

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

*In re Organon & Co. Securities  
Litigation*

Case No. 2:25-cv-005322-JXN-CF

DEMAND FOR JURY TRIAL

**AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS  
OF THE FEDERAL SECURITIES LAWS**

**TABLE OF CONTENTS**

I. NATURE OF THE ACTION AND OVERVIEW ..... 1

II. JURISDICTION AND VENUE ..... 12

III. PARTIES ..... 13

    A. Lead Plaintiff..... 13

    B. Defendants ..... 13

    C. Relevant Former Employees ..... 15

IV. SUBSTANTIVE ALLEGATIONS OF FRAUD ..... 15

    A. Industry and Regulatory Background ..... 15

    B. Organon’s Spin-off from Merck ..... 18

    C. Organon Tied Its Prospects to Nexplanon ..... 23

    D. Organon Offered a Substantial Shareholder Dividend, Assuring Investors of the Company’s Long-Term Stability ..... 26

    E. Unbeknownst to Investors, Organon Concealed Challenges Facing Nexplanon That Impacted the Company’s Ability to Sustain Its Promised Dividend ..... 28

        1. Organon Misrepresented the Risk a Generic Competitor Would Seek FDA Approval for a Nexplanon Biosimilar..... 28

        2. To Conceal Nexplanon’s Underperforming Revenues, Organon Pulled Sales Forward to Make Quarterly Goals ..... 37

        3. Organon Paid (and Promised to Continue Paying) a Robust Shareholder Dividend, Even as Nexplanon’s Deteriorating Prospects Depleted Cash Available for Dividend Payments ..... 43

V. DEFENDANTS’ MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS ..... 48

    A. Defendants’ Materially False and Misleading Statements and Omissions Regarding the Timetable for Nexplanon’s LOE,

Which Concealed the Risk, Introduced by FDA Guidance, of Competition from Biosimilars.....	48
B. Defendants’ Materially False and Misleading Statements Regarding Nexplanon’s Revenues, Performance, and Growth Prospects.....	61
C. Defendants’ Materially False and Misleading Statements About Organon’s Free Cash Flow and Ability to Continue Making Robust Quarterly Dividend Payments.....	76
D. Defendants’ Materially False and Misleading Statements About Sales Practices for Wholesalers and the Effect Upon Revenues and Product Demand, as Well as Defendant Ali’s Fitness to Serve on the Board of Directors.....	89
E. Organon’s Class Period SEC Filings Contained Actionable Half-Truths Regarding Sales, Revenue, and Demand for Nexplanon That Violated Item 303 of Regulation S-K .....	101
VI. THE TRUTH IS REVEALED .....	107
VII. POST-CLASS PERIOD DEVELOPMENTS .....	115
VIII. SUMMARY OF SCIENTER ALLEGATIONS .....	118
IX. LOSS CAUSATION .....	121
X. PRESUMPTION OF RELIANCE .....	124
XI. CLASS ACTION ALLEGATIONS.....	126
XII. THE INAPPLICABILITY OF THE STATUTORY SAFE HARBOR AND THE BESPEAKS CAUTION DOCTRINE .....	128
XIII. CLAIMS FOR RELIEF UNDER THE EXCHANGE ACT.....	130
XIV. PRAYER FOR RELIEF .....	138
XV. JURY DEMAND.....	139

Lead Plaintiff International Brotherhood of Teamsters Local No. 710 Pension Fund (“Teamsters 710” or “Lead Plaintiff”), individually and on behalf of all others similarly situated, alleges the following based upon personal knowledge as to Lead Plaintiff’s own acts and upon information and belief as to all other matters based on the ongoing investigation conducted by and through counsel, which includes, among other things, a review and analysis of: (i) the public U.S. Securities and Exchange Commission (“SEC”) filings of Organon & Co. (“Organon” or the “Company”); (ii) Company press releases; (iii) transcripts of the Company’s conference calls with analysts and investors; (iv) investor presentations; (v) research reports issued by securities and financial analysts; (vi) news and media reports and other public reports and information regarding the Company and Defendants (defined below); (vii) the movement and pricing of the Company’s publicly traded securities; and (viii) interviews of former employees of the Company (referred to herein as “FE-\_\_”). Lead Counsel’s investigation is ongoing and many of the relevant facts are known only by Defendants or are exclusively within their custody or control. Lead Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

## **I. NATURE OF THE ACTION AND OVERVIEW**

1. This is a securities class action on behalf of all persons and entities that purchased or otherwise acquired Organon common stock from November 3, 2022

through October 26, 2025, inclusive (the “Class Period”). Lead Plaintiff brings this action to recover damages caused by violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder, by Defendants Organon, former Chief Executive Officer (“CEO”) Kevin Ali (“Defendant Ali” or “Ali”), and Chief Financial Officer (“CFO”) Matthew Walsh (“Defendant Walsh” or “Walsh”) (collectively, “Defendants”). This case arises from a series of materially false and misleading statements by Defendants that concealed, minimized, or dismissed operational constraints and material risks facing Organon’s most important product, Nexplanon, which undercut Organon’s ability to continue paying a robust dividend of \$0.28 per share to shareholders.

2. Organon spun off from Merck in 2021 with the mission of “set[ting] a new direction for the future of women’s health,” a mission embodied by the Company’s new women-focused slogan: “Here for her health.” Yet Organon’s future as a recently spun-off company in the women’s health space faced uncertainty from the start due to operational constraints and material risks that Defendants concealed from investors.

3. In 2024, approximately 28% of the Company’s total revenues came from “women’s health” products, 10% came from immunology and oncology biosimilars, and the balance derived from Organon’s “Established Brands” portfolio of cardiovascular and respiratory drugs it inherited from Merck. Most of Organon’s Established Brands products had experienced loss of exclusivity (“LOE”) years prior,

and as such, were easy targets for competition from lesser priced generics and biosimilars, resulting in little opportunity for growth, and in fact declining sales. Making matters worse, the Company did not have the infrastructure to research and develop new women's health products. Relatedly, the Merck spin-off required Organon to assume \$9.5 billion in debt, sharply limiting the Company's liquidity and thus its ability to acquire or develop new women's health products.

4. Given these constraints, Organon seized on one product in its portfolio as the future of cutting-edge women's health products, and promoted it as a significant reason to invest in the Company: Nexplanon, a long-acting reversible contraceptive ("LARC"). With Nexplanon, the Company touted a history of sales growth, albeit interrupted temporarily—as Organon led investors to believe—by the COVID-19 pandemic. Moreover, Organon touted Nexplanon's seemingly strong intellectual property and regulatory protections, minimizing the risk of generic competition and leading investors to believe Nexplanon would not experience LOE and inroads from competitors until 2027 at the earliest. Buoyed by Nexplanon's apparent strength and contribution to the business, Organon conveyed to the market that it would continue to pay a quarterly shareholder dividend of \$0.28 per share—a remarkably high dividend for a company of Organon's age, share price, and liquidity.

5. Organon led investors to believe that the Company's focus on Nexplanon would pay off, projecting to the market that Nexplanon would reach \$1 billion in

annual sales by 2025. But, behind closed doors, Defendants knew of or recklessly disregarded material risks—namely, the threat of competition from generic Nexplanon products and slower-than-desired growth in customer demand for Nexplanon—that threatened Nexplanon’s continued growth. These constraints would ultimately impede the Company’s ability to continue paying a large dividend to shareholders, as Organon’s ability to make dividend payments depended on the free cash flow generated by Nexplanon sales. According to one analyst, sales of Nexplanon accounted for as much as two-thirds of Organon’s overall free cash flow during the Class Period; in the analyst’s words, a “VERY significant portion” of Organon’s free cash flow.

6. In reality, patients’ adoption of Nexplanon was not at the aggressive rates Organon’s senior management represented to investors via Organon’s annual guidance. And, as the Company itself has since admitted, to create the appearance of growing sales in line with the Company’s guidance and analyst expectations, Organon secretly executed a scheme over six quarters—under the direction of its CEO Ali and other senior management—to induce its two largest U.S. wholesalers to purchase more Nexplanon than they wanted or needed in exchange for perks such as waived inventory management fees (a scheme known as “channel stuffing”).

7. As Organon later disclosed, Defendant Ali applied inappropriate pressure to meet targets through Nexplanon sales that were unsupported by actual demand, and

the Company failed to design and maintain effective controls to evaluate its disclosures and financial reporting related to sales practices to wholesalers. Yet Defendants failed to acknowledge these deficiencies until Organon identified them as material weaknesses in the Company's internal control over financial reporting in November 2025—years after the Nexplanon channel stuffing began, in 2022. When this conduct ultimately came to light, an Audit Committee investigation ensued, Ali immediately resigned as CEO without severance or equity payouts, and Organon's stock price dropped sharply.

8. Furthermore, the regulatory barriers protecting Nexplanon from generic competition in the long term were far less robust than Defendants portrayed. While Defendants told investors that any generic Nexplanon competitor would need to conduct a three- or five-year clinical trial to match the duration for which Nexplanon is inserted in a patient's arm, in reality, on August 5, 2022, the U.S. Food and Drug Administration ("FDA") issued Draft Guidance stating that a Nexplanon generic would only need to provide six months of clinical data. Organon recognized that the FDA's position threatened Nexplanon's exclusivity and prospects and promptly filed a Citizen Petition lobbying the FDA to require three or more years of data for any competitor. Yet, publicly, Organon continued to tell investors that Nexplanon's competitors would need to demonstrate at least three years of clinical data—voicing this position even after the FDA issued an August 14, 2024, Interim Response Letter

stating that it could not resolve Organon's petition without additional analysis. As Organon knew, the FDA does not resolve Citizen Petitions promptly, and often takes years before rendering a final determination—if at all.

9. Defendants' concealment of these issues was critical to enabling Organon to deceive the market regarding the Company's ability to continue its longtime practice of paying quarterly dividends of \$0.28 per share. Throughout the Class Period, Organon told investors that it could sustain these dividend payments going forward, with Defendant Walsh representing that these payments were Organon's "#1 capital allocation priority." Although Organon's ability to pay such a large dividend rested on positive cash flow generated by Nexplanon sales, it never disclosed that the sustainability of these cash flows was overstated because of Organon's channel stuffing scheme with wholesalers.

10. Moreover, because Organon's most important product (Nexplanon) appeared to be meeting estimates through sales driven by actual demand, investors were led to believe that the Company's free cash flow—and, thus, the sustainability of Organon's dividend—rested on solid foundations. Investors were not told, however, that Nexplanon demand was weaker than represented and that Organon resorted to improper pull-forward sales to preserve the appearance of meeting expectations. Nor were investors told that Nexplanon's greater-than-disclosed LOE risk imperiled the revenue Organon could expect to generate from Nexplanon, heightening the

Company's need to develop new free cash flow drivers by acquiring or developing new products because its other product markets were mature and experiencing stagnant growth. But there simply was not enough money to go around: Organon lacked the cash flow to acquire or develop new products while also paying an outsized dividend to shareholders.

11. Organon's capital situation became even more constrained in September 2024, when the Company expended \$1.2 billion of its dwindling free cash flow to acquire a dermatology brand, Dermavant. Yet Organon continued to falsely maintain that it possessed sufficient capital to carry on paying a robust shareholder dividend at its historical level. In other words, Defendants' repeated emphasis on the Company's "commitment" to a quarterly dividend of \$0.28 per share misled investors into believing that Organon's cash flow was healthy enough to pay such a large dividend going forward.

12. Organon's fraud was gradually revealed to the market through a series of disclosures from May to October of 2025. First, on Thursday, May 1, 2025, Organon announced it would slash the quarterly shareholder dividend from \$0.28 per share to just \$0.02 per share, **an over 90% decrease**. In an earnings call that same day, Organon's senior management acknowledged that the Company could not afford to pay such a large dividend, citing the need to acquire new products and pay down debt. Investors were stunned by this abrupt departure from the Company's stated

commitment to paying a large dividend; the market price of Organon's common stock cratered more than \$3 per share, from a closing price of \$12.93 per share on April 30, 2025 to \$9.45 per share on May 1, 2025. Analysts reacted to this news with shock, with one analyst calling the announcement of the dividend cut "unexpected" because "none of the [C]ompany's prior comments suggest[ed] this was something OGN was exploring."

13. Additional details of Organon's fraud were revealed to the market on May 2, 2025, when, in connection with the filing of its first quarter 2025 quarterly report with the SEC on Form 10-Q, the Company disclosed it had sued a rival pharmaceutical company, Xiromed LLC ("Xiromed"), for seeking to produce and sell a Nexplanon generic. Organon's complaint revealed not only Xiromed's pending FDA application and the FDA Draft Guidance requiring a mere six months of clinical data, but also the Company's efforts, by way of its Citizen Petition, to prevent that Guidance from going into effect. The market price of Organon common stock traded even lower on this news, closing down at \$8.72 per share on Monday, May 5, 2025. Analysts reacted to this news with further shock, with one analyst stating that generic competitors would "clearly target" Nexplanon in light of the unexpected news.

14. Further details of Organon's fraud were revealed to the market on October 27, 2025, when Organon disclosed that its Audit Committee had uncovered that Organon "asked certain 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 . . . than they otherwise would have purchased based on wholesaler demand.” Organon further disclosed that these wholesalers “receive[d] incentive fees from the Company that they otherwise would not have received” in exchange for their participation in the channel-stuffing scheme.

15. In the same press release, Organon announced that its CEO, Defendant Ali, had resigned without severance or equity payouts. Along with Ali’s departure, Organon disclosed that it had terminated its Head of U.S. Commercial & Government Affairs—a senior-level executive of the Company since its founding. With the exposure of the lengthy channel-stuffing scheme tied to these (and presumably other) executives, investors finally learned that Defendants solicited and secured shareholder approval of Ali’s reelection to Organon’s Board of Directors in 2024 and 2025 based on misstatements in Company proxy statements regarding Nexplanon’s growth, sales performance, and customer demand, as well as Ali’s fitness to serve in that position or as an executive of the Company. They also learned that the Company leveraged these misstatements to secure approval of an expansion of Organon’s insider stock plan. As then-CEO of Organon, Ali played a major role in vetting, authoring, and approving these materially misleading statements in SEC filings during the Class Period.

16. This news wiped out any recovery Organon's stock had made since the May disclosures, with the price of Organon shares falling from \$9.16 at the close of trading on Friday, October 24, 2025, to \$7.06 on Monday, October 27, 2025.

17. On November 10, 2025, Organon filed amendments to three of its periodic SEC filings: its February 28, 2025, Form 10-K for the fiscal year ended December 31, 2024; its May 2, 2025, Form 10-Q for the first quarter ended March 31, 2025; and its August 6, 2025, Form 10-Q for the second quarter ended June 30, 2025. The amended SEC filings corrected Defendants' prior disclosures regarding increased sales, revenue, and demand for Nexplanon—which they admitted on October 27, 2025, were “inaccurate” and, therefore, misleading. The amendments confirmed that the increase in Nexplanon's sales, revenue, and demand for those (and other) periods resulted from inducing wholesaler purchases through unwarranted incentives, which was concealed from the public until October 27, 2025. The amendments revealed material weaknesses in the Company's internal control over financial reporting, and maintaining effective controls related to information and communication, resulting from the failure to set an appropriate “tone at the top.”

18. Accordingly, the February 28, 2025, Form 10-K, May 2, 2025, Form 10-Q, and August 6, 2025, Form 10-Q misrepresented the nature and cause of the upward trend in Nexplanon's sales, revenue, and demand for the first and second quarters of 2025 and the 2024 fourth quarter and full-year. Additionally, because channel stuffing

inflated Nexplanon sales, revenue, and demand for the fourth quarter of 2022 and third quarter of 2024, the quarterly SEC filings for those periods misrepresented the nature and cause of the upward trend in Nexplanon’s sales, revenue, and demand. And because that conduct artificially inflated demand in earlier periods (by inducing wholesalers to purchase more Nexplanon product than they wanted or needed), this conduct also had the foreseeable effect of depressing future sales (as the wholesalers decreased or halted purchases thereafter)—a predictable consequence Defendants appreciated, yet concealed from public investors. Therefore, Organon’s quarterly and annual SEC filings for this period contained half-truths that are also actionable under Item 303 of SEC Regulation S-K, as detailed further below.

19. After the Class Period, the Company revealed additional information to the market concerning Defendants’ fraud. On February 12, 2026, before the market opened, Organon reported a 15% decline in Women’s Health revenue for the 2025 fourth quarter (as compared to the 2024 fourth quarter), resulting, in part, from the “approximate \$17 million decrease in sales due to the cessation” of the Nexplanon channel stuffing. And after the market closed on February 24, 2026, Organon issued its 2025 Form 10-K, disclosing, for the first time, that the SEC had been investigating the Company’s channel stuffing since it self-reported the conduct to the SEC back in October 2025.

20. The Class Period fraud alleged herein thus had a profound and continuing impact on Organon even after its revelation, as the market continued to consider the implications of the adverse developments Defendants misrepresented and concealed from the investing public during the Class Period. As a result of these wrongful acts and omissions, and the significant decline in the market value of the Company's stock due to the revelation of the fraud, Lead Plaintiff and other members of the Class (defined herein) have suffered significant damages.

## **II. JURISDICTION AND VENUE**

21. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

22. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

23. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa). The Company's principal offices are located in this District. Substantial acts in the furtherance of the alleged fraud or the effects of the fraud have occurred in this District. Defendants' wrongful acts also arose in, emanated from, and caused harm in this District. Such acts include the dissemination of materially false and misleading statements into this District.

24. In connection with the acts, transactions, and conduct alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange, the New York Stock Exchange.

### **III. PARTIES**

#### **A. Lead Plaintiff**

25. Lead Plaintiff Teamsters 710 purchased Organon stock during the Class Period, as reflected in the certification filed herewith, and was injured as a result of Defendants' false and misleading statements and omissions. Teamsters 710 is a Taft-Hartley defined pension fund representing more than 21,000 participants, with \$4.6 billion in investments held for their benefit and that of their families.

#### **B. Defendants**

26. Defendant Organon is incorporated in Delaware and headquartered in Jersey City, New Jersey. Organon common stock trades on the New York Stock Exchange under the ticker symbol "OGN."

27. Defendant Ali was the CEO of Organon and a member of its Board of Directors until October 27, 2025, when he unexpectedly resigned without severance or equity payouts.

28. Defendant Walsh is, and was at all relevant times, an Executive Vice President and CFO of Organon.

29. Defendants Ali and Walsh are collectively referred to herein as the “Individual Defendants.” The Individual Defendants, together with Organon, are referred to herein as “Defendants.”

30. As a result of their positions with the Company, the Individual Defendants possessed the power and authority to control the contents of Organon’s reports to the SEC, press releases, and presentations to securities analysts, money portfolio managers and investors, *i.e.*, the market, and are presumptively responsible for the statements in SEC filings and press releases. The Individual Defendants were provided with copies of the Company’s reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Defendants Ali and Walsh signed each of Organon’s relevant SEC filings on Form 10-K, and all other relevant SEC filings, including Organon’s filings on Form 10-Q, were signed by Defendant Walsh.

31. Because of their positions and access to material non-public information available to them, the Individual Defendants knew or recklessly disregarded that the adverse facts herein had not been disclosed to, and were being concealed from, the public, and that the positive representations that were being made were then materially false or misleading. The Individual Defendants are liable for the false and misleading

representations pleaded herein, as those statements were each “group-published” information, the result of the collective actions of the Individual Defendants.

### **C. Relevant Former Employees**

32. FE-1 served as Director of Business Technology at Organon from February 2020 through the summer of 2025.<sup>1</sup>

33. FE-2 worked at Organon as an Associate Director in Research and Development (“R&D”) from September 2024 to March 2026.

## **IV. SUBSTANTIVE ALLEGATIONS OF FRAUD**

### **A. Industry and Regulatory Background**

34. The pharmaceutical industry is a global behemoth, with drug companies generating approximately \$1.6 trillion in revenue in 2024. But women’s health products—that is, pharmaceutical products treating medical conditions that are unique to women or that affect women differently—are a surprisingly small part of the total market. Indeed, while women make up over half of the global population, they have been notoriously underrepresented in pharmaceutical drug research, development, marketing, and production. In fact, women’s health drugs only accounted for \$49.3 billion (or about 3%) of the pharmaceutical market in 2024.

---

<sup>1</sup> To preserve confidentiality, the FEs are referred to herein in the feminine regardless of their actual gender.

35. The pharmaceutical industry is highly regulated. Companies seeking to market a new drug or biologic<sup>2</sup> in the United States must first submit a New Drug Application (“NDA”) to the FDA containing data on the product’s effectiveness and safety. The FDA approval process is long and arduous, yet it is illegal to market a drug or biologic without the FDA’s approval.

36. The regulatory process is much simpler for bioequivalents—that is, generic versions of drug products that have lost patent protection, thereby paving the way for competitors to enter the market. Companies seeking to market a bioequivalent must submit an Abbreviated New Drug Application (“ANDA”) demonstrating, among other requirements, that the bioequivalent performs similarly to the patented product (called the “reference product”), notwithstanding immaterial differences in the products’ compositions. The number of months of data a bioequivalent manufacturer must provide to demonstrate similarity to the reference product is determined by the FDA on a product-by-product basis.

37. These requirements are initially outlined by the FDA in a Draft Guidance document. The FDA then sometimes memorializes its Draft Guidance in final form. These Guidance documents are of critical importance because, even when presented in draft form, they reflect the FDA’s prevailing views on a given issue. The ANDA

---

<sup>2</sup> Biologics are pharmaceutical products composed of or isolated from natural substances, such as genes or cells.

pathway excuses bioequivalent manufacturers from having to duplicate the extensive clinical trials required for a reference product, potentially leading to faster approval and increased patient access.

38. Before submitting an ANDA for a bioequivalent, a pharmaceutical company must send the reference product's manufacturer a certification (called a "paragraph IV certification") stating that the generic product does not, in the company's opinion, infringe on the manufacturer's patent(s). Upon receipt of the generic manufacturer's paragraph IV certification, the reference product's manufacturer has 45 days to file a patent infringement lawsuit against the generic product's manufacturer.

39. Manufacturers of reference products have multiple opportunities to influence the ANDA process. Most directly, the manufacturer can submit comments on the FDA's Draft Guidance. The FDA typically considers comments when deciding whether to finalize a Draft Guidance document; that said, the FDA is under no obligation to do so, and the FDA may elect not to reduce its Draft Guidance to a final form while still expecting the Draft Guidance to represent its prevailing views. Alternatively, the manufacturer can file a Citizen Petition, formally requesting that the FDA take a particular action. The FDA is obligated by statute to provide an interim response to a Citizen Petition within 180 days of filing.

40. The point at which a drug's patent and regulatory protections no longer prevent generic competitors from entering the market is referred to in the

pharmaceutical industry as “loss of exclusivity” (or “LOE,” as noted above). Given the natural increase in competition that may occur when a product experiences LOE, which naturally induces a lower price for what is now no longer an exclusive drug, publicly traded companies with reference products appreciate the implications of losing exclusivity. Thus, these public companies typically strive to provide transparent communications about the timing, risks, and consequences of losing exclusivity for a given product—information inherently critical to public investors, who are entitled to rely on official corporate communications.

**B. Organon’s Spin-off from Merck**

41. The Organon corporate brand dates back to the 1923 founding of Zwanenberg-Organon, a Dutch pharmaceutical company. One of the largest European pharmaceutical companies of its time, the original Organon was known for innovative women’s health products like desogestrel, a compound commonly used in birth control pills, and NuvaRing, a pioneering insertable contraceptive device. The original Organon was acquired by Schering-Plough in 2007. Later, Organon’s original suite of products was subsumed into Merck when it acquired Schering-Plough in 2009.

42. On March 11, 2020, Merck announced its intent to spin off parts of its portfolio, including the women’s health division, into a new company with a familiar name: Organon & Co. The revival of Organon’s name reflected its positioning as a global leader in women’s health. As Merck’s CEO Kenneth C. Frazier explained in a

press release announcing the spin-off, “[t]he new Organon will carry forward [the original Organon’s] legacy by continuing to focus on meeting the unmet healthcare needs of women around the world.” Organon’s soon-to-be CEO, Defendant Ali, proclaimed in the same press release that the Company would “set a new direction for the future of women’s health bringing new hope and treatments worldwide[.]”

43. As Merck’s President for Global Enterprise Portfolio Strategy, Defendant Ali orchestrated the Organon spin-off and hand-selected executives to serve on the Company’s senior leadership team. Ali assembled a C-suite dominated by Merck alumni, such as Organon’s Chief Commercial Officer, Susanne Fiedler; Organon’s Head of Research & Development, Sandra Milligan, M.D.; and Organon’s Head of Manufacturing & Supply, Joseph Morrissey. For the CFO role, Ali recruited Defendant Walsh, who had previously served as CFO of the pharmaceutical company Allergan.

44. In addition to dominating Organon’s management ranks, former Merck employees made up about 80% of the Company’s approximately 9,300 employees, with employees largely carrying over their duties and roles from Merck.

45. At its launch, the new Organon consisted of over 60 products across three portfolios: Established Brands, Biosimilars, and Women’s Health. Drugs in the Established Brands portfolio made up, and continue to make up, the vast majority of Organon’s recorded sales. For example, in 2021—the first year of the Company’s

existence—drugs in the Established Brands portfolio accounted for roughly \$4 billion of Organon’s approximately \$6 billion in sales. The Established Brands portfolio consists of drugs spanning a variety of treatment areas that have little to do with women’s health, ranging from asthma medicine like Singulair to hair loss products like Propecia.

46. Drugs in the Biosimilars portfolio made up (and continue to make up) the smallest portion of Organon’s revenues, accounting for a mere \$424 million (roughly 7%) of the Company’s sales in 2021. This portfolio consists of biosimilars of products produced by other pharmaceutical companies. For example, Organon produces and sells HADLIMA, a biosimilar version of Abbott Laboratories’ biologic HUMIRA. As a producer of biosimilars, Organon is well versed in the complex intellectual property and regulatory frameworks governing the production and sale of generic pharmaceuticals, including the requirements of the FDA’s ANDA process.

47. At Organon’s launch in 2021, Women’s Health drugs accounted for about \$1.6 billion, or roughly 26%, of its global revenues. Defendant Ali emphasized the Company’s renewed focus on women’s health products in the lead-up to Organon’s official spin-off from Merck, positioning Nexplanon as a core driver of the Company’s future growth.

48. For example, in a June 3, 2021, interview with industry publication Fierce Pharma, Ali proclaimed that Organon would give the Women’s Health portfolio a

“prioritization and focus” that was lacking at Merck, a company known for its focus on vaccines and cancer treatments. In the same interview, Ali again drew on the legacy of the original Organon, stating: “OB-GYNs . . . have incredible respect and incredible memories for the name of Organon[.] So we brought back Organon on a version 2.0 because we wanted the world to know what we were about.” At the end of the interview, Ali emphasized the new Organon’s women’s health focus even more explicitly, stating: “This is a women’s health company[.] We feel that the world needs a company that is not watered down but focused on women’s health and solving these needs. And that vision and that passion and that purpose is what drives us.”

49. Organon’s ostensible focus on its Women’s Health portfolio was echoed in the Company’s website, slogans, trade dress, and other marketing materials. The Company’s main slogan, for example, is “*Organon, here for her health.*” The Company’s website further states, “We are an independent global healthcare company with a strategy to improve the health of women throughout their lives,” and features depictions of stylized females silhouetted interacting or performing everyday tasks, like shaking hands or exercising. Other Organon advertising materials tout the Company’s “Her Plan is Her Power” initiative, a campaign aimed at “prevent[ing] 120 million unplanned pregnancies worldwide by 2030[.]”

50. Analysts reacted favorably to the Company’s stated focus on women’s health issues at the time of the spin-off. For example, in a June 15, 2021 piece, a

*Forbes* analyst highlighted the pharmaceutical industry's underinvestment in women's health products, opining that "[s]tepping into a space which is largely ignored and focusing on ground-breaking contraceptives could be the secret weapon in [Organon's] armory."

51. Despite the fanfare surrounding its spin-off from Merck, however, Organon was beset by problems from the beginning. **First**, the terms of Merck's acquisition of Organon required the Company to assume approximately \$9.5 billion in debt.

52. **Second**, the drugs in Organon's largest portfolio by revenue, Established Brands, had all lost or were in the process of losing exclusivity. Revenues from these drugs, though totaling billions of dollars, had declined and were expected to decline further due to competition from cheaply priced generics and biosimilars.

53. **Third**, the Company had no formal research & development capabilities, making it dependent on acquisitions and partnerships to develop new drugs. As Defendant Walsh told a financial journal, *Investor's Business Daily*, for an article published in June 2021, Organon planned to "outsourc[e]" the research side of its R&D efforts to other companies.

54. Moreover, the Company was required to pay off the debt it assumed in the spinoff from Merck, requiring capital that could otherwise have been used to acquire or develop new drugs.

55. *Fourth*, Organon's brand identity as a women's health company did not reflect the Company's actual operations. The Company positioned itself as a women's health company, yet the vast majority of Organon's products had little to do with women's health.

### **C. Organon Tied Its Prospects to Nexplanon**

56. Following the spin-off, Organon promoted Nexplanon, a LARC device, as its flagship product and main source of future growth. Nexplanon consists of a matchstick-sized rod that is inserted into a patient's upper arm. The rod releases a hormone, etonogestrel, which prevents pregnancy by thickening cervical mucus and suppressing ovulation.

57. Nexplanon has features that set it apart from competitor products, making it uniquely central to Organon's growth strategy during the Class Period. Given its placement in a patient's upper arm, Nexplanon is less invasive than other LARCs that are inserted into a patient's uterus. Another difference is that the Nexplanon rod is radiopaque, meaning that its presence in the body can be detected by X-ray technology. As a result, Nexplanon is popular with medical providers, as inserting or removing the Nexplanon rod only requires an X-ray machine. Many other LARCs, by contrast, can only be detected within the body using MRI or ultrasound devices, which are more expensive and less widely available.

58. Nexplanon's intellectual property protections are based on two patents, both of which Organon acquired in its spin-off from Merck: the patent on Nexplanon's radiopaque drug delivery device, U.S. Patent No. 8,722,037 (filed Mar. 14, 2005), and the patent on the applicator used to insert the Nexplanon device, U.S. Patent No. 9,757,552 (filed Jan. 20, 2006). Organon's patents on the Nexplanon device and applicator expire on September 28, 2027, and July 28, 2030, respectively.

59. Like other long-acting contraceptive products, Nexplanon is highly regulated by the FDA. To perform Nexplanon insertions, medical providers must complete a mandatory 2-3 hour in-person training required by the FDA.

60. During the Class Period, FDA regulations limited the duration for which Nexplanon may be inserted into a patient's body to three years. On January 16, 2026, the FDA approved Nexplanon for use for up to five years. In granting Organon's application to extend Nexplanon's use period, the FDA did not approve or deny Organon's Citizen Petition seeking to heighten the clinical data requirements for Nexplanon bioequivalent applications, which remains outstanding.

61. Nexplanon demonstrated sustained growth in the years before Organon's spin-off from Merck. Merck's reported revenues from Nexplanon sales increased every year between 2017 and 2019 from \$686 million in 2017, to \$703 million in 2018, to \$787 million in 2019—an increase of almost 15% over just two years.

62. The COVID-19 pandemic temporarily interrupted Nexplanon's growth, causing the product's annual sales to decline to \$680 million in 2020. Nexplanon's COVID-era downturn in sales was confirmed by Defendant Ali on Organon's August 4, 2022, earnings call, where he noted that OBGYN office visits during the COVID-19 pandemic "lag[ged] behind pre-pandemic levels[.]"

63. At Organon's launch in 2021, the COVID-19 pandemic was beginning to subside, seemingly positioning Nexplanon to regain its pre-pandemic sales momentum. Nexplanon also stood to benefit from newly enacted state laws that restricted abortion access, which increased demand for LARCs. In contrast, Organon's Established Brands portfolio of products, which consisted of off-patent products facing generic competition, operated in mature, stagnant markets.

64. Against this backdrop, Defendants repeatedly emphasized Nexplanon's growing sales and importance to Organon's overall financial performance. For example, on Organon's February 13, 2025, earnings call, Defendant Ali told investors that the Company was "very optimistic about the future [of Nexplanon.]" Likewise, on Organon's October 31, 2024, analyst call, Defendant Ali told investors that Nexplanon was the Company's "largest product" and contributed to Organon's "very strong" commercial execution in the 2024 fiscal year. Defendants also repeatedly assured investors that Nexplanon would retain exclusivity until 2030, *see infra* Section V.B, thereby seemingly buying time for Organon to build up its portfolio before Nexplanon

lost exclusivity and the concomitant commercial advantage afforded by its U.S. intellectual property protections.

65. Importantly, Nexplanon's central role in Organon's growth strategy also underpinned the Company's portrayal of itself as a women's health company. For example, an Evercore analyst described Nexplanon as the Company's "biggest product."

66. Underscoring Nexplanon's importance, Defendants repeatedly predicted that Nexplanon would reach \$1 billion in annual revenue in 2025.

**D. Organon Offered a Substantial Shareholder Dividend,  
Assuring Investors of the Company's Long-Term Stability**

67. Another key aspect of Organon's appeal to the market was the Company's practice of paying a substantial shareholder dividend of \$0.28 per share. Beginning in the third quarter of 2021—the Company's first fiscal quarter as a publicly traded company—Organon began paying this robust dividend. While more established pharmaceutical companies sometimes paid a larger shareholder dividend in terms of price per share, in terms of dividend yield—that is, the ratio of Organon's annual dividend per share to Organon's share price—Organon's dividend approached and even exceeded those paid by competitor companies. In 2022, for example, Organon's dividend yield was roughly 4.18%, which was greater than the dividend yield paid by AbbVie (4.1%), Pfizer (2.9%), and Johnson & Johnson (2.55%), all well-established pharmaceutical companies.

68. Defendants repeatedly cited Organon’s generous dividend as an indicator of the long-term stability of the Company’s cash flow. As Defendant Walsh told investors on Organon’s Q3 2021 earnings call—the Company’s first-ever earnings call—the Company’s decision to pay the dividend reflected that Organon “generates strong cash flow today.” On the same call, Walsh described the dividend as Organon’s “number one [cash allocation] priority.” Defendants Walsh and Ali would continue to represent to investors that the Company’s large dividend was its “number one” cash allocation priority throughout the Class Period.

69. Analyst reports from before and during the Class Period confirmed that the market interpreted Organon’s supposed commitment to dividend payments as an indicator of the Company’s cash solvency. For example, an analyst at Evercore remarked, “[i]t’s nice to hear mgmt confidence and reiteration of commitment to [the] dividend,” after Organon’s February 15, 2024, fourth-quarter 2023 earnings call, where Defendant Ali stated that the Company was “very committed to be able to service our dividend.”

70. However, Organon’s ability to continue paying a \$0.28 per share dividend was directly tied to the Company’s Nexplanon sales. During the Class Period, sales of Nexplanon were Organon’s largest generator of free cash flow, which Organon used to pay the dividend. Yet Organon’s use of its free cash flow for its outsized dividend payments consumed capital the Company otherwise could have spent on developing

and acquiring new products and thus reducing the Company's dependence on Nexplanon alone.

**E. Unbeknownst to Investors, Organon Concealed Challenges Facing Nexplanon That Impacted the Company's Ability to Sustain Its Promised Dividend**

71. Organon finalized its separation from Merck on June 3, 2021. Shares of Organon stock commenced trading on the New York Stock Exchange the same day.

72. As early as August 2022, however, headwinds emerged that threatened Nexplanon's short- and long-term viability as Organon's keystone product. These issues threatened Organon's ability to pay its promised dividend at historic levels, yet Defendants misleadingly downplayed them and led investors to believe that the dividend was sacrosanct and the Company would never compromise it.

**1. Organon Misrepresented the Risk a Generic Competitor Would Seek FDA Approval for a Nexplanon Biosimilar**

73. On August 5, 2022, the FDA issued Draft Guidance addressing the ANDA process for Nexplanon bioequivalents. The Draft Guidance (FDA Docket No. FDA-2007-D-0369-0653) stated, in pertinent part, that a proposed generic competitor only had to conduct a single *six-month* clinical trial, not a three-year trial matching the duration of how long a Nexplanon insert is left in a patient's arm. Specifically, the Draft Guidance's "Recommended Studies" required "[s]ix months of in vitro etonogestrel drug release data demonstrating comparable release profiles for the test product and the RS [Reference Standard] product . . . ."

74. The Draft Guidance, which reflected the FDA’s prevailing views, posed a grave threat to Nexplanon’s exclusivity. Requiring six months of data demonstrating the generic’s comparable release profile to Nexplanon meant that a competitor could submit a Nexplanon bioequivalent for FDA approval much sooner than the 2027 and 2030 expiration dates for Nexplanon’s underlying patents—conceivably, as early as February 2023 (a mere six months after the Draft Guidance’s publication).

75. Defendants repeatedly downplayed the risk of competition posed by the Draft Guidance and the likelihood that the risk would materialize within the decade. For example, on Organon’s February 15, 2024, earnings call, an analyst raised the possibility that the Draft Guidance would accelerate Nexplanon’s LOE. In response, Defendant Ali stated in no uncertain terms that “there’s nothing ... I see from the FDA in terms of guidance around kind of breaking the patent that we have[.]”:

Analyst: My question, Kevin, is just regarding, I guess, this year, Teva disclosed the generic NEXPLANON program.<sup>3</sup> I’m wondering how you’re thinking about barriers to entry prior to 2027. I’m looking at the FDA kind of generic equivalent guidance for NEXPLANON. And it does mention there’s a provision for like accelerated comparative in vitro release testing. And so if you get this 5-year study for the intended period of use, do you expect generics are going to need to do 5-year comparative in vitro

---

<sup>3</sup> Though the analyst question referred to Teva’s “generic NEXPLANON program,” Teva has not announced a Nexplanon bioequivalent as of the date this Complaint was filed. Even so, Defendant Ali’s response to the analyst’s question clearly states his and Organon’s false and misleading position that Nexplanon would not face generic competition until “the end of the decade.”

release testing? Or do you think that this provision for an accelerated in vitro release testing is something that is surmountable? Just curious sort of any perspective you can offer on that would be great.

\* \* \*

**Ali: Yes, Jason, there's nothing that I see from the FDA in terms of guidance around kind of breaking the patent that we have. Clearly, through the end of 2027.** But the issue to keep in mind and more importantly, right? Whoever announces what their intent is in terms of their focus on where they want to come in next.

The FDA has never approved any complex generic drug during the first cycle review. I mean we expect – historically, it's been anywhere between 2.5- to 4-year approval time line from the initial ANDA submission. I'll give you an example. For us, NuvaRing, which is by far much less complex, by far, by a magnitude of many times than something like NEXPLANON, which is a medicated vaginal ring for contraception.

The first generic received FDA approval after almost a 30-month delay and Teva's NuvaRing, now that you're bringing up Teva, Teva's NuvaRing generic took 8 years to get to the market. If we take that time line, you're talking about a 2030 minimum introduction. And on top of that, we have the – you're going to have to have your own proprietary device.

Our device, our applicator device has patent protection through 2030. So you're going to have to do your own proprietary applicator device design and then launch it. And finally, you're going to have to start investing in sales force and medical affairs people because you need to have people who actually are training physicians in order to be able to insert and remove this product. And keep in mind, finally, this is a buy-and-build product.

This is not a normal product in that respect. It's much more difficult. **So I have been saying for years, and I can get**

**into all the intricacies that I do not expect any major issue with NEXPLANON between now and the end of the decade.** I do expect that we're going to have the data at the end of this year for the 5-year indication, and we'll be able to launch that probably when we decide in the 2025, 2026 timeframe, which will take essentially exclusivity through the end of the decade.

76. Notwithstanding Defendant Ali's insistence that the Draft Guidance posed no threat to Nexplanon's exclusivity, just days later, on March 5, 2024, Organon filed a Citizen Petition—which Ali did not disclose during the February 15 call—asking the FDA to alter Guidance to expand Nexplanon's protections from generic competition. Specifically, Organon requested that the FDA require at least three years—instead of six months—of data demonstrating a Nexplanon bioequivalent's comparable release profile. Organon also requested that any Nexplanon generic be required to employ applicator and device designs equivalent to those approved for Nexplanon, a bid to further buy time before a competitor could enter the market. Additionally, Organon requested that the FDA impose medical provider training and certification requirements similar to those it required for Nexplanon.

77. On August 14, 2024, the FDA issued an Interim Response Letter to the Citizen Petition, stating that the Citizen Petition raised “complex issues requiring extensive review and analysis by Agency officials” and that the FDA would “respond to [the] petition as soon as [it had] reached a decision on [the] request.” The FDA's failure to promptly respond to the Citizen Petition should have come as no surprise to

Defendants, who are well-versed in matters before the FDA given their experience in navigating the Company's highly-regulated industry.

78. As Defendants knew, while the FDA is required by regulation to decide a Citizen Petition within 180 days of receipt, it rarely, if ever, does. In fact, in a recent empirical study from 2023, titled “Unpacking Averages: FDA’s Extraordinary Delay in Resolving Citizen Petitions,” lawyer Bradley Merrill Thompson, then of Epstein Becker & Green, P.C., indicated that the oldest Citizen Petitions have remained outstanding for upwards of 22 years.<sup>4</sup> An earlier research article published in 2016, “Petitioning the FDA to Improve Pharmaceutical, Device and Public Health Safety by Ordinary Citizens: A Descriptive Analysis,” found that “the time to a decision is potentially very long, with some petitions [filed by individuals] still pending 10 to 13 years after submission.”<sup>5</sup>

79. Because the FDA’s typical delay (or inaction) is known throughout the pharmaceutical industry, Defendants knew that the prospect of receiving a prompt yet favorable determination from the FDA was bleak. Indeed, Defendants knew when

---

<sup>4</sup> See Bradley Merrill Thompson, *Unpacking Averages: FDA’s Extraordinary Delay in Resolving Citizen Petitions*, HEALTH LAW ADVISOR (Oct. 3, 2023), available at <https://www.healthlawadvisor.com/unpacking-averages-fdas-extraordinary-delay-in-resolving-citizen-petitions>.

<sup>5</sup> See Brian K. Chen, et al., *Petitioning the FDA to Improve Pharmaceutical, Device and Public Health Safety by Ordinary Citizens: A Descriptive Analysis*, Public Library of Science (“PLOS”), PLOS One Research Article (May 12, 2016), available at <https://pmc.ncbi.nlm.nih.gov/articles/PMC4865109/pdf/pone.0155259.pdf>.

they submitted the Citizen Petition that receiving any determination at all was unlikely. Recognizing that established pharmaceutical companies often file Citizen Petitions to protect and prolong their market dominance, the FDA has long viewed Citizen Petitions from drug companies with a degree of skepticism. In fact, in 2019, the FDA even adopted Guidance “[t]o address concerns regarding the use of citizen petitions to delay FDA’s action on a generic or other abbreviated application”—an explicit effort “to deter brand name drug companies from ‘gaming’ the system by taking advantage of certain rules, or exploiting loopholes, to delay competition.”<sup>6</sup> Thus, Defendants could not have sincerely believed that the Citizen Petition had a reasonable possibility of success in delaying Nexplanon’s impending LOE by imposing similar testing standards on proposed bioequivalents.

80. Defendants, of course, were also keenly aware of the threat that the FDA’s Draft Guidance posed to Nexplanon, the Company’s most important product. As experienced marketers of generic products, Defendants knew of or at least recklessly disregarded the risk that the FDA’s Draft Guidance would attract generic competition much sooner than they were telling investors. By contrast, Organon’s public investors were unaware of the Draft Guidance, Organon’s Citizen Petition, and the FDA’s August 2024 Interim Response Letter, which remained unmentioned in Organon’s

---

<sup>6</sup> See FDA Sixteenth Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action, FY 2023 (available at <https://www.fda.gov/media/184951/download>).

SEC filings and public representations for most of the Class Period, until May 2025. Thus, investors were unaware that Nexplanon faced an impending loss of exclusivity. Market analysts also took Defendants at their word, believing—and repeatedly echoing—Defendants’ false and misleading assurances that Nexplanon would not face LOE in the near term.

81. For instance, in a report published October 31, 2024, a Barclays analyst noted “OGN remains confident that Nexplanon will be on a \$1B annual run rate in 2025, with significant runway for growth post-2025 and up until the LOE in the US—*which OGN believes will not occur until 2030.*” [Emphasis added]. Similarly, on February 15, 2024, an Evercore analyst echoed Organon’s talking points on Nexplanon LOE, stating:

Meanwhile, some questions around generic Nexplanon persist[.]

There will inevitably be generic pressure on Nexplanon at some point... but thats [sic] not in 2027 ... for [a] few reasons:

1. Additional exclusivity from 5 yr trial
2. IP on the nexplanon [sic] device goes out to 2030
3. Teva [and other generic competitor companies] will likely need [their] own device for non-infringement ... which would then mean more training using reps etc. for device’s insertion and renewal (normally I don’t buy such arguments on salesforce needs, but I’ve seen videos on Nexplanon insertion and removal process – and it is NOT trivial)

82. Similarly, in a September 18, 2024 report, a Morgan Stanley analyst referenced the “likely impact from Nexplanon generics beginning in the 2027-2030 timeframe[.]” A few months later on February 14, 2025, the analyst again echoed the Company’s representations with confidence, stating, “Nexplanon US LOE is a 2030 event, given the 3-year data exclusivity for new indication and the patent protection on the application device until 2030.”

83. Importantly, the FDA’s August 2022 Draft Guidance was issued on the same day it announced product-specific guidance on ANDAs for 28 other products, including such notable products as Acetaminophen (FDA Docket No. FDA-2007-D-0369-0670), Amphetamine (FDA Docket No. FDA-2007-D-0369-0667), Famotidine (FDA Docket No. FDA-2007-D-0369-0644), and Ibuprofen (FDA Docket No. FDA-2007-D-0369-0638). As one of many product-specific ANDA guidance documents issued by the FDA on August 5, 2022, the Draft Guidance concerning Nexplanon was hardly positioned to capture the attention of industry specialists, let alone investors.

84. The FDA’s August 2022 Draft Guidance also was not reported in leading industry publications like Fierce Pharma and BioSpace, and the Draft Guidance only received one comment—from Organon’s Associate Vice President for Regulatory Affairs, Sandip Roy (FDA Docket No. FDA-2007-D-0369-0691). This lack of public engagement further obscured the Draft Guidance from analysts and investors. Indeed, analysts reacted with shock when the Draft Guidance, Citizen Petition, and Interim

Response Letter were finally brought to the market's attention by Organon in May 2025. Organon's failure to disclose this information departed from its usual practice of disclosing regulatory updates to investors regarding other products, and rather than disclose the existence of the Draft Guidance, or the seriousness of the risk it posed to Nexplanon LOE, Defendants assured the market the time horizon for Nexplanon LOE would be much longer.

85. Unfortunately for Organon—and unknown to investors at the time—the risk that a competitor would seek FDA approval to market a Nexplanon generic materialized on February 20, 2025, when rival pharmaceutical company Xiromed notified Organon it had filed a Paragraph IV certification with the FDA to market a Nexplanon bioequivalent. On April 2, 2025, following Xiromed's Paragraph IV notice, Organon sued Xiromed, seeking a declaratory judgment that Xiromed's generic infringed upon Organon's patents on Nexplanon's rod and applicator. *See Merck Sharp & Dohme B.V., et al. v. Xiromed Pharma Espaa, S.L., et al.*, No. 25-cv-02254, Complaint for Patent Infringement (D.N.J. Apr. 2, 2025). Again, Organon did not disclose its filing of a patent infringement lawsuit to investors until a month later, on May 2, 2025, when it finally disclosed Xiromed's Paragraph IV certification with the FDA in the Company's quarterly report on Form 10-Q.

## **2. To Conceal Nexplanon's Underperforming Revenues, Organon Pulled Sales Forward to Make Quarterly Goals**

86. Leading up to and during the Class Period, Defendants told investors that Nexplanon would reach \$1 billion in annual revenue by 2025. But, behind the scenes, Defendants knew that substantially increasing Nexplanon revenues would be difficult (if not impossible) to achieve through organic sales alone.

87. The COVID-19 pandemic depressed demand for elective procedures, driving patients away from LARCs—which required insertion by a trained provider, in-person. In addition, COVID-19 forced hospitals to lay off or reassign many nurses and mid-level practitioners certified by the FDA to perform Nexplanon insertions. With the COVID-19 pandemic easing more slowly than hoped, Organon faced the daunting task of attracting new patients while rebuilding Nexplanon's corps of qualified providers.

88. Nexplanon's sales team struggled to meet Organon's projections from the start. Between 2021 and 2022, Nexplanon's annual sales grew from \$769 million to \$834 million—a modest increase of roughly 8.5%, far short of the aggressive growth desired by Organon's management. In the same period, sales for Organon's Women's Health portfolio as a whole grew only modestly, from approximately \$1.615 billion to \$1.673 billion, roughly 3.6%. This slow growth cast doubt on Organon's ability to achieve \$1 billion in annual Nexplanon sales by 2025, and also undermined the Company's branding as a women's health-focused drug maker. Nevertheless,

Defendants continued touting Organon's growth—with Nexplanon sales as the engine driving it.

89. What happened next is a matter of public record, acknowledged in the Company's recent public statements. Beginning in the fourth quarter of 2022, Organon pressured two U.S.-based wholesalers to pull forward Nexplanon sales that were planned for the following quarter. In exchange, Organon agreed to calculate the wholesalers' inventory management fees as if the sales had not then occurred. Organon and the wholesalers resumed this arrangement in the third quarter of 2024, continuing through to the third quarter of 2025, after which Organon's improper use of pulled-forward sales was disclosed to the market in a shocking press release, wherein the Company also announced the immediate resignation of its CEO, without severance or equity payouts, and its Head of U.S. Commercial & Government Affairs.

90. As subsequently disclosed by Organon, "without these sales practices, the Company's consolidated revenue for certain of [the fiscal periods between Q3 2024 and Q3 2025] would have fallen short of the Company's guidance and/or certain external revenue expectations." In other words, Organon's pulled-forward sales, by which it stuffed the sales channels using these two large U.S.-based wholesalers to order Nexplanon despite the lack of customer demand, created the false appearance that Nexplanon was meeting quarterly sales guidance for these periods—internally

and externally. Specifically, the Company has disclosed the following in terms of pulled-forward sales amounts and timing:

- Q4 2022: Organon pulled forward an undisclosed amount of Nexplanon sales.
- Q3 2024: Organon pulled forward an estimated \$5 million in Nexplanon sales, representing an estimated 0.3% of quarterly consolidated revenue.
- Q4 2024: Organon pulled forward an estimated \$15 million in Nexplanon sales, representing an estimated 0.9% of quarterly consolidated revenue.
- Q1 2025: Organon pulled forward an estimated \$17 million in Nexplanon sales, representing an estimated 1.1% of quarterly consolidated revenue.
- Q2 2025: Organon pulled forward an estimated \$15 million in Nexplanon sales, representing an estimated 0.9% of quarterly consolidated revenue.
- Q3 2025: Organon pulled forward an estimated \$17 million in Nexplanon sales, representing an estimated 1.1% of quarterly consolidated revenue.

91. The following slide, which Organon released for its November 10, 2025 investor call discussing the results of the Audit Committee's investigation, illustrates the financial manipulations that Defendant Ali and others executed both before and during the Class Period (while omitting information for Q4 2022):

## Revenue pull-forward analysis

	Q3 2024	Q4 2024	Q1 2025	Q2 2025	Q3 2025	Implied Q4 2025
<b>Total Revenue (in mil)</b>	\$1,582	\$1,592	\$1,513	\$1,594	\$1,602	\$1,490 - \$1,540
Estimated pull-forward <sup>(1)</sup>	~5	~15	~17	~15	~17	0
		~(5)	~(15)	~(17)	~(15)	~(17)
<b>Estimated net pull-forward</b>	<b>~5</b>	<b>~10</b>	<b>~2</b>	<b>~(2)</b>	<b>~2</b>	<b>~(17)</b>
Estimated pull-forward as % of consolidated revenue	0.3%	0.9%	1.1%	0.9%	1.1%	~(1.1)%
<b>Estimated net pull-forward as % of revenue</b>	<b>0.3%</b>	<b>0.6%</b>	<b>0.1%</b>	<b>(0.1)%</b>	<b>0.1%</b>	<b>~(1.1)%</b>
<b>Inventory value at quarter end</b>	<b>71</b>	<b>71</b>	<b>74</b>	<b>75</b>	<b>79</b>	

(1) Estimated pull forward is based on days on hand at certain wholesalers being above targeted days of coverage times the average net selling price. Days Inventory On-Hand at certain wholesalers are estimated based on inventory on hand at the wholesalers/average daily sales.



92. Thus, Organon pulled forward \$20 million in Nexplanon sales in 2024 and \$49 million in Nexplanon sales for the first three quarters of 2025.

93. According to the Company’s telling, this improper conduct was directly traceable to then-CEO Defendant Ali and others involved in senior management. Specifically, Organon has admitted that Ali, in concert with the Company’s former Head of U.S. Commercial & Government Affairs, “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.” At that time, Organon’s Head of U.S. Commercial & Government Affairs was Michael Pergine, who was credited on its website as a founding executive of the Company and had spent 25 years at Merck.

94. Organon further disclosed that Defendant Ali and the former Head of U.S. Commercial & Government Affairs “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.” What is more, Defendant Ali “resigned” from the Company suddenly—and without severance or equity payments—in conjunction with Organon’s announcement of the Audit Committee investigation into Nexplanon channel stuffing.

95. On November 10, 2025—15 days after Organon announced Defendant Ali’s resignation and the Audit Committee’s investigation into the Nexplanon sales stuffing—Organon filed amendments to the Company’s 2024 Form 10-K, Q1 2025 Form 10-Q, and Q2 2025 Form 10-Q. The amendments reflect the findings of an investigation conducted by Organon’s Audit Committee into the pulled-forward Nexplanon sales. In pertinent part, Organon’s amended filings acknowledged that the Audit Committee’s investigation had identified undisclosed material weaknesses in the Company’s internal controls over financial reporting during the time periods covered by the original filings:

- *Tone at the top* – “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.”

- *Ineffective controls related to information and communication*—  
“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.”

96. Organon’s amended filings further acknowledged 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[.]” Accordingly, Organon admitted that its disclosures in SEC filings and elsewhere concerning these issues were, at a minimum, misleading, because they concealed that insiders had manipulated customer demand—just to meet forecasts—by inducing two U.S.-based wholesalers to purchase Nexplanon.

97. In comments after the Class Period at the December 3, 2025 Piper Sandler Healthcare Conference, Interim CEO Joseph Morrissey placed responsibility entirely on senior management for Organon’s channel stuffing scheme and acknowledged that employees knew about it, explaining: “it really does start with the tone at the top and how we engage the organization,” and “when you look at the weakness that we had, employees didn’t escalate their concerns.” That Defendant Ali authorized and directed this conduct—which was widespread enough internally for employees to harbor

concerns about it—underscores its material nature and Defendants’ conscious disregard for the truth of the Class Period misstatements.

**3. Organon Paid (and Promised to Continue Paying) a Robust Shareholder Dividend, Even as Nexplanon’s Deteriorating Prospects Depleted Cash Available for Dividend Payments**

98. In light of the difficulties described above, Organon’s free cash flow—and, thus, its ability to continue paying a robust cash dividend—faced significant short- and long-term constraints.

99. In the short term, Nexplanon sales were growing much slower than the rate projected in Organon’s guidance. With its best-selling drug underperforming, Organon was generating less cash than necessary to sustain the Company’s large dividend going forward. Indeed, as explained above, Defendant Ali and other senior executives manipulated customer demand—with the purpose of meeting guidance—by inducing wholesalers to place advance purchases of Nexplanon, despite a lack of customer demand, they neither needed nor wanted. This conduct undoubtedly had the impact of convincing the market, including investors and analysts, that Organon was performing exactly in line with expectations and thus could fund its dividend.

100. In the long term, Organon knew of the substantial risk that the FDA’s Draft Guidance could attract a Nexplanon generic ANDA and thus hasten the end of Nexplanon’s exclusivity much earlier than the Company’s projected 2027 LOE date, which would adversely impact its sales revenues. This increased the onus on Organon

to develop new drugs that could replace Nexplanon's contributions to the Company's bottom line. But because Organon lacked the means to develop new products internally, the Company had to engage in acquisitions to add products to its portfolio—requiring large cash expenditures, and further consuming the free cash flow needed to pay a large shareholder dividend.

101. In a report published on January 22, 2026, an Evercore analyst confirmed that Nexplanon was crucial to Organon's free cash flow during the Class Period, and that the "genericization of Nexplanon" would cause "a direct readacross to FCF [free cash flow]." Based on an analysis of Organon SEC filings on Form 10-Q for the first three fiscal quarters of 2025, the Evercore analyst concluded that Nexplanon contributed between \$400 million and \$500 million to Organon's estimated annual cash flow of approximately \$600 million for 2025—meaning that Nexplanon accounted for two-thirds of its overall free cash flow. "My point[,]" the analyst stressed, is that "Nexplanon is a VERY significant portion of [Organon's] FCF."

102. The Evercore analyst further pointed to the example of Organon's product NuvaRing, explaining that the free cash flow generated by Organon's suite of products decreased by \$736 million between 2019 and 2020, corresponding to when NuvaRing lost exclusivity in the U.S. in December 2019. While the analyst's report was published post-Class Period, it confirms that the "genericization of Nexplanon" posed a critical threat to Organon's free cash flow during and after the Class Period.

103. Organon's ability to pay the dividend at its historically high level was also threatened by the Company's heavy debt load. Simply put, Organon could not afford to maintain large shareholder dividend payments and acquire new products while also paying down the Company's debt, even without the added pressure from Nexplanon's diminished short- and long-term prospects.

104. Similarly, FE-1 recalled a "pervasive sense" within the Company "that Organon was carrying an enormous and crushing amount of debt," which created a "feeling of inevitability or pessimism about the company's prospects." For example, FE-1 recalled discussions in which employees speculated about whether Merck might reacquire Organon, followed by immediate dismissal of the idea on the grounds that no company would want to buy Organon given the amount of debt it carried.

105. FE-1 also recalled "internal pep talks" attended by employees across Organon, where the Company's senior leaders encouraged employees "not to give up hope" and expressed that the Company would "get through" its economic difficulties by "being lean, making cuts, working with fewer resources, and paying down debt." According to FE-1, these internal pep talks happened about twice a year and were handled by executive staff that reported to Defendant Ali. Yet, despite preaching austerity and discipline, Ali represented to analysts and investors that the Company could afford to continue paying a robust shareholder dividend of \$0.28 per share.

106. Initially, Organon tried to maintain its dividend and debt repayment commitments while also expending cash on new product acquisitions. Organon acquired JADA, a medical device for treating abnormal postpartum uterine bleeding, in June 2021, shortly before the Company’s spin-off from Merck was finalized. Organon also acquired a promising endometriosis treatment, Forendo, a few months later in November 2021. But Organon did not make any significant acquisitions of market-ready products in 2022 or 2023. The Company’s free cash flow simply did not support further acquisitions, as Organon’s commitment to the dividend and heavy interest burden forced management to scale back ambitions.

107. Organon did not make any significant product acquisitions until September 2024, when it shocked the market—and its employees—by acquiring Dermavant, manufacturer of the psoriasis drug VTAMA, for \$1.2 billion. This acquisition was notable both for its high price and seeming inconsistency with Organon’s branding as a women’s health company. An Evercore analyst described the deal as a “master stroke” for Dermavant’s former parent company, Roivant, that would net Organon only “modest” returns. A BNP Paribas analyst echoed this view, noting that the acquisition was “not strictly women’s health” and would “bring[] higher leverage” on top of Organon’s already high debt.

108. As Organon grew increasingly desperate to acquire new cash flow drivers, the Company resorted to desperate measures designed to generate immediate results.

Organon's acquisition of Dermavant occurred towards the end of the third quarter of 2024, when the Company resumed its pull-forward sales arrangement with certain Nexplanon wholesalers. This timing was no coincidence. The Dermavant acquisition pushed free cash flow to the breaking point, such that Organon could barely afford to maintain its robust shareholder dividend for another quarter, let alone indefinitely. Defendants concealed this critical fact by telling investors that the Company would continue to pay a robust dividend going forward, *see infra* Section V.C, thus implicitly representing that Organon had sufficient cash flows to do so.

109. Investors could not have learned the truth about the true state of Organon's free cash flow, or Defendants' attempts to buoy the Company's financial reserves and cash flow through channel stuffing Nexplanon for several quarters beginning in 2022, because the Company's recorded and published sales figures were artificially inflated by the misconduct—which had the intended effect of disguising inadequate demand and growth and supporting the misleading impression that the Company was meeting internal and external performance expectations.

110. Notably, although FE-2's job duties did not involve interaction with Organon's sales team, during her employment at the Company she regularly spoke with a colleague in Organon's commercial operations. The colleague's role involved oversight of Organon's commercial performance including the monitoring of the results of Organon's salespeople. After Defendant Ali departed the Company, FE-2's

colleague told her that Organon's commercial team was "not surprised" by Ali's resignation or the corresponding announcement of an investigation into Nexplanon channel stuffing.

111. According to FE-2's colleague, it was viewed as a "not-so-secret secret" within the commercial team that Organon engaged in channel stuffing for Nexplanon, because the product's sales and distribution figures did not line up with Company forecasts. According to the colleague, while Organon's commercial employees noticed these discrepancies, they deferred to senior leadership, assuming that Nexplanon's numbers must have been approved by Defendant Walsh and other C-suite employees.

112. FE-2 indicated that her colleague and other commercial employees were not surprised by the departures of Defendant Ali and U.S. Commercial Head Pergine, but that they were shocked by the Company's decision to retain Defendant Walsh given his responsibility over reporting Organon's Nexplanon sales and Nexplanon's importance to Organon's operations.

## **V. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS**

### **A. Defendants' Materially False and Misleading Statements and Omissions Regarding the Timetable for Nexplanon's LOE, Which Concealed the Risk, Introduced by FDA Guidance, of Competition from Biosimilars**

113. During the Class Period, Defendants addressed Nexplanon's anticipated LOE and misleadingly represented that expiration would not begin until 2027, when,

in fact, the Draft Guidance from 2022 created the risk that a generic competitor could seek FDA approval long before then—based on clinical data over a shorter period.

114. On Organon’s Q1 2023 earnings call on May 4, 2023, for example, an analyst asked Defendant Ali “[h]ow important are the 2024 pipeline updates to driving BD [business development] strategy as those assets will hopefully replace Nexplanon when it goes LOE.” Defendant Ali responded:

But on the other topic of Nexplanon, **the LOE in the United States is 2027**. But as I mentioned a number of times before, the entire kind of erosion model for Nexplanon, I would probably look and start to look at a benchmarking, say, for example, Mirena from Bayer as kind of the situation, because it’s a device that has [a] drug-eluting device, it’s a very difficult product to manufacture, and all of the other downstream investments that need to be made in terms of training, in terms of pharmacovigilance, in terms of all the other things that go along with the complexities of managing something like a Nexplanon in terms of your own applicator device. **So, we still believe that Nexplanon is not going to essentially resemble what you might have in your models in terms of the standard kind of historical erosion rates.** And so, those two together, I think, kind of signal that we’re on the right path going forward.

115. Defendant Ali’s statement that Nexplanon would face LOE in 2027 and would not “resemble . . . the standard kind of historical erosion rates” was false and misleading, and lacked a reasonable basis, when made. Under the Draft Guidance, a competitor could seek approval to market a Nexplanon generic with only six months of clinical data demonstrating comparable release to Nexplanon, thus ending

Nexplanon's exclusivity much earlier than 2027. Moreover, in choosing to speak publicly on the topic of Nexplanon's LOE, Ali had a duty to disclose the risk, inherent in the Draft Guidance's minimal clinical data requirements, that a generic competitor could seek FDA approval to market a Nexplanon biosimilar earlier than 2027.

116. Thus, Defendant Ali's statement misleadingly omitted—and Defendants collectively failed to disclose—the material risk that a generic competitor could seek FDA approval, and Nexplanon's exclusivity could begin to end, earlier than 2027. Defendant Ali was no doubt aware of this risk given the potential consequences of the Draft Guidance, as well as the importance of Nexplanon and the FDA biosimilar approval process to Organon's operations.

117. Defendants reinforced the misleading impression that Nexplanon's future LOE insulated Organon from generic competition on November 29, 2023, at the Piper Sandler Healthcare Conference. In response to an analyst question about Nexplanon's slower-than-expected sales growth, Defendant Ali stated: “**we have plenty of runway ahead of us before LOE** to be able to create the kind of, as you say, volume uptick that we think this [product] deserves.”

118. Defendant Ali's statement that Nexplanon had “plenty of runway” before LOE was false and misleading, and lacked a reasonable basis, when made. Indeed, rather than possessing “plenty of runway” before LOE, Nexplanon faced potentially imminent competition from a generic product due to the Draft Guidance. Moreover, in

choosing to speak publicly on the topic of Nexplanon's LOE, Defendant Ali had a duty to disclose the risk, inherent in the Draft Guidance's minimal clinical data requirements, that a competitor could seek approval to market a Nexplanon generic earlier than 2027. Without disclosure of the risk that a generic competitor could seek FDA approval with less clinical data based on the Draft Guidance, Defendant Ali's statement materially misrepresented Nexplanon's "runway" for LOE.

119. Defendants also addressed Nexplanon's LOE on February 15, 2024, during Organon's Q4 2023 earnings call. In his opening remarks, Defendant Ali emphasized that "[a]t the end of 2024, we anticipate having Phase III data from our 5-year study," which, "[i]f approved, . . . **will give NEXPLANON 3 years of exclusivity on the 5-year efficacy claim in the U.S. market,**" and thus "extend the growth ramp well past the \$1 billion run rate we are aiming for in 2025."

120. Defendant Ali's statement that Nexplanon would gain additional years of exclusivity through FDA approval of the product's 5-year version was false and misleading. The Draft Guidance did not distinguish between the 3-year Nexplanon efficacy claim (that is, implanting Nexplanon in a patient's arm for three years) and the hypothetical 5-year efficacy claim for which Organon planned to seek additional FDA approval. Thus, far from "extend[ing] the growth ramp" on Nexplanon sales, Organon's plan to seek approval for a 5-year efficacy claim was not likely to deter generic competitors from seeking FDA approval for Nexplanon biosimilars.

121. Later, on the February 15, 2024, earnings call, an analyst asked Defendant Ali “about barriers to a generic entry prior to 2027,” referencing Nexplanon’s LOE. Framing the question, the analyst noted “one thing when I look at the FDA’s generic equivalence guidance for NEXPLANON is whether or not one can do an accelerated comparative in vitro release test . . . .” Without addressing the nature or scope of the Draft Guidance or its implications for Nexplanon, or mentioning Organon’s plan to momentarily file a Citizen Petition challenging that Draft Guidance, Defendant Ali denied that the Draft Guidance would have any effect, stating, in pertinent part:

**Yes, Jason, there’s nothing that I see from the FDA in terms of guidance around kind of breaking the patent that we have. Clearly, through the end of 2027.** But the issue to keep in mind and more importantly, right? Whoever announces what their intent is in terms of their focus on where they want to come in next.

The FDA has never approved any complex generic drug during the first cycle review. I mean we expect – historically, it’s been anywhere between 2.5- to 4-year approval time line from the initial ANDA submission. I’ll give you an example. For us, NuvaRing, which is by far much less complex, by far, by a magnitude of many times than something like NEXPLANON, which is a medicated vaginal ring for contraception.

The first generic received FDA approval after almost a 30-month delay and Teva’s NuvaRing, now that you’re bringing up Teva, Teva’s NuvaRing generic took 8 years to get to the market. If we take that time line, you’re talking about a 2030 minimum introduction. And on top of that, we have the – you’re going to have to have your own proprietary device.

**Our device, our applicator device has patent protection through 2030. So you're going to have to do your own proprietary applicator device design and then launch it. And finally, you're going to have to start investing in sales force and medical affairs people** because you need to have people who actually are training physicians in order to be able to insert and remove this product. And keep in mind, finally, this is a buy-and-build product.

**This is not a normal product in that respect. It's much more difficult.** So I have been saying for years, and I can get into all the intricacies that **I do not expect any major issue with NEXPLANON between now and the end of the decade.** I do expect that we're going to have the data at the end of this year for the 5-year indication, and we'll be able to launch that probably when we decide in the 2025, 2026 timeframe, **which will take essentially exclusivity through the end of the decade.**

122. Defendant Ali's statements that "nothing" from the FDA "in terms of guidance" threatened Nexplanon's exclusivity and that he did not "expect any major issue with NEXPLANON between now and the end of the decade," were false and misleading, and lacked a reasonable basis, when made. In reality, the Draft Guidance required a Nexplanon generic to demonstrate only six months of clinical data, thus significantly shortening the FDA approval process for any generic competitor. Moreover, at the time of Defendant Ali's statement, Organon was in the process of finalizing a Citizen Petition it would file in March 2024 to request that the FDA impose additional hurdles to bioequivalent approval for generic competitors.

123. Defendant Ali's statement that Nexplanon's "applicator device has patent protection through 2030" was also false and misleading, for the same reasons already

described. It was also materially misleading for Ali to reference patent protection through 2030 and other factors as barriers to entry for any generic, or claim that Nexplanon is “not a normal product,” when Defendants knew that the FDA’s Draft Guidance specifically permitted a generic product to secure approval with only six months of clinical data.

124. Additionally, Defendant Ali’s statement that seeking approval for a 5-year Nexplanon claim would “take essentially exclusivity through the end of the decade” was, again, false and misleading. As explained above, the Draft Guidance did not distinguish between the 3-year Nexplanon efficacy claim and the hypothetical 5-year efficacy claim for which Organon planned to seek FDA approval. Thus, far from promising exclusivity “through the end of the decade,” Organon’s plan to seek approval for a 5-year efficacy claim was not likely to deter generic competitors from seeking FDA approval for Nexplanon generics.

125. Defendant Ali again addressed Nexplanon’s LOE on the Company’s Q1 2024 earnings call, held on May 2, 2024. There, Defendant Ali stated:

**[B]eyond 2025, we believe there is still significant runway for growth up until the loss of exclusivity for Nexplanon in the U.S., which, in our view, will not occur until 2030 for 3 specific reasons.** First, our 5-year study is on track to close this year. And pending FDA review and approval, our planning assumption is that we will be able to market [it] with a five-year label in 2026. **A differentiated label will give us three years of data exclusivity on that 5-year duration of use claim, which we know from our market research is preferred by women and providers.**

\* \* \*

**This is not just suppositions, a lot of fact that would lead one to believe that this is a 2030 event.** Our applicator alone globally has patent protection until 2030, and somebody would have to develop their own applicator, which in itself is not as easy as you may think because you've got to do studies around safety, around efficacy of the applicator device alone before you can actually show anything else in regards to the rod itself. **So, I think this is [a] 2030 event globally and beyond.**

126. Defendant Ali's statements that Nexplanon LOE would be a "2030 event" were false and misleading, and lacked a reasonable basis, when made. He knew that the Draft Guidance did not distinguish between the 3-year Nexplanon efficacy claim and the hypothetical 5-year efficacy claim for which Organon planned to seek FDA approval; and, further, that Organon's plan to seek approval for a 5-year efficacy claim was not likely to (and, indeed, ultimately would not) deter generic competitors.

127. Additionally, Defendant Ali's statements came after Organon had already filed a Citizen Petition challenging the Draft Guidance and requesting that the FDA impose additional hurdles for regulatory approval on Nexplanon bioequivalent applications. Thus, Ali was well aware of the live threat to Nexplanon's exclusivity posed by the Draft Guidance and knew or recklessly disregarded that Nexplanon could not hold onto exclusivity until 2030 and beyond.

128. Defendants again addressed Nexplanon's exclusivity on August 6, 2024, when Organon held its Q2 2024 earnings call. This time, Defendant Ali stated:

With regard to the Nexplanon five-year study, the study met its primary end points, showing contraceptive effectiveness and no new safety signals. Based on this data, we are beginning to prepare for regulatory submission in the US, EU and UK. We continue to believe that would put us on track for a potential[] US launch of the Nexplanon five-year indication in 2026 pending FDA approval. **We see this launch as an important event because it would mean that we would have data exclusivity on the five-year claim for three years. That means between 2026 and 2029, no generic with five-year duration could come to the US market;** and further, any generic would need to have a different insertion device until our device patent expires in 2030. We remain very optimistic about Nexplanon’s future prospects and the expanding potential of the brand.

129. Defendant Ali’s statement that launching Nexplanon’s 5-year indication would extend Organon’s exclusivity until at least 2029 was false and misleading, and lacked a reasonable basis, when made. Again, the Draft Guidance simply did not distinguish between the 3-year Nexplanon efficacy claim and the hypothetical 5-year efficacy claim for which Organon planned to seek additional FDA approval. And Ali’s comments came months after Organon filed a Citizen Petition, essentially challenging the Draft Guidance and requesting that the FDA impose more stringent hurdles for regulatory approval on Nexplanon generic applications.

130. Later in the Q2 2024 earnings call, Defendant Ali again highlighted the continued viability of Nexplanon to the Company, stating that Nexplanon **“will continue to be with us in a very robust manner until the end of the decade** and possibly beyond just because of the fact, as I mentioned, our inserter device, which is

very unique and it is a very clear differentiator, has exclusivity until 2030.” This statement was also false and misleading, and lacked a reasonable basis when made, for the reasons described above.

131. Defendants again addressed the topic of Nexplanon’s LOE at the JP Morgan Healthcare Conference on January 13, 2025. There, Defendant Ali again stated that Nexplanon would retain exclusivity until 2030, stating:

Now, if we end up at \$1.6 billion, that means essentially [it] will be the biggest contraception [] ever. Essentially, we’ll have set the record in that regard as a benchmark. **So, going forward, I’m feeling comfortable by 2030 saying that’s what I feel comfortable saying.**

**Beyond that, we’ll have to see. But there’s a lot of potential longevity.** Because as I mentioned before, if you crack the code of being able to get it onto the market, you still need a sales force, medical affairs groups to teach and train physicians on how to insert, how to remove pharmacovigilance, all the things that one would say that you would have with a branded product. So, it’s quite an investment to get there.

132. Defendant Ali’s statements that Nexplanon would retain exclusivity until 2030 and possessed “a lot of potential longevity” were false and misleading because Defendants knew the Draft Guidance’s clinical data requirements set a low bar for generic competitors to seek FDA approval for bioequivalents well before then. In fact, nearly a year before Ali made these statements, Organon filed its Citizen Petition.

133. Also during the JP Morgan Healthcare Conference, an analyst asked Ali if he was “aware of anyone working on a generic [version of Nexplanon] in the US at this point[?]” Ali responded:

No. I mean I’ve heard noises and . . . they’ve kind of gone quiet . . . [And] remember, by the way, that our applicator device has patent through 2030. **So, if somebody wants to come on to the market, they’re going to have to do clinical studies on their own proprietary . . . applicator in order to be able to say to the FDA that we’ve got the applicator now, it’s our own proprietary.** It takes quite a bit of effort because you have to show no deep vein insertion, you’ve got to be able to show the efficacy and safety. **And that’s not an easy thing to do.**

134. Defendant Ali’s statements about the difficulty of bringing a Nexplanon competitor to market, and that it would “not [be] an easy thing to do,” were false and misleading, and lacked a reasonable basis, when made. Ali knew the Draft Guidance’s reduced clinical trial requirements lessened impediments for competitors seeking to develop Nexplanon generics. As Defendants recognized, but failed to disclose, Organon faced the very real and impending risk that a generic competitor would seek FDA approval, and Nexplanon’s exclusivity would begin to end, in the short-term, without significant FDA difficulties.

135. These material misstatements continued on Organon’s Q4 2024 earnings call, held on February 13, 2025, when Defendants again addressed Nexplanon’s LOE. In response to an analyst’s question whether Organon had received a Paragraph IV

filing indicating a generic competitor's intent to seek ANDA approval from the FDA,

Defendant Ali answered:

[I]n terms of your first question around Nexplanon, no Paragraph IV right now that we've received. And right now, I've been saying for – I don't know, for the last two years, **I don't see really any risk to a large degree of a Nexplanon three or five-year for that matter introduction in terms of a generic or biosimilar between now and the end of the decade.** After the end of the decade, I mean, then we'll determine what happens then. **But right now, when I start to see the fact that our applicator device is – got patent protection through 2030, when I start to see that our five-year indication, which we will hopefully launch by the end of this year, we'll have exclusivity through 2029.**

If I start to look at all the various issues around a – an implant that has a product in it, there's no precedent there. When I start to think about the benchmarks of either Mirena, a medicated IUD, no generic so far. **So, I don't feel we'll see any generics to challenge Nexplanon through 2030.** And so, as a result of that, when you start to see that we've got \$1 billion expectation in this year, and you put down essentially the growth expected to the end of the decade, you see how big product can be. And it's our most profitable product.

136. Defendant Ali's statements that there was no "risk to a large degree" of a Nexplanon biosimilar, that Nexplanon would retain exclusivity "through 2029," and that no generics would "challenge Nexplanon through 2030," were materially false and misleading when made. In reality, the Draft Guidance required a Nexplanon biosimilar to demonstrate only six months of clinical data, significantly smoothing the FDA approval process for any generic competitor. Defendant Ali's statements, which

implied that Nexplanon was insulated from generic competition, disregarded the implications of the Draft Guidance and far lower barriers to entry.

137. Later in Organon’s Q4 earnings call, Defendant Ali emphasized that **“you’ve heard me say many times the reasons to believe and I feel very confident that we won’t see, at least until the end of the decade, a competitor for Nexplanon.”** This statement—that Nexplanon would not see a competitor “at least until the end of the decade”—was false and misleading for the same reasons described above.

138. Lastly, Defendants addressed Nexplanon LOE in Organon’s 2024 Form 10-K, filed on February 28, 2025. In a section describing business risks, Organon purported to disclose the risk of a generic Nexplanon competitor seeking FDA approval, stating:

**In addition, Nexplanon is an important Organon brand that continues to have good market exclusivity, especially in the United States. This complex drug-device combination has different components with different patent exclusivities. In the United States, patents claiming key aspects of the Nexplanon applicator will expire in 2030 and patents for the Nexplanon rod will expire in late 2027.** Patents for the majority of countries where Nexplanon is commercialized outside the United States will expire between 2025 and 2026.

139. These representations, like other statements made previously, were false and misleading for the same reasons: the Draft Guidance reduced burdens associated with establishing a viable bioequivalent and Defendants appreciated the resulting risks to

Nexplanon's exclusivity and business. Nevertheless, Defendants deceived public investors into believing that Nexplanon's patents rendered it impervious to potential competition from generics, when, in truth, they knew Nexplanon was especially vulnerable based on the FDA's prevailing views reflected in the Draft Guidance.

**B. Defendants' Materially False and Misleading Statements Regarding Nexplanon's Revenues, Performance, and Growth Prospects**

140. On October 31, 2024, Organon issued a press release regarding the Company's third quarter 2024 financial results. In the press release, Organon stated: "In 2024 our commercial execution has been very strong. **Our largest product, Nexplanon, is well positioned to deliver \$1 billion of revenue next year . . . .** Further, we have been extremely disciplined on operating costs and driving Adjusted EBITDA growth in support of achieving \$1 billion of free cash flow before one-time costs for full year 2024."

141. Defendants' statement that Nexplanon was "well positioned to deliver \$1 billion of revenue" in 2025 was false and misleading, and lacked a reasonable basis, when made. This statement implied that Nexplanon's sales growth was organic and would continue. As Organon subsequently disclosed, however, the Company had resumed stuffing Nexplanon's sales channels in the third quarter by inducing two wholesalers to buy more Nexplanon than they needed or wanted. Organon's senior management knew of or recklessly disregarded the existence of these undisclosed,

improper sales practices. Indeed, Defendant Ali participated in or knew of these practices, as evidenced by the Company's announcement of his "resignation" without severance or equity payouts at the same time it disclosed these improper sales and his responsibility for them. Rather than being "well positioned" to reach \$1 billion in revenue, Nexplanon's sales were artificially inflated by this practice.

142. Moreover, in choosing to speak publicly on the issue of Nexplanon's sales and market positioning, Defendants had a duty to disclose that the Company engaged in pull-forward sales to meet Nexplanon quarterly sales guidance. This illicit conduct—which was not exposed publicly until the Class Period's end—reflected the resumption of pre-Class Period channel stuffing, which took place in the fourth quarter of 2022. Thus, when claiming Nexplanon was "well positioned to deliver \$1 billion of revenue," Defendants omitted the material fact that Nexplanon's sales growth was neither organic nor likely to continue.

143. Later that day, Defendants Ali and Walsh addressed investors on the Company's third quarter 2024 earnings call. On the call, Defendant Ali opened his remarks by stating:

So let's review the rest of the business in greater detail. **Growth in Women's Health was driven by continued strength in Nexplanon, which was up 11% ex-FX in the third quarter. In the US, Nexplanon grew 18% in the third quarter.** We benefited from Nexplanon's leadership in the US contraception market, our pricing strategy, including management of the 340B discount program, as well as continued physician demand growth outside the US.

Nexplanon was down 3% ex-FX in the third quarter, primarily due to the timing of tenders in Latin America. Given strong year-to-date performance, we expect Nexplanon can achieve constant currency full-year revenue growth in the low- to mid-teens. **This would be our best year yet with Nexplanon and positions us extremely well to achieve the \$1 billion milestone that we had signaled for the next year.**

144. Defendant Ali’s statement describing Nexplanon’s positioning to achieve \$1 billion in sales in 2025 was false and misleading for the reasons described above.

145. Additionally, Defendant Ali’s statement relaying Nexplanon’s purported 18% quarterly sales growth was materially false and misleading, because it implied that Nexplanon’s sales growth was organic and would continue incrementally—despite the illicit channel stuffing that Defendant Ali and other senior executives knew or recklessly disregarded was occurring in that very quarter.

146. During the third quarter 2024 earnings call, Defendant Ali again invoked the \$1 billion figure, claiming “we’ll reach \$1 billion . . . faster than I anticipated,” citing the U.S. as “obviously driving a big portion of that [growth],” as follows:

And then, our Nexplanon business continues to go along very – very well in the US. We’re a market leader in the contraception space, especially in terms of LARCs. And we see continued growth not only in terms of demand, but . . . our 340B business is also growing with the federally qualified health centers. There’s a great opportunity for us in the future. **So we’ll reach \$1 billion which is faster than I anticipated for Nexplanon globally with US obviously driving a big portion of that in the – for us next year for Organon.** And that’s our first kind of major

blockbuster milestone for the product, and we see a lot of years ahead of it in terms of the runway.

147. Defendant Ali’s statement describing Nexplanon’s sales growth was false and misleading for the same reasons as the similar statements discussed above. Defendant Ali’s statement implied that Nexplanon’s sales growth was organic and would continue, when, in fact, the Company was secretly pulling forward sales in the quarter by inducing two U.S. wholesalers to purchase product they did not need or want—conduct that contributed to the misleading impression of strong customer demand and organic and continuing sales. Without disclosing this conduct and the resulting artificial demand for Nexplanon, Ali’s statement that the U.S. was “obviously driving a big portion” of Nexplanon sales, and would continue to do so, was misleading. And Ali lacked a reasonable basis to proclaim that Nexplanon sales would hit \$1 billion when sales growth was in fact slowing, which prompted Organon to pull forward sales to satisfy internal and external sales expectations.

148. Defendant Walsh also addressed Organon’s supposedly strong cash flow on the earnings call, stating that the Company remained “**well on track to deliver our commitment of approximately \$1 billion of free cash flow**” in FY24. He also emphasized that, in 2024, Organon “set ourselves up to deliver a trifecta of growth in revenue and EBITDA dollars, a leveraged P&L ex-milestones, and **\$1 billion of free cash flow**,” adding “**we feel very good about our ability to deliver on that goal.**”

149. Defendant Walsh’s assertion that Organon was “on track” and “fe[lt] very good” about its ability to deliver \$1 billion of free cash flow misleadingly implied that Organon’s free cash flow and, by extension, Nexplanon’s sales growth, were organic and sustainable. As explained, however, Organon was then experiencing difficulty meeting sales targets, which prompted the Company to induce wholesalers to engage in unwanted Nexplanon purchases—about which Defendant Walsh knew or recklessly disregarded, as a member of Organon’s senior management with access to and control and oversight of the Company’s financial information and aspects of its sales processes. The true state of affairs at Organon, then concealed from the public, undermined the notion that Organon was “on track” and “fe[lt] very good” about its ability to deliver \$1 billion of free cash flow.

150. In remarks closing out the earnings call, Defendant Ali again emphasized Nexplanon’s supposedly strong sales and positioning, stating:

[I]n 2024, our commercial execution, I believe, has been very strong. **Our largest product, Nexplanon, is well-positioned as I mentioned earlier to deliver \$1 billion of revenue next year.** And we’ve added other notable growth drivers with Emgality, and most recently, what we’ve just discussed this morning VTAMA.

Further, we’ve been extremely disciplined on operating costs and driving adjusted EBITDA growth in support of achieving \$1 billion of free cash flow before one-time costs for the full year 2024. So we’re well on track to delivering a very solid year and we want to thank you for dialing in today and we’ll talk to you soon.

151. Again, Defendant Ali’s statement that Nexplanon was “well-positioned” to “deliver \$1 billion of revenue” in 2025 was false and misleading for the reasons discussed above.

152. Moreover, as for the other misstatements, in choosing to speak publicly on the issue of Organon’s sales, Defendants had the duty to disclose that the Company engaged in undisclosed pulled-forward sales to meet Nexplanon quarterly sales guidance and record inflated free cash flow; Defendant Ali’s statement omitted these material facts. Defendant Ali participated in or knew of these undisclosed, improper sales practices, as evidenced by the Company’s announcement of his “resignation” without severance or equity payouts at the same time it disclosed these improper sales.

153. Defendants next addressed Nexplanon’s sales and growth prospects at the JP Morgan Healthcare Conference on January 13, 2025. Asked about “the biggest growth drivers going into next year,” Defendant Ali responded by lauding Nexplanon’s supposedly strong and organic growth, stating in pertinent part as follows:

**[W]e feel like 2025 will be the year we cross the \$1 billion threshold. We’ll be in excess of \$1 billion in 2025.** And we see . . . the runway on this through the end of the decade. So, if you’re . . . conservative about mid-single digit growth over the coming period of time until the end of the decade, this is a \$1.5 billion, \$1.6 billion business.

154. Defendant Ali’s statements that Nexplanon sales would “cross the \$1 billion threshold” and “be in excess of \$1 billion” in 2025 were false and misleading, and lacked a reasonable basis when made, for the reasons described above. Indeed,

Organon continued to stuff the sales channels for Nexplanon during the first quarter of 2025, artificially inducing sales to maintain the appearance of customer demand and growth in line with publicly reported sales forecasts and expectations.

155. Defendants addressed Nexplanon sales and growth again a month later, on February 13, 2025, during Organon's fourth quarter 2024 earnings call. In opening remarks, Defendant Ali stated:

Let's move now to discuss the growth drivers within the franchises in 2024. **The Women's Health franchise grew 5%, ex-exchange, led by performance of Nexplanon, which was up 17%, ex-FX, for the full year of 2024. This was Nexplanon's best annual performance ever and positions the product to achieve at least \$1 billion of revenue in 2025.**

**In 2024, Nexplanon grew double digit both in the US and in international markets.** Outside the US, growth in the LAMERA region was particularly strong, driven by increased demand, tender expansions as well as strong performance in Brazil. We also had a strong growth in the UK where Nexplanon is a market leader.

In the US, we benefited from Nexplanon's market leadership, coupled with our pricing strategy, which includes management of the 340B discount program, as well as continued growth in physician demand. We remain very optimistic about the future of Nexplanon, especially with the potential of a five-year indication to sustain long-term Nexplanon growth.

156. Defendant Ali's statements about Nexplanon's purported sales growth in 2024 were false and misleading, given Organon's continued channel stuffing—illicit conduct that resumed in the fourth quarter of 2024, for the purpose of ensuring that

Nexplanon met sales forecasts. Defendant Ali’s statement omitted the material fact that Nexplanon’s sales growth was neither organic nor continuing, but rather inflated by these undisclosed, improper sales practices.

157. Later on the fourth quarter 2024 earnings call, an analyst asked a question concerning Nexplanon revenues. Defendant Ali responded:

**And in 2024, as you rightfully stated, it was the best year that we’ve actually ever had with 17% growth both outside the US and inside the US. And we’ll pretty comfortably get beyond \$1 billion in 2025 . . . .** But I think it’s a prudent way to say, look, just factor in high-single-digit growth through the end of the decade, it’ll get you to somewhere in the neighborhood of the \$1.5 billion, which again is very different than you see in some of the models out there.

158. Defendant Ali’s assertions—that Nexplanon saw “17% growth . . . inside the US” and would “get beyond \$1 billion in 2025”—were, again, false and misleading, for the reasons already described.

159. On February 28, 2025, Organon filed with the SEC its Form 10-K for the fourth quarter and year ended December 31, 2024. In the “Notes to Consolidated Financial Statements” section of the Form 10-K, Organon stated as follows:

#### Evaluation of Disclosure Controls and Procedures

Our management with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures. **Based on their evaluation, as of the end of the period covered by this Form 10-K, our Chief Executive Officer and Chief Financial Officer have**

**concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) promulgated under the Exchange Act) are effective.**

\* \* \*

### Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America.

Management conducted an evaluation of the effectiveness of internal control over financial reporting as of December 31, 2024 based on the framework in Internal Control — Integrated Framework issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. **Based on this evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2024.**

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

PricewaterhouseCoopers LLP, an independent registered public accounting firm, which has audited the consolidated financial statements as of and for the year ended December 31, 2024 included in the Annual Report, has issued its report on the effectiveness of the Company's internal

control over financial reporting as of December 31, 2024, as stated in their attestation report which appears under Item 8 of this Annual Report.

160. Organon’s representation that its disclosure controls and procedures and internal control over financial reporting were “effective” was false and misleading. In truth, Organon’s disclosure and internal controls were not effective. On November 10, 2025, the Company filed an Amendment to the 2024 Form 10-K, acknowledging that “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[.]” The amended filing identified two material weaknesses in the Company’s internal control over financial reporting that should have been, but were not, disclosed in the original Form 10-K filing: a “fail[ure] to set an appropriate tone at the top,” and a failure to “design and maintain effective controls related to the information and communication component of the COSO Framework.”

161. The amended filing also represented that “certain of the Company’s prior disclosures relating to [Organon’s] sales practices for wholesalers and their effect upon revenues and product demand in [Organon’s] periodic filings were inaccurate or incomplete, including certain disclosures in the Original Form 10-K [for 2024].” Organon’s senior management knew of or recklessly disregarded the existence of the Company’s undisclosed, improper pulled-forward sales of Nexplanon. Indeed,

Defendant Ali participated in or knew of these sales, as evidenced by the Company's announcement of his "resignation" without severance or equity payouts at the same time it disclosed these improper sales.

162. On May 1, 2025, Organon held its first quarter 2025 earnings call. At the start of the call, Defendant Ali emphasized Nexplanon's supposedly strong sales growth, stating: "**Nexplanon grew double-digit and is set to achieve more than \$1 billion in revenue in 2025.**" During the call, Defendants emphasized Nexplanon's outsized and continuing contribution to growth:

Defendant Walsh: Our constant currency guidance remains the same, which is about flat versus prior year at the midpoint. **We expect the uptake of Vtama, continued solid performance in Emgality, and organic growth in Nexplanon and other products in our portfolio will help to offset the LOE of Atozet in Europe** along with pricing headwinds in other parts of the portfolio. That's a pretty strong statement, given that Atozet's LOE represents a headwind of approximately \$200 million alone between volume and price.

\* \* \*

Defendant Ali: We're doing this from a position in terms of what we've done with the dividend today what we announced from a position of strength. **Over the last few years, we have, for example, reestablished Nexplanon, our key product, where we're going to surpass \$1 billion this year.** We have stabilized the Established Brands business.

163. Defendant Ali's statements that Organon "grew double-digit," was set to "achieve" or "surpass" \$1 billion in annual sales, and experienced organic growth,

were false and misleading, given that the Company continued to engage in channel stuffing during the second quarter of 2025. Thus, the implication that Nexplanon’s sales growth was organic and would continue was contradicted by undisclosed, illicit practices that Defendants directed, authorized, or endorsed. These practices inflated Nexplanon revenues, maintaining the misleading impression—which Defendants reaffirmed throughout the Class Period—that Nexplanon was capable of reaching \$1 billion in revenue by 2025.

164. Additionally, Defendant Ali’s statement that Organon had “reestablished Nexplanon” was false and misleading, and lacked a reasonable basis, when made. In choosing to speak publicly on the subject of Nexplanon’s sales, Defendant Ali had a duty to disclose the improper pulled-forward sales—which created the misleading impression that Organon had “reestablished” Nexplanon through organic sales by consistently meeting Nexplanon sales targets.

165. On May 2, 2025, Organon filed with the SEC its Form 10-Q for the first quarter of 2025. In the “Item 4” section of the Form 10-Q, Organon stated as follows:

Item 4. Controls and Procedures

Our management, with the participation of our Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”), evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the [Securities] Exchange Act of 1934, as amended (the “Exchange Act”)) as of the period ending March 31, 2025. **Based upon that evaluation, our CEO and our CFO**

**concluded that, as of March 31, 2025, the end of the period covered by this report, 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.**

166. Organon’s representation that its disclosure controls and procedures were “effective” for the reporting period covered by the Q1 2025 Form 10-Q was false and misleading. On November 10, 2025, the Company filed an Amendment to that filing which acknowledged that management had “re-evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2025 . . . [and] concluded that our disclosure controls and procedures were not effective as of March 31, 2025[.]” The amended filing further identified two material weaknesses in the Company’s internal control over financial reporting that should have been but were not disclosed in the original Form 10-Q filing: a “fail[ure] to set an appropriate tone at the top,” and a failure to “design and maintain effective controls related to the information and communication component of the COSO Framework.”

167. The amended filing also represented that “certain of the Company’s prior disclosures relating to [Organon’s] sales practices for wholesalers and their effect upon revenues and product demand in [Organon’s] periodic filings were inaccurate or

incomplete, including certain disclosures” from the originally filed Q1 2025 Form 10-Q. Organon’s senior management knew of or recklessly disregarded the existence of these undisclosed, improper sales practices. Indeed, Defendant Ali participated in or knew of these practices, as evidenced by the Company’s announcement of his “resignation” without severance or equity payouts at the same time it disclosed these improper sales.

168. On August 6, 2025, Organon filed with the SEC its Form 10-Q for the second quarter of 2025. In the “Item 4” section of the Form 10-Q, Organon stated as follows:

#### Item 4. Controls and Procedures

Our management, with the participation of our Chief Executive Officer (“CEO”) (our principal executive officer) and Chief Financial Officer (“CFO”) (our principal financial officer), evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the [Securities] Exchange Act of 1934, as amended (the “Exchange Act”)) as of the period ending June 30, 2025. **Based upon that evaluation, our CEO and our CFO concluded that, as of June 30, 2025, the end of the period covered by this report, 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.**

169. Organon’s representation that its disclosure controls and procedures were “effective” for the reporting period covered by the Company’s Q2 2025 Form 10-Q was false and misleading. On November 10, 2025, Organon filed an Amendment to that filing which acknowledged that Organon’s management had “re-evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2025 . . . [and] concluded that our disclosure controls and procedures were not effective as of June 30, 2025[.]” The amended filing further identified two material weaknesses in the Company’s internal control over financial reporting that should have been, but were not, disclosed in the original Form 10-Q filing: a “fail[ure] to set an appropriate tone at the top,” and a failure to “design and maintain effective controls related to the information and communication component of the COSO Framework.”

170. The amended filing also represented that “certain of the Company’s prior disclosures relating to [Organon’s] sales practices for wholesalers and their effect upon revenues and product demand in [Organon’s] periodic filings were inaccurate or incomplete, including certain disclosures” from the originally filed Q2 2025 Form 10-Q. Organon’s senior management knew of or recklessly disregarded the existence of these undisclosed, improper sales practices. Indeed, Defendant Ali participated in or knew of these practices, as evidenced by the Company’s announcement of his “resignation” without severance or equity payouts at the same time it disclosed these improper sales.

**C. Defendants’ Materially False and Misleading Statements About Organon’s Free Cash Flow and Ability to Continue Making Robust Quarterly Dividend Payments**

171. On November 3, 2022, on the Company’s third quarter 2022 earnings call, Defendant Walsh stated that “[p]art of the Organon investment thesis for stakeholders is that the standalone business generates significant free cash flow. We set the dividend at a rate that would imply that we expect Organon to generate north of \$1 billion of free cash flow per year, **and that basic math still holds.**”

172. Defendant Walsh’s statement that the “basic math” behind Organon’s robust shareholder dividend payments “still h[e]ld” as of November 2022 was false and misleading. In reality, the “math” did not support Organon’s outsized dividend payments, as Nexplanon was generating lower sales than anticipated (decreasing the amount of free cash flow available for dividend payments in the short term). The Draft Guidance also cast doubt on Nexplanon’s continued exclusivity, heightening Organon’s need to invest capital in new product acquisitions at the expense of the dividend in the long term. Combined with the Company’s continuing obligation to pay down the debt from the Merck spin-off, Nexplanon’s lower-than-expected sales and sooner-than-expected LOE meant that Organon lacked or would soon lack the free cash flow to pay a quarterly shareholder dividend of \$0.28 per share.

173. Defendant Walsh’s statement was also false and misleading in view of the undisclosed channel stuffing involving Nexplanon that occurred in the fourth quarter

of 2022, when he made that statement. As Organon later admitted, the Company began inducing two wholesalers to purchase more Nexplanon than they wanted or needed that quarter, creating the impression that Nexplanon was hitting internal and external sales forecasts. This conduct occurred on the Individual Defendants' watch, and Ali and another senior executive were forced out of Organon when the conduct became public. That Defendants were engaged in channel stuffing when Walsh made this statement undermines any reasonable possibility that they "expect[ed] Organon to generate north of \$1 billion of free cash flow per year" or that the "basic math still holds" regarding Organon's free cash flow.

174. Furthermore, in choosing to speak publicly on the issue of the Company's ability to continue paying an outsized shareholder dividend, Defendant Walsh had a duty to disclose the known material fact that Nexplanon's slower-than-expected sales and earlier-than-expected LOE risk imperiled the sustainability of Organon's ability to continue making outsized dividend payments. Thus, Defendant Walsh's statement omitted—and Defendants collectively failed to disclose—the material fact that Organon could not afford to indefinitely pay a robust shareholder dividend. Defendant Walsh was aware of this material fact due to his role as CFO in monitoring and reporting Organon's financials, as well as the importance of Nexplanon sales, free cash flow, the Company's outstanding debt, and the shareholder dividend to Organon's operations.

175. Later in the third quarter 2022 earnings call, Defendant Walsh expressed Organon's supposed commitment to the dividend more emphatically, stating: "**Our capital allocation priorities remain consistent with past communications. Our first priority, of course, is servicing the dividend . . . .** We're committed to maintaining our BB/Ba2 parent rating . . . ."

176. Defendant Walsh's statements that Organon's "first priority" was "servicing the dividend" and that Organon's "capital allocation priorities remain[ed] consistent with past communications," expressing commitment to sustaining the outsized dividend, were false and misleading for all of the same reasons as his previous statements about the dividend during the call were.

177. A few months later, at the JP Morgan Healthcare Conference Fireside Chat on January 10, 2023, Defendant Walsh again emphasized the Company's supposed commitment to dividend payments in conversation with an analyst, stating:

When we launched, you were launching into a spec pharma space, which is very heterogeneous and there are not a lot of comps out there for Organon . . . . So, the thought was let's put a nice attractive dividend on the company and that'll provide a baseline for the valuation, and that, at the time, the dividend was sized to be low 20s percent of free cash flow before any one time items related to the spin . . . . So that math is still good math.

178. Defendant Walsh's statement that the "math" behind Organon's outsized shareholder dividend payments was "still good math" was false and misleading for the reasons already described. Indeed, the Company had just engaged in stuffing the sales

channel with Nexplanon during the quarter immediately before—recognition, at least internally, that that “math” was not, in fact, “still good math” (if it ever was). Rather, manipulating customer demand and sales for Nexplanon reflected weakness in Organon’s financial health that threatened its ability to pay an outsized dividend.

179. A few months later, on the Q4 2022 earnings call held February 16, 2023, Defendant Walsh stated: “We ended the year with a net leverage ratio of about 3.8 times, which ticked up from the 3.6 times we reported at the end of the third quarter,” explaining: “[W]e could see leverage tick higher before leveling back down by the end of the year. **This doesn’t have a significant impact on our capital allocation priorities, given the strong cash flow characteristics of the business.**” Defendant Walsh went on to again affirm Organon’s supposed ability to afford further dividend payments, stating: “**Our capital allocation priorities remain consistent with past communications. We will continue to prioritize servicing the current dividend[.]**”

180. Defendant Walsh’s statement that the increase in Organon’s net leverage ratio in 2022 would not “have a significant impact on [the Company’s] capital allocation priorities, given the strong cash flow characteristics of the business,” was false and misleading. In reality, the increase in Organon’s net leverage ratio would have a significant impact on the Company’s previously identified “capital allocation priorit[y]”—the quarterly shareholder dividend—because Nexplanon was generating less sales income than anticipated (decreasing the amount of free cash flow available

for dividend payments in the short term), and the Draft Guidance cast doubt on Nexplanon's continued exclusivity (heightening Organon's need to invest capital in new product acquisitions at the expense of the size of the dividend). Walsh was aware of the impact of Nexplanon's underperforming sales, its sooner-than-expected LOE, and the Company's outstanding debt posed to Organon's capital allocation priorities due to his role as CFO in monitoring and reporting Organon's financials, as well as the importance of Nexplanon sales, free cash flow, the Company's outstanding debt, and the shareholder dividend to Organon's operations.

181. Moreover, Defendant Walsh's statement was false and misleading in that it implied that the Company possessed the free cash flow to continue paying an outsized shareholder dividend despite its increased net leverage ratio, when in reality, the Company knew or recklessly disregarded that it could not do so. In choosing to speak publicly on the issue of the Company's ability to continue paying an outsized shareholder dividend, Defendant Walsh had a duty to disclose the known material fact that Nexplanon's lower-than-expected sales and earlier-than-expected LOE risk would imperil Organon's ability to make dividend payments.

182. Defendant Walsh's statement that Organon would "continue to prioritize servicing the current dividend" was also false and misleading, for the reasons already described above.

183. Defendants again addressed the Company's supposed ability to afford robust dividend payments on November 2, 2023, when Defendant Walsh told investors on Organon's Q3 2023 earnings call:

In terms of capital allocation, we've been, since the spin-off, trying to achieve a balance of capital allocation between investments and growth for the future, and balancing that against the near term and certain benefits of leverage reduction. That equation has been tilted a little bit more, given where interest rates have gone, the near-term benefits of debt reduction look more attractive. So as we've said in the past a few times, it raises the bar on the type of business development and M&A transactions that we would execute. And that's one of the reasons why you've seen, relatively speaking, a lower level of activity in BD in 2023 than you saw in 2022. **We continue to believe that the business – the cash flow profile that the business exhibits supports a dividend, certainly at the level that we have. There's no plans to change that in the near term.**

184. Defendant Walsh's statements that Organon's cash flow profile "supports a dividend . . . at the level that we have," and that there were "no plans to change [Organon's dividend] in the near term," were false and misleading. In reality, senior management, including Defendants, understood that Organon's financial condition was deteriorating due to the Company's massive debt and because Nexplanon was generating less sales revenue than anticipated. For these reasons, Organon's "cash flow profile" could not support the robust dividend of \$0.28 per share that Organon maintained at the time.

185. Defendants once again emphasized Organon's supposed ability to continue dividend payments on January 9, 2024, at the JP Morgan Health Conference. There, Defendant Ali predicted that 2024 would be "a year of growth, stability, potentially focused on delivering, **paying the dividend** and ultimately gaining more, I think, shareholder and investor confidence." Then, asked "**should we think of that as kind of a rock solid commitment to the dividend,**" Ali gave a single-word answer: "**Yes.**" Asked "more broadly, how do you think about capital market allocation priorities, just given, I guess, the environment we're in, where your stock is trading? Like, how are you thinking about balancing the different uses of your cash going forward?," Ali responded affirmatively, saying: "I do believe that going forward, **we're committed to the dividend.**" Later in Organon's presentation at the conference, Walsh echoed Ali's words, stating "**we've always said our number one priority is the dividend now that we have it.**"

186. Defendants' statements affirming Organon's "rock solid commitment to the dividend," and describing the dividend as Organon's "number one priority," were false and misleading. In reality, between Nexplanon's underperforming sales, the ever-present and increasing need to invest in new products (especially due to Nexplanon's sooner-than-expected LOE), and Organon's outstanding debt, Defendants knew or recklessly disregarded that the Company lacked the free cash flow to continue paying an outsized dividend. Having just concluded the fourth

quarter of 2023 when making these statements, Defendants were aware of Nexplanon's underperformance and the adverse implications for free cash flow and, ultimately, financial resources available to continue paying such a large dividend.

187. Looming large was the fact that for full-year 2023, Nexplanon experienced a decrease of \$4 million in total revenue as compared to 2022. This shortfall primed Defendants to resume stuffing Nexplanon's sales channels in 2024—a practice that, until then, had last occurred in 2022. Yet Organon continued to suffer from a decline in natural demand for Nexplanon, and the Company reported a 3% ex-FX revenue decline for Nexplanon during the 2024 fourth quarter. Unadjusted figures, which Defendants knew internally (and Organon would later report, on February 15, 2024), indicated that Nexplanon sales decreased for the 2024 fourth quarter and full-year.

188. Defendants reiterated Organon's supposed ability to afford continued dividend payments on the Q4 2023 earnings call, held February 15, 2024. Responding to an analyst's inquiry, Defendant Ali declared: **“Yes, you heard me at JPM being very declarative that we are very committed to be able to service our dividend.”** Later in the call, Ali reiterated: **“Look, the combined businesses generate what we expect to be close to \$1 billion of free cash flow before onetime charges in 2024. This gives us ample financial flexibility to continue to service our dividend,** continue to execute on our business development agenda, and to make progress towards achieving a net debt-to-EBITDA ratio of below 4 by the end of this year.”

189. Defendant Ali’s statements, which reiterated Organon’s commitment to the dividend and attested to the Company’s “ample financial flexibility to continue to service our dividend,” were false and misleading. In fact, Organon reported only slowing growth and stale performance for Nexplanon for the 2024 fourth quarter and year-end, reflecting an overall sales decrease. Between such underperforming sales, the ever-present and increasing need to invest in new products (especially due to Nexplanon’s sooner-than-expected LOE), and Organon’s outstanding debt, Defendant Ali knew or recklessly disregarded that Organon lacked the free cash flow, and thus the “financial flexibility,” to continue paying an outsized shareholder dividend.

190. Defendants next addressed Organon’s dividend payments on May 2, 2024, during the Company’s first quarter 2024 earnings call. Defendant Ali’s opening remarks emphasized that “[f]rom a capital allocation standpoint, **we continue to believe this business can generate \$1 billion of free cash flow before one-time costs**, and we will be driving towards that number in 2024,” adding that “**strong cash flow will provide financial flexibility to comfortably service our dividend**, [and] make progress on achieving a leverage ratio below 4 times by the end of 2024 . . . .”

191. Defendant Ali’s statement that Organon could generate “\$1 billion of free cash flow before one-time costs” was false and misleading, particularly because of Nexplanon’s sales difficulties. In choosing to speak publicly on Organon’s free cash flow, Defendant Ali owed a duty to disclose material facts related to present and

future limitations on Organon’s free cash flow, including Nexplanon’s slower-than-expected sales growth and the risks posed to Nexplanon’s exclusivity by the Draft Guidance. Thus, Defendant Ali’s statement was also false and misleading because it omitted—and Defendants collectively failed to disclose—the material fact that Organon lacked and would continue to lack the free cash flow to justify a robust shareholder dividend.

192. Moreover, Defendant Ali’s statement that Organon’s purportedly “strong” cash flow would permit the Company to “comfortably service our dividend” was also false and misleading. Contrary to that representation, Organon’s cash flow was not “strong,” for the reasons already described. Furthermore, in choosing to speak on Organon’s supposed ability to continue paying a robust shareholder dividend, Ali had a duty to disclose known facts imperiling the Company’s ability to allocate cash flow to making dividend payments, including Nexplanon’s slower-than-expected sales growth and the risk of Nexplanon losing exclusivity sooner than expected.

193. A few months later, on August 6, 2024, Defendants addressed investors on the Company’s second quarter 2024 earnings call. There, Defendant Ali stated: **“strong cash flow will provide financial flexibility to comfortably service our dividend, which is our number one capital allocation priority.”**

194. Defendant Ali’s statements that Organon’s “strong cash flow” allowed the Company to “comfortably service our dividend,” and that the dividend was its

“number one capital allocation priority,” were false and misleading. In truth, the Company did not have strong cash flow but was struggling to ensure that Nexplanon achieved sales forecasts. Indeed, Defendants resumed stuffing sales channels for Nexplanon during the 2024 third quarter—squarely when Ali made these statements, despite addressing second-quarter earnings. Thus, Defendant Ali knew or recklessly disregarded that Organon lacked the “strong cash flow” sufficient to “service [the] dividend” going forward.

195. On September 18, 2024, Organon issued a press release disclosing the Company’s \$1.2 billion acquisition of Dermavant to investors. The release stated that **“the transaction [was] not expected to result in a revision to Organon’s capital allocation priorities.”**

196. Defendants’ statement that the Dermavant acquisition would not affect “Organon’s capital allocation priorities” was false and misleading. In truth, Organon continued to engage in channel stuffing to maintain the impression of brisk demand for Nexplanon, which deceived analysts and investors. And Defendants knew that the Dermavant acquisition would compel changes to Organon’s capital allocation priorities. Indeed, expending \$1.2 billion on the transaction strained the Company’s already limited capital resources, such that Organon could not continue paying an outsized shareholder dividend. As explained above, Organon had the obligation to make debt payments and needed to acquire new products as a hedge against

Nexplanon's heightened LOE risk, while Nexplanon was continuing to experience slower-than-expected sales growth.

197. On October 31, 2024, Organon held its third quarter 2024 earnings call. Defendant Ali opened the call, stating that Organon remained "well on track to deliver [its] commitment of approximately \$1 billion of free cash flow . . . in 2024," and that its "**significant free cash flow enables us to comfortably service the dividend.**"

198. Defendant Ali's statement that Organon's "free cash flow enable[d] [it] to comfortably service the dividend" was false and misleading. Defendants continued stuffing sales channels for Nexplanon during the 2024 fourth quarter, when Ali made these statements (despite purportedly addressing third-quarter earnings). Organon was by no means "comfortably [able to] service the dividend" given Nexplanon's slower-than-expected (or reported) growth and all of the Company's other onerous financial obligations, discussed above.

199. On February 13, 2025, Organon held its Q4 2024 earnings call. There, Defendant Ali stated: "**We're committed to our regular dividend as our number one capital allocation priority.**" He also addressed the Company's commitment to "delivering on the promise of our growth products and pipeline," explaining:

This includes eclipsing the \$1 billion mark for Nexplanon for the calendar year of 2025. We also have a line of sight to delivering more than \$300 million of revenue from our recent business development transactions, specifically Emgality and the Dermavant acquisition with \$150 million of that coming from Vtama.

200. Defendant Ali’s statement that Organon was “committed to our regular dividend as our number one capital allocation priority” was false and misleading. In truth, the Company continued to secretly engage in channel stuffing during both the fourth quarter of 2024 and the first quarter of 2025—a practice Defendants continued through the second and third quarters of 2025, as well, as Organon failed again and again to reach Nexplanon sales and revenue targets through organic sales. Indeed, Defendant Ali was ultimately forced to resign from the Company, without severance or equity payouts, due to his involvement in Organon’s channel-stuffing scheme that falsely inflated Nexplanon’s sales. Defendant Ali also knew or recklessly disregarded that Organon could not continue to maintain its outsized shareholder dividend as the Company’s “number one capital allocation priority,” given Nexplanon’s disappointing, inflated sales, the need to acquire new products because of Nexplanon’s sooner-than-expected LOE, the Dermavant acquisition, and Organon’s outstanding debt.

201. Later in the call, Defendant Walsh expressed agreement with Ali, stating:

**As we think about capital allocation, the priority, as Kevin [Ali] mentioned, is our dividend.** And in the past two years, the highest and best use of the remaining cash flow has been opportunistic business development. In 2024, we made upfront and milestone payments totaling about \$350 million. In 2025, we expect to pay a little over \$200 million in commercial milestones. We’ve already paid about \$130 million between Vtama’s AD approval and Emgality commercial milestones. An additional \$30 million

to \$70 million would be due if milestones for Henlius and SJ02 are met.

The achievement of these milestones means that we're realizing value for business development already signed and validates the path to low to mid-single digit revenue growth post-2025 that we've been saying Organon should be able to deliver.

202. Defendant Walsh's statement that the dividend was Organon's capital allocation "priority" was false and misleading for the reasons previously discussed. Thus, Defendant Walsh knew or recklessly disregarded that Organon lacked the free cash flow to continue prioritizing the payment of an outsized shareholder dividend. Further, Defendant Walsh was aware of the impact these operational and financial constraints posed to Organon's capital allocation priorities due to his role as CFO.

**D. Defendants' Materially False and Misleading Statements About Sales Practices for Wholesalers and the Effect Upon Revenues and Product Demand, as Well as Defendant Ali's Fitness to Serve on the Board of Directors**

203. As explained herein, on October 27, 2025, Organon issued a press release, attached to a Form 8-K filed with the SEC, reporting that Defendants had engaged in stuffing sales channels for Nexplanon during six quarters since 2022. The release disclosed that "concerns regarding the Company's wholesaler sales practices for its Nexplanon product were brought to the Board's attention," and that the Audit Committee "found that certain wholesalers in the United States were asked to buy more Nexplanon than they needed 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."

204. The Form 8-K indicated that, “[i]n certain instances, the Company waived inventory management fee performance metrics associated with caps on days of inventory in exchange for such wholesalers accepting the *Nexplanon* sales,” which, the Company admitted, “enabl[ed] the wholesalers to receive incentive fees from the Company that they otherwise would not have received.” Organon also disclosed that “without these sales practices, the Company’s consolidated revenue for certain of those periods would have fallen short of the Company’s guidance and/or certain external revenue expectations.”

205. Organon also revealed that “the Company’s Board determined that the wholesaler sales practices were improper and certain of the Company’s prior statements were inaccurate or incomplete.” In the 2024 Amended Form 10-K, filed with the SEC on November 10, 2025, Organon confirmed that, “[a]s 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 [in which they pulled forward such purchases] until their days of inventory on hand were reduced to levels within the contractual range.”

206. In the 2024 Amended Form 10-K and Amended Forms 10-Q for the first and second quarters of 2025, the Company disclosed that without these practices, consolidated revenue for fiscal year 2024 and other periods—reported in the original Form 10-K and other SEC filings—would have “fallen short” of internal guidance and

external expectations. The amended SEC filings indicated that: (1) Defendant Ali and the executive in charge of Organon’s U.S. commercial organization “applied inappropriate pressure to achieve sales targets”—resulting in unwanted purchases by two U.S. wholesalers—and “engaged in inappropriate business conduct that violated the Company’s Code of Conduct”; (2) Defendant Ali “withheld” information from the Board and others; and (3) Organon’s “processes with respect to reporting and documenting the sales practices for wholesalers . . . were not followed[.]”

207. The amended SEC filings also identified information that Defendants now admit was inaccurate and incomplete—and, consequently, misleading—when it was disseminated during the Class Period. Conceding that the Nexplanon sales practices described above were “improper,” for example, the amended Form 10-K indicated that “certain of the Company’s prior disclosures relating to these sales practices for wholesalers and their effect upon revenue and product demand in its periodic filings were inaccurate or incomplete, including certain disclosures . . . amended [therein].”

208. According to the amended Form 10-K, the amended disclosures included “Management’s Discussion and Analysis of Financial Condition and Results of Operations” as to increased demand for Nexplanon in the U.S., and the discussion of results of operations as related to Nexplanon sales, for the affected periods. The amendments also related to Organon’s internal controls over financial reporting, and the report of PricewaterhouseCoopers LLP, which were changed to reflect that the

Company had ineffective disclosure controls and procedures as a result of material weaknesses resulting from the improper sales and reporting practices. Organon also supplied executive certifications, and a consent from PricewaterhouseCoopers LLP, to reflect these deficiencies and amendments.

209. These amended disclosures, coupled with Organon’s admissions, confirm that the Company misrepresented material information in Class Period SEC filings and other public statements about customer demand, sales, revenues, and wholesaler relationships involving Nexplanon. For example, Item 7 of the amended Form 10-K reported that sales in 2022 and 2024 included revenue from improper practices relating to Nexplanon involving U.S. wholesalers. These disclosures explained that Nexplanon sales increased in 2022 and 2024 due to those practices, but not in 2023—a year in which Nexplanon’s total sales declined, evidently because Defendants did not engage in those improper sales practices.

210. The original 2024 Form 10-K, by contrast, provided that sales increased in 2024 primarily “due to increased demand” for Nexplanon, without mentioning the improper practices. The original 2024 Form 10-K also contrasted the 2024 results with the 2023 results without mentioning those improper practices, conveying that demand had rebounded in 2024 when it had not. The original 2024 Form 10-K also presented 2022 sales and revenue figures, alongside 2023 and 2024 numbers, without disclosing the improper conduct that influenced the 2022 results. The original Forms 10-Q and

press releases for the fourth quarter of 2022, third and fourth quarters of 2024, and first, second, and third quarters of 2025, also reported sales, revenues, and demand without mentioning these improper practices. Yet the improper practices—disguised as increased customer demand—contributed to the increase in Nexplanon sales and revenues for those periods. In this way, the practices converted what would have been negative sales trends (had the practices not occurred) into positive sales trends (because the increase resulted from the practices).

211. It was materially misleading for these disclosures to misrepresent a source of the increase in Nexplanon sales and revenues, when the improper sales practices enabled Organon to report an increase—as opposed to a decrease—in Nexplanon sales for various quarters in 2022, 2024, and 2025. It was also materially misleading for these disclosures to attribute the increase in sales and revenue to “demand,” when Defendants induced two U.S. wholesalers to purchase Nexplanon product they did not want or need—in contravention of the wholesalers’ contracts and Organon’s sales policies and practices and Code of Conduct—in exchange for rebate kickbacks and other benefits to which the wholesalers would not have otherwise been entitled.

212. The Board of Directors evidently found Defendant Ali largely at fault for these transgressions, resulting in his forced resignation without severance or equity payouts. During the Class Period, however, Organon issued materially misleading annual proxy materials to investors that Ali, as CEO, participated in preparing and

approving. Organon used these materials to secure shareholder approval of: (1) Ali's reelection to the Board in 2024 and 2025; (2) the compensation of named executive officers—including Defendants Ali and Walsh—in 2023, 2024, and 2025; and (3) amending and restating the 2021 Incentive Stock Plan in 2025 to increase the shares issuable thereunder for Organon employees, including Defendants Ali and Walsh.

213. In the 2023 annual proxy statement, filed with the SEC on April 27, 2023, Organon represented that Nexplanon “grew 11%” in 2022 in “its second consecutive year of double-digit growth” and referenced the 2022 Form 10-K. But that metric, and the 2022 Form 10-K, referenced growth from Nexplanon revenue based, in part, on the (then-undisclosed) improper sales practices involving Nexplanon in the 2022 fourth quarter. It was materially misleading for the disclosures to address Nexplanon growth and revenue without disclosing that improper practices contributed to both—disguising the manipulation of wholesaler relationships in the 2022 fourth quarter, in violation of Company policy and practice, as an increase in customer demand.

214. Additionally, Defendants used the 2023 annual proxy statement to solicit shareholder approval of named executive officer compensation, indicating that CEO Ali's compensation was 30% fixed and 70% performance-based and CFO Walsh's compensation was 35% fixed and 65% performance-based. The fixed aspect of their compensation consisted of base salary and restricted stock units; the performance-based aspect consisted of a benefit under the Annual Incentive Plan if performance

targets were achieved, performance share units as to relative total shareholder return, and non-qualified stock options. Thus, the Individual Defendants' compensation was predominately tied to Organon's financial results and achieving its financial targets, which necessarily included Nexplanon sales and revenue results and targets.

215. To induce shareholder approval of compensation for the named executive officers, including Defendants Ali and Walsh, the 2023 annual proxy statement cited Organon's financial performance in 2022, including the results discussed above. The 2023 annual proxy statement also discussed compensation paid to named executive officers, including Defendants Ali and Walsh, in 2022—the performance-based aspect of which was tied, at least in part, to Nexplanon sales and revenues resulting from the improper, yet undisclosed, sales practices during the fourth quarter of 2022. The 2023 annual proxy statement thus sought approval of 2023 compensation plans based, in part, on materially misleading information from 2022.

216. It was critical for investors to know the truth about these practices and the involvement of, and/or financial or other benefits flowing to, the Individual Defendants, when deciding how to vote on 2023 compensation for the named executive officers. But the 2023 annual proxy statement did not describe those practices or their impact on Organon's financial results and operations. The 2023 proxy statement therefore concealed material weaknesses in Organon's internal controls, as well as Defendant Ali's violation of the Company's Code of Conduct,

resulting from the improper sales practices during the fourth quarter of 2022. As reported in the 2024 annual proxy statement, filed with the SEC on April 25, 2024, approximately 93% of shareholder votes cast at the 2023 annual meeting approved the proposed compensation plan for named executive officers.

217. The 2024 annual proxy statement, in turn, solicited shareholder approval of the proposed compensation plan for 2024 for named executive officers, including Defendants Ali and Walsh. To do so, the 2024 annual proxy statement discussed Organon's financial results in 2023 and performance into 2024. In the introductory "Message to Our Shareholders," which Defendant Ali co-authored and signed (along with the Chairman of the Board), Defendants represented:

We enter 2024 with strong momentum, and a clear roadmap for again delivering low single-digit revenue growth, with an aim to drive growth in profitability measures even faster. Our focus now is to build on the strong foundation we set in 2023 by driving profitable growth, remaining disciplined on operating costs, and investing in new opportunities—inside and outside our business—that complement our strengths.

218. In reality, Organon resumed its improper Nexplanon sales practices within weeks of the 2024 annual meeting, held June 4, 2024—no later than the third quarter, which began on July 1, 2024. This conduct, which first occurred in the fourth quarter of 2022, resumed and continued in the second half of 2024—all on Defendant Ali's watch, and ostensibly at his direction. The 2024 annual proxy statement indicated that key topics of engagement during 2023 included Organon's "[b]usiness drivers and

performance,” “[c]apital allocation priorities,” and “[g]rowth strategy”—all of which this pre- and post-improper sales conduct adversely implicated and artificially manipulated to convey a misleadingly favorable impression.

219. It was materially misleading for the 2024 annual proxy statement to solicit shareholder approval of the largely performance-based compensation packages for Defendants Ali and Walsh when Organon had secretly engaged in illicit channel stuffing in 2022 and would resume the conduct in the 2024 fiscal year relating to the pay plan. Investors could not possibly cast an informed vote without information regarding Defendants’ improper sales practices, which happened before the 2024 annual meeting and would happen again shortly thereafter.

220. The 2024 annual proxy statement also solicited shareholder approval for Defendant Ali’s reelection to the Board as a Class III director with a one-year term (slated to end at the 2025 annual shareholder meeting). According to the 2024 annual proxy statement, Defendant Ali was qualified in all eleven skill categories on which the Board evaluated directors and director nominees, ranging from leadership to marketing and sales. The 2024 annual proxy statement further indicated that each director nominee must satisfy “minimum criteria” to qualify for the Board, including having “proven integrity,” “demonstrated ability and sound judgment,” and strong management skills to objectively consider “management’s plans and programs.”

221. It was materially misleading for the 2024 annual proxy statement to portray Defendant Ali's qualifications, as well as to describe the criteria required of directors and nominees, without disclosing his role and responsibility in the Nexplanon sales misconduct—conduct that occurred several quarters earlier and that would resume almost immediately after the 2024 annual meeting. Based on this misinformation, shareholders approved Ali's reelection to the Board with the most support, and least opposition, of any director up for reelection: over 176 million votes cast in favor, and just 2.2 million votes cast against. Shareholders also overwhelmingly approved the 2024 compensation plan for the named executive officers, including Defendants Ali and Walsh.

222. Organon's 2025 annual proxy statement, filed with the SEC on April 25, 2025 for the meeting slated for June 10, 2025, also solicited shareholder approval of Defendant Ali's reelection to the Board. Beginning with the 2025 annual meeting, Organon eliminated its three-tiered classified Board structure, which required Class I, II and III directors to stand for reelection sequentially. Instead, starting in 2025, the Company no longer divided its Board into three classes and required all directors to stand for reelection to a one-year term each year. Thus, the 2025 annual proxy statement once again discussed Ali's fitness and qualifications to continue to serve on the Board, portrayed Ali in a favorable light as someone who satisfied all of the

criteria necessary to serve on the Board, and requested shareholders to vote in favor of his reelection.

223. Like the 2023 and 2024 annual proxy statements, the 2025 annual proxy statement engendered the positive impression that Defendant Ali and other members of management were operating Organon in a prudent and responsible manner, citing past financial performance, results, and growth as evidence. But like the other proxy filings, the 2025 annual proxy statement failed to disclose, and purposely concealed, the Company's improper Nexplanon sales practices—practices that were ongoing at that time, having resumed in the third quarter of 2024. As Organon later admitted, the undisclosed Nexplanon channel stuffing and wholesaler kickbacks continued through the third quarter of 2025 (which ended September 30, 2025).

224. The 2025 annual proxy statement therefore obtained shareholder approval of Ali's reelection on the basis of materially misleading information. Had investors known before the vote that this misconduct took place on Ali's watch beginning in 2022 and continuing through 2025 and that he bore substantial responsibility for the conduct—which impugned his integrity, judgment, and management style—they would have overwhelmingly voted against his reelection. Instead, Organon and Defendant Ali once again misled investors by deceptively curating the nature of disclosure in the 2025 annual proxy statement, resulting in a landslide of shareholder support for Ali's reelection at the annual meeting. Unsurprisingly, shareholders also

overwhelmingly approved the named executive officers' proposed compensation, as in years past.

225. Additionally, shareholders approved an amendment and restatement to the Company's 2021 incentive stock plan. Specifically, using the materially misleading 2025 annual proxy statement, Defendants obtained authorization to: (1) increase the number of shares of common stock issuable to employees under the plan as incentive awards by 7.8 million; and (2) require that 95% or more of shares subject to awards under the plan have a one-year vesting period. As the 2025 annual proxy statement represented: "We believe that cash and stock-based incentives play an important role in attracting, retaining and motivating key talent and align employee incentives with long-term shareholder value."

226. Accordingly, the 2025 annual proxy statement solicited approval of these amendments with the same materially misleading information used to garner support for Defendant Ali's reelection and the named executive officers' compensation. It was materially misleading to describe the stock plan amendments without revealing Organon's persistent channel stuffing scheme or the involvement of Defendant Ali and other executives in it. Of course, Defendant Ali played a role in preparing and approving the 2025 annual proxy statement, and he knew or should have known that the SEC filing contained material misrepresentations when filed with the SEC or otherwise disseminated to shareholders.

**E. Organon’s Class Period SEC Filings Contained Actionable Half-Truths Regarding Sales, Revenue, and Demand for Nexplanon That Violated Item 303 of Regulation S-K**

227. Item 303 of Regulation S-K, 17 C.F.R. § 229.303, requires annual and quarterly SEC filings to include management’s discussion and analysis of financial condition and results of operations (“MD&A”). The “objective” of MD&A, as Item 303(a) indicates, “is to provide material information relevant to an assessment of the financial condition and results of operations of the registrant.” Therefore, MD&A “must focus specifically on material events and uncertainties known to management that are reasonably likely to cause reported financial information not to be necessarily indicative of future operating results or of future financial condition.”

228. Item 303(b)(2)(ii) accordingly requires an issuer to “[d]escribe any known trends or uncertainties that have had or that are reasonably likely to have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations.” In May 1989, the SEC issued an interpretive release on Item 303 (“1989 Interpretive Release”), providing, in pertinent part, as follows:

Required disclosure is based on *currently known trends, events, and uncertainties that are reasonably expected to have material effects*, such as: A reduction in the registrant’s product prices; erosion in the registrant’s market share; changes in insurance coverage; or the likely non-renewal of a material contract.

\* \* \*

A disclosure duty exists where a trend, demand, commitment, event or uncertainty is both presently known to management and reasonably

likely to have material effects on the registrant's financial condition or results of operation.

229. The 1989 Interpretive Release also set forth a standard, still applied today, to dictate when disclosure is required under Item 303:

Where a trend, demand, commitment, event or uncertainty is known, management must make two assessments:

(1) Is the known trend, demand, commitment, event or uncertainty likely to come to fruition? If management determines that it is not reasonably likely to occur, no disclosure is required.

(2) If management cannot make that determination, it must evaluate objectively the consequences of the known trend, demand, commitment, event or uncertainty, on the assumption that it will come to fruition. Disclosure is then required unless management determines that a material effect on the registrant's financial condition or results of operations is not reasonably likely to occur.

230. In interpretive guidance, effective December 29, 2003 ("2003 Guidance"), the SEC expressly emphasized the importance of clear and accurate MD&A-related disclosure, stating:

We believe that management's most important responsibilities include communicating with investors in a clear and straightforward manner. MD&A is a critical component of that communication. The Commission has long sought through its rules, enforcement actions and interpretive processes to elicit MD&A that not only meets technical disclosure requirements but generally is informative and transparent.

231. In the 2003 Guidance, the SEC also identified as a "principal" objective of MD&A disclosure the need "[t]o provide information about the quality of, and potential variability of, a company's earnings and cash flow, so that investors can

ascertain the likelihood that past performance is indicative of future performance.” As the SEC explained in its 2003 Guidance:

MD&A should be a discussion and analysis of a company’s business as seen through the eyes of those who manage that business. Management has a unique perspective on its business that only it can present. As such, MD&A should not be a recitation of financial statements in narrative form or an otherwise uninformative series of technical responses to MD&A requirements, neither of which provides this important management perspective.

232. Subsequently, in guidance effective February 25, 2020 on key performance indicators and metrics (“2020 Guidance”), the SEC provided further instruction on the nature of MD&A disclosure required of financial and other operational metrics. In its 2020 Guidance, the SEC underscored a “need to include such further material information, if any, as may be necessary to make the presentation of the metric, in light of the circumstances under which it is presented, not misleading.” As the 2020 Guidance indicated, Item 303 “requires disclosure of information not specifically referenced [therein] ... that the company believes is necessary to an understanding of its financial condition, changes in financial condition and results of operation.”

233. As detailed herein, stuffing Nexplanon’s sales channels over five quarters during the Class Period allowed Defendants to report an increase in sales, revenue, and demand for Nexplanon that their undisclosed conduct had artificially induced. In this way, Defendants manufactured increasing trends based on artificial demand that, in reality, masked decreasing sales and revenue at the end of those quarters—sales and

revenue figures that, if uninfluenced by Nexplanon channel stuffing, would have missed Organon's internal estimates and external expectations.

234. Organon's amended Form 10-K and Forms 10-Q, issued after the October 27, 2025 channel stuffing revelation, corrected disclosures in the earlier SEC filings that falsely attributed the increase in Nexplanon sales and revenue for those periods to an increase in wholesaler demand. The amended and revised disclosures, detailed above, now indicate that the increase in Nexplanon sales and revenue resulted from "improper" channel stuffing, exposing misleading half-truths in earlier SEC filings. Other Class Period SEC filings that Organon did not amend—such as those relating to the third and fourth quarters of 2024—contained similar misrepresentations.

235. At the same time, the Company artificially depressed demand in quarters after the Nexplanon channel stuffing took place, because that conduct had the effect of pulling forward purchases the two wholesalers would have made in later quarters. As the Company explained in its November 10, 2025, Form 10-Q for the third quarter ended September 30, 2025: "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."

236. This conduct was no doubt material to Organon and also its shareholders. For example, in the February 24, 2026, Form 10-K for the year ended December 31, 2025, the Company disclosed:

[W]ithout these sales practices, our consolidated revenue for the fiscal year ended December 31, 2024 and for the quarters ended March 31, 2025, June 30, 2025 and September 30, 2025 would have fallen short of our guidance range and/or certain external revenue expectations.

237. Accordingly, Defendants: (i) caused two of Organon's wholesalers to buy more Nexplanon than they wanted or needed, despite contractual purchase quantities and the Code of Conduct; (ii) induced the purchases by offering incentives to which the wholesalers were not entitled; (iii) portrayed a trend of increasing quarterly sales and revenue that met internal and external expectations based on artificial "demand" that they created; (iv) masked what would have been a decline in sales and revenue, while depressing future sales (because the wholesalers understandably "decreased or even halted their purchases" in later quarters); and (v) engaged in this conduct for six quarters, including five within the Class Period.

238. This conduct ultimately resulted in: a management shakeup involving the ouster of Defendant Ali as CEO (without severance or equity awards) and of the Head of U.S. & Commercial Governmental Affairs; the adoption of remediation efforts and processes designed to augment Board communications and address employee concerns; the public admission of material operational weaknesses; the filing of new SOX Certifications and revised SEC filings; and an SEC investigation.

239. Additionally, when the channel stuffing conduct was publicly revealed, the Company's stock price plummeted by nearly 23% on exceptionally high volume of approximately 35 million shares traded—a tenfold increase in volume from the prior trading day. The market's reaction underscored the importance of the previously-concealed conduct, which Defendants shrouded during the Class Period with repeated material misrepresentations (in SEC filings and other public statements).

240. Consequently, the 2024 third quarter Form 10-Q and the 2024 Form 10-K (covering the 2024 fourth quarter and full year), and Forms 10-Q for the first, second, and third quarters of 2025, contained material half-truths in violation of Item 303. Those filings attributed Nexplanon sales and revenue to increased customer demand, when, in reality, Defendants induced purchases of Nexplanon by bribing wholesalers with ordinarily unavailable incentives. In this way, those filings misrepresented the nature and cause of the underlying demand for Nexplanon, as well as the reason for the increase in sales and revenue resulting from Nexplanon purchases.

241. Analysts recognized the significance of this conduct. As detailed herein, for example, Piper Sandler noted in an October 27, 2025, report that “[e]ngaging in channel stuffing in order to meet stated financial expectations is clearly an egregious betrayal of the trust of investors (and other key stakeholders),” placing pressure on the Company to redeem itself and weighing down the stock price for the foreseeable future. Evercore expressed other concerns in a November 10, 2025 report, noting that

Organon's Chief Commercial Officer inexplicably departed in February 2025 and questioning why discounts and rebates increased by \$171 million year-over-year in 2024 if the channel stuffing-related revenue supposedly was limited in amount.

## **VI. THE TRUTH IS REVEALED**

242. Investors began to learn of Organon's fraud on May 1, 2025, when, in connection with the announcement of the Company's first quarter 2025 financial results, Organon shocked investors by slashing its dividend from \$0.28 per share to \$0.02 per share—a 90% decrease.

243. In Organon's press release announcing the news, Defendant Ali attempted to defend the dividend cut, stating that the Company had “reset [its] capital allocation priorities to accelerate progress towards deleveraging, enabling a path to achieve a net leverage ratio of below 4.0x by year-end.” The press release further quoted Defendant Ali as emphasizing that the Company's primary “capital allocation priorit[y]” was now “maintaining lower leverage”—a noted deviation from the Company's statements during the Class Period, which had framed payment of the shareholder dividend as Organon's “#1 capital allocation priority.”

244. In Organon's quarterly earnings call held the same day, Defendant Walsh admitted that Organon needed to slash the dividend in order to redirect capital to product development, stating:

The biggest issues we face that can improve Organon's valuation in the near term relate to managing our leverage

and relate to growth. And we need capital to solve both of those issue[s]. And so, returning capital to shareholders is right now is less of a priority.

245. Later, during the Q&A segment of the call, Defendant Walsh again stressed that “[t]he biggest issues we face that can improve Organon’s valuation in the near term relate to managing our leverage and relate to growth.” “[W]e need capital to solve both of those issues,” he added.

246. The dividend cut was met with immediate shock from market analysts. For example, in a particularly scathing report issued the same day, an Evercore analyst reduced Organon’s rating from “Outperform” to “In-Line.” Describing the dividend cut as a “surprise,” Evercore’s analyst noted that Organon’s quarterly remarks seemed to signal a shift in the Company’s capital allocation priorities from allocation payments to growth. “There’s nothing wrong with [this] logic,” the analyst continued, “except for one thing: it is coming at the expense of [the] dividend.” The analyst went on to highlight the disconnect between Organon’s dividend cut and Defendant Walsh’s comments on recent earnings calls, in which Walsh said Organon could “comfortably service [the] dividend.”

247. Organon’s announcement of the dividend cut precipitated a large drop in the price of the Company’s stock. Overnight from April 30, 2025, to May 1, 2025, the price of Organon common stock fell from \$12.93 per share to \$9.45—wiping out 27%

of the stock's value—with more than 31 million shares trading, seven times the average daily volume over the preceding ten trading days.

248. Analyst criticism continued in the days following the stock's sharp decline. For example, on May 4, 2025, Morgan Stanley pruned its price target on Organon stock from \$15 to \$10, explaining that the change was “justified given [Organon's] lower dividend yield[.]” Analysts continued to express shock and disappointment in the following months. On July 9, 2025, for example, JP Morgan analysts called the announcement of the dividend cut “unexpected,” noting that “none of the company's prior comments suggest[ed] this was something OGN was exploring.”

249. More details of Organon's fraud were revealed to the market on May 2, 2025, when, in connection with its filing of its first quarter 2025 financial report with the SEC on Form 10-Q, the Company disclosed that, “[o]n 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 [Organon's Nexplanon patents].” Organon further disclosed that it had filed a patent infringement lawsuit against Xiromed on April 2, 2025, thus triggering a regulatory stay of Xiromed's ANDA for up to 30 months.

250. These disclosures alerted the market to the existence of the FDA’s Draft Guidance, Organon’s Citizen Petition, and the FDA’s Interim Response Letter, as Organon had not previously disclosed these regulatory filings in its SEC filings and other representations to investors. In response, Organon’s stock price dropped even further, falling from \$9.45 per share on May 1, 2025, to \$8.72 per share on Monday, May 5, 2025.

251. Following this additional decline, analysts reacted with renewed concern. On May 8, 2025, for example, Deutsche Bank analysts cited “risks that could have an impact on [the Company’s] bond prices,” including “heightened concerns around Nexplanon loss of exclusivity[.]” Citing these concerns, the analysts referenced the Xiromed filing and Organon’s Citizen Petition, as well as Defendants’ earnings call comments, and even included a link in its report to the Citizen Petition.

252. In a July 9, 2025, report, analysts at JP Morgan remarked that, in light of the Draft Guidance, “we would anticipate generic manufacturers will clearly target [Nexplanon], and we cannot rule out a late-decade generic competitor.” JP Morgan’s analysts further remarked that they “expect[ed] the potential for generic competition to remain an overhang on the stock despite the hurdles to an actual generic approval and we expect little incremental clarity on this topic in the coming quarters/years.” In a similar vein, analysts at TD Cowen, on July 14, 2025, noted that one of Organon management’s ostensible justifications for projecting a late LOE date—namely, the

Company's patent on the Nexplanon applicator—"will be tested in the first Paragraph IV proceedings which will take many months."

253. Over the next several months, the price of Organon stock regained some of its former value, as investors believed (incorrectly) that all details of Organon's fraud had been revealed to the market. At the close of trading on Friday, October 24, 2025, the price of Organon's common stock traded at \$9.16 per share.

254. Additional details of Organon's fraud were revealed to the market before trading began on Monday, October 27, 2025. In a press release, Organon disclosed that Defendant Ali had "resigned as Chief Executive Officer of Organon & Co. . . . as a member of the Company's Board of Directors . . . in connection with" an investigation into Organon's sales practices concerning Nexplanon. The press release further disclosed that Defendant Ali "agreed that he will not be entitled to severance or equity-related retirement benefits in connection with his resignation."

255. The press release also disclosed details of Organon's previously undisclosed investigation into Nexplanon sales, stating, in pertinent part:

After concerns regarding the Company's wholesaler sales practices for its Nexplanon product were brought to the Board's attention, the Audit Committee of the Board oversaw an independent, internal investigation into its sales to wholesalers. The investigation found that certain wholesalers in the United States were asked to buy more Nexplanon than they needed 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. The investigation found these sales . . . enabled Organon to meet guidance and/or

certain external revenue expectations. The Company's Board determined that these wholesaler sales practices were improper and certain of the Company's prior statements were inaccurate or incomplete . . . . In connection with the investigation, the Company terminated the employment of its Head of U.S. Commercial & Government Affairs.

256. The disclosure of Defendant Ali's resignation and the improper Nexplanon channel stuffing roiled analysts, including those that previously seemed bullish on Organon's prospects despite the earlier disclosures.

257. For example, in an October 27, 2025, report, analysts at Piper Sandler—one of few major investment firms to categorize Organon as “Overweight” despite the LOE and dividend disclosures—delivered a sobering analysis of the announcement, titled “Downgrade to Underweight: An Egregious Breakdown in Internal Controls.” In the report, Piper Sandler decreased Organon's price rating from “Overweight” to “Underweight” and cut its price target from \$18 to \$5. Further, Piper Sandler's analysts apologized to investors for previously advising that they retain Organon's stock despite the May 2025 disclosures regarding Nexplanon LOE and Organon's dividend, stating: “Looking back, we had viewed senior management as steady and responsible commercial operators. We were wrong.”

258. Piper Sandler's analysts also discounted the disclosure's relatively small impact on Organon's overall numbers, noting that the on-paper effect of the fraud was “less important than the reality that the malfeasance was committed with a clear eye towards meeting stated financial expectations.” As Piper Sandler recognized,

“Nexplanon . . . accounted for ~15% of global revenues in 2024, and U.S. Nexplanon sales accounted for ~10% of global revenues in 2024.” Piper Sandler also noted the length of the scheme, observing that the misconduct occurred “over multiple quarters spanning ~3 years, inclusive of the 5 most recent quarters (through 3Q25)[.]” The report included a passage emphasizing the importance of this conduct when viewed in the context of Organon’s “lower-margin business on the whole,” as follows:

**An even bigger impact on EBITDA given the nature of Nexplanon’s margins.** This is a relatively high-margin brand product (gross margins likely north of ~80%) that is a key driver of what is a lower-margin business on the whole. Corporate gross margins in 2Q25 and 2024 were ~62% and ~62% (this is bearing in mind that global established brands (i.e., off-patent products) accounted for ~59% and ~60% of the overall top-line in 2Q25 and 2024, respectively). Looking at 2024, reported U.S. Nexplanon sales totaled \$672M. If we assume that operating margins for the product are ~40%~50%, that implies near ~\$269M-\$336M in Nexplanon operating income, accounting for ~14%~17% of 2024 corporate EBITDA. In that vein, it strikes us as more than a bit disingenuous for the Board to simply cite top-line impacts of the malfeasance here.

259. Piper Sandler also placed in perspective the significant implications for the Company of the channel stuffing scheme, noting the conduct “enabled management to meet its stated financial guidance” and “that it will likely take quite some time for the Board and new senior leadership to build any modicum of credibility with the broader investor community” even if no further instances of malfeasance emerge. The Piper Sandler report concluded by stressing that “this is the kind of malfeasance that can

render a company/stock as uninvestable for an extended period,” and that “[e]ngaging in channel stuffing in order to meet stated financial expectations is clearly an egregious betrayal of the trust of investors (and other key stakeholders).”

260. Similarly, in an October 27, 2025, report, analysts at BNP Paribas asserted that Organon’s announcement would “weigh on management credibility going forward, notwithstanding [that] the current CEO is leaving, given the understanding that Organon would have missed revenue targets without the additional Nexplanon sales.” Also noting that “Organon terminated the employment of its Head of U.S. Commercial & Government Affairs” in connection with this development, the report acknowledged that the Company’s “board determined these sales practices were improper, and that certain prior statements were inaccurate or incomplete.”

261. And in a report on October 27, 2025, JP Morgan analysts voiced concern over “what appears to be several qtrs of consecutive channel build,” indicating that the misconduct “adds another layer of controversy and further credibility questions to an already controversial and out-of-favor story.”

262. The announcement of Defendant Ali’s resignation and the existence and results of the Audit Committee’s investigation wiped out the small gains Organon’s stock had made since the Company’s May 2025 disclosures. When trading reopened on Monday, October 27, 2025, Organon’s stock plummeted by 23%, from \$9.16 per

share to \$7.06 per share, as investors digested the news that Defendants had engaged in illicit channel stuffing of Nexplanon for six quarters over the past several years.

263. The stock price continued to decline thereafter, falling to an (unadjusted) close price of \$6.34 per share on October 29, 2025, on elevated volume, as analysts and investors continued to consider and digest news of these developments.

## VII. POST-CLASS PERIOD DEVELOPMENTS

264. On November 10, 2025, Organon held a call with investors to discuss the results of the Audit Committee's investigation. On the call, Defendant Walsh confirmed that, in various quarters during the Class Period, "[c]ertain revenue transactions were advanced or pulled forward into the current quarter in excess of estimated patient demand [for Nexplanon] and/or contractually agreed inventory holding levels."

265. That same day, Organon filed amendments to the Company's previously filed financial statements for the fiscal year ended 2024, as well as for the fiscal quarters ended March 31, 2025, and June 30, 2025. Organon's amended financial statements revealed the following previously undisclosed material weaknesses in Organon's internal control over financial reporting.

- **The Company failed to set an appropriate tone at the top. Specifically, our former CEO [Defendant Ali] 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.**

266. Organon's amended financial statements also revealed certain remedial actions the Company had taken or was planning to take to address the material weaknesses identified in the Audit Committee's investigation. These remedial actions included: (1) the appointment of a new Interim CEO and appointment of a new Head of U.S. Commercial & Governmental Affairs; (2) enhancing Organon's Code of Conduct to "clarify responsibilities related to the Company's financial reporting and disclosures"; (3) enhancing compliance training and communication on the Company's Code of Conduct regarding ethical tone and corporate culture; and (4) evaluating and enhancing "internal controls related to sales monitoring."

267. Subsequently, during an investor conference on December 3, 2025, Interim CEO Joseph Morrissey placed responsibility for the channel stuffing scheme squarely on Defendant Ali's shoulders, explaining that employee conduct "really does start

with the tone at the top” and that guidance for employees in making the right choices “goes into the training of the true ethics and integrity.” As the Interim CEO further explained when commenting on Organon’s recent remediation efforts, “employees didn’t escalate their concerns” so “we have a lot of tools and mechanisms to do that,” and “we’re driving that through in terms of the communication to make sure our employees know about those escalations.”

268. On February 12, 2026, the Company filed its financial statements for the quarter ended December 31, 2025, on Form 8-K. As forecasted in Defendant Walsh’s remarks on the November 10, 2025, investor call, Organon’s Q4 2025 financial statements recorded a decrease in the Company’s sales of Nexplanon compared with the prior year period. In its press release accompanying the Q4 2025 financial statements, Organon explained that this decrease was “primarily due to . . . an approximate \$17 million decrease in sales due to the cessation of certain identified U.S. wholesaler sales practices[.]”

269. On February 24, 2026, the Company filed its Form 10-K for the year ended December 31, 2025. In that filing, the Company disclosed that the SEC “opened an investigation” into the Class Period channel stuffing conduct. The Company further disclosed that it “intends to cooperate with any inquiries from the SEC or any other regulatory authorities.”

## VIII. SUMMARY OF SCIENTER ALLEGATIONS

270. At all relevant times, Defendants acted with scienter. As set forth below, the Individual Defendants and Organon knew or recklessly disregarded the truth about Nexplanon sales, the risk of a generic Nexplanon product entering the market, and the impact of these and other capital expenditure issues on the Company's free cash flow and continued ability to pay a robust shareholder dividend. Organon possesses the scienter of its management-level employees, including each of the Individual Defendants and executives who facilitated the channel stuffing scheme. When viewed holistically, these facts support a strong inference of scienter.

271. *First*, Defendant Ali abruptly resigned without severance or equity payouts when Organon's pull-forward sales practices were disclosed to investors and the Company terminated the Head of U.S. Commercial & Government Affairs—a senior-level executive of the Company since its founding. Organon also disclosed that Defendant Ali “applied inappropriate pressure to achieve sales targets,” “engaged in inappropriate business conduct that violated the Company's Code of Conduct,” and “withheld [relevant information] from the Company's independent directors, the Audit Committee, and the independent registered public accounting firm[.]” Ultimately, after the Class Period, Organon revealed that the SEC initiated an investigation into the improper channel stuffing whose revelation resulted in the ouster of these two executives.

272. The timing and circumstances of Defendant Ali's departure and the termination of the Head of U.S. Commercial & Government Affairs, coupled with Organon's damning admissions about their conduct, support the inference that they knew of or recklessly disregarded Organon's use of secret pull-forward sales and wholesaler kickbacks to artificially increase Nexplanon revenues and create the appearance of increased demand. Indeed, Ali appears to have spearheaded these very practices, and it is inconceivable that he and other senior executives did not have direct awareness of the practices given their nature, length, and purpose: sales of Nexplanon over six quarters in three years to two U.S. wholesalers—who received kickbacks and other benefits in exchange for purchasing product they did not want or need—to enable Organon to satisfy internal and external sales expectations.

273. *Second*, Nexplanon and the quarterly shareholder dividend were significant focuses for the Company, and Defendants spoke about both issues frequently on earnings calls throughout the Class Period. Indeed, Defendants' own statements concede that Organon viewed these issues as critical to generating and maintaining investor interest in the Company. For example, Defendants repeatedly described the shareholder dividend to investors as Organon's "number one capital allocation priority." Furthermore, Defendant Walsh acknowledged on the Company's November 3, 2022, earnings call that the shareholder dividend payments were "[p]art of the Organon investment thesis for stakeholders." Similarly, on the Company's February

15, 2024, earnings call, Defendant Walsh conceded that “[f]ree cash flow generation is obviously important to the investment thesis of Organon.” Regarding Nexplanon, Defendant Ali twice described Nexplanon as Organon’s “key product,” in conference remarks on January 10, 2022, and on January 10, 2023. Similarly, Defendant Ali referred to Nexplanon as the Company’s “most important product” at the 2025 JP Morgan Healthcare Conference.

274. **Third**, Nexplanon and the dividend were “core matters” of central importance to Organon, and thus Plaintiff has also established scienter by way of the core operations inference. For example, an Evercore analyst referred to Nexplanon as the Company’s “biggest product.” Analysts also remarked on the centrality of the dividend to Organon’s investment story. As another example, an analyst at Evercore remarked, “[i]t’s nice to hear mgmt confidence and reiteration of commitment to [the] dividend,” after Organon’s February 15, 2024, fourth-quarter 2023 earnings call, in which Defendant Ali discussed Organon’s commitment to the dividend. As a manufacturer and marketer of drugs and biosimilars requiring FDA approval, Organon possessed sophisticated knowledge of the patent and regulatory issues determining the exclusivity of drugs.

275. **Fourth**, as Organon’s senior-most officers, the Individual Defendants exercised control over and were responsible for the material misstatements alleged herein, by virtue of their positions within the Company. Accordingly, the Individual

Defendants knew, or were deliberately reckless in not knowing, that the adverse, undisclosed facts alleged herein had not been disclosed to the public, such that the representations made to investors were materially false and misleading, or omitted facts necessary to render those statements not misleading.

276. *Fifth*, the Individual Defendants' compensation was predominately tied to performance-based targets, which further incentivized them to engage in the fraud. As noted above with respect to the 2023, 2024 and 2025 annual proxy statements, the majority of the Individual Defendants' compensation was tied to metrics derived from the Company's sales and revenues, which inherently incorporated Nexplanon's U.S.-based sales and revenues. The Individual Defendants were thus motivated to disseminate and perpetuate false and misleading statements intended to increase the stock price, and for Defendant Ali to facilitate, direct, or disregard six quarters of improper sales practices relating to Nexplanon. This misconduct not only allowed Nexplanon to achieve internal and external sales targets, but also increased overall sales and revenues for the Company, which, in turn, made it easier for the Individual Defendants and other named executive officers to achieve the performance-related targets associated with their compensation.

## **IX. LOSS CAUSATION**

277. As detailed herein, Defendants engaged in a scheme to deceive the market and a reckless, if not purposeful, course of conduct which artificially inflated the price

of Organon stock and operated as a fraud or deceit on Class Period purchasers, including Lead Plaintiff.

278. During the Class Period, Defendants made materially false and misleading statements regarding the most critically important aspects of Organon's operations, including Nexplanon's LOE, customer demand, revenue, and growth, and the health and sustainability of the Company's quarterly dividend. These representations had the intended effect of artificially increasing the price of Organon stock, damaging investors—who were unaware of the misstatements when purchasing the stock.

279. Defendants disseminated these misrepresentations from the Class Period's start on November 3, 2022, until its end, on October 26, 2025. As explained above, Organon's announcement of the dividend cut resulted in a 27% stock price decline from April 30, 2025, to May 1, 2025, as the market began to appreciate that Organon's increasingly precarious financial condition and slowing growth required an adjustment of capital allocation priorities.

280. The stock price continued to decline on May 2, 2025, on news of heightened risks surrounding Nexplanon's LOE. These new developments included Organon's receipt of a Paragraph IV Certification Letter, notifying it that Xiromed had filed an ANDA to the FDA seeking to market a generic version of Nexplanon in the U.S. before the Nexplanon patents expired. These developments also included Organon's submission of its Citizen Petition to the FDA, challenging aspects of the Draft

Guidance—including the reduced criteria associated with bringing a generic drug to market. These developments implicated the FDA’s Response Letter, in which it expressed an intent to delay any determination of the Citizen Petition—and thus deprive the Company of any relief in the short term.

281. The stock price declined by another 23% on October 27, 2025, when Organon revealed that Defendants had engaged in stuffing Nexplanon sales channels for six quarters—including the first three quarters of 2025. This improper conduct, which involved supplying incentive-based kickbacks to two U.S. wholesalers, led to Defendant Ali’s resignation and the termination of another senior executive. This conduct also required the Company to acknowledge that it had long misrepresented critical information about Nexplanon’s demand, sales, revenues, and growth and the adequacy of the Company’s internal controls.

282. When the misrepresentations and fraudulent conduct were exposed and became apparent to the market, the trading price of the stock fell precipitously as the artificial inflation dissipated and otherwise was removed. As a result of their Class Period purchases, Lead Plaintiff and other Class members suffered economic loss, *i.e.*, damages, under the federal securities laws. Accordingly, Defendants’ wrongful conduct directly and proximately caused these losses and damages, which this action seeks to recover.

## **X. PRESUMPTION OF RELIANCE**

283. To the extent that Lead Plaintiff alleges that Defendants made affirmative misstatements, Lead Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

- a. Defendants made public misrepresentations or statements that became inaccurate or misleading by failing to disclose material facts during the Class Period;
- b. the omissions and misrepresentations were material;
- c. Organon's common stock traded in an efficient market;
- d. the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of Organon common stock;
- e. Lead Plaintiff and other members of the Class purchased Organon common stock between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts;
- f. Organon common stock met the requirements for listing, and was listed and actively traded on the NYSE, a highly efficient and automated market;
- g. as a regulated issuer, Organon filed periodic public reports with the SEC and the NYSE;

- h. Organon regularly communicated with investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;
- i. Organon was followed by securities analysts employed by major brokerage firms who wrote reports, which were distributed to those brokerage firms' sales forces and certain customers and that were publicly available and entered the public marketplace; and
- j. unexpected material news about Organon was reflected in and incorporated into the Company's stock price during the Class Period.

284. As a result of the foregoing, the market for Organon common stock promptly digested current information regarding the Company from all publicly available sources and reflected such information in the price of Organon common stock. All persons and entities who or which purchased or otherwise acquired Organon common stock during the Class Period suffered similar injuries through their purchases of Organon common stock at artificially inflated prices, and thus, the presumption of reliance applies.

285. A class-wide presumption of reliance is also appropriate under the United States Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*,

406 U.S. 128 (1972), to the extent the claims asserted herein against Defendants are predicated upon omissions of material fact for which there is a duty to disclose.

## **XI. CLASS ACTION ALLEGATIONS**

286. Lead Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class of all persons and entities who or which purchased or otherwise acquired the publicly traded common stock of Organon during the Class Period, from November 3, 2022, through October 26, 2025, inclusive, and were damaged thereby (the “Class”). Excluded from the Class are: (i) Defendants; (ii) members of the immediate family of any Defendant who is an individual; (iii) any person who was an officer, director, or control person of Organon during the Class Period and their immediate family members; (iv) any firm, trust, corporation or other entity in which any Defendant has or had a controlling or beneficial interest; and (v) the legal representatives, affiliates, subsidiaries, heirs, successors-in-interest, or assigns of any such excluded person or entity, in their capacities as such.

287. The members of the Class are so numerous that joinder is impracticable. During the Class Period, Organon had more than 250 million shares of common stock outstanding and actively trading on the NYSE. While the exact number of Class members is unknown to Lead Plaintiff at this time and can only be ascertained through appropriate discovery, Lead Plaintiff believes there are hundreds or thousands of members in the Class, and they are geographically dispersed. Record owners and other

Class members may be identified from records procured from or maintained by the Company or its transfer agent and may be notified of the pendency of this action using a form of notice similar to that customarily used in securities class actions.

288. Lead Plaintiff's claims are typical of the claims of the members of the Class. Lead Plaintiff and all other members of the Class purchased or otherwise acquired shares of Organon common stock during the Class Period and were similarly affected by Defendants' alleged conduct in violation of the Exchange Act as complained of herein.

289. Lead Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class action and securities litigation. Lead Plaintiff has no interests antagonistic to or in conflict with those of the Class.

290. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members, including:

- a. whether the federal securities laws were violated by Defendants' acts as alleged herein;
- b. whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Organon;

- c. whether the Individual Defendants caused Organon to issue false and misleading statements during the Class Period;
- d. whether Defendants acted knowingly or recklessly in issuing false and misleading statements;
- e. whether the prices of Organon stock during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- f. whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

291. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Because the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it exceedingly difficult, if not impossible and impracticable, for Class members to individually redress the wrongs alleged. There will be no difficulty in managing this action as a class action.

## **XII. THE INAPPLICABILITY OF THE STATUTORY SAFE HARBOR AND THE BESPEAKS CAUTION DOCTRINE**

292. The Private Securities Litigation Reform Act's statutory safe harbor and/or the "bespeaks caution doctrine" applicable to forward-looking statements under certain circumstances do not apply to any of the materially false or misleading statements alleged herein.

293. Statements complained of herein were not forward-looking statements. Rather, they were historical statements or statements of purportedly current facts and conditions at the time each statement was made and/or statements that omitted material current or historical facts necessary to make the statements made not misleading.

294. To the extent that any materially false or misleading statement alleged herein, or any portion thereof, can be construed as forward-looking, such statement was a mixed statement of present and/or historical facts and future intent, and is not entitled to safe harbor protection with respect to the part of the statement that refers to the present and/or past.

295. To the extent that any materially false or misleading statement alleged herein, or any portions thereof, may be construed as forward-looking, such statement was not accompanied by meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the statement or portion thereof. As alleged above in detail, given the then-existing facts contradicting Defendants' statements, any generalized risk disclosures made by Defendants were not sufficient to insulate Defendants from liability for their materially false or misleading statements.

296. To the extent that the statutory safe harbor may apply to any materially false or misleading statement alleged herein, or a portion thereof, Defendants are liable for

any such false or misleading statement because at the time such statement was made, the speaker knew the statement was false or misleading, did not actually believe the statement, had no reasonable basis for making the statement, or the statement was authorized and approved by an executive officer of Organon who knew that such statement was false or misleading.

### **XIII. CLAIMS FOR RELIEF UNDER THE EXCHANGE ACT**

#### **COUNT I**

##### **For Violation of Section 10(b) of the Exchange Act and Rule 10b-5(b) Against Defendants**

297. Lead Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

298. Lead Plaintiff asserts this Count on behalf of itself and all other members of the Class against Defendants for violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5(b) promulgated thereunder, 17 C.F.R. § 240.10b-5(b).

299. As alleged herein, throughout the Class Period, Defendants, individually and in concert, directly and indirectly, by the use of the means or instrumentalities of interstate commerce, the mails and/or the facilities of national securities exchanges, made untrue statements of material fact and/or omitted to state material facts necessary to make their statements not misleading and/or carried out a plan, scheme, and course of conduct, in violation of Section 10(b) of the Exchange Act and Rule 10b-5(b).

300. During the Class Period, Defendants disseminated or approved the false and/or misleading statements specified above, which they knew or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

301. As alleged herein, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(b) in that they made untrue statements of material facts and/or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading. Defendants intended to and did, as alleged herein: (i) deceive the investing public, including Lead Plaintiff and the other members of the Class; (ii) artificially inflate the price of Organon common stock and maintain the Company's common stock at artificially inflated prices; and (iii) cause Lead Plaintiff and the other members of the Class to purchase or otherwise acquire the Company's common stock at artificially inflated prices.

302. Defendants were individually and collectively responsible for making the materially false and misleading statements and omissions alleged herein. Defendants engaged in a plan, scheme, and course of conduct designed to deceive Lead Plaintiff and the other members of the Class, by virtue of making public statements and preparing, approving, signing, and/or disseminating documents that contained false

statements of material fact and/or omitted material facts necessary to make the statements therein not misleading.

303. As set forth above, Defendants made the materially false and misleading statements and omissions and engaged in the fraudulent activity described herein knowingly and intentionally, or in such a deliberately reckless manner as to constitute willful deceit and fraud upon Lead Plaintiff and the other members of the Class who purchased or otherwise acquired Organon common stock during the Class Period.

304. Lead Plaintiff and Class members have suffered damages in that, in ignorance of the materially false and misleading nature of Defendants' statements and omissions, and in reliance on the integrity of the market, they paid artificially inflated prices for Organon stock. Lead Plaintiff and Class members would not have purchased Organon stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

305. As alleged herein, when the true facts were subsequently disclosed, or the risks concealed by Defendants' public statements materialized, the price of Organon's common stock declined precipitously. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiff and the other members of the Class suffered damages in connection with their purchases of Organon stock during the Class Period.

306. By reason of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they made untrue statements of material fact or

omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

307. This claim is timely within applicable statutes of limitations and repose.

## COUNT II

### **For Violation of Section 10(b) of the Exchange Act and Rule 10b-5(a) and (c) Against Defendants**

308. Lead Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth therein.

309. Lead Plaintiff asserts this Count on behalf of itself and all other members of the Class against Defendants for violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5(a) and (c), 17 C.F.R. § 240.10b-5(a), (c).

310. Defendants violated Section 10(b) of the Exchange Act and Rules 10b-5(a) and (c) in that they: (1) employed devices, schemes, and artifices to defraud; and (2) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon Lead Plaintiff and others similarly situated in connection with their purchases or acquisitions of Organon common stock during the Class Period in an effort to maintain artificially high market prices for Organon common stock.

311. Defendants, individually and in concert, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or of the mails, employed devices, schemes, and artifices to defraud and engaged and participated in a continuous course of conduct that operated as a fraud and deceit upon Lead Plaintiff

and the Class in connection with the purchases or acquisitions and sale of Organon common stock. This scheme: (i) deceived the investing public, including Lead Plaintiff and the Class, regarding, among other things, Organon's undisclosed use of channel stuffing to hit sales targets and maintain the appearance of rapidly growing Nexplanon sales; (ii) artificially inflated and maintain the market price of Organon common stock; and (iii) caused Lead Plaintiff and other members of the Class to purchase or acquire Organon common stock at artificially inflated prices and suffer losses when the true facts became known.

312. As part of their scheme to defraud investors in violation of Rules 10b-5(a) and (c), Defendants engaged in a fraudulent scheme by which, according to Organon, "certain wholesalers in the United States were asked to buy more Nexplanon than they needed 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." Organon also acknowledged that "the Company waived inventory management fee performance metrics associated with caps on days of inventory in exchange for such wholesalers accepting the Nexplanon sales," which "enabl[ed] the wholesalers to receive incentive fees from the Company that they otherwise would not have received." Organon also admitted that, "[a]s 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 [in which they pulled forward such purchases] until their days of inventory on hand were reduced to levels within the contractual range.”

313. These deceptive acts were part of a course of conduct that operated as a fraud and deceit upon Lead Plaintiff and others similarly situated in connection with their purchases or acquisitions of Organon common stock during the Class Period in an effort to maintain artificially high market prices for Organon common stock.

314. As described above, Defendants acted with scienter throughout the Class Period, in that they had actual knowledge of the misrepresentations or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and disclose the true facts, even though such facts were available to them. Defendants engaged in this misconduct to conceal Organon’s true Nexplanon sales from the investing public and to support the artificially inflated prices of the Company’s common stock.

315. Lead Plaintiff and the Class have suffered damages in that, in direct reliance on the integrity of the market, they paid artificially inflated prices for Organon common stock, and this artificial inflation was removed from the stock when the true facts regarding Defendants’ fraudulent course of conduct became known. Lead Plaintiff and the Class would not have purchased or acquired such stock at the prices they paid, or at all, had they been aware that the market prices for the stock had been artificially inflated by Defendants’ fraudulent course of conduct.

316. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiff and the other members of the Class suffered damages attributable to the fraud alleged herein in connection with their respective purchases or acquisitions of the Company's common stock during the Class Period.

317. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(a) and (c).

318. This claim is timely within applicable statutes of limitations and repose.

### **COUNT III**

#### **For Violation of Section 20(a) of the Exchange Act Against the Individual Defendants**

319. Lead Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

320. Lead Plaintiff asserts this Count on behalf of itself and all other members of the Class against the Individual Defendants for violations of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

321. Defendants Ali and Walsh, by virtue of their positions and specific acts described above, were, at the time of the wrongs alleged herein, controlling persons of the Company within the meaning of Section 20(a) of the Exchange Act.

322. By reason of their high-level positions of control and authority as Organon's most senior officers, Defendants Ali and Walsh had the authority to influence and control, and did influence and control, the day-to-day decision-making and activities

of Organon and its employees, and to cause Organon to engage in the wrongful conduct complained of herein. The Individual Defendants were able to influence and control, and did influence and control, directly and indirectly, the content and dissemination of the public statements made by Organon during the Class Period, thereby causing the dissemination of the materially false and misleading statements and omissions of material facts as alleged herein.

323. The Individual Defendants communicated with investors or the public on behalf of Organon during the Class Period. Defendants Ali and Walsh were provided with, or had unlimited access to, copies of the Company's press releases, public filings, and other statements alleged by Lead Plaintiff to be materially false or misleading prior to and/or shortly after these statements were made and had the ability to prevent the issuance of the statements or to cause the statements to be corrected. Therefore, Defendants Ali and Walsh were able to influence and control, and did influence and control, directly and indirectly, the content and dissemination of the public statements made by Organon during the Class Period, thereby causing the dissemination of the materially false and misleading statements and omissions of material facts as alleged herein.

324. The Individual Defendants had the power and influence, and exercised same, to cause Organon to engage in the misconduct and practices complained of herein.

325. By reason of such conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act.

326. As a direct and proximate result of the Individual Defendants' conduct, Lead Plaintiff and the other members of the Class suffered damages in connection with their purchases or acquisitions of Organon common stock.

327. This claim is timely within applicable statutes of limitations and repose.

#### **XIV. PRAYER FOR RELIEF**

328. WHEREFORE, Lead Plaintiff, individually, and on behalf of the proposed Class, respectfully prays for relief and judgment against Defendants as follows:

- a. determining that this action is a proper class action and certifying Lead Plaintiff as a class representative under Rule 23 of the Federal Rules of Civil Procedure and Lead Plaintiff's counsel as Class Counsel;
- b. awarding Lead Plaintiff and the Class compensatory damages against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, together with pre-judgment interest thereon;
- c. awarding Lead Plaintiff and the Class their reasonable costs and expenses incurred in this action, including, but not limited to, attorneys' fees and costs incurred by consulting and testifying expert witnesses; and

d. granting such other, further, and/or different relief as the Court deems just and proper.

**XV. JURY DEMAND**

Lead Plaintiff hereby demands a trial by jury of all issues so triable.

Dated: May 8, 2026

Respectfully submitted,

/s/ Christopher A. Seeger

---

**SEGER WEISS LLP**  
CHRISTOPHER A. SEGER  
STEPHEN A. WEISS  
JUSTIN M. SMIGELSKY  
55 Challenger Road, 6th Floor  
Ridgefield Park, NJ 07660  
Telephone: 973/639-9100  
cseeger@seegerweiss.com  
sweiss@seegerweiss.com  
jsmigelsky@seegerweiss.com

*Liaison Counsel*

**COHEN MILSTEIN SELLERS  
& TOLL PLLC**  
CAROL V. GILDEN (*pro hac vice*)  
200 S. Wacker Drive, Suite 2375  
Chicago, IL 60606  
Telephone: 312/357-0370  
cgilden@cohenmilstein.com

**COHEN MILSTEIN SELLERS  
& TOLL PLLC**  
S. DOUGLAS BUNCH (*pro hac vice*)  
NATHAN L. WEISER (*pro hac vice*)  
1100 New York Avenue, N.W., Suite 800  
Washington, DC 20005-3964  
Telephone: 202/408-4600  
dbunch@cohenmilstein.com

nweiser@cohenmilstein.com

BRENDAN R. SCHNEIDERMAN (*pro hac vice*)

88 Pine Street, 14th Floor

New York, NY 10005

Telephone: 212/838-7797

bschneiderman@cohenmilstein.com

– and –

**ROBBINS GELLER RUDMAN  
& DOWD LLP**

SAMUEL H. RUDMAN

JOSEPH RUSSELLO (*pro hac vice*)

JEREMY YOHANNAN (*pro hac vice*)

58 South Service Road, Suite 200

Melville, NY 11747

Telephone: 631/367-7100

srudman@rgrdlaw.com

jrussello@rgrdlaw.com

jyohannan@rgrdlaw.com

*Lead Counsel for Lead Plaintiff*