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Organon & Co. (OGN)

Q3 2025 Earnings Call

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Joseph T. Morrissey
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MANAGEMENT DISCUSSION SECTION

Operator: Hello and welcome to the Organon Third Quarter 2025 Earnings Call and Webcast. All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question-and-answer session. [Operator Instructions]

I would now like to turn the conference over to Jennifer Halchak, Vice President, Investor Relations. You may begin.

Jennifer Halchak
Vice President-Investor Relations, Organon & Co.

Thank you, operator. And good morning, everyone. Today we will be referencing a presentation that is visible during this call for those of you on our webcast, this presentation will also be available following this call on the Events & presentations section of our Organon Investor Relations website. Please reference slides 2 and 3 for some brief reminders.

I would like to caution listeners that certain information discussed by management during this call will include forward-looking statements. Forward-looking statements can be identified because they do not relate strictly to historical or current facts and use words such as potential, should, will, continue, expects, believes, future, estimates, believes, and other words of similar meaning.

Actual results could differ materially from those stated or implied by forward-looking statements through the risks and uncertainties associated with the company's business, which are discussed in the company's filings with the

SEC. This includes our most recent Form 10-K and Forms 10-Q and those amended forms that we filed earlier this morning, as well as our October 27, 2025 Form 8-K. These statements are based on information as of today, November 10, 2025, and except as required by law, Organon undertakes no obligation to update or revise any of these forward-looking statements.

In addition, we will discuss certain non-GAAP financial measures on this call, which should be considered a supplement to and not a substitute for financial measures prepared in accordance with GAAP. Descriptions of these measures and reconciliations to the comparable GAAP measures are included in today's earnings press release and conference call presentation, both of which are available on our Investor Relations website and have been furnished to the SEC on a current report on Form 8-K.

I note that while our full year 2025 guidance measures other than revenue are provided on a non-GAAP basis, Organon does not provide GAAP financial measures on a forward-looking basis because we cannot predict with reasonable certainty and without unreasonable effort the ultimate outcome of those legal proceedings, unusual gains and losses, the occurrence of matters creating GAAP tax impacts and acquisition-related expenses. These items are uncertain, depend on various factors and could be material to our results computed in accordance with GAAP.

On the call today Carrie, Joe and Matt will address certain information about our internal investigation. Additional information about the investigation is available in our SEC filings. Beyond the statements today and the information in our filings, we will not be taking questions on the investigation. Today, the team will discuss our business, third quarter results and guidance, and they will take questions on those matters after their prepared remarks.

And now I'll turn the call over to Carrie.

Carrie Smith Cox

Executive Chairman, Organon & Co.

Thank you, Jen. Hello, everyone, and thank you all for joining us today.

I've had the privilege of serving as Board Chair of Organon since 2021. I've been in the pharma industry now over four decades, and about half of those years were spent in global leadership roles, which required navigating businesses through periods of transformation and growth. A good part of that experience was leading Schering-Plough global pharmaceutical until the merger with Merck. So, I have a deep understanding of many of our products and markets here at Organon.

Since Organon's inception, our mission has been to deliver impactful medicines and solutions for a healthier every day. There is a shared passion at Organon to advance the complete health of women at all stages of her life and that's what drew me to Organon from the beginning. While we focus on Women's Health, we also have a diverse portfolio of Biosimilars and Established Brands that are important in markets around the world.

I'm here today because I have assumed a new role at Organon as Executive Chair, following the board's investigation into the company's improper sales practices with two distributors, with respect to US sales of an Nexplanon. I will be supporting Joe Morrissey, who I will speak about in a minute as our Interim CEO. The board has formed a search committee and will be conducting a search for our permanent CEO.

In this role, my focus will be on working closely with our leadership team to ensure that we align our resources to our highest priorities and drive operational performance across the portfolio. I will be deeply engaged in

monitoring progress, addressing challenges quickly, and ensuring that every part of the business is working towards our shared goals.

The independent internal investigation relating to the company's Nexplanon sales to wholesalers in the US is complete and our remediation efforts are underway, including enhanced controls, certain personnel actions, additional training and expanded written procedures. The company's wholesaler sales practices identified through this investigation have ceased and we have new leadership at the company and in our US commercial sales area to ensure this does not happen again.

The board and I are confident that Joe is the right person to assume the role of Interim CEO of Organon and to oversee the remediation measures. He brings integrity, a strong focus on operational excellence and a deep commitment to executing our strategy. Joe came to Organon from Merck, where he spent more than 30 years. At Organon he was already a member of the executive leadership team and has served as head of global manufacturing and supply chain since Organon's inception, leading the company's efforts to deliver medicines and solutions around the world. We appreciate Joe agreeing to step in at this critical juncture.

Importantly, I want to stress that our drive for operational excellence and meeting our goals to move our company forward into the future remains unchanged.

With that said, I'll hand it over to Joe so that he can talk a bit about his and Organon's strategic priorities.

Joseph T. Morrissey

Interim Chief Executive Officer, Organon & Co.

Thank you, Carrie. I appreciate the introduction and the opportunity to speak with everyone today. As Carrie mentioned, I spent more than three decades at Merck, where I led a number of manufacturing businesses, as well as corporate strategy. That experience, combined with my deep understanding of our products, our markets and our supply chains made joining Organon a natural step, as I was excited to build something meaningful from the ground up, leveraging our strong history.

We have faced many challenges in these first 4.5 years, but we have a resilient and capable global team. Our diverse product portfolio and footprint help us to generate meaningful revenue and deliver real value to patients and communities around the world.

As Carrie has said, our strategic priorities have not changed. Moving forward, we remain focused on executing against these priorities. As we've previously shared, these include deleveraging the business, driving cost savings and achieving revenue growth. I believe deeply in Organon's mission, our values and our people around the world. I'm fully committed to helping Organon succeed.

And with that, I hand it over to Matt.

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

Thank you, Joe.

Beginning on slide 4. Third quarter revenue was $1.6 billion and adjusted EBITDA was $518 million, representing an adjusted EBITDA margin of 32.3%. Before I go deeper into a discussion of third quarter results, I'd like to spend a minute walking through some specifics about the company's US wholesaler sales practices that Carrie

referenced. It's important that investors understand this issue properly. There is limited revenue impact and no financial restatement is necessary. All revenue was properly recorded in accordance with US GAAP.

On slide 5. You'll see a summary of the revenue impact from these practices for the recent quarterly periods identified by the investigation. The revenue that we're highlighting is that of Nexplanon sales to two US wholesalers with specific emphasis on revenue transactions occurring close to quarter-end. Certain revenue transactions were advanced or pulled forward into the current quarter in excess of estimated patient demand and/or contractually agreed inventory holding levels.

For example, for the third quarter of 2024, on the left hand side of this chart. The sales practices in question resulted in approximately $5 million of pull-forward revenue from the fourth quarter of that year. In the fourth quarter of 2024, there was approximately $15 million pulled forward from the first quarter of 2025. So, the net impact in the fourth quarter of 2024 was $10 million. Importantly, because we're talking about the pull-forward of sales, these quarterly numbers are not cumulative. Our financial statements have been consistently reflecting the net impact, which is clearly not material to our consolidated revenue.

Three other important points to make here. First, revenue recognition in all cases was appropriately recognized in accordance with US GAAP, specifically Section ASC 606. Two, during these periods, product returns were at or below historical levels. And three, in every relevant period, the units that were pulled forward occurred late in the third month of that quarter and were absorbed through patient demand by approximately the end of the first month of the following quarter. Since this practice has ceased and will not continue in the future. We will see the most significant impact in the fourth quarter of this year because the $17 million pull-forward in Q3 2025 will not have an offsetting buy-in in Q4 2025. As a result, the pull-forward dynamic rolls off in the fourth quarter and will be contained within the 2025 fiscal year with no carryover impact to 2026.

One last point on this topic. In the 8-K filing on October 27, the financial impact of these practices for the relevant periods was described as being less than 1% of consolidated revenue for the full year 2022 and full year 2024, and less than 2% of consolidated revenue for the relevant quarterly periods. Subsequently, we have completed our testing and detailed reviews, resulting in the more narrow estimates that you see here on slide 5, which are clearly within the range as disclosed in the 8-K.

Now, moving to a discussion of third quarter 2025 results. To be clear, when I refer to revenue and revenue variances, unless otherwise noted, those references are to revenue recorded in our financial statements without adjusting to back out the pull-forward. So, let's go franchise by franchise and then we'll move to a discussion of revenue by driver.

So, turning to slide 6. The Women's Health franchise declined 4% at constant currency in the third quarter of 2025, compared with the third quarter of 2024, with growth in contraceptives, Marvelon, Mercilon and NuvaRing, partially offsetting a 9% decline in Nexplanon at constant currency. Global Nexplanon sales in the third quarter were $223 million. In the US, Nexplanon declined 15%, while internationally the product grew 7%, ex-exchange. The biggest challenge facing Nexplanon this quarter was unfavorable US policy, which emerged in Q2, accelerated in Q3 and had the biggest impact in the budget constrained public segments, Planned Parenthood and Federally Qualified Health Centers, where Nexplanon and has a leading market share among long-acting reversible contraceptives.

In the second quarter, we cited US policy decisions that impact Title X funding and Planned Parenthood. In the third quarter, formalization of these policies intensified budget and access constraints with the greatest impact being realized in Planned Parenthood.

On the commercial side, our Nexplanon business is primarily comprised of integrated delivery networks and to a lesser extent, independent healthcare clinics. In the independent commercial clinics, we've seen a shift away from bulk purchasing or buy and bill towards single unit specialty pharmacy fulfillment of these claims, as these small businesses try to preserve cash. This is also largely macro driven and related to inflationary and economic factors that independent healthcare clinics are facing.

We see these headwinds persisting in the fourth quarter in the US and likely to result in full year US Nexplanon sales that are down mid- to high-single digit for the full year. We expect international sales of Nexplanon to grow mid- to high-single digits, ex-FX, this year. Putting that together that means we expect global Nexplanon sales will be down low-single digit in 2025 compared with full year 2024 on an ex-exchange basis. In the fourth quarter that implies global Nexplanon sales will be down by mid-teens, ex-exchange, compared with the fourth quarter of 2024. The discontinuation of the wholesaler practices I mentioned will likely explain about two-thirds of the year-over-year variance in the fourth quarter.

Turning to other components of our Women's Health business. Our fertility business was flat in the third quarter and up 13% year-to-date, ex-FX. For the full year, we expect high-single digit growth driven by the US, which represents about 40% of our global fertility business, as well as market expansion outside the US. And rounding out Women's Health, on November 6, we announced that Organon has entered into a definitive agreement to divest the Jada system for $440 million, plus another $25 million contingent on 2026 revenue targets. Since acquiring Jada four years ago, the Jada team successfully launched the product in the US, secured approvals across multiple countries and managed design iterations as part of continuous improvement activities, all leading to Jada being recognized as the standard of care in postpartum hemorrhage management.

With this divestiture, Organon can delever faster by applying the proceeds to debt reduction and put Jada in the hands of a medtech company well positioned to build on our great work and the very successful launch of the product.

Turning now to Biosimilars on slide 7. Year-to-date performance is largely driven by Hadlima, which is up 63%, ex-FX, globally through September and continues to rank among the leading biosimilars in terms of total prescriptions in the US. This performance reflects the strong clinical profile of Hadlima which includes the recent interchangeability approval in the US. Hadlima has also benefited from the effectiveness of our low-price strategy, as well as expansion into Canada and Puerto Rico.

The third quarter also benefited from an international tender for Ontruzant and to a lesser extent, contribution from our new denosumab biosimilar, which was approved by the FDA and launched in the US in late September, and Tofidence, which the company acquired in the second quarter of 2025.

Wrapping up the franchise discussion with Established Brands now on slide 8. Vtama revenue in the third quarter was $34 million and $89 million year-to-date. Our ongoing focus here remains to differentiate Vtama in the market. We have the largest addressable market with a single product in both indications across all severities. Vtama is notable for its safety profile, powerful skin clearance and rapid, effective itch relief. Its once daily dosing regimen and lack of restrictions on duration of use or percentage of body surface area affected further illustrate Vtama's potential for disease management in adults suffering from plaque psoriasis, and adults and children down to two years of age with atopic dermatitis.

The launch is at a flatter curve than we expected, but we are further investing behind the brand to effect a more rapid uptake in the atopic dermatitis indication. We still believe this product could get close to $0.5 billion globally

at peak, even if our $150 million target for this year is now likely out of reach and closer to $120 million to $130 million. Elsewhere in Established Brands, the third quarter marked the last quarter of significant impact from the LOE of Atozet since we lapped that event in September. Importantly, we saw a continuation of softening in our respiratory business. Performance in the respiratory portfolio was primarily driven by declines in Singulair, resulting from lower demand outside of the US.

The montelukast molecule is losing share to newer respiratory products, especially in pediatrics, and is facing mandatory price reductions in Japan and China. Dulera was also down significantly in the quarter, primarily due to increased discount rate pressure in the United States, coupled with temporary supply constraints and the negative impact from the loss of a customer contract early this year.

As you know, our respiratory business can be seasonal, and given the historical stability of these offerings, at mid-year we believe this business would rebound. Based on Q3 results and current projections for the remainder of the year, we anticipate that erosion in the respiratory business will persist through this year and into next year.

Moving to slide 9, where we detail the drivers of our 1% as reported revenue increased year-on-year for the third quarter. Starting on the left, loss of exclusivity was about $50 million for the quarter, which primarily reflects the impact of the LOE of Atozet in Europe, which occurred in September of 2024. As we lapped that LOE, we anticipate a relatively smaller impact in the fourth quarter. Year-to-date, we're tracking at the high-end of the $170 million to $190 million range we provided last quarter. And so we now estimate LOE impact to be about $200 million for the full year 2025.

VBP in China was de minimis in the third quarter and year-to-date. We now expect Fosamax's inclusion in round 11 to be an early 2026 event, so we expect very minimal impact from VBP in 2025, less than our previous estimate of $30 million to $50 million.

There was an approximate $30 million impact from price for the third quarter, or about 1.9%. That was mainly driven by the mandatory pricing revisions in respiratory that I mentioned, competitive pricing pressures in fertility and the LOE of Atozet. We expect the full year impact from price to be in the range of $135 million to $145 million, or about 2% with those same Q3 drivers of price being the most significant. This is an improvement over a prior range of $155 million to $185 million. Volume is increased $70 million in the third quarter, representing growth of about 4.5%, driven by the addition of Vtama to the portfolio, continued growth in Emgality and solid performance of Hadlima.

Given year-to-date performance and our view into the fourth quarter, we estimate that volume could grow about 2.5% for the full year 2025, a revision from our former estimate of 6% to 7%. This would imply low-single digit decline in the fourth quarter and is reflective of continued softness in the respiratory portfolio, persisting policy headwinds in US Nexplanon and a flatter than expected ramp of Vtama. In supply/other, here we capture the lower margin contract manufacturing arrangements that we have with Merck, which have been declining since the spinoff, as expected.

And lastly, foreign exchange translation had an approximate $40 million favorable impact in the quarter or about 200 basis points, which reflects the weaker US dollar versus the majority of foreign currencies in which we transact. For the full year, we now expect the impact for FX to represent about a 50- to 70-basis-point tailwind to total revenue.

Now let's turn to slide 10, where we show key non-GAAP P&L line items and metrics for the quarter. For reference, GAAP financials and reconciliations to the non-GAAP financial measures are included in our press

release and the slides in the appendix of this presentation. For gross profit, we are excluding purchase accounting amortization and onetime items and cost of goods sold which can be seen in our appendix slides. Adjusted gross margin was 60.3% for the third quarter, compared with 61.7% in the third quarter of 2024. This year-over-year decline in the non-GAAP adjusted gross margin is primarily attributable to pricing pressure, unfavorable product mix and unfavorable foreign exchange on our inventory turns.

Adjusted EBITDA this quarter was $518 million, representing a 32.3% margin. Year-to-date, adjusted EBITDA margin is running favorable, in part based on the timing of SG&A spend. There are planned increases in our SG&A spend in the fourth quarter as we support growing products such as Vtama and Tofidence. Year-to-date, non-GAAP SG&A as percentage of sales is 25.4%. And given the investments I just mentioned, our latest estimate is about 0.5 point higher than that for the full year.

Turning to free cash flow on slide 11. Year-to-date, we've delivered $813 million of free cash flow before onetime costs. Onetime costs related to the spinoff were completed in 2024 following the rollout of our global ERP system. What remains are margin enhancing restructuring and manufacturing separation activities for 2025, which were $244 million year-to-date, in line with our expectation of $250 million to $300 million for the full year. Year-to-date these break out as follows. Approximately $100 million relates to cash payments associated with the restructuring initiatives that we're executing to deliver $200 million of operating expense savings this year, $20 million relates to the final payment on the Microspherix legal settlement, and the remaining $120 million relates to the planned exits from supply agreements with Merck.

These are activities that will enable Organon to redefine our appropriate sourcing strategy and move to fit-for-purpose supply chains while focusing on delivering efficiencies in terms of gross margin expansion, which we expect to begin realizing in 2027.

Below the free cash flow line, our estimate of business development cash investments for 2025 is approximately $240 million related to contractual milestones for Vtama, Emgality, and the biosimilar programs with Shanghai Henlius. Through the first nine months of the year, the majority of those payments have already been made.

Turning now to leverage on slide 12. Net leverage as of September 30 was approximately 4.2 times, down from 4.3 times at June 30. Earlier in the year, we took action to realign our capital allocation priorities and target a net leverage ratio of below 4 times. To that end, in the second quarter, we repaid approximately $350 million in principal of long-term debt instruments. As I mentioned, once the Jada transaction closes, which we estimate will be Q1 of 2026, we will apply the net proceeds after taxes and transaction costs to lowering our debt balance as well. Given our revised guide, we will likely end the year in line with Q3 with proceeds from the Jada sale helping to move the needle on leverage in early 2026.

Now turning to 2025 full year revenue guidance on slide 13. Given year-to-date performance and risk adjusting the fourth quarter for what we see as persisting US policy and Nexplanon, and the challenges in the respiratory business, we're lowering our full year range to $6.2 billion to $6.25 billion from $6.275 billion to $6.375 billion, which represents a year-over-year nominal decline of 3.2% to 2.4% negative. Given the approximate $35 million to $45 million tailwind we expect from FX for the full year, that means we're revising our constant currency revenue guide down about 300 basis points at the midpoint. We continue to expect adjusted gross margin to be in the range of 60% to 61%. Year-to-date strength in adjusted gross margin is likely to be partially offset in the fourth quarter due to product mix.

For OpEx, as I mentioned earlier, given expected investments in Vtama, we expect full year SG&A spend as a percentage of revenue to be about 0.5 point higher than the year-to-date figure, which puts us in the 26% area for

the full year. We continue to expect R&D as a percentage of sales to be in the upper-single digit range. The map on all those components gets you closer to the lower end of the 31% to 32% adjusted EBITDA margin range we laid out in August of this year. So, we are revising our adjusted EBITDA margin to approximately 31% for the full year.

For below-the-line items, our estimate for full year 2025 interest expense remains at $510 million. The lower interest expense from voluntarily retired debt is essentially fully offset by higher euro-denominated interest expense due to FX translation and an acceleration of non-cash amortization of capitalized fees related to the early debt retirement. As we think about next year, we would expect the interest expense to be closer to a $450 million to $475 million run rate as a result of the voluntarily debt repayments completed, lower variable interest rates and applying the net proceeds from the Jada to debt repayment.

For 2025, we continue to estimate our non-GAAP tax rate to be in the range of 22.5% to 24.5%. The uptick from 2024 is largely due to the impact of the 15% global minimum tax rate required under the OECD's Pillar Two. Depreciation of $135 million remains our estimate for the full year 2025.

At a very high level, next year pro forma for the Jada divestiture, we would expect consolidated revenue to be about flat as Vtama, Emgality and biosimilars growth offset the headwinds across the respiratory portfolio. For Nexplanon, assuming existing headwinds in the US don't worsen and factoring in the volume and price variables associated with a five-year launch in the US and continued growth internationally, we expect global Nexplanon revenues could be about flat next year.

We remain confident in our ability to continue to delever the balance sheet through disciplined expense management and prudent capital allocation, all of which will strengthen Organon's financial position and support greater financial flexibility in the future. Importantly, even in a challenging environment, our diverse portfolio continues to generate strong cash flows and provides a solid foundation for long-term value creation. We are committed to navigating the current headwinds, investing behind our growth drivers and delivering for patients, customers and shareholders.

And finally, while the issue raised around certain of the company's wholesaler sales practices is receiving a lot of focus, the financial impacts are small. Remediation is well underway, and as an organization, we are moving forward.

With that, operator, let's open the line for questions.

QUESTION AND ANSWER SECTION

Operator: Thank you. [Operator Instructions] Thank you. Your first question comes from Jason Gerberry with Bank of America. Your line is open.

Jason M. Gerberry
Analyst, BofA Securities, Inc.

Q

Hey, guys. Thanks for taking my questions. My question is mainly given the Jada divestiture, are there opportunities within the portfolio for additional divestitures as you look across?

And then as my follow-up, on Vtama, appreciate the updates, as it pertains to the growth dynamics into year-end. When should we start thinking about a growth inflection? Do you feel like next year when the access barriers improve that – that 2026 is the time point to really evaluate whether or not the growth inflection this year with the AD label. Thanks.

Matthew M. Walsh
Chief Financial Officer, Organon & Co.

A

Okay. Thanks, Jason. We'll start with the divestiture question. So, to be clear, we've got nothing that's been announced or is definitively planned on asset divestitures. We're constantly from a strategic basis looking at all of the assets in our portfolio and anything additional would be opportunistic.

I think in the case of Jada, we looked very hard at what is the economic value created in a hold-and-invest scenario and compared that against the opportunity to put that product in the hands of a better owner, and the right economic answer in the math indicated that divestiture was the right answer in that case. But that is the kind of rigor that we'll put across all the assets in our portfolio.

And as regards Vtama, Vtama has grown nicely this year, will grow again next year. To your point, we have made significant strides to improve access in 2026. And so I think full year 2026 will be a very good basis for us to be judging, where we are on the growth trajectory to achieving long-term peak revenue of that – roughly $0.5 billion that underpinned the investments for us in the first place. So, yes, 2026 will be a key year.

Jason M. Gerberry
Analyst, BofA Securities, Inc.

Q

Got it. Thanks.

Operator: The next question comes from David Amsellem with Piper Sandler. Your line is open.

David Amsellem
Analyst, Piper Sandler & Co.

Q

Thanks. So, couple for me. Firstly, can you talk more about the pressure on respiratory? And should we think of this long-term as declining business, not just 2026 but beyond? And then secondly, how are you thinking about other potential trouble spots, I should say, regarding Established Brands? So, that's number one.

And then number two is on the Vtama. Just wanted to get your thoughts on competitive dynamics here. Is there anything you feel like you're missing regarding the topical landscape vis-à-vis the roflumilast product in particular, and how we should think about that and how that plays into your thinking regarding the product. Thank you.

Matthew M. Walsh
Chief Financial Officer, Organon & Co.

A

Sure. So, we'll start with the respiratory piece of your question, David. So, in the early part of the year, we were noting that the allergy season, specifically in the Asia Pacific region, including China, was off to a very slow start. That put a dent in our thinking about the full year performance of the respiratory business. But then as the year progressed, we were noting that, competitively speaking, the age of certain products in the respiratory portfolio was working against them. Various health ministries around the world were starting to prioritize other molecules above, for example, Singulair. And then, elsewhere in the portfolio, thinking about Dulera. We talked about that in the prepared comments in terms of the rate pressures that product is facing in the United States. And then rounding it out, just mandatory price-downs in China and Japan and also just around the world hit that business pretty hard this year. So, as we said, we expect that softness to continue into 2026. We'll see what sort of allergy season we have. But some of the other dynamics I've spoken about are more longer term in nature.

Apart from that, the rest of the Established Brands portfolio is showing the stability that those products have demonstrated over long periods of time. But we've always said about the Established Brands business, it is a business that we felt, if managed very tightly, we could keep about flat or maybe very, very low-single digit rate of decline. [ph] That is not a CAGR (00:35:21) basis. Some years will be different than others.

We've added to the Established Brands portfolio, having a global commercial infrastructure like we do is in assets. So products like Emgality tucked in very nicely and Emgality continues to grow and now the wave two markets now that we've added them I think are a case in point for what we can do with the infrastructure that we have. So, no other trouble spots that we're managing at the moment.

Vtama from a competitive standpoint, we are forced to market in the atopic dermatitis space with a nonsteroidal offering. That has set the stage, I think, as what you would say about competition. The product, as we mentioned in the prepared comments, is really differentiated in terms of no drug-to-drug interactions, no restrictions on use, no limitations on a percentage of body. So, it's a very safe product. And we're looking to differentiate it with those patients for whom those characteristics are very important, including pediatrics.

So, next question, please.

Operator: The next question comes from Umer Raffat with Evercore ISI. Your line is open.

Umer Raffat
Analyst, Evercore ISI

Q

Morning, guys. I wanted to start by commending you for getting the 10-Q out. But I realize we haven't been able to speak at all since the inventory disclosures few days ago. So, I feel like it's only fair that we don't limit to just one question. So here's what I wanted to address on this public call.

First, the audit committee investigation focused on Nexplanon. How do we know that the behavior was just limited to Nexplanon because inventory visibility is always lower ex-US, so how do we know?

Second, the filings point to the CEO and the Head of U.S. Commercial as where the divergence happened. But I also saw your Chief Commercial Officer left back in February this year as well. Why was that?

Third, for 2024, your net pull-forward is only $10 million. But the discounts and rebates paid to the channel went up by $177 million in 2024, which puzzles me. So, could you elaborate on that?

Additionally, 4Q 2022 had some inventory as well, but I didn't see any color on that.

And then finally, the scale of these issues seems fairly low, fairly manageable, $10 million, $15 million – sub-$20 million. But if that's the case, then why the need to start this divestiture plan? Thank you very much.

Jennifer Halchak
Vice President-Investor Relations, Organon & Co.

A

Maybe Carrie you want to start with a couple [indiscernible] (00:38:24)

Carrie Smith Cox
Executive Chairman, Organon & Co.

A

Sure. Thanks, Umer. So, as I mentioned in my comments, the independent internal investigation around the improper sales practices with Nexplanon in the US was with two wholesalers and it's now complete. The investigation also looked through other product areas and found nothing else at this time. So, we believe that we are done with the investigation now and we're moving forward into the remediation efforts.

Again, as I mentioned, that's things like enhancing our controls, we have taken certain personnel actions, we believe that completed, we're doing additional training and we've got more written procedures and more training yet to come. So, with the new leadership at the company, we're comfortable that we're moving forward and we will continue to execute against our goals as stated.

Matt, do you want to take the others?

Matthew M. Walsh
Chief Financial Officer, Organon & Co.

A

Yeah. So, for the Nexplanon piece, as we stated in the prepared commentary, Umer, the marketplace for long-acting reversible contraceptives has gotten more competitive. And so we are meeting that competition partially on price. So that would result in some of the increases in rebates and discounts that you noted. This is just, I would say, normal business and Nexplanon operating in a competitive marketplace where women have lots of options for contraception.

Jennifer Halchak
Vice President-Investor Relations, Organon & Co.

A

Then on the Q4 2022 disclosure here.

Carrie Smith Cox
Executive Chairman, Organon & Co.

A

If we didn't, it wasn't on our slide, but the 2024 amount is disclosed in the 10-K.

Matthew M. Walsh
Chief Financial Officer, Organon & Co.

A

Yeah.

Carrie Smith Cox
Executive Chairman, Organon & Co.

A

...2022.

Matthew M. Walsh
Chief Financial Officer, Organon & Co.

A

Umer, you had a number of other questions. I just want to make sure we get to them all. Can you repeat the ones that you don't think we've answered yet?

Umer Raffat
Analyst, Evercore ISI

Q

Yeah. Sure. Maybe [indiscernible] (00:40:19) 4Q 2022, that wasn't disclosed. Also the Chief Commercial Officer who left separate from the Head of U.S. Commercial. Why was that? And then, why do all the divestitures now?

Matthew M. Walsh
Chief Financial Officer, Organon & Co.

A

Oh. So, for Q4 of 2022, the revenue was impacted, but I think it was about 1.5% on the quarter, 0.3% for the year.

And the divestitures, I think we've already addressed that. Umer, we had an opportunistic chance to divest in assets for which the economic value received on an immediate basis was what was superior to the hold-and-invest option. And we had an employee retire towards the end of last year, that was for that employee's personal reasons and not tied to the investigation in any way.

Umer Raffat
Analyst, Evercore ISI

Q

Thank you very much.

Jennifer Halchak
Vice President-Investor Relations, Organon & Co.

A

Thanks, Umer. Can we have the next question, please?

Operator: Thank you. The next question comes from Chris Schott of JPMorgan. Your line is open.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

Great. Thanks very much. Just two questions for me. Maybe, Carrie, can you just talk a little bit about the new CEO search and kind of what's the optimal background and profile you're looking for here? And as part of either the search or with a new CEO coming in, should we assume a review of the broader strategy at Organon as part of this process.

And then my follow-up, just on Nexplanon. Thank you for the comments about the flat growth next year. Just [ph] can you add up (00:42:13) a little bit more in what that – in terms of what that implies for these funding challenges and the impact of the five year launch on the US revenue. Thanks so much.

Carrie Smith Cox
Executive Chairman, Organon & Co.

A

Thanks, Chris. The board formed a search committee essentially immediately. The search committee has been hard at work. So, we are in the process of conducting that search. And like any company at this point, we need someone who's got the global experience, the strategic experience, the operational depth and a deep understanding of the businesses in which we operate. So, we are confident that we not only have a great Interim CEO that we'll continue to find good candidates as we go forward.

I think the strategic discussion obviously waits for a permanent CEO, but at this point, we've been reaffirming that we don't see any strategic changes. So, I would say we are what we are right now and we intend to continue that way and very much focused on driving towards our goals.

Matthew M. Walsh
Chief Financial Officer, Organon & Co.

A

And I'll take the second part of the question on Nexplanon. So, in terms of our current view of Nexplanon being about flat next year, the components of that, we expect the product to continue to grow internationally from a policy perspective. Assuming things don't get any worse, what we would probably see is an annualized of the issues that we experienced in the second half.

And then the five year, which we are assessing the relative weighting of the impacts of volume growth as the product would be appealing to a larger segment of the addressable population with a five-year indication versus three. The volume decline that would come from lower reinsertions, right, as women who would be coming up to the three-year limit can leave the rod in their arms now for longer. And then what we're able to do on the pricing front. So, we'll have all of this sorted out more precisely when we guide in February. But these are the things, Chris, that would be pushing in, pulling on the overall belief that revenue will be about flat next year.

Operator: The next question comes from Terence Flynn with Morgan Stanley. Your line is open.

Terence C. Flynn
Analyst, Morgan Stanley & Co. LLC

Q

Hi. Thanks for taking the questions. I was – just had one follow-up on the CEO search. I was wondering if you can speculate on the duration of the search when you hope to have someone in place on a permanent basis.

And then on denosumab, on that product, obviously, one of your newer biosimilars that you're launching. Amgen has expressed a lot of optimism about maintaining more share on the Prolia side versus XGEVA. Can you just talk through your expectations for fourth quarter but then also into 2026? Thank you.

Carrie Smith Cox
Executive Chairman, Organon & Co.

A

So, on timing of the CEO search, you know it's always impossible to predict how long these things take. The board did begin right away. So, I'm confident we're doing what's necessary to go as fast as we can. But we also feel very good about putting Joe in as our Interim CEO, and I stepped in to assist him along with Matt, of course.

So, we're confident we can continue to run the company well in the interim and we'll be moving through the search as fast as appropriately we can go.

Matthew M. Walsh
Chief Financial Officer, Organon & Co.
A

And on the denosumab piece, we're obviously very excited about that product, its launch now. We don't guide to specific products, as you know. But what we are excited about is we continuously are adding products to the bag in our US biosimilars business and that's giving us increasing commercial presence and access advantages that we look forward to 2026, for Tofidence and for all of our US biosimilars.

Operator: The next question comes from Navann Ty with BNP Paribas. Your line is open.

Navann Ty
Analyst, BNP Paribas Exane
Q

Hi, Good morning. I have some questions on capital allocation if you could discuss the future BD in Women's Health biopharma only, understand, and the timing of business development versus deleveraging progress. And second, if you could also discuss your pipeline versus the cost discipline strategy, including lower R&D. Thank you.

Matthew M. Walsh
Chief Financial Officer, Organon & Co.
A

Yeah. Thank you, Navann. So, our business development activities in Women's Health continue. To the question that you're asking, we – just because of where the balance sheet is, we'd had to focus on later stage assets or currently marketed assets. You can see that clearly in the kinds of deals that we've announced recently.

And the challenge in Women's Health is, there aren't a lot of those assets that are available late stage or currently marketed. A lot of the truly exciting things in Women's Health are preclinical, or generally speaking, much earlier in the development cycle. So, we are somewhat constrained in our ability to go after those. And that's one of the reasons why we've been prioritizing leverage reduction, debt repayment in our capital allocation strategies so that we can free up the ability, balance sheet and P&L to bring on the clinical programs, especially Women's Health that are preclinical or early stage.

Once again, because of the financial challenges facing the company, we've applied that same rigor not just to the BD we're looking at, but also to the pipeline that we are managing in-house. We've had to trim some programs. Those weren't restricted to Women's Health, we've got lifecycle management activities across a number of products in the portfolio. It's incumbent upon us to apply that same kind of financial rigor and discipline to things inside the company, as well as any capital deployments we may do externally.

Operator: The next question comes from Mike Nedelcovych with TD Cowen. Your line is open.

Michael Nedelcovych
Analyst, TD Cowen
Q

Hi. Thank you for the question. I have one and actually something of a follow-up on the BD response you just gave. I think with today's update, it's fair to say that business development track record is somewhat mixed. So, I'm wondering what you could do from here to improve it, especially given how important BD is to potential growth

for Organon? And, could that option set include expanding to therapeutic categories well beyond Women's Health?

Matthew M. Walsh
Chief Financial Officer, Organon & Co.

A

So, thank you for the question. I think we've shown success in the BD program, especially with latter stage assets where we've got synergies with our existing commercial capabilities. So, the broad strategy, just doing more of what we already do well. I think Emgality is a terrific example of that. And with the addition of Dermavant we actually did already add a completely new vertical in the United States with dermatology. Right now, the Dermavant team that we added, which is now Organon's dermatology sales force is selling just one product. So, we would have synergies going forward as we look to add additional derm products to that team.

When you look at the Established Brands business, we're already in a pretty broad range of therapeutic categories outside the United States. So, we believe that we've got lots of opportunities with the therapeutic areas we're already in with what we've already added with Dermavant so that we wouldn't necessarily need to add another therapeutic category in order to be successful with capital deployments, although we certainly wouldn't rule it out if it capitalizes, once again, on some functional expertise that we already have, whether it's the global commercial network, or perhaps there's something that aligns particularly well with our manufacturing capabilities, for example.

Operator: This concludes the question-and-answer session and will conclude today's conference call and webcast. Thank you for joining. You may now disconnect.