applicable Term. Organon shall not contest or aid others in contesting the validity of the Trademarks for the SB17 Product or Samsung's ownership of the Trademarks for the SB17 Product. Organon shall not apply for, or aid or cause others to apply for, any registration of the Trademarks for the SB17 Product or other trademarks similar to the Trademarks for the SB17 Product. Organon shall not take any other action inconsistent with Samsung's ownership of the Trademarks for the SB17 Product. Organon shall not use the Trademarks for the SB17 Product in any way that might prejudice their distinctiveness or validity in Canada. As between the Parties, any benefits (including, without limitation, goodwill) accruing from Organon's use of the Trademarks for the SB17 Product shall automatically vest in Samsung. Organon shall furnish to Samsung a sample of each use of the Trademarks for the SB17 Product by Organon for Samsung's approval prior to use, provided that any subsequent uses of the sample previously approved by Samsung are permitted without an additional approval. Organon shall cooperate with Samsung in facilitating inspection and quality control over Organon's use of the Trademarks for the SB17 Product. Organon shall not use the Trademarks for the SB17 Product, except as permitted under this Agreement in Canada. Organon's use of the Trademarks for the SB17 Product shall not tarnish, blur, or dilute the quality associated with the Trademarks for the SB17 Product or the associated goodwill in Canada. Organon shall not use any other trademarks that are

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confusingly similar to the Trademarks for the SB17 Product in Canada. Organon shall ensure that its permitted Affiliates and sublicensees also comply with the requirements provided in this Section 3.7.2. For clarity, subject to Section 10.6.2, in the event this Agreement expires or terminates with respect to the SB17 Product, the license to use the applicable Trademarks for the SB17 Product in Canada will terminate automatically.

(c) Samsung shall not use, or license any Third Party to use, any other Trademarks that are confusingly similar to the Trademarks for the SB17 Product in Canada.

2.19 Article 5 of the DCA is hereby amended to exclude the SB17 Product from the definition of “Product” therein.

2.20 In Section 6.2, the second sentence is deleted in its entirety and replaced with the following:

2.21 The Parties acknowledge that Organon intends to build and maintain for Launch an inventory [* * *] of the expected Requirements of each Product (other than SB17 Product), as estimated in good faith to be needed at the time of Launch of such Product. For Launch of the SB17 Product, Organon will order those quantities of SB17 set forth on Schedule 6.2.

2.22 In Section 6.3.3(a), the following Primary-Packaged Presentations are added:

(xiv) [* * *];

(xv) [* * *]; and

(xvi) [* * *].

2.23 In Section 6.3.5, the definition of “Operational Costs” is deleted in its entirety and replaced with the following:

2.24 “**Operational Costs**” shall include (i) for Products other than SB17 Product, (a) the costs of any raw materials, resins or other consumables which Samsung is not able to use for scheduled Manufacturing, whether for Organon, for Samsung or for any Third Party, as well as (b) the other costs included in “Samsung Costs” as defined in Schedule 1.54 (excluding, however, royalties and license fees and personnel-related expenses of Commercialization support departments) that Samsung is unable to

mitigate or avoid through the exercise of Commercially Reasonable Efforts and (ii) for SB17 Product, any out-of-pocket expenses incurred or committed to by Samsung associated with a cancellation or deferral of Manufacturing of SB17 Product, including (a) the costs of any raw materials, resins or other consumable which Samsung is not able to use for scheduled Manufacturing, whether for Organon, for Samsung or for any Third Party and (b) costs incurred or paid to external contract manufacturing organizations for production of such SB17 Product and/or the Compound incorporated or contained in such SB17 Product.

2.25 In Section 6.3.6, the following sentence is added at the end:

2.26 For clarity, the foregoing sentence shall not apply to SB17 Product.

2.27 Section 6.15 is deleted in its entirety and replaced with the following:

2.28 **Responsibility for Losses.** The Parties agree to allocate losses or damages to Products (other than SB17 Product) or destruction of Products (other than SB17 Product) due to expiration of the shelf-life as described in Schedule 6.15. If Samsung deems necessary and should Organon accept SB17 Product which is delivered with less shelf life than the required remaining shelf life pursuant to Section 6.5, the Parties agree to discuss in good faith the sharing of the Supply Price for any SB17 Product supplied with such lesser shelf life which cannot be sold in the Territory and Samsung shall credit such amount against the next purchase order. Notwithstanding the foregoing, if Samsung deems necessary and should Organon accept SB17 Product for the Launch quantities as per Schedule 6.2, which is delivered with less shelf life than the required remaining shelf life pursuant to Section 6.5, then Samsung shall reimburse Organon for the Supply Price paid by Organon to Samsung for all remaining quantities of such SB17 Product that are no longer accepted for purchase by wholesalers due to the remaining shelf life.

2.29 Section 7.1 is deleted in its entirety and replaced with the following:

2.30 **7.1 Booking of Revenue; Records; Payment of Supply Price.** Organon shall book revenue for sales of the Products throughout the Territory. Organon shall maintain records, in sufficient detail for accounting purposes and for purposes of this Agreement (including, without limitation, the Supply Price True-up Mechanism and the Net Sales Share Mechanism) which shall fully and properly reflect all work done and results achieved in the Commercialization of the Compounds and Products by Organon. The Supply Price for each Product (other than SB17 Product) shall be set,

and adjusted, on a Calendar Year basis in accordance with the Supply Price True-up Mechanism attached hereto as Schedule 1.54. The Supply Price for SB17 Product shall be set and adjusted in accordance with Schedule 1.54A (“**Net Sales Share Mechanism**”). Within the later of (i) [* * *] following the delivery of Product to a carrier designated by Organon and (ii) [* * *] following the delivery of the invoice for such Product to Organon, Organon shall pay Samsung the Supply Price for such Product.

2.31 The Parties agree to provide the following additional representations and warranties solely with respect to this Amendment No. 8 and for the SB17 Product.

2.31.1 New Section 8.1A is added to the DCA as follows:

8.1A. Representations and Warranties Each Party. Solely with respect to this Amendment No. 8, and with respect to the SB17 Product, each of Samsung and Organon hereby represents and warrants to the other Party as of the Amendment No. 8 Effective Date:

- (a) it has the full right, power and authority to enter into this Amendment No. 8 and to perform its obligations hereunder;
- (b) this Amendment No. 8 has been duly authorized by all necessary corporate action on its part, has been duly executed by it and is legally binding upon it, enforceable in accordance with its terms; and
- (c) this Amendment No. 8 does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law, rule, regulation, judgment, decree or order of any court, governmental body or administrative or other agency having jurisdiction over it.

2.31.2 New Section 8.2A is added to the DCA as follows

2.31.3 **8.2A. Samsung Representations and Warranties.** Solely with respect to this Amendment No. 8 and with respect to the SB17 Product, Samsung hereby represents and warrants to Organon as of the Amendment No. 8 Effective Date that:

- (a) it has the full right, power and authority to Develop the SB17 Product and to grant the licenses granted under Article 3; it has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the Samsung Patent Rights or Samsung Know-How, in each case, related to the SB17 Product other than (i) an exclusive license granted to [* * *] with respect to SB17, which license has been terminated for Canada prior to the Amendment No. 8 Effective Date, and (ii) non-exclusive, non-transferable, royalty-free, fully-paid-up license granted to Third Party contract manufacturing organizations (“**CMOs**”) under certain Samsung Patent Rights and Samsung Know-How for the purpose of enabling the CMOs to fulfill their contract manufacturing obligations thereunder;
- (b) there are no claims, judgments or settlements against or owed by Samsung, and no pending or threatened claims or litigation against Samsung, relating to the Samsung Patent Rights or Samsung Know-How, in each case, related to the SB17 Product;
- (c) there are no actions or lawsuits pending or to Samsung’s knowledge threatened, against Samsung, its Affiliates or its CMOs alleging infringement of a Third Party’s intellectual property rights based on the Commercialization of the SB17 Product in Canada or the Manufacture of the SB17 Product for Commercialization in Canada as contemplated by this Amendment No. 8 and, to the knowledge of Samsung as of the Amendment No. 8 Effective Date, the Commercialization of the SB17 Product in Canada and the Manufacture of the SB17 Product for Commercialization of the SB17 Product in Canada as contemplated by this Amendment No. 8, in each case, do not and will not infringe any intellectual property rights of any Third Party; and
- (d) Samsung has disclosed to Organon all reasonably relevant information regarding the Samsung Patent Rights, Samsung Know-How and Trademarks licensed under this Agreement for the SB17 Product (“**SB17 Product Licensed IP**”) and the existence of any patent opinions relating thereto, which, in each case, Samsung actually possesses or knows as of the Amendment No. 8 Effective Date.

2.31.4 New Section 8.2B is added to the DCA as follows:

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8.2B Additional Representations, Warranties and Covenants of Samsung. Samsung hereby represents, warrants and covenants, as applicable, to Organon that:

- (a) it shall at all times during the Term retain (but only for so long as the intellectual property licenses granted to Organon under the Samsung Know-How, Samsung Patent Rights and Trademarks for the SB17 Product for the Development, Manufacturing and Commercialization of the SB17 Product remain in effect) the full right, power, and authority to Commercialize the SB17 Product in Canada and to Manufacture the SB17 Product and to grant and maintain in effect all of the licenses and sublicenses granted to Organon with respect to SB17 Product Licensed IP, provided that for clarity, the foregoing representation and warranty shall not be construed to be a representation or warranty as to non-infringement of a third party's intellectual property rights. For further clarity, Samsung is the sole and exclusive legal and beneficial owner of, or otherwise has the full right, power, and authority to grant the rights and licenses granted under this Agreement with respect to, the SB17 Product Licensed IP;
- (b) [* * *];
- (c) [* * *];
- (d) [* * *];
- (e) neither it nor any of its Affiliates or, to its knowledge as of the Amendment No. 8 Effective Date, any of its licensors has, as of the Amendment No. 8 Effective Date, assigned, transferred, conveyed or otherwise encumbered any right, title and interest in the SB17 Product Licensed IP, or will make or permit such an assignment, transfer, conveyance or encumbrance during the Term, in each case to the extent such assignment, transfer, conveyance or encumbrance would conflict with any of the terms of this Agreement;
- (f) no Third Party or any individual, whether an employee, officer, consultant or other Person who participated in any respect in the invention or authorship of any SB17 Product Licensed IP owned by

Samsung, or with respect to the SB17 Product Licensed IP licensed by Samsung, to Samsung's knowledge as of the Amendment No. 8 Effective Date, has any right, claim, title or interest in or to such SB17 Product Licensed IP and the SB17 Product Licensed IP owned by Samsung, or the SB17 Product Licensed IP licensed by Samsung, to Samsung's knowledge, is free and clear of any liens, encumbrances, security interests, licenses, or other restrictions which would conflict with any of the terms of this Agreement; and

- (g) except as disclosed as of the Effective Date, each of the Trademarks for the SB17 Product is valid, subsisting, and enforceable in Canada and is not subject to any pending or threatened opposition, cancellation, invalidity, or similar proceedings.

2.31.5 Section 8.2.9 is deleted in its entirety and replaced with the following:

EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES EXPRESSLY SET FORTH IN SECTION 8.1, THIS SECTION 8.2, SECTION 8.1A, SECTION 8.2A, SECTION 8.2B AND ELSEWHERE IN THIS AGREEMENT, NEITHER SAMSUNG NOR ANY OTHER PERSON ACTING ON BEHALF OF SAMSUNG MAKES ANY REPRESENTATION OR WARRANTY (INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR USE AND NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS), EXPRESS OR IMPLIED, TO ORGANON.

2.32 Section 8.3 is deleted in its entirety and replaced with the following:

8.3 Samsung Covenant. Samsung shall use Commercially Reasonable Efforts throughout the Term to identify any Third Party Patent Rights claiming or covering any of the Compounds or Products, or the Development, Manufacture or Commercialization thereof, that may potentially hinder or restrict the Development, Manufacture or Commercialization of any Compound or Product pursuant to this Agreement, and shall update Organon twice per Calendar Year (at regular intervals) with respect to the results of such activities (including the status of any litigation with respect to SB17 Product), provided that, for SB17 Product, Samsung shall also update Organon within five (5) business days of Organon's request for an update. If any such Third Party Patent Rights are found, in conjunction with the update provided pursuant

to the foregoing sentence, Samsung shall update Organon with respect to its strategy for achieving freedom of operation with respect to the Development, Manufacture and Commercialization of the Compounds and Products throughout the Territory pursuant to this Agreement.

2.33 New Section 8.4A is added to the DCA as follows:

8.4A Additional Representations and Warranties of Organon. Solely with respect to this Amendment No. 8 and the SB17 Product, Organon hereby represents and warrants to Samsung as of the Amendment No. 8 Effective Date that it has the full right, power and authority to Commercialize the SB17 Product in Canada and to grant the licenses granted under Article 3.

2.34 Section 8.4.5 is amended in its entirety as follows:

EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES EXPRESSLY SET FORTH IN SECTION 8.1, THIS SECTION 8.4, SECTION 8.1A, SECTION 8.4A, AND ELSEWHERE IN THIS AGREEMENT, NEITHER ORGANON NOR ANY OTHER PERSON ACTING ON BEHALF OF ORGANON MAKES ANY REPRESENTATION OR WARRANTY (INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR USE AND NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS), EXPRESS OR IMPLIED, TO SAMSUNG.

2.35 Section 8.5 (but, for clarity, not Section 8.5.1, which shall remain in full force and effect) is deleted in its entirety and replaced with the following:

8.5 Indemnification by Samsung. Samsung shall indemnify and defend Organon, its Affiliates and its and such Affiliates' respective directors, officers, employees, and agents from and against any and all Liabilities arising out of or relating to

(i) Samsung's breach of any of its representations, warranties, covenants and obligations in this Agreement (including those relating to the Development and Manufacturing of the Products and the SB17 Product Licensed IP), any of the PDP Program Supply Agreement, or any of the PDP Program Agreements,

(ii) Samsung's or its Affiliate's failure to comply with any applicable laws, rules, or regulations, including those related to the PDP Program or any Technology Transfer activities related thereto,

(iii) Samsung's or its Affiliate's willful misconduct or negligence,

(iv) any Liability, penalty, fine, interest, responsibility and obligation claimed or imposed by any entity, including law enforcement authorities, of the Brazilian Federal Government as a result of Samsung's failure to implement the Technology Transfer in accordance with the PDP Program Agreements, or

(v) any claim, demand, action, or proceeding by a Third Party alleging that Organon's use of any of the SB17 Product Licensed IP or Commercialization of the SB17 Product in accordance with this Agreement infringes, misappropriates, or otherwise violates any intellectual property or proprietary rights of such Third Party. For the sake of clarity, any Liability, penalty, fine, interest, responsibility or obligation for which Samsung is obligated to indemnify Organon under Section 8.5(iv) or (v), or Section 8.5.1 below shall not be subject to the damages cap in Section 8.8. In addition, notwithstanding Section 9.3(C) of the PDP Program Supply Agreement which requires Organon and Samsung to share [* * *] of all Cancellation Costs (as defined in the PDP Program Supply Agreement) incurred in connection with the cancellation of the Binding Forecasts (as defined in the PDP Program Supply Agreement), if the cancellation of the Binding Forecasts is due to termination of the PDP Program Supply Agreement based on the breach of the Technology Transfer Agreements by [* * *], then Organon shall have no obligation to pay any portion of the Cancellation Fee and Samsung shall indemnify and hold Organon harmless from any Liability that is based on such obligation to pay the Cancellation Fee.

For further clarity, the Parties are in agreement that where one and the same set of facts qualifies under more than one provision entitling a Party to a claim or indemnification under this Agreement, there shall be only one claim or indemnification.

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2.36 New Section 9.7 is added to the DCA as follows:

9.7 Treatment of Patent Rights and Trademarks for SB17 Product.

Notwithstanding the foregoing Sections of this Article 9, the Parties agree that with respect to the Commercialization of the SB17 Product in Canada, including the Manufacture of the SB17 Product outside of Canada for Commercialization in Canada, the following Sections 9.7 and 9.8 replace and supersede the foregoing Sections of this Article 9.

9.7.1 Patent Rights for SB17 Product. Samsung shall, at its own expense and discretion, use Commercially Reasonable Efforts to maintain Samsung Patent Rights for the SB17 Product owned by Samsung. Samsung shall consult with Organon and keep Organon reasonably informed of the status of such Samsung Patents for the SB17 Product and shall provide Organon with all material correspondence received from the Canada Intellectual Property Office (“**CIPO**”) in connection therewith. Samsung may abandon or cease prosecution or maintenance of any Samsung Patent Right for the SB17 Product in Canada (or any other jurisdiction) in its sole discretion, provided that, if Samsung determines to abandon or cease prosecution or maintenance of Samsung Patent Right for the SB17 Product in or for Canada, Samsung shall provide reasonable prior written notice to Organon of such intention to abandon (which notice shall, to the extent possible, be given no later than [* * *] prior to the final deadline for any action that must be taken with respect to any such Samsung Patent Right for the SB17 Product with respect to the relevant patent authority). In such case, upon Organon’s written election provided no later than [* * *] after such notice from Samsung, Organon may assume prosecution and maintenance of such Samsung Patent Right for the SB17 Product at Organon’s sole cost and expense in the name of Samsung. If Organon does not provide such election within [* * *] after such notice from Samsung, Samsung may, in its sole discretion, discontinue prosecution and maintenance of such Samsung Patent Right for the SB17 Product.

9.7.2. Trademarks for SB17 Product. Samsung shall, at its own expense and discretion, prepare, file, prosecute and maintain the Trademarks for the SB17 Product. Samsung shall, and shall require its licensor to, consult with Organon and keep Organon reasonably informed of the status of such Trademarks for the SB17 Product and shall, provide Organon with all material correspondence received from the CIPO in connection therewith. Samsung may abandon or cease prosecution or maintenance of any Trademarks for the SB17 Product in Canada (or any other jurisdiction) in its

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sole discretion, provided that, if Samsung determines to abandon or cease prosecution or maintenance of any Trademarks for the SB17 Product in or for Canada, Samsung shall provide reasonable prior written notice to Organon of such intention to abandon (which notice shall, to the extent possible, be given no later than [* * *] prior to the final deadline for any action that must be taken with respect to any such Trademarks for the SB17 Product with respect to the relevant trademark authority). In such case, upon Organon's written election provided no later than [* * *] after such notice from Samsung, Samsung shall assign the applicable Trademarks for the SB17 Product to Organon and Organon may assume prosecution and maintenance of such Trademarks for the SB17 Product at Organon's sole cost and expense in the name of Organon. If Organon does not provide such election within [* * *] after such notice from Samsung, Samsung may, in its sole discretion, discontinue prosecution and maintenance of such Trademarks for the SB17 Product.

2.37 New Section 9.8 is added to the DCA as follows:

2.38 **9.8 Infringement of Intellectual Property Rights relating to SB17 Product.** Each Party will promptly inform the other Party of any actual, alleged, or suspected infringement of any Samsung Patent Rights owned by Samsung or Trademarks for the SB17 Product by a Third Party, as well as any actual, alleged or suspected claims by Third Parties of infringement of such Third Party's intellectual property right by the Development, Manufacture or Commercialization of SB17 Product in or for Canada, of which it becomes aware.

- (a) Administrative and litigation proceedings, including but not limited to infringement action, declaratory judgment action, *inter partes* review, opposition proceeding, post grant review, interference, or other equivalent action ("Proceedings") alleging infringement of or challenging (including any claims within the Samsung Patent Rights) SB17 Product Licensed IP relating to SB17 Product or its exploitation in Canada will be conducted and controlled by Samsung (or Samsung's licensor), in Samsung's (or Samsung's licensor's) sole discretion. Samsung (or Samsung's licensor) will have sole control of such Proceedings, and Samsung shall keep Organon regularly informed of the progress of such Proceedings. Samsung (or Samsung's licensor) will bear all costs of conducting such Proceedings, including any payment of Third Party costs or damages that may be agreed to or awarded by the Courts. If Organon's and/or its Affiliate's joinder is necessary for Samsung (or Samsung's licensor) to establish standing in such Proceedings, Organon will, at the request of Samsung, join such Proceedings, cooperate and provide reasonable

assistance in any such Proceedings, all at Samsung's costs. If Samsung fails to bring a Proceeding with respect to any actual, alleged, or suspected infringement of any SB17 Product Licensed IP owned by Samsung within [* * *] (or such shorter period in the event of a relevant deadline) following notice of such actual, alleged, or suspected infringement (or such shorter period as required by a relevant deadline), Organon shall have the right, but not the obligation, to bring and control any such Proceeding. If Organon initiates such Proceeding, Organon shall keep Samsung regularly informed of the progress of such Proceedings. If Samsung's and/or its Affiliate's joinder is necessary for Organon to establish standing in such Proceedings, Samsung and/or its Affiliate will join, such Proceedings. If Organon commences such a Proceeding, Samsung will, at the request of Organon, cooperate and provide reasonable assistance in any such Proceedings at its own cost. If such Proceedings are the subject of a settlement, the controlling Party will consider the non-controlling Party's suggestions in good faith. All costs of any Proceeding commenced or defended solely by the controlling party will be borne by the controlling Party. Any recovery or damages derived or realized as a result of any Proceeding will be retained by the controlling Party.

- (b) Proceedings involving any claim by a Third Party for infringement of such Third Party's Patent Rights, know-how, trade secrets, trademarks or other intellectual property rights, by the Manufacture, use, import, export, offer for sale, or sale of the SB17 Product in Canada, or the Manufacture, use, import or export of the SB17 Product outside of Canada for purposes of Commercialization in Canada, or any claim challenging or related to the use of the SB17 Product Licensed IP (but only to the extent such use is pursuant to any license and/or sublicense hereunder or as otherwise directed or authorized by Samsung in writing) will be conducted and controlled by Samsung (or Samsung's licensor), including any settlement of such claims, using Commercially Reasonable Efforts, in Samsung's (or Samsung's licensor) sole discretion. Samsung (or Samsung's licensor) will have sole control of such Proceedings, while keeping Organon regularly informed (including Samsung's response to Organon's request for a status update) of the progress of such Proceedings. If Organon's and/or its Affiliate's joinder is necessary for Samsung (or Samsung's licensor) to establish standing in such Proceedings, Organon and/or its such Affiliate will join such Proceedings. Organon will, at the request of Samsung, cooperate and provide reasonable assistance in any such Proceedings at Samsung's costs. If such Proceedings are the subject of a settlement, Samsung will discuss with Organon in reasonable detail the proposed

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settlement terms (unless confidentiality obligations to a third party prohibits such disclosure) that could materially impact Commercialization of the SB17 Product in Canada, and consider Organon's suggestions in good faith and will not agree to any settlement that could adversely impact Organon's right to Commercialize SB17 Product in Canada. All costs of any Proceedings conducted and controlled solely by Samsung (or Samsung's licensor), regardless of whether Organon assists or joins such Proceedings, and all royalties payable to any Third Party related to a settlement of, or Court order arising from, any such Proceeding will be borne by Samsung (or Samsung's licensor); provided that Organon may elect to participate in any such Proceedings at its own expense and Samsung will not be obligated to bear any such expenses of Organon if it is not otherwise required or requested to join or assist as provided hereunder. Any recovery or damages derived or realized as a result of any Proceeding, except as otherwise provided in this Section 9.8, will be retained by Samsung (or Samsung's licensor). Notwithstanding the foregoing or any other provision of this Agreement to the contrary, Samsung shall have no obligation to control, conduct, defend or pay for any damages, costs, fees, or expenses in connection with any Proceedings, or any claims involved in any Proceedings, arising from Organon's use of the SB17 Product Licensed IP outside the scope of any license or sublicense hereunder or for which Samsung has otherwise authorized Organon in writing to use such SB17 Product Licensed IP.

- (c) Proceedings involving any claim by a Third Party for infringement of such Third Party's Patent Rights, know-how, trade secrets, trademarks or other intellectual property rights related to the use of the Other Brand Elements in Canada (but only to the extent such use is as directed or authorized by Organon in writing), including but not limited to Organon's logos, Organon's name on packaging, Organon's campaigns (concepts and other elements such as: visuals, photos, graphs, fonts and tables), promotional and non-promotional messages and claims, will be conducted and controlled by Organon, including any settlement of such claims, in Organon's sole discretion. Organon will have sole control of such Proceedings, while keeping Samsung regularly informed of the progress of such Proceedings. If Samsung's and/or its Affiliate's joinder is necessary for Organon to establish standing in such Proceedings, Samsung and/or its such Affiliate will join such Proceedings at Organon's costs. Samsung will, at the request of Organon, cooperate and provide reasonable assistance in any such Proceedings at Organon's costs. Organon will bear all costs of conducting Proceedings conducted and controlled solely by Organon, regardless of whether Samsung assists or joins such Proceedings,

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including payment of Third Party costs or damages agreed to or awarded by the Courts; provided that Samsung may elect to participate in any such Proceedings at its own expense and Organon will not be obligated to bear any such expenses of Samsung if it is not otherwise required or requested to join or assist as provided hereunder. Any recovery or damages derived or realized as a result of any Proceeding will be retained by Organon. Notwithstanding the foregoing or any other provision of this Agreement to the contrary, Organon shall have no obligation to control, conduct, defend or pay for any damages, costs, fees, or expenses in connection with any Proceedings, or any claims involved in any Proceedings, arising from Samsung's use of Other Brand Elements outside the scope for which Organon has authorized Samsung in writing to use such Other Brand Elements.

- (d) For the purposes of this Section 9.8, "**Other Brand Elements**" shall mean any Trademarks in the Territory (a) that are Controlled by Organon or any of its Affiliates and (b) that are held for use (i.e., subject to a pending trademark application or a trademark registration in jurisdictions where use is not required to register) or are used to Develop, Manufacture, perform medical affairs, or Commercialize the Product in the Territory, but excluding Trademarks included within the SB17 Product Licensed IP.
- (e) Notwithstanding any other provision in the DCA, including Sections 2.4, 9.3 and 10.3, if (i) the Commercialization in Canada of the SB17 Product is prevented or enjoined for a period of [* * *] or more by Proceedings challenging or responding to any claims with respect to a Third Party's patent rights, including a settlement arising from such Proceedings, or (ii) any challenge, opposition, cancellation, infringement claim, or other legal or regulatory issue, including any Proceedings, which results in any settlement or any unfavorable court decision (whether it is unfavorable in whole or in part, or whether the decision is an interim or final decision, or could be subject to appeal), that prevents, hinders or delays Organon from being able to use the Trademarks for SB17 Product, then, in each case of (i) and (ii), Organon shall have the right to terminate this Agreement as it relates to SB17 Product, upon providing [* * *] notice to Samsung of such termination.
- (f) In the event of a conflict between this Section 9.8 and any other Section in Article 9 with respect to the SB17 Product, this Section 9.8 controls.

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2.39 New Section 10.2A is added to the DCA as follows:

10.2A. Termination for Convenience. Organon shall have the right to terminate this Agreement with respect to SB17 at any time following the [* * *] of the Launch of SB17 in Canada upon providing [* * *] written notice of its decision to exercise such termination right with respect to SB17.

2.40 In Section 10.3.1, the following sentences are added to the last paragraph:

Notwithstanding the foregoing, in the case of termination under Section 10.3.1(a) due to a material breach relating to SB17 Product, the terminating Party may only terminate this Agreement with respect to SB17 Product and not with respect to any other Product. In addition, in the case of termination under Section 10.3.1(a) due to a material breach relating to a Product other than SB17 Product, the terminating Party may only terminate this Agreement with respect to Products other than the SB17 Product, and, for the avoidance of doubt, this Agreement shall continue in full force and effect with respect to SB17 Product.

2.41 Section 10.3.2 is deleted in its entirety and replaced with the following:

2.42 **10.3.2 Effect of Termination for Cause on License.** If Samsung or Organon terminates this Agreement in its entirety or only with respect to a particular Product in a particular Region or in all Regions under Section 10.3.1(a) or 10.3.1(b), subject to Section 10.6.2, the Parties' licenses granted under Article 3 shall terminate with immediate effect with respect to all of the Products in all Regions or only with respect to such particular Product in such particular Region or in all Regions, as the case may be, but without prejudice to any rights of the terminating Party to claim and recover from the other Party monetary damages suffered in connection with or arising out of such termination (or the underlying material breach that is the cause of such termination).

2.43 Section 10.4 is deleted in its entirety and replaced with the following:

2.44 **10.4 Termination Due to Infringement Claim, or Newly Issued Third Party Patent.** Organon shall have the right to terminate this Agreement with respect to a particular Product (other than SB17 Product) in a particular Region in accordance with the terms of Section 9.1 and have the right to terminate this Agreement with respect to SB17 Product in Canada in accordance with the terms of Section 9.8. Each Party shall have the right to terminate this Agreement with respect to a particular

Product (other than SB17 Product) in a particular Region in accordance with the terms of Section 9.3

2.45 Section 10.6.2 is deleted in its entirety and replaced with the following:

2.46 **10.6.2** Without limiting the generality of the foregoing sentences, in the event of termination of this Agreement pursuant to Section 9.8(d), 10.2, 10.2A, 10.3, 10.4 or 10.5 (whether in its entirety or only with respect to a particular Product in a particular Region or in all Regions), those portions of the Binding Forecast for Primary-Packaged Presentations and the Binding Forecast for Secondary-Packaged Presentations that are outstanding as of the effective date of such termination, which are for the Product(s), Presentation(s) and Region(s) for which this Agreement has been so terminated (such portions of such outstanding Binding Forecasts referred to herein are collectively “**Remaining Binding Forecasts**” and individually a “**Remaining Binding Forecast**”), shall be treated as follows:

2.47 (a) In the event that this Agreement is terminated by Organon under Section 10.2 or 10.3, Organon shall have the right, but not the obligation, to take delivery of the Product(s) to be supplied pursuant to the Remaining Binding Forecasts (collectively, the “**Post-Termination Delivery Products**”), in whole or in part (at Organon’s election), in accordance with the terms of this Agreement, and Samsung shall perform its obligations relating to such Remaining Binding Forecasts and Post-Termination Delivery Products accordingly; provided that, Organon shall be entitled to retain any Post-Termination Delivery Products of which Organon took delivery pursuant to this Section 10.6.2(a) and which have not been sold to a Third Party by [* * *] after the end of the last Calendar Quarter covered by the Remaining Binding Forecast for Primary-Packaged Presentations, without any accounting or payment obligations to Samsung other than the payment of the Supply Price for such Post-Termination Delivery Products (which Supply Price, and the Post-Termination Delivery Products for which such Supply Price is payable, shall be reflected and taken into account in determining (i) “Organon Profit” and “Samsung Profit” for the purpose of calculating “Profit Differential” for the Final True-up Period under Schedule 1.54 for Products other than SB17 Product and (ii) the Quarterly True-Up Amount under Schedule 1.54A for SB17 Product);

2.48 (b) In the event that this Agreement is terminated by Organon under Section 10.5 (*i.e.*, pursuant to Section (c) of Schedule 1.54) with respect to a Product other than SB17 Product, Samsung shall have the right, but not the obligation, to sell and deliver the Post-Termination Delivery Products, in whole or in part (at Samsung’s

election), to Organon in accordance with the terms of this Agreement, and Organon shall perform its obligations relating to the Remaining Binding Forecasts and such Post-Termination Delivery Products accordingly; provided that with respect to Products other than SB17 Product, Organon shall return to Samsung (as soon as reasonably practicable after the expiration of the period referred to below) any Post-Termination Delivery Products of which Organon took delivery pursuant to this Section 10.6.2(b) and which have not been sold to a Third Party by after the end of the last Calendar Quarter covered by the Remaining Binding Forecast for Primary-Packaged Presentations, and Samsung shall be entitled to retain such Post-Termination Delivery Products, as well as the Supply Price paid or payable therefor, without any accounting or payment obligations to Organon (except that such Supply Price, and the Post-Termination Delivery Products for which such Supply Price is payable, shall be reflected and taken into account in determining “Organon Profit” and “Samsung Profit” for the purpose of calculating “Profit Differential” for the Final True-up Period under Schedule 1.54);

(c) In the event that this Agreement is terminated by Samsung under Section 10.3, Samsung shall have the right, but not the obligation, to sell and deliver the Post-Termination Delivery Products, in whole or in part (at Samsung’s election), to Organon in accordance with the terms of this Agreement, and Organon shall perform its obligations relating to the Remaining Binding Forecasts and such Post-Termination Delivery Products accordingly; provided that with respect to Products, Organon shall return to Samsung (as soon as reasonably practicable after the expiration of the [* * *] period referred to below) any Post-Termination Delivery Products of which Organon took delivery pursuant to this Section 10.6.2(c) and which have not been sold to a Third Party by [* * *] after the end of the last Calendar Quarter covered by the Remaining Binding Forecast for Primary-Packaged Presentations, and Samsung shall be entitled to retain such Post-Termination Delivery Products, as well as the Supply Price paid or payable therefor, without any accounting or payment obligations to Organon (it being understood and agreed that neither such Supply Price nor the Post-Termination Delivery Products for which such Supply Price is payable shall be reflected or taken into account in determining (i) “Organon Profit” or “Samsung Profit” for the purpose of calculating “Profit Differential” for the Final True-up Period under Schedule 1.54 for Products other than SB17 Product and (ii) the Quarterly True-Up Amount under Schedule 1.54A for SB17 Product);

2.49 (d) In the event that Organon has any inventory of Product on the date of expiration or termination, or chooses (under Section 10.6.2(a) above), or is required (under Section 10.6.2(b) or 10.6.2(c) above), to receive delivery of any Post-

Termination Delivery Products, Organon shall retain the right to Commercialize such inventory of Product and such Post-Termination Delivery Products and the obligation to take delivery of and pay for such Post-Termination Delivery Products in accordance with the terms of this Agreement as if, solely for the purpose of and with respect to such inventory of Product and Post-Termination Delivery Products (and not for any other purposes), this Agreement had not been so terminated; provided, however, that for the purpose of the preceding sentence, immediately upon termination of this Agreement pursuant to Section 10.2, 10.3, 10.4 or 10.5, all of the licenses and Commercialization rights granted by Samsung to Organon under Article 3 shall become non-exclusive with respect to the inventory of Product and Post-Termination Delivery Products; and

(e) In the event that this Agreement is terminated by either Party under Section 10.4, (i) the Remaining Binding Forecasts shall be automatically cancelled, and (ii) the Operational Costs associated with all Post-Termination Delivery Products covered by the Remaining Binding Forecasts shall be: (A) borne by Organon and paid to Samsung within thirty (30) days following such termination if this Agreement is so terminated by Organon under Section 9.1 or 9.3, (B) borne by Samsung if this Agreement is so terminated by Samsung under Section 9.3 or (C) borne by Samsung if this Agreement is so terminated by Organon under Section 9.8(d). For the avoidance of doubt, in the event of termination by either Party under Section 10.4, (i) under and for the purpose of the Supply Price True-up Mechanism, (1) no Post-Termination Delivery Products covered by the Remaining Binding Forecasts so cancelled shall be included in determining "Supply Volume" and (2) no Operational Costs paid by Organon to Samsung or borne by Samsung pursuant to this Section 10.6.2(e) shall be reflected or taken into account in determining "Samsung Costs" or "Organon Costs" and (ii) no Post-Termination Delivery Products covered by the Remaining Binding Forecasts so cancelled and no Operational Costs paid by Organon to Samsung or borne by Samsung pursuant to this Section 10.6.2(e) shall be reflected or taken into account determining the Quarterly True-Up Amount.

2.50 The third sentence of Section 10.6.4 is deleted in its entirety and replaced with the following:

2.51 Following the expiration and/or termination of this Agreement with respect to a Product in all of its Presentations and all Regions, such Product (including its applicable Compound) shall cease to be a Product (or a Compound) for purposes of this Agreement (including Section 2.4). Following expiration and/or termination of this Agreement with respect to a Product in any Region(s) (but not in all Regions),

such Product (including its applicable Compound) shall cease to be a Product (or a Compound) for purpose of such Region(s).

2.52 New Section 10.6.4A is added to the DCA as follows:

2.53 If Organon is unable to Launch SB17 Product and terminates this Agreement with respect to SB17 Product in accordance with Section 10.2 or Section 10.4, as applicable, Samsung shall reimburse Organon for the Supply Price paid for SB17 Product within [* * *] of the effective date of termination of this Agreement with respect to SB17 Product.

2.54 Section 11.5 is deleted in its entirety and replaced with the following:

11.5 Notices. All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by internationally-recognized express courier or sent by registered or certified airmail, postage prepaid, return receipt requested, addressed as follows:

if to Samsung, to: Samsung Bioepis Co., Ltd.
76, Songdogoyoyuk-ro
Yeonsu-gu, Incheon, 21987
Republic of Korea
Attention: Representative Director
Attention: Chief Financial Officer
e-mail: [* * *]

if to Organon, to: Organon LLC
30 Hudson Street
Jersey City, NJ, 07302
USA
Attention: Office of the General Counsel, Vice President, Mergers & Acquisitions and Licensing
Legal
e-mail: [* * *]

or to such other address(es) as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given on the day on which such notice is delivered to the recipient Party (or if so delivered on a non-Business Day, then on the next Business Day).

2.55 New Schedule 1.41A (Product Criteria) to the DCA is attached hereto.

2.56 New Schedule 1.54A (Net Sales Share Mechanism for SB17 Product) to the DCA is attached hereto.

2.57 New Schedule 3.7.2 (Trademarks for SB17 Product) to the DCA is attached hereto.

III. MISCELLANEOUS

3.1 In the event a Party is required to file a copy of this Amendment No. 8 with a Regulatory Authority or any other governmental authority or agency, (i) such Party shall redact commercially sensitive information from such copy to the extent permitted under applicable law and (ii) such Party shall provide the other Party with an advance draft of the redacted form of this Amendment No. 8 that the disclosing Party proposes to file, with not less than ten (10) Business Days for review, and shall incorporate the non-disclosing Party's comments to the extent additional or other redactions requested by the non-disclosing Party are permitted, and may reasonably be afforded confidential treatment, under applicable law and such authority or agency's then-current practice.

3.2 Sections 11.4, 11.6, 11.7, 11.9, and 11.11 through 11.17 of the Agreement shall apply to this Amendment No. 8, *mutatis mutandis*.

3.3 The Agreement, as amended by this Amendment No. 8, together with the Schedules to the Agreement and any other agreements executed by authorized representatives of the Parties that make reference to the Agreement, contains the entire understanding of the Parties with respect to the Compounds and Products. Any other express or implied agreements, understandings, negotiations, writings and commitments, either oral or written, with respect to the subject matter of the Agreement are superseded by the terms of the Agreement as amended by this Amendment No. 8.

[Signatures on the Following Page]

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IN WITNESS WHEREOF, the Parties, intending to be legally bound, have caused this Amendment No. 8 to be executed by their duly authorized representatives as of the Amendment No. 8 Effective Date.

ORGANON LLC

SAMSUNG BIOEPIS CO., LTD.

By: /s/ Matthew M. Walsh

By: /s/ Kwang Ryu

Name: Matthew M. Walsh

Name: __Kwang Ryu

Title: Chief Financial Officer

Title: VP, Head of Global Business Development

Date: May 27, 2026

Date: May 22, 2026

[* * *]=[CONFIDENTIAL PORTION HAS BEEN OMITTED BECAUSE IT (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.]

SCHEDULE 1.41A

[* * *]

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[* * *]=[CONFIDENTIAL PORTION HAS BEEN OMITTED BECAUSE IT (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.]

Schedule 1.54A

[* * *]

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Schedule 3.7.2 - Trademarks for SB17 Product

[* * *]

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[* * *]=[CONFIDENTIAL PORTION HAS BEEN OMITTED BECAUSE IT (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.]

Schedule 6.2

[* * *]

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**AMENDMENT NO. 9
TO
DEVELOPMENT AND COMMERCIALIZATION AGREEMENT**

This Amendment No. 9 to Development and Commercialization Agreement (this “**Amendment No. 9**”) is effective as of May 26, 2026 (the “**Amendment Effective Date**”) and is entered into by and between **SAMSUNG BIOEPIS CO., LTD.**, a corporation organized and existing under the laws of the Republic of Korea with a place of business at 76, Songdogyoyuk-ro, Yeonsu-gu, Incheon, 21987, Republic of Korea (hereinafter referred to as “**Samsung**”) and **ORGANON LLC**, a limited liability company organized and existing under the laws of the State of Delaware, USA, with a place of business at 30 Hudson Street, Jersey City, NJ 07302(hereinafter referred to as “**Organon**”). Samsung and Organon are hereinafter referred to jointly as the “**Parties**” and individually as a “**Party**”.

RECITALS

WHEREAS

- (i) On February 18, 2013, Samsung and Merck Sharp & Dohme Corporation (“**Merck**”) executed the Development and Commercialization Agreement, as amended on July 21, 2014, July 11, 2017, October 1, 2017, September 1, 2018, October 15, 2018, December 19, 2018, May 15, 2020 and May 22, 2026 (“**DCA**” or “**Agreement**”), for the purpose of, among other things, granting Merck an exclusive license (even as to Samsung) to Commercialize any and all Compounds and Products in the Territory.
- (ii) Pursuant to Amendment No. 7 to Development and Commercialization Agreement effective May 15, 2020, Merck assigned all of its rights and obligations under the DCA to Organon.
- (iii) Pursuant to Amendment No. 6 to Development and Commercialization Agreement effective December 19, 2018 (“Amendment No. 6”), Organon and Samsung entered into an amendment regarding the establishment of a PDP Program (as defined in Amendment No. 6) for certain Products including Trastuzumab/Herceptin Biosimilar (SB3) (the “Trastuzumab PDP Program”).
- (iv) The Parties have agreed to extend the term of the DCA for certain Products in certain countries, terminate the DCA for Trastuzumab/Herceptin Biosimilar (SB3) in certain countries and terminate Bevacizumab/Avastin Biosimilar (SB8) in all of the countries in the world.

NOW THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1 DEFINITIONS

- 1.1 The Parties agree that capitalized terms used but not otherwise defined in this Amendment No. 9 shall have the meanings ascribed thereto in the DCA.

1.2 All references to Merck in the DCA are replaced with Organon.

1.3 Definition of Affiliate in Section 1.2 is amended to read in its entirety as follows:

“Affiliate” shall mean (i) any corporation or business entity (A) of which, now or hereafter, fifty percent (50%) or more of the securities or other ownership interests representing the equity, the voting stock or general partnership interest are owned, controlled or held, directly or indirectly, by Organon or Samsung or (B) which, now or hereafter, is controlled directly or indirectly by Organon or Samsung; or (ii) any corporation or business entity (A) which, now or hereafter, directly or indirectly, owns, controls or holds fifty percent (50%) (or the maximum ownership interest permitted by law) or more of the securities or other ownership interests representing the equity, the voting stock or, if applicable, the general partnership interest, of Organon or Samsung or (B) which, now or hereafter, directly or indirectly controls Organon or Samsung; or (iii) any corporation or business entity (A) of which, now or hereafter, fifty percent (50%) or more of the securities or other ownership interests representing the equity, the voting stock or general partnership interest are owned, controlled or held, directly or indirectly, by a corporation or business entity described in (i) or (ii) or (B) which, now or hereafter, is controlled directly or indirectly by a corporation or business entity described in (i) or (ii). For the purpose of this Section 1.2 and Section 1.13, the term “control” shall mean the power and ability to direct the management and policies of the controlled corporation or business entity, whether directly or indirectly through one or more intermediaries, through ownership of voting securities or other ownership interests of the controlled corporation or business entity or by contract or otherwise, and the terms “controlled” and “controlling” shall be construed accordingly.

1.4 The following Definitions in Article 1 are added or revised as follows:

- i. A new Section 1.18A is added as follows: **“Extended Product(s)”** means Product(s) that is/are comprised of, incorporate(s), or contain(s) the following Compound(s) set forth in the first column of the table below but only in the applicable countries for the applicable duration in each case as set forth in the table below:

Product	Countries	Extended Term
SB2 (Infliximab/Remicade Biosimilar)	Australia, Canada, Brazil, United Arab Emirates and Saudi Arabia.	[* * *] extension following the expiration of the Term of the Product in the ROW Region beginning on [* * *] and ending on [* * *]
SB4 (Etanercept/Enbrel Biosimilar)	Australia, Canada, Brazil, United Arab Emirates and Saudi Arabia.	[* * *] extension following the expiration of the Term of the Product in the ROW Region beginning on [* * *] and ending on [* * *]

- 1.5 A new section 1.18B is hereby added as follows: “**Extended Term**” shall mean the timeframe set forth in the last column of the table contained in Section 1.18A for a particular Product, in particular countries in the Territory where the Parties have agreed to extend the duration of the Agreement with respect to such Product in such countries following the date which would have represented the expiration of such Product in such Region in the Territory absent the extension provided for in this Amendment No. 9.
- 1.6 Section 1.56 is amended to read in its entirety as follows: “Territory” shall mean the following:
- 1.56.1 With respect to Cetuximab/Erbitux Biosimilar, all of the countries in the world, and their territories and possessions, excluding, however, the Republic of Korea and Greater China;
 - 1.56.2 With respect to Trastuzumab/Herceptin Biosimilar (SB3), all of the countries in the worlds and their territories and possessions, excluding however, the Republic of Korea and Greater China; provided, however, that (i) effective [* * *], the Territory, as it applies to Trastuzumab/Herceptin Biosimilar shall mean, subject to proviso immediately below Section 1.56.5, Canada, USA and their territories and possessions; and (ii) effective [* * *] the Territory, as it applies to Trastuzumab/Herceptin Biosimilar shall mean USA and its territories and possessions
 - 1.56.3 With respect to (i) Adalimumab/Humira Biosimilar (SB5) and (ii) Infliximab/Remicade Biosimilar (SB2), all of the countries in the world, and their territories and possessions, excluding, however, the Republic of Korea, and Greater China, and the countries, territories and possessions set forth on Schedule 1.56A; provided that the countries, territories and possessions set forth on Schedule 1.56B shall be part of the Territory with respect to Adalimumab/Humira Biosimilar (SB5) and Infliximab/Remicade Biosimilar (SB2) commencing on July 1, 2014;
 - 1.56.4 With respect to Etanercept/Enbrel Biosimilar (SB4), all of the countries in the world, and their territories and possessions, excluding, however, the Republic of Korea, and Greater China, and the countries, territories and possessions set forth on Schedule 1.56C; and
 - 1.56.5 With respect to Bevacizumab/Avastin Biosimilar (SB8), the countries, territories and possessions set forth on Schedule 1.56D; provided; however, that (i) effective [* * *], with exception of Canada, all the countries, territories and possessions set forth in Schedule 1.56D are excluded from the Territory applied to Bevacizumab/Avastin Biosimilar and (ii) effective [* * *], Canada will be excluded from the Territory such that, effective [* * *], the DCA for Bevacizumab/Avastin Biosimilar shall be terminated in its entirety for all of the countries in the world, and their territories and possessions.

Notwithstanding the termination date set forth in Section 1.56.2 (i) above, with respect to the Trastuzumab PDP Program in Brazil as set forth in Amendment No. 6 and the Supply Agreement -Trastuzumab effective as of December 20, 2018 by and among Samsung Bioepis Co., LTD, Organon Latin America Services S. de R.L. and Bionovis S.A. (the “PDP Supply Agreement”), such Trastuzumab PDP Program in Brazil shall remain in full force and effect in accordance with each agreements respective terms and conditions until [* * *]; provided, that, such termination is conditioned upon Samsung and Organon obtaining, at no cost to Organon, the consent of Bionovis to the assignment of all of Organon’s rights and responsibilities under the PDP Supply Agreement to Samsung. For the avoidance of doubt any amounts owed Organon under the PDP Supply Agreement for supply to [* * *] occurring prior to the date of assignment shall continue to be due to Organon. In the event such consent to assignment of the PDP Supply Agreement cannot be obtained prior to [* * *], the Trastuzumab PDP Program shall remain in force and effect under the terms and conditions of Amendment 6 and the PDP Supply Agreement until conclusion of the Trastuzumab PDP Program pursuant to the terms of such agreements.

ARTICLE 2 AMENDMENT

2.1 A new Section 5.5A is added as follows:

As of Amendment Effective Date, all financial obligations under Section 5.2 shall be deemed to have been fully satisfied with respect to all Products and no further payment shall be due and payable by either Party under this Section.

In Schedule 1.54, the following is added under Section (b):

Unless the DCA has been terminated or expired in its entirety or terminated or expired with respect to the entire Extended Products, for the period of [* * *] starting the Calendar Year [* * *] and ending for Calendar Year [* * *], by the end of the Quarterly True-up Period for each fourth Calendar Quarter, Organon shall pay Samsung an annual payment of [* * *] which in aggregate shall not exceed [* * *].

2.2 A new Section 10.6.3A is added as follows:

10.6.3A. Transition and Termination Plan for Bevacizumab/Avastin (SB8) and Trastuzumab/Herceptin (SB3) Biosimilars in Europe, Brazil and Canada.

It is understood and agreed by the Parties that promptly upon the Amendment Effective Date, Samsung and Organon shall discuss and mutually agree upon a detailed information transition and termination plan with compensation equal to [* * *] during the term of the plan (“**Transition and Termination Plan**” or “**TTP**”). The TTP will cover the transfer of information and termination with respect to Bevacizumab/Avastin Biosimilar in Canada,

United Kingdom, France, Italy, Spain and Germany and Trastuzumab/Herceptin Biosimilar in the European Union, Brazil and Canada. The term of the TTP shall commence on a date agreed in the TTP and end upon the applicable Cutover Date (as defined below).

For the avoidance of doubt, Organon shall continue to be the Commercializing Party (i) through [* * *] for the United Kingdom, France, Italy, Spain and Germany and their respective territories with respect to Bevacizumab/Avastin Biosimilar and Trastuzumab/Herceptin Biosimilar (“**EU Cutover Date**”); (ii) through [* * *] for Brazil excluding Brazil PDP with respect to Trastuzumab/Herceptin Biosimilar (“**Brazil Private Cutover Date**”); (iii) through [* * *] for Canada with respect to Bevacizumab/Avastin Biosimilar and Trastuzumab/Herceptin Biosimilar (“**Canada Cutover Date**”); and each of the Canada Cutover Date, Brazil Private Cutover Date, or the EU Cutover Date being a “**Cutover Date**”). On the day immediately following the applicable Cutover Date, Samsung shall assume full commercial responsibility with respect to the applicable Product in the applicable country.

The Parties agree the TTP should provide reasonably necessary business information to Samsung in advance of the applicable Cutover Date. The TTP should address the transition of the following items as follows: (a) transfer of promotional materials, list of main customers by country, distribution channels and tender information (b) termination of existing commercial contracts related to distribution channels (customers, payers, GPOs, distributors, providers – as applicable per product and market), commercial accounts and tenders, which are exclusive to the product (c) transfer of pharmacovigilance activities and communications with health authorities (d) transfer of patient support programs data (e) development of a communication plan to main stakeholders (f) transfer of mapping with respect to end-to-end pricing architecture (rebates, chargebacks, government pricing, etc.) and (g) transfer of relevant market access information, such as payer formulary status, prior authorization/step therapy, coverage policies, copay assistance.

As part of the TTP, the Parties shall apply Commercial Reasonable Efforts to mitigate any risk of product discards arising for Product inventory held by Organon at the applicable Cutover Date. In the case Parties cannot eliminate Organon’s inventory with respect to a Product by the applicable Cutover Date, Organon shall have the right to commercialize the remaining saleable inventory of such Product after the applicable Cutover Date until Organon’s inventory of such Product is fully depleted. Organon shall not be liable for any discards of Samsung-owned SB3 and SB8 Bulk Drug Substance or Drug Product. For the avoidance of doubt, both Parties share the costs of discarded/obsolete packaging components for the SB3 and SB8 Secondary-Packaged Presentations in existence as of the applicable Cutover Date.

In the event Parties identify during the TTP preparation, commercial and/or tender contracts extending beyond Cutover Dates which cannot be terminated or assigned to Samsung, Organon shall maintain rights to commercialize the Products after the applicable Cutover Date solely for the purpose of supplying those contracts until its expiration.

Notwithstanding the foregoing, after the expiration of TTP with respect to a particular Product for particular country(ies) at the applicable Cutover Date, upon Samsung’s request, Organon agrees to extend the term of the TTP for such Product in such Country(ies) beyond the

applicable Cutover Date in [* * *] increments; provided that in no event shall the term of the TTP for such Product in such country(ies) exceed [* * *] past the date of the applicable Cutover Date. In consideration for this extension, Samsung shall pay Organon a non-refundable payment to Organon in the amount of [* * *] for every [* * *] of extension.

In accordance with the Section 3.7 in DCA, within [* * *] of the applicable Cutover Date, Organon shall promptly assign to Samsung, for no consideration, all of its rights, title and interests in and to all Trademarks for the applicable Product in the applicable country(ies), including all goodwill arising therefrom.

For avoidance of doubt, the TTP shall not be applicable for the transition of PDP Program for Trastuzumab/Herceptin Biosimilar (SB3) in Brazil.

2.4 A new Section 10.7 is added as follows:

10.7 Updated Binding Forecast for Extended Products and Terminations

As result of (i) extensions for Infliximab/Renflexis (SB2) and Etanercept/Enbrel Biosimilar (SB4) in certain territories, as well (ii) the upcoming termination for Bevacizumab/Avastin (SB8) and Trastuzumab/Herceptin (SB3) in certain territories, the Parties agree to replace the quarterly Binding Forecast submitted by Organon on [* * *] solely with respect to SB3, SB4 and SB8 products with the quarterly Binding Forecast reflected in the Schedule A of this Amendment solely with respect to SB3, SB4 and SB8 products and solely in the specified territories. For the avoidance of doubt, the last Binding Forecast previously submitted by Organon to Samsung for SB5, SB2 and unspecified countries of SB3, SB4 and SB8 remains unchanged. Samsung hereby confirms the quantities set forth in the first Calendar Quarter of the Binding Forecast set forth in Schedule A to this Amendment in accordance with Section 6.4 of the DCA.

ARTICLE 3 MISCELLANEOUS

- 3.1 In the event a Party is required to file a copy of this Amendment No. 9 with a Regulatory Authority or any other governmental authority or agency, (i) such Party shall redact commercially sensitive information from such copy to the extent permitted under applicable law and (ii) such Party shall provide the other Party with an advance draft of the redacted form of this Amendment No. 9 that the disclosing Party proposes to file, with not less than ten (10) Business Days for review, and shall incorporate the non-disclosing Party's comments to the extent additional or other redactions requested by the non-disclosing Party are permitted, and may reasonably be afforded confidential treatment, under applicable law and such authority or agency's then-current practice.
- 3.2 Sections 11.4, 11.5, 11.6, 11.7, 11.9, and 11.11 through 11.17 of the Agreement shall apply to this Amendment No. 9, *mutatis mutandis*.
- 3.3 The Agreement, as amended by this Amendment No. 9, together with the Schedules to the Agreement and any other agreements executed by authorized representatives of the Parties

that make reference to the Agreement, contains the entire understanding of the Parties with respect to the Compounds and Products. Any other express or implied agreements, understandings, negotiations, writings and commitments, either oral or written, with respect to the subject matter of the Agreement are superseded by the terms of the Agreement as amended by this Amendment No. 9.

[Signatures on the Following Page]

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[* * *]=[CONFIDENTIAL PORTION HAS BEEN OMITTED BECAUSE IT (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.]

IN WITNESS WHEREOF, the Parties, intending to be legally bound, have caused this Amendment No. 9 to be executed by their duly authorized representatives as of the Amendment Effective Date.

ORGANON LLC

SAMSUNG BIOEPIS CO., LTD.

By: /s/ Matthew M. Walsh

By: /s/ Kwang Ryu

Name: Matthew M. Walsh

Name: Kwang Ryu

Title: Chief Financial Officer

Title: VP, Head of Global Business Development

Date: May 27, 2026

Date: May 22, 2026

[* * *]=[CONFIDENTIAL PORTION HAS BEEN OMITTED BECAUSE IT (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.]

Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Schedule A

[* * *]

[* * *]=[CONFIDENTIAL PORTION HAS BEEN OMITTED BECAUSE IT (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.]

**AMENDMENT NO. 10 TO
DEVELOPMENT AND COMMERCIALIZATION AGREEMENT**

This Amendment No. 10 to Development and Commercialization Agreement (this “**Amendment No. 10**”) is effective as of June 01, 2026, (the “**Amendment No. 10 Effective Date**”) and is entered into by and between **SAMSUNG BIOEPIS CO., LTD.**, a corporation organized and existing under the laws of the Republic of Korea with a place of business at 76, Songdogyoyuk-ro, Yeonsu-gu, Incheon, 21987, Republic of Korea (hereinafter referred to as “**Samsung**”) and **ORGANON LLC**, a limited liability company organized and existing under the laws of the State of Delaware, USA, with a place of business at 30 Hudson Street, Jersey City, NJ 07302 (hereinafter referred to as “**Organon**”).

Samsung and Organon are hereinafter referred to jointly as the “**Parties**” and individually as a “**Party**”.

RECITALS

WHEREAS

(i) On February 18, 2013, Samsung and Merck Sharp & Dohme Corporation (“**Merck**”) executed the Development and Commercialization Agreement, as amended on July 21, 2014, July 11, 2017, October 1, 2017, September 1, 2018, October 15, 2018, December 19, 2018, May 15, 2020, May 22, 2026, and May 26, 2026 (“**DCA**” or “**Agreement**”), for the purpose of, among other things, granting Merck an exclusive license (even as to Samsung) to Commercialize any and all Compounds and Products in the Territory.

(ii) Pursuant to Amendment No. 7 to Development and Commercialization Agreement effective May 15, 2020, Merck assigned all of its rights and obligations under the DCA to Organon.

(iii) The Parties now wish to amend the DCA to grant to Organon the right to commercialize SB17 Product in Australia.

NOW THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

I. DEFINITIONS

[* * *]=[CONFIDENTIAL PORTION HAS BEEN OMITTED BECAUSE IT (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.]

The Parties agree that capitalized terms used but not otherwise defined in this Amendment No. 10 shall have the meanings ascribed thereto in the DCA.

II. AMENDMENT

2.1 Section 1.41 is deleted in its entirety and replaced with the following:

2.2 “**Product Criteria**” shall mean the criteria with respect to Indications, Presentations, dosage strengths and timing for receipt of Marketing Authorization (or in the case of the [* * *], and timing for filing applications for Marketing Authorization), set forth with respect to each Product on Schedule 1.41, Schedule 1.41A and Schedule 1.41B.

2.3 Section 1.42 is deleted in its entirety and replaced with the following:

“**Region**” shall mean each of (i) the European Union, as a whole, (ii) the USA and its territories and possessions, as a whole, and (iii) the remainder of the Territory excluding the European Union and the USA and its territories and possessions (collectively, the “**ROW Region**”). However, (a) for Bevacizumab/Avastin Biosimilar only, “**Region**” shall mean (1) United Kingdom, France, Italy, Germany and Spain, as a whole until [* * *], (2) the USA (including its territories and possessions), until [* * *], (3) Canada, until [* * *] and (4) the respective territories and possessions of United Kingdom, France, Italy, Germany, Spain and Canada that are set forth on Schedule 1.56D, until [* * *] (with respect to territories and possessions of United Kingdom, France, Italy, Germany, and Spain) or until [* * *] (with respect to territories and possessions of Canada), and (b) for SB17 Product only, “**Region**” shall mean Canada and Australia.

For purposes of this Agreement, “**European Union**” or “**E.U.**” means, collectively, (a) the economic, scientific, and political organization of member states known as the European Union, as its membership may be altered from time to time, and any successor thereto, and (b) the United Kingdom.

2.4 Section 1.53 is deleted in its entirety and replaced with the following:

2.5 “**Supply Price**” of each unit of a Product in a particular Presentation supplied by Samsung to Organon for sale in a Region shall mean (i) with respect to Products other than SB17 Product, the Target Supply Price determined under the Supply Price

True-up Mechanism for such Product in such Presentation in such Region and (ii) with respect to SB17 Product, the Actual Supply Price determined in accordance with Schedule 1.54A for Canada and in accordance with Schedule 1.54B for Australia.

2.6 In Section 1.54, the following sentence is added at the end:

2.7 For clarity, notwithstanding the foregoing, the Supply Price True-up Mechanism is not applicable to SB17 Product. With respect to SB17 Product, the Actual Supply Price will be determined in accordance with Schedule 1.54A for Canada and in accordance with Schedule 1.54B for Australia.

2.8 Section 1.56.5 is deleted in its entirety and replaced by the following:

2.9 1.56.5 With respect to Ustekinumab/Stelara Biosimilar, Canada and Australia.

2.10 Section 3.7.2 is deleted in its entirety and replaced with the following:

3.7.2. Trademarks for SB17 Product.

(a) The Trademarks for the SB17 Product are set forth on Schedule 3.7.2.

(b) Samsung shall own and upon registration maintain the Trademarks for the SB17 Product. Subject to Section 9.7 and Section 9.8, Samsung shall be responsible for filing, prosecuting, registering, maintaining, enforcing and protecting the Trademarks for the SB17 Product, at Samsung's own expense. Organon recognizes that the Trademarks for the SB17 Product are trademarks of Samsung and that Organon has no right or interest in the Trademarks for the SB17 Product other than those rights explicitly granted in this Agreement. Samsung will inform Organon of any action it may take with respect to the Trademarks for the SB17 Product to the extent such action may impact Organon's rights, benefits and obligations hereunder. Samsung hereby grants to Organon an exclusive (even as to Samsung), non-transferable, royalty-free license to reproduce and use the Trademarks for the SB17 Product solely to Commercialize the SB17 Product in Canada and Australia during the applicable Term. Organon shall not contest or aid others in contesting the validity of the Trademarks for the SB17 Product or Samsung's ownership of the Trademarks for the SB17 Product. Organon shall not apply for, or aid or cause others to apply for, any registration of the Trademarks for the SB17 Product or other trademarks similar to the Trademarks for the SB17 Product. Organon shall not take any other action

inconsistent with Samsung's ownership of the Trademarks for the SB17 Product. Organon shall not use the Trademarks for the SB17 Product in any way that might prejudice their distinctiveness or validity in Canada and Australia. As between the Parties, any benefits (including, without limitation, goodwill) accruing from Organon's use of the Trademarks for the SB17 Product shall automatically vest in Samsung. Organon shall furnish to Samsung a sample of each use of the Trademarks for the SB17 Product by Organon for Samsung's approval prior to use, provided that any subsequent uses of the sample previously approved by Samsung are permitted without an additional approval. Organon shall cooperate with Samsung in facilitating inspection and quality control over Organon's use of the Trademarks for the SB17 Product. Organon shall not use the Trademarks for the SB17 Product, except as permitted under this Agreement in Canada and Australia. Organon's use of the Trademarks for the SB17 Product shall not tarnish, blur, or dilute the quality associated with the Trademarks for the SB17 Product or the associated goodwill in Canada or Australia. Organon shall not use any other trademarks that are confusingly similar to the Trademarks for the SB17 Product in Canada and Australia, as applicable. Organon shall ensure that its permitted Affiliates and sublicensees also comply with the requirements provided in this Section 3.7.2. For clarity, subject to Section 10.6.2, in the event this Agreement expires or terminates with respect to the SB17 Product in Canada or Australia, as applicable, the license to use the applicable Trademarks for the SB17 Product in Canada or Australia, as applicable, will terminate automatically.

(c) Samsung shall not use, or license any Third Party to use, any other Trademarks that are confusingly similar to the Trademarks for the SB17 Product in Canada or Australia.

2.11 In Section 6.2, the final sentence is deleted in its entirety and replaced with the following:

2.12 For Launch of the SB17 Product in Canada, Organon will order those quantities of SB17 set forth on Schedule 6.2. For Launch of the SB17 Product in Australia, Organon will order those quantities of SB17 set forth on Schedule 6.2A.

2.13 In Section 6.11, the final sentence is deleted in its entirety and replaced with the following:

2.14 For the purposes of this Agreement, “delivery” of a Product to Organon shall be deemed to occur, and title and risk of loss with respect to the Product shall pass to Organon, upon delivery of the Product to such carrier [* * *]; provided that, notwithstanding the foregoing, the Parties agree that title with respect to SB17 shall pass to Organon in international waters.

2.15 Section 6.15 is deleted in its entirety and replaced with the following:

2.16 **Responsibility for Losses.** The Parties agree to allocate losses or damages to Products (other than SB17 Product) or destruction of Products (other than SB17 Product) due to expiration of the shelf-life as described in Schedule 6.15. If Samsung deems necessary and should Organon accept SB17 Product which is delivered with less shelf life than the required remaining shelf life pursuant to Section 6.5, the Parties agree to discuss in good faith the sharing of the Supply Price for any SB17 Product supplied with such lesser shelf life which cannot be sold in the Territory and Samsung shall credit such amount against the next purchase order. Notwithstanding the foregoing, if Samsung deems necessary and should Organon accept SB17 Product for the Launch quantities as per Schedule 6.2 or Schedule 6.2A, as applicable, which is delivered with less shelf life than the required remaining shelf life pursuant to Section 6.5, then Samsung shall reimburse Organon for the Supply Price paid by Organon to Samsung for all remaining quantities of such SB17 Product that are no longer accepted for purchase by wholesalers due to the remaining shelf life.

2.17 Section 7.1 is deleted in its entirety and replaced with the following:

2.18 **7.1 Booking of Revenue; Records; Payment of Supply Price.** Organon shall book revenue for sales of the Products throughout the Territory. Organon shall maintain records, in sufficient detail for accounting purposes and for purposes of this Agreement (including, without limitation, the Supply Price True-up Mechanism and the Net Sales Share Mechanism) which shall fully and properly reflect all work done and results achieved in the Commercialization of the Compounds and Products by Organon. The Supply Price for each Product (other than SB17 Product) shall be set, and adjusted, on a Calendar Year basis in accordance with the Supply Price True-up Mechanism attached hereto as Schedule 1.54. The Supply Price for SB17 Product shall be set and adjusted in accordance with Schedule 1.54A for Canada and Schedule 1.54B for Australia (“**Net Sales Share Mechanism**”). Within the later of (i) [* * *] following the delivery of Product to a carrier designated by Organon and (ii) [* * *] following the delivery of the invoice for such Product to Organon, Organon shall pay Samsung the Supply Price for such Product.

2.19 The Parties agree to provide the following additional representations and warranties solely with respect to this Amendment No. 10 and for the SB17 Product.

2.19.1 New Section 8.1B is added to the DCA as follows:

8.1B. Representations and Warranties Each Party. Solely with respect to this Amendment No. 10, and with respect to the SB17 Product, each of Samsung and Organon hereby represents and warrants to the other Party as of the Amendment No. 10 Effective Date:

- (a) it has the full right, power and authority to enter into this Amendment No. 10 and to perform its obligations hereunder;
- (b) this Amendment No. 10 has been duly authorized by all necessary corporate action on its part, has been duly executed by it and is legally binding upon it, enforceable in accordance with its terms; and
- (c) this Amendment No. 10 does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law, rule, regulation, judgment, decree or order of any court, governmental body or administrative or other agency having jurisdiction over it.

2.19.2 New Section 8.2C is added to the DCA as follows:

2.19.3 8.2C. Samsung Representations and Warranties. Solely with respect to this Amendment No. 10 and with respect to the SB17 Product, Samsung hereby represents and warrants to Organon as of the Amendment No. 10 Effective Date that:

- (a) it has the full right, power and authority to Develop the SB17 Product and to grant the licenses granted under Article 3;
- (b) it has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the Samsung Patent Rights or Samsung Know-How, in each case, related to the SB17 Product other than a non-exclusive, non-transferable, royalty-free, fully-paid-up license granted to CMOs under certain Samsung Patent Rights and

Samsung Know-How for the purpose of enabling the CMOs to fulfill their contract manufacturing obligations thereunder;

- (c) there are no claims, judgments or settlements against or owed by Samsung, and no pending or threatened claims or litigation against Samsung, relating to the Samsung Patent Rights or Samsung Know-How, in each case, related to the SB17 Product;
- (d) there are no actions or lawsuits pending or to Samsung's knowledge threatened, against Samsung, its Affiliates or its CMOs alleging infringement of a Third Party's intellectual property rights based on the Commercialization of the SB17 Product in Australia or the Manufacture of the SB17 Product for Commercialization in Australia as contemplated by this Amendment No. 10 and, to the knowledge of Samsung as of the Amendment No. 10 Effective Date, the Commercialization of the SB17 Product in Australia and the Manufacture of the SB17 Product for Commercialization of the SB17 Product in Australia as contemplated by this Amendment No. 10, in each case, do not and will not infringe any intellectual property rights of any Third Party; and
- (e) Samsung has disclosed to Organon all reasonably relevant information regarding the SB17 Product Licensed IP and the existence of any patent opinions relating thereto, which, in each case, Samsung actually possesses or knows as of the Amendment No. 10 Effective Date.

2.19.4 New Section 8.2D is added to the DCA as follows:

8.2D. Additional Representations, Warranties and Covenants of Samsung. Samsung hereby represents, warrants and covenants, as applicable, to Organon that:

- (a) it shall at all times during the Term retain (but only for so long as the intellectual property licenses granted to Organon under the Samsung Know-How, Samsung Patent Rights and Trademarks for the SB17 Product for the Development, Manufacturing and Commercialization of the SB17 Product remain in effect) the full right, power, and authority to Commercialize the SB17 Product in Australia and to

Manufacture the SB17 Product and to grant and maintain in effect all of the licenses and sublicenses granted to Organon with respect to SB17 Product Licensed IP, provided that for clarity, the foregoing representation and warranty shall not be construed to be a representation or warranty as to non-infringement of a third party's intellectual property rights. For further clarity, Samsung is the sole and exclusive legal and beneficial owner of, or otherwise has the full right, power, and authority to grant the rights and licenses granted under this Agreement with respect to, the SB17 Product Licensed IP;

- (b) [* * *];
- (c) [* * *];
- (d) neither it nor any of its Affiliates or, to its knowledge as of the Amendment No. 10 Effective Date, any of its licensors has, as of the Amendment No. 10 Effective Date, assigned, transferred, conveyed or otherwise encumbered any right, title and interest in the SB17 Product Licensed IP, or will make or permit such an assignment, transfer, conveyance or encumbrance during the Term, in each case to the extent such assignment, transfer, conveyance or encumbrance would conflict with any of the terms of this Agreement;
- (e) no Third Party or any individual, whether an employee, officer, consultant or other Person who participated in any respect in the invention or authorship of any SB17 Product Licensed IP owned by Samsung, or with respect to the SB17 Product Licensed IP licensed by Samsung, to Samsung's knowledge as of the Amendment No. 10 Effective Date, has any right, claim, title or interest in or to such SB17 Product Licensed IP and the SB17 Product Licensed IP owned by Samsung, or the SB17 Product Licensed IP licensed by Samsung, to Samsung's knowledge, is free and clear of any liens, encumbrances, security interests, licenses, or other restrictions which would conflict with any of the terms of this Agreement; and
- (f) except as disclosed as of the Effective Date, each of the Trademarks for the SB17 Product is valid, subsisting, and enforceable in Australia

and is not subject to any pending or threatened opposition, cancellation, invalidity, or similar proceedings.

2.19.5 Section 8.2.9 is deleted in its entirety and replaced with the following:

EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES EXPRESSLY SET FORTH IN SECTION 8.1, THIS SECTION 8.2, SECTION 8.1A, SECTION 8.1B, SECTION 8.2A, SECTION 8.2B, SECTION 8.2C, SECTION 8.2D AND ELSEWHERE IN THIS AGREEMENT, NEITHER SAMSUNG NOR ANY OTHER PERSON ACTING ON BEHALF OF SAMSUNG MAKES ANY REPRESENTATION OR WARRANTY (INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR USE AND NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS), EXPRESS OR IMPLIED, TO ORGANON.

2.20 New Section 8.4B is added to the DCA as follows:

8.4B Additional Representations and Warranties of Organon. Solely with respect to Amendment No. 10 and the SB17 Product, Organon hereby represents and warrants to Samsung as of the Amendment No. 10 Effective Date that it has the full right, power and authority to Commercialize the SB17 Product in Australia and to grant the licenses granted under Article 3.

2.21 Section 8.4.5 is deleted in its entirety and replaced with the following:

EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES EXPRESSLY SET FORTH IN SECTION 8.1, THIS SECTION 8.4, SECTION 8.1A, SECTION 8.2B, SECTION 8.4A, SECTION 8.4B AND ELSEWHERE IN THIS AGREEMENT, NEITHER ORGANON NOR ANY OTHER PERSON ACTING ON BEHALF OF ORGANON MAKES ANY REPRESENTATION OR WARRANTY (INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR USE AND NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS), EXPRESS OR IMPLIED, TO SAMSUNG.

2.22 Section 8.5(v) is deleted in its entirety and replaced with the following:

2.23 (v) any claim, demand, action, or proceeding by a Third Party alleging that Organon's use of any of the SB17 Product Licensed IP or importation or Commercialization of the SB17 Product in accordance with this Agreement infringes, misappropriates, or otherwise violates any intellectual property or proprietary rights of such Third Party. For the sake of clarity, any Liability, penalty, fine, interest, responsibility or obligation for which Samsung is obligated to indemnify Organon under Section 8.5(iv) or (v), or Section 8.5.1 below shall not be subject to the damages cap in Section 8.8. In addition, notwithstanding Section 9.3(C) of the PDP Program Supply Agreement which requires Organon and Samsung to share [* * *] of all Cancellation Costs (as defined in the PDP Program Supply Agreement) incurred in connection with the cancellation of the Binding Forecasts (as defined in the PDP Program Supply Agreement), if the cancellation of the Binding Forecasts is due to termination of the PDP Program Supply Agreement based on the breach of the Technology Transfer Agreements by [* * *], then Organon shall have no obligation to pay any portion of the Cancellation Fee and Samsung shall indemnify and hold Organon harmless from any Liability that is based on such obligation to pay the Cancellation Fee.

2.24 Section 9.7 is deleted in its entirety and replaced with the following:

9.7 Treatment of Patent Rights and Trademarks for SB17 Product.

Notwithstanding the foregoing Sections of this Article 9, the Parties agree that with respect to the Commercialization of the SB17 Product in Canada and Australia, including the Manufacture of the SB17 Product outside of Canada or Australia, as applicable, for Commercialization in Canada and Australia, as applicable, the following Sections 9.7 and 9.8 replace and supersede the foregoing Sections of this Article 9.

9.7.1 Patent Rights for SB17 Product. Samsung shall, at its own expense and discretion, use Commercially Reasonable Efforts to maintain Samsung Patent Rights for the SB17 Product owned by Samsung. Samsung shall consult with Organon and keep Organon reasonably informed of the status of such Samsung Patents for the SB17 Product and shall provide Organon with all material correspondence received from the Canada Intellectual Property Office ("CIPO") or IP Australia in connection therewith. Samsung may abandon or cease prosecution or maintenance of any Samsung Patent Right for the SB17 Product in Canada or Australia (or any other jurisdiction) in its sole discretion, provided that, if Samsung determines to abandon or

cease prosecution or maintenance of Samsung Patent Right for the SB17 Product in or for Canada or Australia, Samsung shall provide reasonable prior written notice to Organon of such intention to abandon (which notice shall, to the extent possible, be given no later than [* * *] prior to the final deadline for any action that must be taken with respect to any such Samsung Patent Right for the SB17 Product with respect to the relevant patent authority). In such case, upon Organon's written election provided no later than [* * *] after such notice from Samsung, Organon may assume prosecution and maintenance of such Samsung Patent Right for the SB17 Product at Organon's sole cost and expense in the name of Samsung. If Organon does not provide such election within [* * *] after such notice from Samsung, Samsung may, in its sole discretion, discontinue prosecution and maintenance of such Samsung Patent Right for the SB17 Product in such country.

9.7.2. Trademarks for SB17 Product. Samsung shall, at its own expense and discretion, prepare, file, prosecute and maintain the Trademarks for the SB17 Product. Samsung shall, and shall require its licensor to, consult with Organon and keep Organon reasonably informed of the status of such Trademarks for the SB17 Product and shall, provide Organon with all material correspondence received from the CIPO in connection therewith. Samsung may abandon or cease prosecution or maintenance of any Trademarks for the SB17 Product in Canada or Australia (or any other jurisdiction) in its sole discretion, provided that, if Samsung determines to abandon or cease prosecution or maintenance of any Trademarks for the SB17 Product in or for Canada or Australia, Samsung shall provide reasonable prior written notice to Organon of such intention to abandon (which notice shall, to the extent possible, be given no later than [* * *] prior to the final deadline for any action that must be taken with respect to any such Trademarks for the SB17 Product with respect to the relevant trademark authority). In such case, upon Organon's written election provided no later than [* * *] after such notice from Samsung, Samsung shall assign the applicable Trademarks for the SB17 Product to Organon and Organon may assume prosecution and maintenance of such Trademarks for the SB17 Product at Organon's sole cost and expense in the name of Organon. If Organon does not provide such election within [* * *] after such notice from Samsung, Samsung may, in its sole discretion, discontinue prosecution and maintenance of such Trademarks for the SB17 Product in such country.

2.25 Section 9.8 is deleted in its entirety and replaced with the following:

2.26 **9.8 Infringement of Intellectual Property Rights relating to SB17 Product.** Each Party will promptly inform the other Party of any actual, alleged, or suspected infringement of any Samsung Patent Rights owned by Samsung or Trademarks for the SB17 Product by a Third Party, as well as any actual, alleged or suspected claims by Third Parties of infringement of such Third Party's intellectual property right by the Development, Manufacture or Commercialization of SB17 Product in or for Canada or Australia, of which it becomes aware.

- (a) Administrative and litigation proceedings, including but not limited to infringement action, declaratory judgment action, *inter partes* review, opposition proceeding, post grant review, interference, or other equivalent action ("**Proceedings**") alleging infringement of or challenging (including any claims within the Samsung Patent Rights) SB17 Product Licensed IP relating to SB17 Product or its exploitation in Canada or Australia will be conducted and controlled by Samsung (or Samsung's licensor), in Samsung's (or Samsung's licensor's) sole discretion. Samsung (or Samsung's licensor) will have sole control of such Proceedings, and Samsung shall keep Organon regularly informed of the progress of such Proceedings. Samsung (or Samsung's licensor) will bear all costs of conducting such Proceedings, including any payment of Third Party costs or damages that may be agreed to or awarded by the Courts. If Organon's and/or its Affiliate's joinder is necessary for Samsung (or Samsung's licensor) to establish standing in such Proceedings, Organon will, at the request of Samsung, join such Proceedings, cooperate and provide reasonable assistance in any such Proceedings, all at Samsung's costs. If Samsung fails to bring a Proceeding with respect to any actual, alleged, or suspected infringement of any SB17 Product Licensed IP owned by Samsung within [* * *] (or such shorter period in the event of a relevant deadline) following notice of such actual, alleged, or suspected infringement (or such shorter period as required by a relevant deadline), Organon shall have the right, but not the obligation, to bring and control any such Proceeding. If Organon initiates such Proceeding, Organon shall keep Samsung regularly informed of the progress of such Proceedings. If Samsung's and/or its Affiliate's joinder is necessary for Organon to establish standing in such Proceedings, Samsung and/or its Affiliate will join, such Proceedings. If Organon commences such a Proceeding, Samsung will, at the request of Organon, cooperate and provide reasonable assistance in any such Proceedings at its own cost. If such Proceedings are the subject of a settlement, the controlling Party will consider the

non-controlling Party's suggestions in good faith. All costs of any Proceeding commenced or defended solely by the controlling party will be borne by the controlling Party. Any recovery or damages derived or realized as a result of any Proceeding will be retained by the controlling Party.

- (b) Proceedings involving any claim by a Third Party for infringement of such Third Party's Patent Rights, know-how, trade secrets, trademarks or other intellectual property rights, by the Manufacture, use, import, export, offer for sale, or sale of the SB17 Product in Canada or Australia, or the Manufacture, use, import or export of the SB17 Product outside of Canada or Australia, as applicable, for purposes of Commercialization in Canada or Australia, as applicable, or any claim challenging or related to the use of the SB17 Product Licensed IP (but only to the extent such use is pursuant to any license and/or sublicense hereunder or as otherwise directed or authorized by Samsung in writing) will be conducted and controlled by Samsung (or Samsung's licensor), including any settlement of such claims, using Commercially Reasonable Efforts, in Samsung's (or Samsung's licensor) sole discretion. Samsung (or Samsung's licensor) will have sole control of such Proceedings, while keeping Organon regularly informed (including Samsung's response to Organon's request for a status update) of the progress of such Proceedings. If Organon's and/or its Affiliate's joinder is necessary for Samsung (or Samsung's licensor) to establish standing in such Proceedings, Organon and/or its such Affiliate will join such Proceedings. Organon will, at the request of Samsung, cooperate and provide reasonable assistance in any such Proceedings at Samsung's costs. If such Proceedings are the subject of a settlement, Samsung will discuss with Organon in reasonable detail the proposed settlement terms (unless confidentiality obligations to a third party prohibits such disclosure) that could materially impact Commercialization of the SB17 Product in Canada or Australia, and consider Organon's suggestions in good faith and will not agree to any settlement that could adversely impact Organon's right to Commercialize SB17 Product in Canada or Australia. All costs of any Proceedings conducted and controlled solely by Samsung (or Samsung's licensor), regardless of whether Organon assists or joins such Proceedings, and all royalties payable to any Third Party related to a settlement of, or Court order arising from, any such Proceeding will be borne by Samsung (or Samsung's licensor); provided that Organon may elect to participate in any such Proceedings at its own expense and Samsung will not be obligated to bear any such expenses of Organon if it is not otherwise required or requested to join or assist as provided hereunder. Any recovery or

damages derived or realized as a result of any Proceeding, except as otherwise provided in this Section 9.8, will be retained by Samsung (or Samsung's licensor). Notwithstanding the foregoing or any other provision of this Agreement to the contrary, Samsung shall have no obligation to control, conduct, defend or pay for any damages, costs, fees, or expenses in connection with any Proceedings, or any claims involved in any Proceedings, arising from Organon's use of the SB17 Product Licensed IP outside the scope of any license or sublicense hereunder or for which Samsung has otherwise authorized Organon in writing to use such SB17 Product Licensed IP.

- (c) Proceedings involving any claim by a Third Party for infringement of such Third Party's Patent Rights, know-how, trade secrets, trademarks or other intellectual property rights related to the use of the Other Brand Elements in Canada or Australia (but only to the extent such use is as directed or authorized by Organon in writing), including but not limited to Organon's logos, Organon's name on packaging, Organon's campaigns (concepts and other elements such as: visuals, photos, graphs, fonts and tables), promotional and non-promotional messages and claims, will be conducted and controlled by Organon, including any settlement of such claims, in Organon's sole discretion. Organon will have sole control of such Proceedings, while keeping Samsung regularly informed of the progress of such Proceedings. If Samsung's and/or its Affiliate's joinder is necessary for Organon to establish standing in such Proceedings, Samsung and/or its such Affiliate will join such Proceedings at Organon's costs. Samsung will, at the request of Organon, cooperate and provide reasonable assistance in any such Proceedings at Organon's costs. Organon will bear all costs of conducting Proceedings conducted and controlled solely by Organon, regardless of whether Samsung assists or joins such Proceedings, including payment of Third Party costs or damages agreed to or awarded by the Courts; provided that Samsung may elect to participate in any such Proceedings at its own expense and Organon will not be obligated to bear any such expenses of Samsung if it is not otherwise required or requested to join or assist as provided hereunder. Any recovery or damages derived or realized as a result of any Proceeding will be retained by Organon. Notwithstanding the foregoing or any other provision of this Agreement to the contrary, Organon shall have no obligation to control, conduct, defend or pay for any damages, costs, fees, or expenses in connection with any Proceedings, or any claims involved in any Proceedings, arising from Samsung's use of Other Brand Elements outside the scope for which Organon has authorized Samsung in writing to use such Other Brand Elements.

- (d) For the purposes of this Section 9.8, “**Other Brand Elements**” shall mean any Trademarks in the Territory (a) that are Controlled by Organon or any of its Affiliates and (b) that are held for use (i.e., subject to a pending trademark application or a trademark registration in jurisdictions where use is not required to register) or are used to Develop, Manufacture, perform medical affairs, or Commercialize the Product in the Territory, but excluding Trademarks included within the SB17 Product Licensed IP.
- (e) Notwithstanding any other provision in the DCA, including Sections 2.4, 9.3 and 10.3, if (i) the Commercialization of the SB17 Product in Canada or Australia is prevented or enjoined for a period of [* * *] or more by Proceedings challenging or responding to any claims with respect to a Third Party’s patent rights, including a settlement arising from such Proceedings, or (ii) any challenge, opposition, cancellation, infringement claim, or other legal or regulatory issue, including any Proceedings, which results in any settlement or any unfavorable court decision (whether it is unfavorable in whole or in part, or whether the decision is an interim or final decision, or could be subject to appeal), that prevents, hinders or delays Organon from being able to use the Trademarks for SB17 Product, then, in each case of (i) and (ii), Organon shall have the right to terminate this Agreement as it relates to SB17 Product in Canada or Australia, as applicable, upon providing [* * *] notice to Samsung of such termination.
- (f) In the event of a conflict between this Section 9.8 and any other Section in Article 9 with respect to the SB17 Product, this Section 9.8 controls.

2.27 Section 10.2A is deleted in its entirety and replaced with the following:

10.2A. Termination for Convenience. Organon shall have the right to terminate this Agreement with respect to SB17 (a) in Canada at any time following the [* * *] of the Launch of SB17 in Canada and (b) in Australia at any time following the [* * *] of the Launch of SB17 in Australia, in each case of (a) and (b), upon providing [* * *] written notice of its decision to exercise such termination right with respect to SB17.

2.28 Section 10.4 is deleted in its entirety and replaced with the following:

2.29 **10.4 Termination Due to Infringement Claim, or Newly Issued Third Party Patent.** Organon shall have the right to terminate this Agreement with respect to a particular Product (other than SB17 Product) in a particular Region in accordance

with the terms of Section 9.1 and have the right to terminate this Agreement with respect to SB17 Product in Australia and Canada, as applicable, in accordance with the terms of Section 9.8. Each Party shall have the right to terminate this Agreement with respect to a particular Product (other than SB17 Product) in a particular Region in accordance with the terms of Section 9.3

2.30 Section 10.6.2(a) is deleted in its entirety and replaced with the following:

2.31 (a) In the event that this Agreement is terminated by Organon under Section 10.2 or 10.3, Organon shall have the right, but not the obligation, to take delivery of the Product(s) to be supplied pursuant to the Remaining Binding Forecasts (collectively, the “**Post-Termination Delivery Products**”), in whole or in part (at Organon’s election), in accordance with the terms of this Agreement, and Samsung shall perform its obligations relating to such Remaining Binding Forecasts and Post-Termination Delivery Products accordingly; provided that, Organon shall be entitled to retain any Post-Termination Delivery Products of which Organon took delivery pursuant to this Section 10.6.2(a) and which have not been sold to a Third Party by [* * *] after the end of the last Calendar Quarter covered by the Remaining Binding Forecast for Primary-Packaged Presentations, without any accounting or payment obligations to Samsung other than the payment of the Supply Price for such Post-Termination Delivery Products (which Supply Price, and the Post-Termination Delivery Products for which such Supply Price is payable, shall be reflected and taken into account in determining (i) “Organon Profit” and “Samsung Profit” for the purpose of calculating “Profit Differential” for the Final True-up Period under Schedule 1.54 for Products other than SB17 Product and (ii) the Quarterly True-Up Amount under Schedule 1.54A and Schedule 1.54B for SB17 Product);

2.32 Section 10.6.2(c) is deleted in its entirety and replaced with the following:

2.33 (c) In the event that this Agreement is terminated by Samsung under Section 10.3, Samsung shall have the right, but not the obligation, to sell and deliver the Post-Termination Delivery Products, in whole or in part (at Samsung’s election), to Organon in accordance with the terms of this Agreement, and Organon shall perform its obligations relating to the Remaining Binding Forecasts and such Post-Termination Delivery Products accordingly; provided that with respect to Products, Organon shall return to Samsung (as soon as reasonably practicable after the expiration of the [* * *] period referred to below) any Post-Termination Delivery Products of which Organon took delivery pursuant to this Section 10.6.2(c) and which have not been sold to a Third Party by [* * *] after the end of the last Calendar Quarter covered by the

Remaining Binding Forecast for Primary-Packaged Presentations, and Samsung shall be entitled to retain such Post-Termination Delivery Products, as well as the Supply Price paid or payable therefor, without any accounting or payment obligations to Organon (it being understood and agreed that neither such Supply Price nor the Post-Termination Delivery Products for which such Supply Price is payable shall be reflected or taken into account in determining (i) "Organon Profit" or "Samsung Profit" for the purpose of calculating "Profit Differential" for the Final True-up Period under Schedule 1.54 for Products other than SB17 Product and (ii) the Quarterly True-Up Amount under Schedule 1.54A and Schedule 1.54B for SB17 Product);

2.34 Section 10.6.4A is deleted in its entirety and replaced with the following:

2.35 If Organon is unable to Launch SB17 Product in Canada or Australia, as applicable, and terminates this Agreement with respect to SB17 Product in Canada or Australia, as applicable, in accordance with Section 10.2 or Section 10.4, as applicable, Samsung shall reimburse Organon for the Supply Price paid for SB17 Product within [* * *] of the effective date of termination of this Agreement with respect to SB17 Product in Canada or Australia, as applicable.

2.36 New Schedule 1.41B (Product Criteria) to the DCA is attached hereto.

2.37 New Schedule 1.54B (Net Sales Share Mechanism for SB17 Product in Australia) to the DCA is attached hereto.

2.38 Schedule 3.7.2 (Trademarks for SB17 Product) attached hereto replaces the existing Schedule 3.7.2 (Trademarks for SB17 Product) attached to the DCA.

III. MISCELLANEOUS

3.1 In the event a Party is required to file a copy of this Amendment No. 10 with a Regulatory Authority or any other governmental authority or agency, (i) such Party shall redact commercially sensitive information from such copy to the extent permitted under applicable law and (ii) such Party shall provide the other Party with an advance draft of the redacted form of this Amendment No. 10 that the disclosing Party proposes to file, with not less than ten (10) Business Days for review, and shall incorporate the non-disclosing Party's comments to the extent additional or other redactions requested by the non-disclosing Party are permitted, and may reasonably be

afforded confidential treatment, under applicable law and such authority or agency's then-current practice.

- 3.2 Sections 11.4, 11.6, 11.7, 11.9, and 11.11 through 11.17 of the Agreement shall apply to this Amendment No. 10, *mutatis mutandis*.
- 3.3 The Agreement, as amended by this Amendment No. 10, together with the Schedules to the Agreement and any other agreements executed by authorized representatives of the Parties that make reference to the Agreement, contains the entire understanding of the Parties with respect to the Compounds and Products. Any other express or implied agreements, understandings, negotiations, writings and commitments, either oral or written, with respect to the subject matter of the Agreement are superseded by the terms of the Agreement as amended by this Amendment No. 10.

[Signatures on the Following Page]

IN WITNESS WHEREOF, the Parties, intending to be legally bound, have caused this Amendment No. 10 to be executed by their duly authorized representatives as of the Amendment No. 10 Effective Date.

ORGANON LLC SAMSUNG BIOEPIS CO., LTD.

By: /s/ Matthew Walsh By: /s/ Kwang Yong Ryu
Name: Mathew Walsh Name: Kwang Yong Ryu
Title: Chief Financial Officer (CFO) Title: VP, Business Development
Date: 6/02/2026 Date: 6/2/2026

SCHEDULE 1.41B - PRODUCT CRITERIA

[* * *]

Schedule 1.54B

[* * *]

3.7.2

[* * *]

Schedule 6.2A

[* * *]

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

I, Joseph Morrissey, 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.

July 31, 2026

/s/ Joseph Morrissey

Joseph Morrissey

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.

July 31, 2026

/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 June 30, 2026 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.

July 31, 2026

/s/ Joseph Morrissey

Joseph Morrissey

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 June 30, 2026 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.

July 31, 2026

/s/ Matthew Walsh

Matthew Walsh

Chief Financial Officer