Christopher A. Seeger
Stephen A. Weiss
Justin M. Smigelsky
SEEGER WEISS LLP
55 Challenger Road, 6th Floor
Ridgefield Park, New Jersey 07660
(973) 639-9100

Local Counsel

Samuel H. Rudman
Mary K. Blasy
ROBBINS GELLER RUDMAN & DOWD LLP
58 South Service Road, Suite 200
Melville, New York 11747
(631) 367-7100

Attorneys for Plaintiff

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BARRY J. LERNER, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. ORGANON & CO., KEVIN ALI, MATTHEW WALSH and JUAN CAMILO ARJONA FERREIRA, Defendants.	No. CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS DEMAND FOR JURY TRIAL

Plaintiff, Barry J. Lerner ("Plaintiff"), individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and upon information and belief as to all other matters based on the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of U.S. Securities and Exchange Commission ("SEC") filings of Organon & Co. ("Organon" or the "Company"), the Company's press releases, analyst reports, media reports, and other publicly disclosed reports and information about the Company. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a securities class action on behalf of purchasers of Organon publicly traded securities between November 3, 2022 and April 30, 2025, both dates inclusive (the "Class Period"), seeking to pursue remedies under the Securities Exchange Act of 1934 (the "1934 Act").

JURISDICTION AND VENUE

2. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the 1934 Act, 15 U.S.C. §§78j(b) and 78t(a), and SEC Rule 10b-5, 17 C.F.R. §240.10b-5, promulgated thereunder. This Court has jurisdiction over the subject

matter of this action pursuant to 28 U.S.C. §1331 and §27 of the 1934 Act, 15 U.S.C. §78aa.

3. Venue is proper in this District pursuant to 28 U.S.C. §1391(b), and §27 of the 1934 Act, as Organon is headquartered in this District and many of the acts and practices complained of herein occurred in substantial part in this District.

4. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

5. Plaintiff Barry J. Lerner, as set forth in the certification attached hereto and incorporated by reference herein, purchased Organon securities during the Class Period and suffered damages as a result.

6. Defendant Organon is a Delaware Corporation headquartered in Jersey City, New Jersey. As of April 25, 2025, the Company had 260 million shares of its common stock issued and outstanding, which trade in an efficient market on the New York Stock Exchange ("NYSE") under the ticker symbol "OGN."

7. Defendant Kevin Ali ("Ali") is, and was at all relevant times, the Chief Executive Officer ("CEO") of Organon and a member of its Board of Directors.

8. Defendant Matthew Walsh ("Walsh") is, and was at all relevant times, an Executive Vice President and the Chief Financial Officer ("CFO") of Organon.

9. Defendant Juan Camilo Arjona Ferreira ("Ferreira") is, and was at relevant times, Organon's Head of Research & Development and Chief Medical Officer, having joined the Company in those capacities in 2023. Previously, he served as the Executive Director of Clinical Research at Merck & Co. ("Merck") from 2002-2014.

10. Defendants Ali, Walsh and Ferreira are collectively referred to herein as the "Individual Defendants." The Individual Defendants, together with Organon, are referred to herein as "Defendants."

11. Each of the Individual Defendants was directly involved in the management and day-to-day operations of the Company at the highest levels and was privy to confidential proprietary information concerning the Company and its business, operations, services, competition, acquisition plans, and present and future business prospects, as alleged herein. In addition, the Individual Defendants were involved in drafting, producing, reviewing, and/or disseminating the false and misleading statements and information alleged herein, were aware of, or recklessly disregarded, the false and misleading statements being issued regarding the Company, and approved or ratified these statements, in violation of the federal securities laws.

12. As officers and controlling persons of a publicly held company whose securities are registered with the SEC pursuant to the 1934 Act and trade on the NYSE, which is governed by the provisions of the federal securities laws, the Individual Defendants each had a duty to promptly disseminate accurate and truthful information with respect to the Company's operations, business, services, markets, competition, acquisition plans, and present and future business prospects. In addition, the Individual Defendants each had a duty to correct any previously issued statements that had become materially misleading or untrue, so that the market price of the Company's publicly traded common shares would be based upon truthful and accurate information. Defendants' false and misleading misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

13. The Individual Defendants, because of their positions of control and authority as officers and/or directors of the Company, were able to, and did, control the content of the various SEC filings, press releases, and other public statements pertaining to the Company during the Class Period. Each Individual Defendant was provided with copies of the documents alleged herein to be misleading before or shortly after their issuance, participated in conference calls with investors during which false and misleading statements were made, and/or had the ability and/or opportunity to prevent their issuance or cause them to be corrected. Accordingly,

each Individual Defendant is responsible for the accuracy of the public statements detailed herein and is, therefore, primarily liable for the representations contained therein.

14. Defendants are liable for: (i) making false statements; or (ii) failing to disclose adverse facts known to them about Organon. Defendants' fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Organon publicly-traded securities was a success, as it: (i) deceived the investing public regarding Organon's prospects and business; (ii) artificially inflated the price of Organon publicly-traded securities; (iii) kept the Company's corporate debt ratings up high enough to facilitate a $1 billion corporate debt private placement in May 2024 at a lucrative selling price; and (iv) caused Plaintiff and other members of the Class to purchase Organon publicly-traded securities at artificially inflated prices.

BACKGROUND TO THE CLASS PERIOD

15. Organon develops and delivers healthcare solutions through prescription therapies and medical devices in the United States and internationally. The Company's operations include three product portfolios of prescription medicines and medical devices: women's health (contraception and fertility drugs and devices), biosimilars (immunology and oncology drugs) and established brands (cardiovascular, respiratory, dermatology and non-opioid pain management drugs,

most of which lost exclusivity years ago and face generic competition), all of which operate through a single operating segment. The Company sells its products to drug wholesalers and retailers, hospitals, clinics, government agencies, health maintenance organizations, pharmacy benefit managers, and other institutions.

16. Organon's women's health division specializes in a category of Long-Acting Reversible Contraception products, referred to as "LARCs," which are highly effective forms of birth control that last for several years and can be reversed when a woman wishes to become pregnant. LARCs are known for their ease of use, high efficacy, and lower chance of user error compared to methods like birth control pills. Organon's leading LARC, Nexplanon, is a contraceptive implant that is inserted under the skin of the upper arm and provided continuous pregnancy prevention for up to three years at the start of the Class Period. However, the Company was then developing and seeking regulatory approval to market a longer lasting version that could be used for up to five years.

17. Industry practice and government regulations in the United States and most foreign countries provide for the determination of effectiveness and safety of new chemical compounds suitable for pharmaceutical use through pre-clinical tests and controlled clinical evaluation. Before a new drug may be marketed in the United States, recorded data on pre-clinical and clinical investigations are included in a New Drug Application ("NDA") for a drug or a Biologics License Application ("BLA")

for a biologic (or generic), and submitted to the U.S. Food and Drug Administration ("FDA") for the required approval. Obtaining regulatory approval to manufacture and sell a new drug or device through the NDA process is the longer, more arduous and expensive process.

18. It is typically much less burdensome, and thus less costly, to get a biosimilar or a generic drug approved. A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product (the original biologic). The FDA has an abbreviated pathway for the approval of biosimilars (the 351(k) pathway), which only requires demonstrating biosimilarity to another FDA-approved reference product. This pathway allows biosimilar manufacturers to avoid duplicating the extensive clinical trials required for a reference product, potentially leading to faster approval and increased patient access.

19. On May 13, 2011, the U.S. Food and Drug Administration ("FDA") granted an NDA to commercially manufacture and distribute Etongestrel (a form of progestin) in the form of an implant (or "rod") inserted and left in womens' upper arms, under the trade name Nexplanon. Then, on May 14, 2021, Organon was spun off from Merck in a spin-off transaction completed as a tax-free distribution to Merck shareholders, with each receiving one-tenth of an Organon share for each share of Merck then owned. Merck also licensed its Nexplanon patent rights to

Organon and the common stock of the new company, Organon, was listed on the NYSE, opening at $31 per share that day.

20. The spin-off transaction left Organon highly leveraged as Organon took on billions of dollars in additional debt in order to pay Merck a large, one-time dividend. But one of the reasons Organon stock traded at such a high premium compared to other healthcare stocks at the time of its spin-off from Merck was because Organon promised to pay an outsized dividend to its shareholders of more than $1 per share pursuant to what it would repeatedly refer to throughout the Class Period as its ***"#1 capital allocation priority***." Organon also promised to keep a debt to asset ratio (or "net leverage") of below 4x, something it would need to keep a sufficient corporate debt rating to accomplish, in order to lower its costs of capital. As such, continued strong sales growth of its key branded product offering, Nexplanon, was critical.

21. As it would continue to do throughout the Class Period, Organon represented then that the Nexplanon patent rights licensed from Merck on the rod in the spin-off would not expire until 2027, purportedly giving it exclusivity through that date. Additionally, the Company represented that the patent rights licensed from Merck for the key aspects of the Nexplanon applicator were valid through 2030. This exclusivity, Organon repeatedly claimed then and throughout the Class Period,

gave the Company significant pricing power over Nexplanon for at least the following six years by shielding it from competition.

22. Indeed, pharmaceutical companies routinely obtain patents to protect their innovations, including drug formulations, manufacturing processes, and devices. Those patents grant the holders exclusive legal right to the inventions, typically for 20 years from the filing date. Critically though, Organon merely had licensed the patent on the Nexplanon ***implant*** and the key aspects of the Nexplanon ***applicator***, not on the active drug, progestin (which is itself a synthetic form of progesterone).

23. Moreover, in reality, while Organon licenses its patent protection for the Nexplanon implant from Merck until 2027, and while a patent is still in effect, other companies generally cannot market a biosimilar version of a patented product, companies developing biosimilar versions of the Nexplanon implant can use legal and regulatory pathways to prepare for and potentially even launch competing products before or upon patent expiry. These legal pathways involve addressing patent challenges through litigation or settlement and seeking FDA approval via the abbreviated biosimilar pathway provided for in the Biologics Price Competition and Innovation Act ("BPCIA"), among other routes. Critically, as major purveyor of biosimilars itself, Organon and its senior executives were innately aware of the legal and regulatory risks, rights and responsibilities attenuating to biosimilars.

24. So in reality, while Organon then licensed its patent protection rights from Merck for the Nexplanon insert until 2027, and on the key aspects of its proprietary applicator until 2030, it was always true that other companies developing biosimilar versions of the Nexplanon implant could use legal and regulatory pathways to prepare for market entry of competing drugs and/or devices by addressing any patent challenges through litigation or settlement and seeking FDA approval via the abbreviated biosimilar pathway.

25. On August 5, 2022, the FDA issued a Draft Guidance addressing the submission of any abbreviated new drug applications ("ANDAs") for approval of bioequivalents to Etonogestrel (Nexplanon). The Draft Guidance (FDA Docket No. FDA-2007-D-0369-0653) stated, in pertinent part, that any proposed biosimilar 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 the arm, much less than the five year duration Organon was then seeking extended approval for. Instead, the Draft Guidance's "Recommended Studies" only required, in pertinent part, as follows:

One in vivo bioequivalence study with pharmacokinetic endpoints:

1. Type of study: In vivo bioequivalence study with pharmacokinetic endpoints
   Design: *6 months*, single-dose, randomized, parallel
   Strength: 68 mg/implant
   Subjects: Healthy premenopausal, non-pregnant females

Prerequisite: *Six months of in vitro etonogestrel drug release data* demonstrating comparable release profiles for the test product and the RS product should be available prior to administrating the test product in study subjects.

26. Thus, despite Defendants' claims and inferences to the contrary throughout the Class Period, in reality: (i) Organon did in fact then face significant loss of exclusivity ("LOE") and price deterioration risk as to Nexplanon sooner than Defendants' Class Period statements implied; (ii) as a result, Nexplanon sales growth might not be as strong as Defendants' Class Period statements implied; (iii) as a result, Organon was likely not on track to maintain the sub-4.0x debt leverage Defendants claimed; (iv) as a result, Organon would not be able to maintain its corporate debt ratings at a high enough level to keep its corporate capital costs as low as Defendants' Class Period statements implied; and (v) as a result, the Company would lack a reasonable basis to report its Class Period business metrics and financial projections.

MATERIALLY FALSE AND MISLEADING CLASS PERIOD STATEMENTS AND OMISSIONS

27. The Class Period starts on November 3, 2022. On that day, Organon issued a press release and conducted a conference call with investors and stock analysts to report and discuss the Company's third quarter 2022 financial results for the interim period ended September 30, 2022 ("3Q22"), and its fiscal 2022 ("FY22") guidance. In addition to emphasizing that "Women's Health grew 19%," and noting

that "[d]uring the third quarter of 2022, Nexplanon® (etonogestrel implant) grew 34% ex-FX, primarily driven by demand uptake in the United States as well as volume growth outside the United States," Organon updated its FY22 financial guidance, narrowing the range of its FY22 revenue guidance to $6.1 billion to $6.2 billion, blaming FX headwinds, but raising its Adjusted EBITDA margin range guidance to 35.5% to 34.5%. Purporting justifying that updated financial guidance, the release quoted Defendant Ali stating in pertinent part that the Company "continue[d] to build on [its] track record, demonstrating that Organon's ***existing portfolio can deliver sustainable growth***." The release also expressly stated as to Capital Allocation that: "Today, Organon's Board of Directors declared a quarterly dividend of $0.28 for each issued and outstanding share of the company's common stock."

28. During the conference call conducted that day, Defendant Ali opened his remarks again emphasizing the Company's purported "sustainable growth," stating in pertinent part as follows:

> We're building a company that we believe can deliver ***sustainable growth*** driven by the contributions of ***each of our three key franchises***. . . . This was also the first quarter during which we delivered more than $150 million of Nexplanon in the US, where the product grew 26%, and that is ***driven primarily by increased physician demand***.

29. In his opening remarks, Defendant Walsh emphasized how lack of LOE increased the Company's revenue growth, stating in pertinent part as follows:

> The impact of loss of exclusivity or LOE during the third quarter compared to last year was negligible. ***In the first half of this year, the majority of LOE exposure in the portfolio was coming from NuvaRing***. . . .
>
> ***. . . . The most significant LOEs facing the portfolio washed out prior to the spin-off, and we expect only modest new LOE exposure going forward.***
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> * * *
>
> So since the spin-off, we've said we could ***manage this business to very low single-digit erosion on the top line at constant currency***. We think we can deliver at least that performance over the intermediate term.
>
> And there's three reasons why we believe this. First, our actual revenue performance in the first five quarters since the spin-off has exceeded our expectations. Two, more than half of our Established Brands portfolio will have already gone through VBP in China by the end of this year. ***And three, there's very modest LOE left in the portfolio***.

30. Defendant Walsh then emphasized that the strong free cash flow of upwards of $1 billion per year would continue to support the outsized dividend, stating in pertinent part as follows:

> [N]et leverage was about 3.6 times as of September 30. Recall that at the time of the spin-off in 2021, we had a pro forma net leverage ratio of about 4.0 times. ***And we said then that we were targeting a leverage ratio of less than 3.5 times on a sustained basis***. So we've made progress on leverage reduction. . . .
>
> ***. . . . Part 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***.

31. Defendant Walsh then went on to emphasize that continuing to pay that outsized dividend remained the Company's primary capital allocation priority, and likewise promising to maintain the debt ratings, stating in pertinent part as follows:

> ***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. . . .***

32. On February 16, 2023, Organon issued a press release and conducted a conference call with investors and stock analysts to discuss its fourth quarter and FY22 financial results for the period ended December 31, 2022 ("4Q22"), and its fiscal 2023 ("FY23") financial guidance. In addition to highlighting that "Women's Health revenue increased 4% . . . driven by Nexplanon which increased 11%," the release emphasized that "Nexplanon's growth was primarily due to demand uptake and ***favorable pricing in the United States*** . . . ." The Company also provided the following FY23 financial guidance:

2023 Full Year guidance

Revenues	**$6.150 billion - $6.450 billion**
Adjusted Gross Margin	Low-mid 60% range
SG&A (as % of revenue)	Mid 20% range
R&D[1] (as % of revenue)	Upper single-digit
Adjusted EBITDA Margin	**31.0%-33.0%**
Interest	~$510 million
Depreciation	~$130 million
Effective Non-GAAP Tax Rate	19.0% - 21.0%
Fully Diluted Weighted Average Shares Outstanding	~$255 million

33. The release also affirmed the Company's continued capital allocation payment of the $0.28 per share dividend.

34. During the conference call held that day, Defendant Walsh opened his remarks emphasizing how the Company's purported continued ability to shield itself from competitive pricing forces supported its continued strong revenue growth, stating in pertinent part as follows:

> Starting with loss of exclusivity or LOE, for the full-year 2022, LOE impact was modest at about $30 million and it's coming mainly from NuvaRing's LOE in the United States. We didn't have any LOE impact in Established Brands this year. And as we've said before, the most significant LOEs facing the Established Brands portfolio washed out prior to the spin-off, and ***what we expect going forward is a cumulative few hundred million dollars of impact over the next several years***.

35. Defendant Walsh also emphasized that the continued low leverage on the balance sheet and strong cash flows supported the Company's ability to pay its outsized dividend, still its top capital allocation priority, and supported its continuing strong debt ratings, stating in pertinent part as follows:

> 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. . . . . [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***."
>
> * * *
>
> ***Our capital allocation priorities remain consistent with past communications. We will continue to prioritize servicing the current dividend, ...***

* * *

> ***[W]e expect to have significant remaining cash flow available as we continue to balance external growth opportunities against our commitment to our BB/Ba2 rating.***

36. Defendant Ali emphasized the strong Nexplanon sales growth remained on track to continue, such that Nexplanon was "***going to be our first $1 billion product essentially by the end of 2025***."

37. On May 4, 2023, Organon issued a press release and conducted a conference call with investors and stock analysts to report and discuss its first quarter 2023 ("1Q23") financial results and to largely confirm the prior FY23 financial guidance. The release also affirmed the Company's continued capital allocation payment of the $0.28 per share dividend.

38. During his opening conference call remarks, Defendant Ali emphasized that "[g]iven this solid performance, ***together with our visibility into the remainder of the year***, [we're af]firming our financial guidance for the full year," adding: "***We also continue to believe that NEXPLANON can achieve $1 billion in revenue by 2025***, which implies strong growth for the product over the coming years."

39. In his opening remarks, Defendant Walsh emphasized that Organon's "LOE was negligible in the first quarter," adding that "[o]verall, the financial impact of the market action is being realized ***within the parameters that we incorporated***

into our 2023 annual guidance that we previously provided and that we're affirming today."

40. In response to a stock analyst's question about the status of the development of a different product that the analyst questioned might "replace NEXPLANON when it goes LOE," Defendant Ali took the opportunity to emphasize that there was no risk of Nexplanon LOE before 2027 and that even then, due to difficulties manufacturing and complexities in teaching doctors to use the product, Nexplanon would not suffer "the standard kind of historical [pricing] rates," stating in pertinent part as follows:

> 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 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.

41. On August 8, 2023, Organon issued a press release and conducted a conference call with investors and stock analysts to report and discuss the Company's second quarter 2023 financial results for the interim period ended June 30, 2023 ("2Q23") and to update the FY23 financial guidance. In addition to

emphasizing that "Women's Health revenue increased 8% . . . driven primarily by a 12% ex-FX increase in Nexplanon," the FY23 revenue range guidance was increased from $6.150B - $6.450B to $6.250B-$6.450B, and the Adjusted EBITDA margin range was increased from 31.0%-33.0% to 31.5%-33.0%. The release also affirmed the Company's continued capital allocation payment of the $0.28 per share dividend. Defendant Ali opened his remarks on the call stating "[w]e continue to believe that ***Nexplanon will achieve $1 billion in revenue by 2025***," while Defendant Walsh claimed that ongoing low LOE exposure will "drive us towards that approximately ***$1 billion of free cash flow*** before one-time costs on an annual basis ***for 2023***."

42. On November 2, 2023, Organon issued a press release and conducted a conference call with investors and stock analysts to report and discuss the Company's third quarter 2023 financial results for the interim period ended September 30, 2023 ("3Q23") and to updating FY23 financial guidance. Narrowing the FY23 revenue range to between $6.15B and $6.25B and lowering Adjusted EBITDA margin range guidance to between 30.5% and 31.5%, the release quoted Defendant Ali stating the Company still "***expect[ed] to deliver mid-single digit revenue growth*** with the power of [its] existing portfolio" during FY23.

43. During his opening remarks, Defendant Ali again stated the Company had high visibility into Nexplanon demand and pricing and that "***[t]he initiatives undertaken will position Nexplanon for strong growth in 2024, and we expect to***

reach $1 billion run rate in 2025." Discussing FY23 guidance impacts, Defendant Walsh emphasized that "LOE impact ha[d] been minimal so far in 2023," and that Defendants then "***expect[ed] the year to finish similarly***."

44. On November 29, 2023, Defendants Ali and Walsh presented for Organon at the Piper Sandler Healthcare Conference. Asked to explain the current market trends for Nexplanon and why there had not yet been a bigger uptick in sales following the Supreme Court's *Dobbs* decision, Defendant Ali expressly emphasized that the business had been well managed since receiving it from Merck, and expressly emphasizing that "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 deserves."

45. And on January 9, 2024, Defendants Ali and Walsh presented for Organon at the JPMorgan Healthcare Conference, with Defendant Ali predicting FY24 would be: "a year of growth, stability, potentially focused on delevering, ***paying the dividend*** and ultimately gaining more, I think, shareholder, investor confidence." Then, asked by his JPMorgan host "***should we think of that as kind of a rock solid commitment to the dividend***?," Defendant Ali gave a single-word affirmative: "Yes." Asked again "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?," Defendant Ali responded affirmatively "I do believe that going forward, ***we're committed to the dividend***." Asked then by his JPMorgan host "what's a reasonable way to think about leverage targets for 2024?," Defendant Walsh confirmed: "***we've always said our #1 priority is the dividend***." Defendant Ali also confirmed that Nexplanon would "***get to a run rate of about $1 billion by the end of 2025***" and would "***continue to be a very key contributor of growth through the end of the decade***."

46. On February 15, 2024, Organon issued a press release and conducted a conference call with investors and stock analysts to discuss its fourth quarter and FY23 financial results for the period ended December 31, 2023 ("4Q23"), and its fiscal 2024 ("FY24") financial guidance. In addition to declaring the regular dividend of $0.28 per share as the Company's Capital Allocation, the release also provided the following FY24 financial guidance:

2024 Full Year Guidance

Revenues	**$6.2B-$6.5B**
Adjusted gross margin	61.0% - 63.0%
SG&A	$1.5B - $1.7B
R&D (excluding IPR&D)	$400M - $500M
Adjusted EBITDA margin	**31.0% - 33.0%**
Interest	~$520M
Depreciation	~$130M
Effective non-GAAP tax rate	18.5% - 20.5%
Fully diluted weighted average shares outstanding	~259M

47. Defendant Ali opened his remarks on the conference call that day emphasizing that "[a]t the end of 2024, we anticipate having Phase III data from our

5-year study," that "[i]f approved, that ***will give NEXPLANON 3 years of exclusivity*** on the 5-year efficacy claim in the U.S. market," which would also "***extend the growth ramp well past the $1 billion run rate we are aiming for in 2025.***"

48. During his opening remarks, Defendant Walsh again confirmed that as to FY24 free cash flow guidance, "[g]iven our adjusted EBITDA guide for 2024, these components would put us in the range of $1 billion of net free cash flow."

49. During the Q&A portion of the call, responding to an analyst's inquiry, Defendant Ali again explicitly declared: "***Yes, you heard me at JPM being very declarative that we are very committed to be able to service our dividend***." Asked then whether the FDA's August 2022 Draft Guidance would have any impact on the Company's LOE exposure and revenue targets for Nexplanon, Defendant Ali denied it would, stating in pertinent part: "***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***," and that "***[o]ur device, our applicator device has patent protection through 2030,***" such that "***[t]his 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.***" Defendant Ali closed his remarks that day even more adamant, stating in pertinent part as follows:

> 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***.

50. Despite being so confident about his legal conclusions expressed on the 4Q23/FY23 conference call with investors and stock analysts present, on March 5, 2024, unbeknownst to investors because Organon failed to publicly disclose it, the Company filed a so-called Citizen's Petition with the FDA requesting that the Agency require: (1) that approval of any bioequivalents to Nexplanon require clinical data demonstrating at least three years of clinical data (so the same length as the Nexplanon was then approved for use, which was soon going up to five years if approved) rather than the mere six months provided for in the FDA's August 5, 2022 Draft Guidance; (3) that any applicator and device design be equivalent to that approved for use with Nexplanon; (4) that physician and medical staff training required be equivalent to that provided for in the drug Nexplanon label; and (5) that the FDA's August 5, 2022 Draft Guidance be amended to reflect the same changes.

51. On May 2, 2024, Organon issued a press release and conducted a conference call with investors and stock analysts to report and discuss its first quarter 2023 financial results for the interim period ended March 31, 2024 ("1Q24") and affirming its FY24 financial guidance. In addition to emphasizing revenue growth

was "primarily driven by 34% ex-FX growth in Nexplanon," the release confirmed the Company payment of the quarterly dividend of $0.28 per share.

52. Defendant Ali opened his conference call remarks that day emphasizing 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***, make progress on achieving a leverage ratio below 4x by the end of 2024. . . ." Defendant Ali went on to laud the strength of the Company's long-term Nexplanon sales growth and to once again adamantly claim the exclusivity on Nexplanon was all but guaranteed through 2030, stating in pertinent part as follows:

> ***[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 5-year label in 2026. A differentiated label will give us 3 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.***
>
> ***Second, we have IP protection on aspects of the applicator device until 2030. We believe that any generic coming to market before then would have to develop their own device and training programs to go along with it. So it's not until 2030 when IP protection on both implant and device would have expired that we might see the market start to alter with a similar 5-year product and applicator.***

> ***And third, complex drug device combinations have demonstrated strong post-LOE performance, which could be due to the fact complex drug device development can pose significant challenges in terms of showing therapeutic equivalents. So overall, we're confident in the sales longevity of Nexplanon. And further, when competition does come, we do not expect a traditional generics erosion curve.***

53. Defendant Walsh went on to again emphasize that "***in 2024, we expect to reach approximately $1 billion of free cash flow. . . .***"

54. Asked later in the call specifically about the future of Nexplanon sales after fiscal 2025, Defendant Ali adamantly downplayed any risk of an LOE event or any price erosion prior to 2030, stating in pertinent part as follows:

> ***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.***

55. On May 7, 2024, corporate debt rating firm S&P assigned 'BB' issue-level ratings and '3' recovery ratings on Organon's to-be-issued $1.55B senior secured due 2031 and $500 senior secured due 2034. As to the "Key analytical factors" in its report, S&P represented based on its calculations, there was no risk of a "***hypothetical payment default in 2029, precipitated by a 50% decline in EBITDA from 2023 levels . . . . likely from*** price and volume compression in key established brand markets and ***generic competition for Nexplanon in the U.S.***'

56. On May 17, 2024, Organon completed a previously announced private placement of $500 million of its 6.750% senior secured notes due 2034 and $500 million of its 7.875% senior unsecured notes due 2034.

57. On August 6, 2024, Organon issued a press release and conducted a conference call with investors and stock analysts to report and discuss the Company's second quarter 2024 financial results for the interim period ended June 30, 2024 ("2Q24") and to update the FY24 financial guidance. In addition to emphasizing "a 13% ex-FX increase in Nexplanon," "narrowed [the FY24 revenue range] to $6.250 billion to $6.450 billion, mid-point of the range," and "Guidance range for Adjusted EBITDA margin (non-GAAP) affirmed at 31.0%-33.0%." In support of that guidance, the release quoted Defendant Ali stating Organon was still:

> ***[T]racking well to our 2024 objectives of delivering revenue growth at constant currency***, driving year-over-year EBITDA improvement ***and generating approximately $1 billion of free cash flow*** before one-time costs.

58. During the conference call that day, Defendant Ali opened his remarks emphasizing that "***[t]hat strong cash flow will provide financial flexibility to comfortably service our dividend, which is our number one capital allocation priority.***" Later in the call, while once again lauding the long-term strong sales growth in Nexplanon, Defendant Ali again expressly downplayed any potential loss of exclusivity risk through 2030, stating in pertinent part as follows:

> With regard to the Nexplanon five-year study, the study met its primary endpoints, 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***.

59. Defendant Walsh opened his remarks that day emphasizing "[t]his year, ***we're on track to deliver more balanced phasing of free cash flow*** between first half and second half," so that "***our full year expectation of approximately $1 billion in free cash flow before onetime items remains unchanged.***"

60. During the Q&A portion of the call, Defendant Ali responded to a question whether extending the authorized use of Nexplanon from three to five years would increase its pricing level stating in pertinent part as follows:

> ***[M]ore importantly, it really starts to give us a line of sight on the fact that this product 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.

61. On August 14, 2024, the FDA's CDER unit issued an Interim Response Letter to Organon's March 5, 2024 Citizen's Petition stating that the Agency had

been unable to reach a decision the Company's petition because it 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."

62. On September 18, 2024, Organon announced that it was acquiring a company called Dermavant for $1.2B, stating that Organon then "expect[ed] net leverage to be elevated above 4.0x as a result of the transaction," while simultaneously reassuring investors that "***[t]he transaction [was] not expected to result in a revision to Organon's capital allocation priorities.***"

63. On September 18, 2024, corporate debt rating firm S&P Global issued a press release entitled "Organon & Co. Outlook Revised To Negative; 'BB' Rating Affirmed," which demonstrated the firm (along with other investors) believed the Company had the long-term patent protection on the Nexplanon it claimed, stating in pertinent part that: "[t]he negative outlook ***reflects our expectation*** that the company will be increasingly acquisitive, as it seeks to diversify its portfolio and deepen its pipeline ahead of ***its 2027 patent expiration on its lead product, Nexplanon***, resulting in adjusted net leverage potentially above 4x."

64. On October 31, 2024, Organon issued a press release and conducted a conference call with investors and stock analysts to report and discuss the Company's third quarter 2024 financial results for the interim period ended

September 30, 2024 ("3Q24") and to update the FY24 financial guidance. In addition to increasing and narrowing the FY24 revenue guidance range to between $6.375B and $6.425B and revising the Adjusted EBITDA margin range to between 30.0% and 31.0%, and reporting the payment of the $0.28 per share dividend, the release quoted Defendant Ali stating in pertinent part as follows:

> 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.

65. Defendant Ali opened his remarks during the conference call that day emphasizing 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 enable[d] [it] to comfortably service the dividend.***" Defendant Ali further projected that "***[t]his 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***." Defendant Walsh then opened his remarks emphasizing that the Company remained "***well on track to deliver approximately $1 billion of free cash flow***" in FY24. "Closing out" his remarks, Defendant Walsh emphasized that "in 2024, we set ourselves up to deliver ***a trifecta of growth*** in revenue and EBITDA dollars, a leverage P&L ex-milestones, and ***$1 billion of free cash flow***," adding that "***we feel very good about our ability to deliver on that goal***."

66. On December 9, 2024, corporate debt rating firm S&P Global issued a press release entitled "Organon & Co.'s €726 Million Term Loan B Rated 'BB'." Demonstrating that the firm (along with the Company's investors) still believed Defendants' claims about the strength of its ability to avoid competitive pricing pressure on the Nexplanon, the release also stated in pertinent part as follows:

> Our 'BB' issuer credit rating on Organon continues to reflect the company's ***solid women's health franchise anchored by its lead product, Nexplanon***, good geographic and product diversification, and our expectation for S&P Global Ratings-adjusted ***net leverage to decline below 4x before the end of 2025*** despite an active mergers and acquisitions (M&A) appetite. Our negative outlook highlights the risk that adjusted leverage could remain above 4x, ***due to*** potential further M&A and ***possible operating shortfalls as the company approaches the 2027 patent expiration on Nexplanon***.

67. On January 13, 2025, Defendants Ali and Walsh presented for Organon at the JPMorgan Healthcare Conference. Defendant Ali opened his remarks lauding how strong the Nexplanon long-term sales growth prospects were while lamenting that "as we start to exit 2024 and we start to look at 2025, the most important thing to know is that, as we go into 2025, we're kind of focusing on dealing with essentially a loss of exclusivity event for Atozet, which is our second largest product," going on to remark that "our vision right now is to essentially offset, do our best to offset that LOE event in 2025 in this year through the process of continuing growth of our key product, Nexplanon. . . ." Asked by his JPMorgan host "what you see as the biggest growth driver is going to be this year?," Defendant

Ali responded lauding the expected continued strong Nexplanon sales, 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 a – we see the runway on this through the end of the decade. So if you're talking about -- if you're just 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.***

68. Asked next by his JPMorgan host to comment as to any LOE risk as to Nexplanon, Defendant Ali once again adamantly denied the Company faced any reasonable risk of competition as to Nexplanon through the end of the decade, stating in pertinent part as follows:

> Yeah, that's a good question. I think the only benchmark I would use is let's look at Mirena. Very similar, except it's IUD. It's a medicated IUD device. We have something that goes in the arm. Now, very similar in the sense that we still don't see a generic of Mirena seven years post LOE.
>
> ***I think that you'd see something similar.*** It's still a $1 billion product, they don't put much effort at all behind it. As a matter of fact, there might be a -- one could say that they're actually not as much interested in Women's Health. ***But, nevertheless, it's a $1 billion product.***
>
> ***Now if we end up at a $1.6 billion, that means essentially we'll be the biggest contraception as 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.

69. Asked if he thought there was anybody working on a competing drug then, Defendant Ali flatly denied he believed there were any, without disclosing the Citizen's Petition Organon had itself filed in March 2024 seeking to address that very risk, despite having just received notice from the FDA in August 2024 that the FDA had found the Company's Citizen's Petition – which are usually addressed promptly by the FDA – was too complex to resolve yet and providing no determinative date upon which the Company could expect a response. He also went on to deflect when asked about foreign competition risk by claiming that other companies would need to address an unreasonably arduous process of getting FDA approval for their own applicator and FDA approval of their own physician and medical staff training, implying that he had a solid basis for mere legal conclusion as to how the FDA would resolve those issues. In that colloquy, Defendant Ali stated in pertinent part as follows:

Christopher Schott J.P. Morgan Securities LLC - Analyst

Yeah. Are you aware of anyone working on a generic in the US at this point?

Kevin Ali Organon & Co - Chief Executive Officer, Director

No. I mean, I've heard noises and -- ***but they've kind of gone quiet.***

Christopher Schott J.P. Morgan Securities LLC - Analyst

> Okay. Excellent. Maybe some more question ex-US. Is there expectation that you could see a generic coming in ex-US this year or …
>
> **Kevin Ali Organon & Co - Chief Executive Officer, Director**
>
> Well, in Europe, we lose patent in 2025, and ***we haven't seen anything. Anything at all***. Now 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 application - 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.***
>
> **Christopher Schott J.P. Morgan Securities LLC - Analyst**
>
> There are a couple of hurdles here .
>
> **Kevin Ali Organon & Co - Chief Executive Officer, Director**
>
> ***I would say quite a few, yeah.***

70. Then on January 15, 2025, Organon announced that effective that same day, Susanne Fiedler, its Chief Commercial Officer had suddenly and without prior expectation stepped down.

71. On February 13, 2025, Organon issued a press release and conducted a conference call with investors and stock analysts to discuss its fourth quarter and FY24 financial results for the period ended December 31, 2023 ("4Q24"), and its FY25 financial guidance. In addition to emphasizing that "Women's Health revenue increased 4%" and that "Nexplanon grew 17%," the Company also provided the following FY25 financial guidance:

2025 Full Year Guidance	
Revenues	**$6.125B-$6.325B**
FX translation headwind	~$200M
Adjusted gross margin	60.0%-61.0%
SG&A	Mid-20% range
R&D	Upper single-digit
Adjusted EBITDA margin	**31.0%-32.0%**
Interest	~$510M
Depreciation	~$135M
Effective non-GAAP tax rate	22.5%-24.5%
Fully diluted weighted average shares outstanding	~263M

72. Defendant Ali opened his remarks at the conference call that day emphasizing that FY24 had been "Nexplanon's best annual performance ever and ***positions the product to achieve at least $1 billion of revenue in 2025.***" He further remarked that the Company "remain[ed] very optimistic about the future of Nexplanon, ***especially with the potential of a five-year indication to sustain long-term Nexplanon growth***."

73. Defendant Ali also once again explicitly emphasized that Organon remained "***committed to our regular dividend as our number one capital allocation priority*** [and for] delivering on the promise of our growth products and pipeline," stating "***[t]his includes eclipsing the $1 billion mark for Nexplanon for the calendar year of 2025***."

74. During the Q&A portion of the call, Defendant Ali once again lauded the long-term sales growth potential of Nexplanon and denied any reasonable chance of there being a competitor on the horizon, despite the facts that the Company itself

had taken the highly-unusual first steps of filing a Citizen's Petition in March 2024, precisely because of the risk of a competitor coming on the scene only needing to provide six months of clinical data - as provided in the FDA's August 2022 Draft Guidance – and the FDA having expressly advised the Company in August 2022 that the issues raised in its Citizen's Petition were simply too complex to respond to in the typical time that the FDA resolves Citizen's Petitions – ***absolutely none of which had ever been affirmatively disclosed by the Company***. Specifically, Defendant Ali

> [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.***

75. Later during the Q&A portion of the call, Defendant Ali once again engaged with a stock analyst lauding the long-term sales growth potential of

Nexplanon ***even more than he had before, not disagreeing with the stock analyst that Nexplanon could produce double digit revenue growth through the end of the decade***, and again ***expressly denying there was any reasonable chance of their being a competitor on the horizon***, stating in pertinent part as follows:

> Yeah. Jason, in regards to your question on Nexplanon, ***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***. 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.***
>
> * * *
>
> ***As time goes on, you'll start to see the opportunities that do start to materialize for Nexplanon for us, at least for the end of the decade. I see it***. And thereafter, it could easily be longer. If you take the Mirena precedent, it could be significantly longer than that. But ***I'm going to be more responsible and say through the end of the decade***.

76. The statements referenced above in ¶¶ 27-32, 34-49, 51-54, 57-60, 62, 64-65, 67-69 and 71-75 were materially false and misleading when made because they misrepresented and failed to disclose the following adverse facts, which were known to Defendants or recklessly disregarded by them:

(a) Organon faced a higher risk of LOE and price erosion as to Nexplanon than implied by its Class Period statements;

(b) as a result, Organon's long-term Nexplanon sales growth was not as strong as Defendants' portended during the Class Period, and would not reach $1 billion by the end of FY25 (much less upwards of $1.5 billion after that), and the

Company was likely not on track to achieve the $1 billion milestone payment from Merck on its Nexplanon sales thereafter;

(c) as a result, Organon was not on track to achieve, much less maintain, the $1 billion in free cash flow required to sustain its outsized dividend;

(d) as a result, Organon was also not on track to maintain 4.0x debt leverage;

(e) as a result, Organon might not be able to maintain its corporate debt ratings at their then-current Class Period levels; and

(f) as a result, the Company lacked a reasonable basis to report its Class Period business metrics and financial projections.

THE TRUTH BEGINS TO BE REVEALED

77. On April 2, 2025, Organon filed a patent enforcement action against Xiromed/Insud for infringement of Nexplanon patents on both "(1) a matchstick-sized, radiopaque implant containing etonogestrel, a synthetic hormone that prevents pregnancy by inhibiting ovulation, and (2) a novel applicator device used to insert the implant subcutaneously at the proper location in the upper arm." *See MERCK SHARP & DOHME B.V. et al v. XIROMED PHARMA ESPAA, S.L. et al*, Dist. NJ No. 25-cv-02254-CCC, "Complaint for Patent Infringement, filed April 2, 2025. According to its complaint, "By a letter dated February 20, 2025 . . . ., Xiromed notified [Organon] that Xiromed had submitted to the FDA Xiromed's ANDA for

approval to market and sell in the United States a purported generic version of NEXPLANON. . . ."

78. On May 1, 2025, in connection with announcing its first quarter 2025 financial results for the interim period ended March 31, 2025 ("1Q25"), Organon shocked the investment community by slashing its dividend by 90%, down from 28¢ per share per quarter ($1.16 per share annually) down to just 2¢ per share per quarter (or 8¢ per share annually). According to a quote attributed to Defendant Ali in the press release Organon issued that day, it 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," emphasizing that the Company's "primary capital allocation priority" was now "maintaining lower leverage."

79. In his opening remarks during the call that day, Defendant Walsh admitted that the Company ***needed*** to slash the dividend in order to effectively manage its debt load and grow revenue from other products, stating in pertinent part as follows:

> ***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***, and so returning capital to shareholders is right now ***less of a priority***.

80. During the Q&A segment of the call, Defendant Walsh again reiterated 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," again emphasizing "***we need capital to solve both of those issues***."

81. The investment community was incensed and the market price of Organon common stock cratered, ***falling more than $3 per share – or 27%*** – from its close of $12.90 per share to close down at $9.45 per share on May 2, 2025, with more than 31 million shares trading, or seven times the average daily volume over the preceding ten trading days.

82. On May 2, 2025, in connection with filing its 1Q25 quarterly financial report with the SEC on Form 10-Q, the Company finally disclosed that on April 2, 2025, Organon had sued Xiromed for patent infringement in this District, "triggering a stay of regulatory approval of Xiromed's ANDA for up to 30 months." The market price of Organon common stock traded even lower on this news, closing down at $8.70 per share on Monday, May 5, 2025, when the stock resumed trading.

83. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's common shares, Plaintiff and other Class members have suffered significant losses and damages.

84. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Organon securities, by publicly issuing false and misleading statements and omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and misleading. Said

statements and omissions were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company, its business and operations, as alleged herein.

85. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused, or were a substantial contributing cause, of the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false or misleading statements about Organon's business, prospects, and operations. These material misstatements and omissions had the cause and effect of creating, in the market, an unrealistically positive assessment of Organon and its business, prospects, and operations, thus causing the Company's stock to be overvalued and artificially inflated at all relevant times. Defendants' materially false and misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's stock at artificially inflated prices, thus causing the damages complained of herein. When the true facts about the Company were revealed to the market, the inflation in the price of Organon stock was removed and the price of Organon securities declined dramatically, causing losses to Plaintiff and the other members of the Class.

86. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of Organon securities, Plaintiff and other Class members (defined below) have suffered significant losses and damages.

ADDITIONAL SCIENTER ALLEGATIONS

87. As alleged herein, Organon and the Individual Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading, knew that such statements or documents would be issued or disseminated to the investing public, and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, these Defendants, by virtue of their receipt of information reflecting the true facts regarding Organon, their control over, and/or receipt and/or modification of Organon's allegedly materially misleading statements and/or their associations with the Company, which made them privy to confidential proprietary information concerning Organon, participated in the fraudulent scheme alleged herein.

88. Defendants were further incentivized to mislead investors about all they knew about the Company's true business metrics and financial prospects during the Class Period in order to keep the Company's corporate debt ratings up high enough to facilitate the May 2024 $1 billion corporate debt private placement.

LOSS CAUSATION/ECONOMIC LOSS

89. During the Class Period, as detailed herein, Defendants made false and misleading statements by misrepresenting the Company's business and prospects and engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Organon securities and operated as a fraud on Class Period purchasers of Organon securities. Later, when Defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the price of Organon securities fell precipitously, as the prior artificial inflation came out. As a result of their purchases of Organon securities during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

NO SAFE HARBOR

90. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pled in this Complaint. Many of the specific statements pled herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pled herein,

Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Organon who knew that those statements were false when made.

APPLICABILITY OF THE PRESUMPTION OF RELIANCE AND FRAUD ON THE MARKET

91. 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 failed to disclose material facts during the Class Period;

(b) The omissions and misrepresentations were material;

(c) Organon stock traded in an efficient market;

(d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of Organon stock; and

(e) Plaintiff and other members of the Class purchased Organon securities 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.

92. At all relevant times, the market for Organon securities was efficient for the following reasons, among others:

(a) Organon securities met the requirements for listing, and was listed and actively traded on the NYSE, a highly efficient, national stock market;

(b) As a regulated issuer, Organon filed periodic public reports with the SEC; and

(c) Organon regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services.

93. Plaintiff and the Class are also entitled to a presumption of reliance under *Affiliated Ute Citizens v. United States*, 406 U.S. 128 (1972), because the claims asserted herein against defendants also include omissions of material fact for which there was a duty to disclose.

CLASS ACTION ALLEGATIONS

94. 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 consisting of all those who purchased the securities of Organon during the Class Period and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families

and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

95. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Organon shares were actively traded on the NYSE. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Organon or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

96. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

97. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

98. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(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; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

99. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I

Violation of §10(b) of the 1934 Act and Rule 10b-5 Promulgated Thereunder Against All Defendants

100. Plaintiff incorporates ¶¶1-99 by reference as if fully set forth herein.

101. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or deliberately 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.

102. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

(a) employed devices, schemes, and artifices to defraud;

(b) made untrue statements of material facts 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; or

(c) engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Plaintiff and others similarly situated in connection with their purchases of Organon securities during the Class Period.

103. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Organon securities. Plaintiff and the Class would not have purchased Organon securities 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.

104. As a direct and proximate result of these Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their purchases of Organon securities during the Class Period.

COUNT II

Violation of §20(a) of the 1934 Act Against All Defendants

105. Plaintiff incorporates ¶¶1-104 by reference as if fully set forth herein.

106. The Individual Defendants acted as controlling persons of Organon within the meaning of §20(a) of the Exchange Act. By reason of their positions as officers and/or directors of Organon, and their ownership of Organon stock, the Individual Defendants had the power and authority to cause Organon to engage in the wrongful conduct complained of herein. Organon controlled each of the Individual Defendants and all of its employees. By reason of such conduct, the Individual Defendants and Organon are liable pursuant to §20(a) of the 1934 Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

A. Designating Plaintiff as Lead Plaintiff and declaring this action to be a class action properly maintained pursuant to Rule 23 of the Federal Rules of Civil Procedure and Plaintiff's counsel as Lead Counsel;

B. Awarding compensatory damages in favor of plaintiff and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper, including permitting any putative Class members to exclude themselves by requesting exclusion through noticed procedures.

JURY DEMAND

Plaintiff hereby demands a trial by jury.

DATED: July 8, 2025

SEEGER WEISS LLP

s/ *Christopher A. Seeger*

CHRISTOPHER A. SEEGER
STEPHEN A. WEISS
JUSTIN M. SMIGELSKY
55 Challenger Road, 6th Floor
Ridgefield Park, New Jersey 07660
Telephone: 973/639-9100
Facsimile: 973/679-8656
cseeger@seegerweiss.com
sweiss@seegerweiss.com
jsmigelsky@seegerweiss.com

ROBBINS GELLER RUDMAN
& DOWD LLP
SAMUEL H. RUDMAN
MARY K. BLASY
58 South Service Road, Suite 200
Melville, New York 11747
Telephone: 631/367-7100
srudman@rgrdlaw.com
mblasy@rgrdlaw.com

Attorneys for Plaintiff

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that aspects of the matter in controversy in this action are currently the subject of pending litigation in the following case: *Hauser v. Organon & Co.*, No. 2:25-cv-05322 (D.N.J.).

To the best of my knowledge, the matter in controversy in this action is not the subject of any pending arbitration or administrative proceeding.

I certify under penalty of perjury that the foregoing is true and correct.

DATED: July 8, 2025

SEEGER WEISS LLP

s/ *Christopher A. Seeger*
CHRISTOPHER A. SEEGER

55 Challenger Road, 6th Floor
Ridgefield Park, New Jersey 07660
Telephone: 973/639-9100
Facsimile: 973/679-8656
cseeger@seegerweiss.com