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

Form 10-Q/A

Amendment No. 1

(Mark One)

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

For the quarterly period ended March 31, 2025

OR

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

For the transition period from _____ to _____

Commission File No. 001-40235

Organon & Co.

(Exact name of registrant as specified in its charter)

Delaware	**46-4838035**
(State or other jurisdiction of incorporation)	(I.R.S. Employer Identification No.)

30 Hudson Street, Floor 33
Jersey City,New Jersey 07302
(Address of principal executive offices) (zip code)

(Registrant's telephone number, including area code) **(551) 430-6900**

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 April 25, 2025: 259,956,063

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The following notations in this Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, as amended, have the meanings as set forth below:

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

"2" Indicates, in this Quarterly Report on Form 10-Q, as amended, brand names of products that are trademarks not owned by Organon & Co. or its subsidiaries. *Actemra* is a trademark registered in the United States in the name of Chugai Seiyaku KK.; *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); and *Rayvow* is a registered trademark of Eli Lilly in the European Union and other countries (used under license). Brand names of products that are in all italicized letters, without the footnote, are trademarks of, or are otherwise licensed by, Organon & Co. and/or one of its subsidiaries.

Explanatory Note

On October 27, 2025, Organon & Co. ("Organon," the "Company," "we," "our," or "us") announced an internal investigation conducted by the Audit Committee (the "Audit Committee") of the Company's Board of Directors (the "Board") regarding the Company's sales practices for wholesalers as described in the Current Report on Form 8-K filed with the U.S. Securities and Exchange Commission (the "SEC") on October 27, 2025 (the "Form 8-K"). Following the Audit Committee investigation findings and as a result of the material weaknesses in our internal control over financial reporting that were identified and are described below, the Company (i) filed Amendment No. 1 (the "Form 10-K Amendment") to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2024 (the "Original Form 10-K") and (ii) is filing this Amendment No. 1 (the "Amendment") to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2025 that was filed with the SEC on May 2, 2025 (the "Original Form 10-Q").

This Amendment amends and/or restates:

(i) Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations" solely for the purpose of amending certain disclosures regarding the increased sales with respect to *Nexplanon* ® in the U.S. that appears in our discussion of our financial condition and results of operations for the quarter ended March 31, 2025 (as relates to *Nexplanon* sales during this first quarter of 2025);

(ii) Item 4. "Controls and Procedures," to reflect the ineffective disclosure controls and procedures as of March 31, 2025 as a result of the material weaknesses; and

(iii) Item 6. "Exhibits" to reflect the new certifications referenced above.

This Amendment also includes the following exhibits to replace exhibits previously filed:

(i) new currently dated certifications (as required by Rule 12b-15 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), by the Company's principal executive officer and principal financial officer.

Except as set forth herein, this Amendment does not modify or update disclosures included in the Original Form 10-Q, nor does it reflect events occurring after the filing of the Original Form 10-Q. Among other things, forward-looking statements made in the Original Form 10-Q have not been revised to reflect events that occurred or facts that became known to us after the filing of the Original Form 10-Q, and any such forward-looking statements should be read in their historical context. Accordingly, this Amendment should be read in conjunction with the Company's filings with the SEC that were made subsequent to the filing of the Original Form 10-Q and this Amendment.

Overview of Audit Committee Investigation and Findings

As disclosed in the Form 8-K and the Form 10-K Amendment, after concerns regarding the Company's sales practices for wholesalers for *Nexplanon* were brought to the Board's attention, the Audit Committee oversaw an independent, internal investigation into these sales practices. The Audit Committee's investigation focused on the Company's sales of *Nexplanon* to wholesalers. The investigation found that the Company asked two wholesalers in the United States to purchase greater quantities of *Nexplanon* at the end of the fourth quarter of 2022, the third and fourth quarters of 2024 and the first, second and third quarters of 2025 (collectively, the "Relevant Periods") than they otherwise would have purchased based on wholesaler demand. In certain instances, the Company waived inventory management fee performance metrics associated with caps on days of inventory to allow wholesalers to be paid the inventory management fees they would have earned but for the Company's ask to purchase additional inventory. As a result of these purchases, the United States wholesalers significantly decreased or even halted their purchases of *Nexplanon* during the early weeks of the following quarters until their days of inventory on hand were reduced to levels within the contractual range. Although the incremental amount of *Nexplanon* sales that occurred during the Relevant Periods represented less than 1% of the Company's consolidated revenue for the year ended December 31, 2022 or December 31, 2024 as applicable (and less than 2% of the Company's consolidated revenue for the relevant quarterly periods), based on the results of the investigation, the Company has determined that without these sales practices, the Company's consolidated revenue for the fiscal year ended December 31, 2024 reported in the Original Form 10-K (and certain of the other Relevant Periods) would have fallen short of the Company's guidance range and/or certain external expectations. The Audit Committee investigation did not find that the use of these sales practices for wholesalers extended to sales other than sales of *Nexplanon* in the United States during the Relevant Periods, or that these sales practices for wholesalers were otherwise used for any other Company products.

In connection with the investigation, the Audit Committee found that (i) the Company's former Chief Executive Officer and leader of the Company's U.S. commercial organization applied inappropriate pressure to achieve sales targets, which resulted in two United States wholesalers being asked to purchase inventory in excess of current customer demand for *Nexplanon*, (ii) the Company's processes with respect to reporting and documenting the sales practices for wholesalers during the Relevant Periods, including with respect to inventory management fee performance metric waivers, were not followed, (iii) the former Chief Executive Officer did not reasonably ensure that relevant information was appropriately communicated; rather, relevant information was withheld from the Company's independent directors, the Audit Committee, and the independent registered public accounting firm, and (iv) the former Chief Executive Officer and leader of the Company's U.S. commercial organization engaged in inappropriate business conduct that violated the Company's Code of Conduct. There were no investigative findings that other members of the Company's executive leadership team, including the Company's Chief Financial Officer, or any member of the Company's accounting and financial reporting group involved in the preparation of the Company's financial statements, were aware that these sales practices resulted in the United States wholesalers being asked to purchase inventory that exceeded their demand or contractual limits, or that waivers were given so that the United States wholesalers would continue to receive inventory management fees. The Audit Committee's investigation is complete.

Based on the results of the Audit Committee's investigation, the Company determined that these sales practices for wholesalers involving *Nexplanon* in the United States during the Relevant Periods were improper, and that certain of the Company's prior disclosures relating to these sales practices for wholesalers and their effect upon revenues and product demand in its periodic filings were inaccurate or incomplete, including certain disclosures, as listed above, that are being amended by this Amendment.

Company Determinations Following the Audit Committee Findings

Additionally, as a result of the investigation and the Audit Committee findings, Company management, in consultation with the Audit Committee, has re-assessed the effectiveness of the Company's disclosure controls and procedures and its internal control over financial reporting as of December 31, 2024, as reported in the Original Form 10-K. As a result as reported in the Form 10-K Amendment, the Company concluded that there were material weaknesses in the Company's internal control over financial reporting as of December 31, 2024 and that management's assessment of its disclosure controls and procedures and its internal control over financial reporting as of December 31, 2024 that were included in Item 9A of the Original Form 10-K should no longer be relied upon, as a result of the material weaknesses disclosed in the Form 10-K Amendment and also described herein. 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 the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

The Company has determined that there will be no restatement or revision to its previously issued financial statements, including those filed with the Original Form 10-K and the Original Form 10-Q.

Change in Management

In connection with the Audit Committee investigation, on October 26, 2025, (i) Kevin Ali resigned as Chief Executive Officer of the Company and as a member of the Company's Board of Directors, (ii) Joseph Morrissey, the then-current Executive Vice President and Head of Manufacturing & Supply of the Company, was appointed Interim Chief Executive Officer (and principal executive officer) of the Company, (iii) Carrie S. Cox, Chair of the Board, was appointed Executive Chair for an interim period, and (iv) Robert Essner, a member of the Board, was appointed to the position of Lead Independent Director. Additionally and in connection with the Audit Committee investigation, on October 26, 2025, the Company terminated the employment of its Head of U.S. Commercial & Government Affairs.

PART I - FINANCIAL INFORMATION

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," "should," "estimate," "anticipate," "plan," "forecast," "intend," "would," "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, expanded brand and class competition in the markets in which Organon & Co. ("Organon," the "Company," "we," "our," or "us") operates; trade protection measures and import or export licensing requirements, including the direct and indirect impacts of tariffs (including any potential 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 Organon's customers and business partners; economic factors over which we have no control, including changes in inflation, interest rates, recessionary pressures, and foreign currency exchange rates; market volatility, downgrades to the U.S. government's sovereign credit rating or its perceived creditworthiness, changing political or geopolitical conditions, market contraction, boycotts, and sanctions, as well as Organon's ability to successfully manage uncertainties related to the foregoing; difficulties with performance of third parties we rely on for our business growth; the failure of any supplier to provide substances, materials, or services as agreed; the increased cost of supply, manufacturing, packaging, and operations; difficulties developing and sustaining relationships with commercial counterparties; competition from generic products as our products lose patent protection; any failure by us to retain market exclusivity 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 continued impact of the September 2024 loss of exclusivity ("LOE") for *Atozet*™ (ezetimibe and atorvastatin); restructurings or other disruptions at the U.S. Food and Drug Administration ("FDA"), the U.S. Securities and Exchange Commission and other U.S. and comparable government agencies; difficulties and uncertainties inherent in the implementation of our acquisition strategy or failure to recognize the benefits of such acquisitions; pricing pressures globally, including rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and health care reform, pharmaceutical reimbursement and pricing in general; the impact of higher selling and promotional costs; changes in government laws and regulations in the United States and other jurisdictions, including laws and regulations governing the research, development, approval, clearance, manufacturing, supply, distribution, and/or marketing of our products and related intellectual property, environmental regulations, and the enforcement thereof affecting our business; efficacy, safety or other quality concerns with respect to our marketed products, whether or not scientifically justified, leading to product recalls, withdrawals or declining sales; delays or failures to demonstrate adequate efficacy and safety of our product candidates in pre-clinical and clinical trials, which may prevent or delay the development, approval, clearance, or commercialization of our product candidates; future actions of third-parties, including significant changes in customer relationships or changes in the behavior and spending patterns of purchasers of health care products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and forgoing health care insurance coverage; legal factors, including product liability claims, antitrust litigation and governmental investigations, including tax disputes, environmental claims and patent disputes with branded and generic competitors, any of which could preclude commercialization of products or negatively affect the profitability of existing products; lost market opportunity resulting from delays and uncertainties in clinical trials and the approval or clearance process of the 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; loss of key employees or inability to identify and recruit new employees; changes in accounting pronouncements promulgated by standard-setting or regulatory bodies, including the Financial Accounting Standards Board and the SEC, that are adverse to us; volatility of commodity prices, fuel, 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 and Current Reports on Form 8-K, 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 in this Amendment 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 the Original Q1 Form 10-Q 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, 2024, as amended by the Form 10-K Amendment. Operating results discussed herein are not necessarily indicative of the results of any future period.

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

Recent Developments

Business Development

Biogen Inc. ("Biogen")

In March 2025, we acquired from Biogen the regulatory and commercial rights in the United States for *Tofidence*® (tocilizumab-bavi), a biosimilar to *Actemra*[2] (tocilizumab), for intravenous infusion. *Tofidence*, launched in the U.S. market in May 2024, is indicated in certain patients for the treatment of moderately to severely active rheumatoid arthritis, giant cell arthritis, polyarticular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis, and COVID-19. Under the terms of the agreement, we will pay an upfront payment of $51 million in July 2025, as well as tiered royalty payments based on net sales and tiered annual net sales milestone payments of up to $45 million from a previous in-license arrangement with Bio-Thera Solutions Ltd., the product developer for *Tofidence*. In the first quarter of 2025, we recognized an intangible asset of $51 million, related to the upfront payment to Biogen, which will be amortized over 10 years.

Other Macroeconomic Considerations

Geopolitical developments, global trade issues such as tariffs imposed by or on the United States, shifting U.S. federal government policies, policies hindering market access, and worsening macroeconomic conditions could impact our business and results of operations and may stress our working capital resources. While tariffs have not, to date, had a material impact on our business, future tariff actions could potentially have a significant effect on our supply chain and operating costs. Regulatory agency developments, including disruptions at the FDA and other agencies, could increase the time needed for review and approval of new drugs and medical devices, potentially delaying our product launches and impacting our business operations. Additionally, proposed cuts to Medicaid and changes in federal funding policies could reduce access to healthcare services for low-income individuals and impact our ability to develop new drugs. Management will continue to evaluate the potential impacts of the shifting geopolitical and macroeconomic landscape on our business, results of operations, liquidity, and capital resources. For additional information, please refer to Item 1A — Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2024.

Operating Results

Sales Overview

($ in millions)	Three Months Ended March 31, 2025	2024	% Change	% Change Excluding Foreign Exchange
United States	$ 412	$ 371	11%	11%
International	1,101	1,251	(12)	(9)
Total	$ 1,513	$ 1,622	(7)%	(4)%

Worldwide sales were $1.5 billion for the three months ended March 31, 2025, a decrease of 7%, compared to 2024. Worldwide sales during the three months ended March 31, 2025 were negatively impacted by approximately 3%, or $44 million, due to unfavorable foreign exchange rates.

Excluding the impact of foreign exchange rates, sales increases for the three months ended March 31, 2025, primarily reflect the performance of:

- *Nexplanon,* due to increased sales (including an estimated $17 million of sales resulting from the identified sales practices for wholesalers described in the "Explanatory Note" above, offset by an estimated $15 million of sales from such sales practices for wholesalers that were pulled forward into the year ended December 31, 2024, resulting in an estimated net impact of $2 million for the three months ended March 31, 2025, with the impact estimated using average daily sales, inventory levels at the wholesaler and days on hand at the wholesaler) and favorable pricing in the United States and the acceleration of our institutional business in Africa in order to meet demand;

- *Vtama,* reflecting the acquisition of Dermavant in the fourth quarter of 2024;

- *Follistim AQ,* due to a one-time buy-in as a result of our exit from our interim operating model agreement in the United States with Merck during the fourth quarter of 2023, which resulted in lower sales in the first quarter of 2024, demand increase and favorable discount rates in the United States; and

- *Emgality,* due to the acquisition of the distribution and promotion rights from Lilly in 2024 in certain markets outside of the United States.

This performance was more than offset by decreases for the three months ended March 31, 2025 in:

- *Atozet,* primarily due to LOE in France and Spain partially offset by increased demand in South Korea and the Asia Pacific cluster;

- *Singulair*® (montelukast sodium), due to the lower rate of respiratory infections in China when compared to 2024, lower demand in Japan and the impact of the mandatory annual price reductions in Japan; and

- *Ontruzant,* driven by the return to normalized levels of the contracted volume in Brazil and lower demand in the United States.

LOE negatively impacted sales of certain of our products by approximately $63 million during the three months ended March 31, 2025, based on the decrease in volume period over period. This was primarily driven by the LOE of *Atozet* in France and *Rosuzet*™ (ezetimibe and rosuvastatin) in Japan. Volume-based procurement ("VBP") in China had an immaterial impact on our sales during the three months ended March 31, 2025. We expect VBP to continue to impact our established brands product portfolio for the next several quarters.

Our operations include a portfolio of products. Highlights of the sales of our products for the three months ended March 31, 2025 and 2024 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 March 31, 2025	2024	% Change	% Change Excluding Foreign Exchange
Nexplanon/Implanon NXT	$ 248	$ 220	13%	14%
NuvaRing	22	38	(43)	(41)
Marvelon/Mercilon	39	33	19	21
Follistim AQ	69	46	49	52
Jada	15	13	20	20

Contraception

Worldwide sales of *Nexplanon,* a single-rod subdermal contraceptive implant, increased 13% for the three months ended March 31, 2025, compared to 2024, primarily due to increased sales and favorable pricing in the United States and the acceleration of our institutional business in Africa in order to meet demand. The increased sales for *Nexplanon* for the quarter ended March 31, 2025 included an estimated $17 million of sales resulting from the identified sales practices for wholesalers described in the "Explanatory Note" above, offset by an estimated $15 million of sales from such sales practices for wholesalers that were pulled forward into the year ended December 31, 2024, resulting in an estimated net impact of $2 million for the three months ended March 31, 2025. The impact was estimated using average daily sales, inventory levels at the wholesaler and days on hand at the wholesaler.

Worldwide sales of *NuvaRing*, a vaginal contraceptive product, declined 43% for the three months ended March 31, 2025, compared to 2024, due to ongoing generic competition and the negative impact of increased government discount rates in the United States. We expect a continued decline in *NuvaRing* sales as a result of generic competition.

Worldwide sales of *Marvelon*™ (desogestrel and ethinyl estradiol pill) and *Mercilon*™ (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, increased 19% for the three months ended March 31, 2025, compared to 2024, as a result of increased demand and the phasing of shipments in China.

Fertility

Worldwide sales of *Follistim AQ*, a fertility treatment, increased 49% for the three months ended March 31, 2025, compared to 2024, due to a one-time buy-in as a result of our exit from our interim operating model agreement in the United States with Merck during the fourth quarter of 2023, which resulted in lower sales in the first quarter of 2024, demand increase and favorable discount rates in the United States.

Other Women's Health

Worldwide sales of *Jada,* a device intended to provide control and treatment of abnormal postpartum uterine bleeding or hemorrhage when conservative management is warranted, increased 20% for the three months ended March 31, 2025, compared to 2024. The sales increase is due to continued uptake in the United States following the *Jada* launch in early 2022 and favorable price and discount rates in the United States.

Biosimilars

($ in millions)	Three Months Ended March 31, 2025	2024	% Change	% Change Excluding Foreign Exchange
Renflexis	$ 57	$ 69	(18)%	(17)%
Hadlima	47	30	55	57
Ontruzant	18	39	(54)	(54)
Brenzys	14	24	(39)	(35)

Renflexis is a biosimilar to *Remicade*[2] (infliximab) for the treatment of certain autoimmune conditions. Sales declined 18% for the three months ended March 31, 2025, compared to 2024, primarily due to unfavorable discount rates in the United States.

Hadlima is a biosimilar to *Humira*[2] (adalimumab) for the treatment of certain autoimmune and autoinflammatory conditions. We have commercialization rights to *Hadlima* in countries outside of the European Union, South Korea, China, Turkey, and Russia. We recorded sales of $47 million during the three months ended March 31, 2025, reflecting sales that have continued to ramp up since its July 2023 launch in the United States and a modest increase in international markets, partially offset by unfavorable discount rates in the United States. *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 months ended March 31, 2025, compared to 2024, declined 54%, following the return to normalized levels of the contracted volume in Brazil and lower demand in the United States. 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 months ended March 31, 2025, compared to 2024, declined 39%, as a result of the timing of international tenders in Brazil. We have commercialization rights to *Brenzys* in countries outside of the United States, Europe, South Korea, China, and Japan.

Established Brands

Established brands represents a broad portfolio of well-known brands, which generally are beyond market exclusivity, including leading brands in cardiovascular, respiratory, dermatology and non-opioid pain management, for which generic competition varies by market.

Cardiovascular

($ in millions)	Three Months Ended March 31, 2025	2024	% Change	% Change Excluding Foreign Exchange
Atozet	$ 77	$ 132	(42)%	(39)%
Zetia/Vytorin	107	112	(4)	(1)
Cozaar/Hyzaar	55	67	(18)	(16)

Sales of *Atozet*, a medicine for lowering LDL cholesterol, declined 42% for the three months ended March 31, 2025, compared to 2024, primarily due to LOE in France and Spain, partially offset by increased demand in South Korea and the Asia Pacific cluster. We anticipate a continued significant decline in sales of *Atozet* in 2025 due to LOE, which occurred late in the third quarter of 2024, in certain markets in Europe.

Combined global sales of *Zetia*® (ezetimibe) and *Vytorin*® (ezetimibe / simvastatin), medicines for lowering LDL cholesterol, declined 4% for the three months ended March 31, 2025, compared to 2024, primarily driven by the decrease in demand and pricing pressure in various international markets, partially offset by increased demand in China.

Combined global sales of *Cozaar*® (losartan potassium) and *Hyzaar*® (losartan potassium and hydrochlorothiazide), medicines for the treatment of hypertension, declined 18% for the three months ended March 31, 2025, compared to 2024, driven by decreased demand in China and Japan and mandatory annual price reductions in Japan.

Respiratory

	Three Months Ended March 31,			% Change Excluding Foreign
($ in millions)	2025	2024	% Change	Exchange
Singulair	$ 74	$ 98	(24)%	(22)%
Nasonex	72	77	(7)	(4)
Dulera	43	56	(22)	(21)

Worldwide sales of *Singulair*, a once-a-day oral medicine for the chronic treatment of asthma and for the relief of symptoms of allergic rhinitis, decreased 24% for the three months ended March 31, 2025, compared to 2024, due to the lower rate of respiratory infections in China when compared to 2024, lower demand in Japan and the impact of the mandatory annual price reductions in Japan.

Global sales of *Nasonex*® (mometasone), an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, declined 7% for the three months ended March 31, 2025, compared to 2024, due to the prior year phasing of shipments related to the implementation of our enterprise resource planning ("ERP") system in various international markets.

Global sales of *Dulera*® (formoterol/fumarate dihydrate), which is also marketed as *Zenhale*™ in certain markets outside of the United States, a combination medicine for the treatment of asthma, declined 22% for the three months ended March 31, 2025, compared to 2024, primarily due to the loss of a customer contract, discount rate pressure in the United States and decreased demand in Canada.

Non-Opioid Pain, Bone and Dermatology

	Three Months Ended March 31,			% Change Excluding Foreign
($ in millions)	2025	2024	% Change	Exchange
Arcoxia	$ 62	$ 75	(18)%	(16)%
Vtama	24	—	*	*

** Calculation not meaningful.*

Sales of *Arcoxia*™ [1] (etoricoxib), a medicine for the treatment of arthritis and pain, declined 18% for the three months ended March 31, 2025, compared to 2024, primarily due to 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, were $24 million for the three months ended March 31, 2025. *Vtama* is a product that we acquired as part of our acquisition of Dermavant in the fourth quarter of 2024.

Other

($ in millions)	Three Months Ended March 31, 2025	2024	% Change	% Change Excluding Foreign Exchange
Emgality/Rayvow	$ 32	$ 10	229%	247%

Sales of *Emgality* a medicine for the preventive treatment of migraine and *Rayvow,* a medicine for acute treatment of the headache phase of migraine attacks, increased for the three months ended March 31, 2025, compared to 2024, primarily due to a full quarter of sales in 2025 as compared to a partial quarter of sales in 2024 as a result of our the acquisition of the distribution and promotion rights from Lilly in January of 2024 in certain markets outside of the United States.

Gross Profit, Expenses and Other

($ in millions)	Three Months Ended March 31, 2025	2024	% Change
Cost of sales	$ 672	$ 665	1%
Gross profit	841	957	(12)
Selling, general and administrative	420	431	(3)
Research and development	96	112	(14)
Acquired in-process research and development and milestones	6	15	(60)
Restructuring costs	86	23	*
Interest expense	124	131	(5)
Exchange (gains) losses	(4)	6	*
Other expense, net	12	3	*

** Calculation not meaningful.*

Cost of Sales

Cost of sales increased 1% for the three months ended March 31, 2025, compared to 2024, primarily due to increased amortization expense due to the acquisition of intangibles in the prior year, amortization of $9 million associated with the inventory fair value adjustment related to the Dermavant acquisition, partially offset by foreign exchange translation. Cost of sales includes amortization of intangible assets of $50 million and $33 million for the three months ended March 31, 2025 and 2024, respectively. Separation costs associated with manufacturing-related headcount reductions have been incurred and are reflected in *Restructuring costs.*

Gross Profit

Gross profit decreased 12% for the year ended March 31, 2025, compared to 2024, due to the impact of unfavorable price and decreased sales due to volume and foreign exchange translation.

Selling, General and Administrative

Selling, general and administrative expenses decreased 3% for the three months ended March 31, 2025, compared to 2024, due to lower costs related to the prior year implementation of our ERP system offset by increased costs associated with the promotion of our recently acquired products.

Research and Development

Research and development expenses decreased 14% for the three months ended March 31, 2025, compared to 2024, primarily due to a decrease in clinical study activity.

Acquired In-Process Research and Development and Milestones

For the three months ended March 31, 2025, we recognized $6 million in acquired in-process research and development and milestones, related to the exit of our current agreement with Centergene, due to the evolving fertility landscape in China. We will continue to assess and evaluate future commercial opportunities with Centergene. For the three months ended March 31, 2024 acquired in-process research and development and milestones of $15 million represents the research and development milestones related to Henlius that were determined to be probable of being achieved.

Restructuring Costs

For the three months ended March 31, 2025, we incurred $86 million of headcount-related restructuring expense associated with restructuring initiatives that were aimed at driving operational efficiencies in 2025. The restructuring activities combined with other Company cost savings initiatives are expected to result in approximately $200 million of annual savings. For the three months ended March 31, 2024 we incurred $23 million of headcount-related restructuring expense related to the optimization of our internal operations, primarily the research and development function.

Interest Expense

Interest expense decreased 5% for the three months ended March 31, 2025, compared to 2024, reflecting lower interest rates as a result of refinancing a portion of our long-term debt in the prior year and lower reference rates on our variable rate debt, partially offset by interest related to the debt acquired as part of the Dermavant acquisition.

Exchange (Gains) Losses

Exchange (gains) losses increased for the three months ended March 31, 2025, compared to 2024, driven by gains in foreign currencies.

Other Expense, net

Other expense increased for the three months ended March 31, 2025, compared to 2024, due to the accretion of the contingent consideration related to the Dermavant acquisition.

Taxes on Income

The effective income tax rate was 13.4% and 14.7% for the three months ended March 31, 2025 and 2024, respectively. These effective income tax rates reflect the beneficial impact of foreign earnings, offset by the impact of U.S. inclusions under the Global Intangible Low-Taxed Income regime and a partial valuation allowance recorded against non-deductible U.S. interest expense. There was a favorable impact to the 2025 year-to-date effective tax rate driven by a tax amortization benefit. The favorable impact to the 2024 year-to-date effective tax rate was driven by the favorable closure of the two non-U.S. tax audits and a return to provision adjustment for an entity in Switzerland.

Liquidity and Capital Resources

As of March 31, 2025, we had cash and cash equivalents of $547 million. We have historically generated and expect to continue to generate positive cash flow from operations. Our ability to fund our operations and anticipated capital needs is reliant upon the generation of cash from operations, supplemented as necessary by periodic utilization of our revolving credit facility. Our principal uses of cash in the future will be primarily to fund our operations, working capital needs, capital expenditures, repayment of borrowings, 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.

Working capital is defined as current assets less current liabilities and was $1.76 billion and $1.63 billion as of March 31, 2025 and December 31, 2024, respectively. Working capital was impacted by our active cash cycle management, which includes the factoring of receivables and timing of vendor payments, as well as an increase in receivables due to the timing of shipments, a lower cash balance due to milestone payments and the timing of annual incentive compensation payments in the first quarter of 2025.

We have accounts receivable factoring agreements with financial institutions in certain countries. Under these agreements, we have factored $249 million and $186 million of our accounts receivable as of March 31, 2025 and December 31, 2024, respectively. See Note 11 “Financial Instruments” to the Condensed Consolidated Financial Statements for information on the Company’s’ accounts receivable factoring and related agreements.

Net cash provided by operating activities was $75 million for the three months ended March 31, 2025, compared to $76 million for the same period in the prior year due to lower operating income offset by our active cash cycle management.

Net cash used in investing activities was $172 million for the three months ended March 31, 2025, compared to $96 million for the same period in the prior year, primarily due to increased milestone payments, partially offset by lower capital spending as a result of the completion of the implementation of our ERP system.

Net cash used in financing activities remained consistent for the three months ended March 31, 2025, compared with the same period in the prior year. The primary activities included routine debt repayments and the payment of dividends.

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

Our contractual obligations as of March 31, 2025, 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, 2024 for further details. As of March 31, 2025, there have been no material changes to our contractual obligations outside of the ordinary course of business.

During the first quarter of 2025, we paid cash dividends of $0.28 per share. On May 1, 2025, the Board of Directors declared a quarterly dividend of $0.02 for each issued and outstanding share of our common stock, which reduces the quarterly dividend from $0.28 per share. We anticipate redirecting the funds from the dividend payment to the repayment and/or repurchase of debt. The dividend is payable on June 12, 2025, to stockholders of record at the close of business on May 12, 2025.

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, 2024. See Note 2 "Basis of Presentation" to the Condensed Consolidated Financial Statements for information on the adoption of new accounting standards during 2025. There have been no changes to our accounting policies as of March 31, 2025. A discussion of accounting estimates considered critical because of the potential for a significant impact on the financial statements due to the inherent uncertainty in such estimates are disclosed in the Critical Accounting Estimates section of Management's Discussion and Analysis of Financial Condition and Results of Operations included in Organon's Annual Report on Form 10-K for the year ended December 31, 2024.

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 elsewhere in this report.

Item 4. Controls and Procedures

Overview

As previously disclosed in the Form 8-K and the Form 10-K Amendment, after concerns regarding the Company's sales practices for wholesalers for *Nexplanon* were brought to the Board's attention, the Audit Committee oversaw an independent, internal investigation into these sales practices. The Audit Committee's investigation focused on the Company's sales of *Nexplanon* to wholesalers. The investigation found that the Company asked two wholesalers in the United States to purchase greater quantities of *Nexplanon* during the Relevant Periods than they otherwise would have purchased based on wholesaler demand. In certain instances, the Company waived inventory management fee performance metrics associated with caps on days of inventory to allow wholesalers to be paid the inventory management fees they would have earned but for the Company's ask to purchase additional inventory. As a result of these purchases, the United States wholesalers significantly decreased or even halted their purchases of *Nexplanon* during the early weeks of the following quarters until their days of inventory on hand were reduced to levels within the contractual range. Although the incremental amount of *Nexplanon* sales that occurred during the Relevant Periods represented less than 1% of the Company's consolidated revenue for the year ended December 31, 2022 or December 31, 2024 as applicable (and less than 2% of the Company's consolidated revenue for the relevant quarterly periods, including the quarter ended March 31, 2025) based on the results of the investigation, the Company has determined that without these sales practices, the Company's consolidated revenue for the fiscal year ended December 31, 2024 reported in the Original Form 10-K (and certain of the other Relevant Periods, including the quarter ended March 31, 2025) would have fallen short of the Company's guidance range and/or certain external revenue expectations.

Based on the results of the Audit Committee's investigation as further set forth in the "Explanatory Note", the Company determined that these sales practices for wholesalers involving *Nexplanon* in the United States during the Relevant Periods were improper, and that certain of the Company's prior disclosures relating to these sales practices for wholesalers and their effect upon revenues and product demand in its periodic filings were inaccurate or incomplete, including certain disclosures in the Original Form 10-Q that are being amended by this Amendment. As also discussed in the "Explanatory Note", the Company identified material weaknesses in its internal control over financial reporting, which are described in the Form 10-K Amendment and below.

Quarterly Evaluation of Disclosure Controls and Procedures (Restated and Amended)

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 Interim 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 our Interim CEO and CFO, re-evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2025 in connection with the filing of this Amendment. At the time that the Original Form 10-Q was filed with the SEC on May 2, 2025, our former CEO and our CFO had concluded that, as of March 31, 2025, the end of the period covered by the Original Form 10-Q, our disclosure controls and procedures were effective and provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the applicable rules and forms, and that it is accumulated and communicated to our management, including our CEO and our CFO, as appropriate, to allow timely decisions regarding required disclosure. Subsequent to this evaluation, the Interim CEO and the CFO concluded that our disclosure controls and procedures were not effective as of March 31, 2025 due to the material weaknesses in internal control over financial reporting as described below.

Notwithstanding the material weaknesses described below, management has concluded that its condensed consolidated financial statements included in the Original Form 10-Q continue to fairly present, in all material respects, our financial position and results as of March 31, 2025 and December 31, 2024, and for the three-month periods ended March 31, 2025 and 2024.

Material Weaknesses in Internal Control Over Financial Reporting (Restated and Amended)

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 the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

Based on the evaluation described above, we identified the following material weaknesses in the Company's internal control over financial reporting:

- The Company failed to set an appropriate tone at the top. Specifically, our former CEO and leader of the Company's 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 the Company's 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. The Company did not design and maintain effective controls related to the information and communication component of the COSO Framework. Specifically, the former CEO and certain senior members of the Company's U.S. commercial organization did not ensure appropriate communication with, or provide complete information to, the Company's 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 consolidated financial statements, including those filed with the Original Form 10-K or the Original Form 10-Q. Each of these material weaknesses could result in a misstatement of substantially all account balances or disclosures that would result in a material misstatement to our annual or interim consolidated financial statements that would not be prevented or detected.

Remediation Plan and Activities

To address the material weaknesses in internal control over financial reporting, the Company, with the oversight of its Audit Committee, has developed a remediation plan, which is described below. We are in the process of implementing measures designed to improve our internal control over financial reporting and remediate the control deficiencies that led to the material weaknesses described above. Actions taken to date include:

- The appointment of a new Interim CEO, the termination and appointment of a new Head of U.S. Commercial & Government Affairs, the appointment of an Executive Chair and the appointment of a Lead Independent Director.

In addition to the remedial actions taken to date, the Company is taking, or plans to take, the following actions, among others, to remediate the material weaknesses identified herein:

- Enhance the Company's Code of Conduct to clarify responsibilities related to the Company's financial reporting and disclosures, including awareness of the options to raise concerns or questions to 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;

- Enhance compliance training and communication on the Company's Code of Conduct regarding ethical tone and corporate culture and enhance training for commercial and finance personnel regarding appropriate business practices;

- Enhance the Company's Annual Ethics and Policy Certifications;

- Implement additional representations within the Company's Quarterly Financial Certification Questionnaire relating to the disclosures of misleading business practices;

- Enhance existing Disclosure Committee responsibilities to include among other requirements, additional questions and more information regarding the representations being made, and provide incremental training on these responsibilities;

- Implement additional and enhance existing sub-certifications and internal management representation letters, including providing training on the purpose of the sub-certification and the process for evaluating the representations;

- Enhance controls and implement written policies and procedures to provide governance, oversight and guidelines for timely communication of management fee arrangements with wholesalers; and

- Evaluate and enhance internal controls related to sales monitoring.

Management continues to evaluate the effectiveness of these remedial measures and expects to continue implementing improvements to the Company's internal control over financial reporting. The process of designing and maintaining effective internal control over financial reporting is a continuous effort that requires management to anticipate and react to changes in our business, economic, and regulatory environments and to expend significant resources. As we continue to evaluate our internal control over financial reporting, we may take additional actions to remediate the material weaknesses or modify the remediation actions described above.

Quarterly Changes in Internal Control Over Financial Reporting

During the quarter ended March 31, 2025, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 6. Exhibits

Number		Description
+10.1	—	Organon Non-Employee Director Savings Plan, as amended and restated on January 1, 2025 (incorporated by reference to Exhibit 10.15 to the Company's Annual Report on Form 10-K (File No. 001-40235) filed on February 28, 2025).
+10.2	—	Form of Global Terms for 2025 Non-Qualified Stock Option Grants Under the Organon & Co. 2021 Incentive Stock Plan (incorporated by reference to Exhibit 10.33 to the Company's Annual Report on Form 10-K (File No. 001-40235) filed on February 28, 2025).
+10.3	—	Form of Global Terms for 2025 Performance Stock Unit Award Under the Organon & Co. 2021 Incentive Stock Plan (incorporated by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K (File No. 001-40235) filed on February 28, 2025).
+10.4	—	Form of Global Terms for 2025 Restricted Stock Unit Award Under the Organon & Co. 2021 Incentive Stock Plan (Stock Default) (incorporated by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K (File No. 001-40235) filed on February 28, 2025).
+10.5	—	Form of Global Terms for 2025 Restricted Stock Unit Award Under the Organon & Co. 2021 Incentive Stock Plan (Cash Default) (incorporated by reference to Exhibit 10.36 to the Company's Annual Report on Form 10-K (File No. 001-40235) filed on February 28, 2025).
*31.1	—	Certification of Principal Executive Officer (Interim 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 (Interim CEO) pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
**32.2	—	Section 1350 Certification of Principal Financial Officer (CFO) pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	—	XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	—	XBRL Taxonomy Extension Schema Document.
101.CAL	—	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	—	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	—	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	—	XBRL Taxonomy Extension Presentation Linkbase Document.
104	—	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith

** Furnished herewith

\+ Management contract or compensatory plan or arrangement

Signatures

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ORGANON & CO.

Date: November 10, 2025

/s/ Lynette Holzbaur

Lynette Holzbaur
Senior Vice President Finance - Corporate Controller

Date: November 10, 2025

/s/ Matthew Walsh

Matthew Walsh
Chief Financial Officer

Exhibit 31.1

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

I, Joseph Morrissey, certify that:

1. I have reviewed this report on Form 10-Q/A 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 in order to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

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

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

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

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

November 10, 2025

/s/ Joseph Morrissey

Joseph Morrissey
Interim Chief Executive Officer
(*Principal Executive Officer*)

Exhibit 31.2

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 report on Form 10-Q/A 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 in order to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

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

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

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

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

November 10, 2025

/s/ Matthew Walsh

Matthew Walsh
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF INTERIM 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/A for the period ended March 31, 2025 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 on Form 10-Q/A fairly presents, in all material respects, the financial condition and results of operations of Organon & Co.

November 10, 2025

/s/ Joseph Morrissey

Joseph Morrissey
Interim Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

Pursuant to 18 U.S.C.§ 1350, the undersigned certifies that, to the best of my knowledge, the Quarterly Report on Form 10-Q/A for the period ended March 31, 2025 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 on Form 10-Q/A fairly presents, in all material respects, the financial condition and results of operations of Organon & Co.

November 10, 2025

/s/ Matthew Walsh

Matthew Walsh
Chief Financial Officer
(Principal Financial and Accounting Officer)