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Organon & Co. (OGN)

Q4 2025 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Hello and welcome to the Organon Fourth Quarter and Full-Year 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. Good morning, everyone. With me today are Joe Morrissey, Organon's Interim Chief Executive Officer; and Matt Walsh, our Chief Financial Officer. Carrie Cox, Organon's Board Chair; and Juan Camilo Arjona Ferreira, Organon's Head of R&D, will also be joining for the Q&A portion of this call.

Today, we are referencing a presentation that will be visible during this call for those of you on our webcast. This presentation will also be available following this call on the Events and Presentations section of our Organon Investor Relations website. Please reference slides 2 and 3 for a couple of 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, believe, outlook, and other words of similar meaning.

Actual results could differ materially from those stated or implied by forward-looking statements due to risks and uncertainties associated with the company's business which are discussed in the company's filings with the Securities and Exchange Commission. This includes our most recent Form 10-K and Forms 10-Q and those amended forms. These statements are based on information as of today, February 12, 2026 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 and a current report on Form 8-K.

I note that while our full year 2026 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 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.

I'd like to turn the call over to Joe Morrissey.

Joseph T. Morrissey

Interim Chief Executive Officer, Organon & Co.

Thank you, Jen. Beginning on slide 4. In 2025, Organon delivered $6.2 billion in revenue and $1.9 billion of adjusted EBITDA. Revenue was down 3% on both the reported and ex-exchange basis. Relative to where we began the year, our biosimilar franchise performed better than expected, driven by solid performance in Hadlima, as well as contributions from new launches.

Vtama delivered $128 million of global revenue in 2025 and Emgality and our fertility business also grew strongly in 2025. That performance helped to offset the continued impact of the LOE of Atozet and headwinds in other parts of the business that emerged during the year. Those include policy-related changes in the US for Nexplanon and a revision to medical guidelines in certain international markets that deprioritize the use of montelukast which impacted Singulair. Though Nexplanon had its challenges this year, the FDA approved our sNDA to extend the duration of Nexplanon from three to five years. The study supporting the approval enrolled a population of women with varying body mass indices, including women with overweight or obesity, a testament to Organon's commitment to inclusive and comprehensive women's healthcare. This is a meaningful milestone for Organon and the Nexplanon brand as it potentially broadens the addressable market for this key product. The approval also includes a new risk evaluation and mitigation strategy program that will enhance Organon's existing clinical training program and control distribution program, which has been in place since 2006.

One of the most important decisions the company made in 2025 was to lower our dividend payout ratio and apply those excess funds to debt reduction. We also divested the JADA system, resulting in approximately $390 million in net proceeds that will help us to reduce net debt in 2026. Together, these decisions mark our commitment to improving capacity in Organon's balance sheet to put us in a position to pursue growth opportunities in the future.

At the same time, we have scrutinized our spending and had to consider tough but necessary changes to our business. In 2025, we were able to keep adjusted EBITDA margins essentially flat with 2024 despite 150 basis points of gross margin degradation. We achieved over $200 million in cost savings in 2025 through significant efforts, which offset investments in growth drivers like Vtama. We also discontinued early-stage clinical programs

and are limiting spend to activities such as medical and regulatory affairs that support products already in the market.

As we look across the portfolio, we expect revenue and adjusted EBITDA this year to be very much in line with 2025, which means, at a high level, we expect to deliver about $6.2 billion in revenue and about $1.9 billion of adjusted EBITDA in 2026. We expect that the annual revenue foregone with the sale of the JADA system will be offset by an FX tailwind of about the same amount, which means we expect revenue to be about flat with prior year on a constant currency basis, pro forma for the JADA system divestiture.

On the profitability front, we continue to thoughtfully curtail OpEx to offset what we believe is about 75 basis points to 100 basis points of deterioration in gross margin in 2026 and that we can manage to an adjusted EBITDA figure of about $1.9 billion. I remain confident in our ability to deliver these results in 2026, and I'm deeply proud of the talented teams across Organon who are driving this work every day.

With that, I hand it over to Matt.

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

Thank you, Joe. Beginning on slide 5, let's talk about the main drivers of performance in Women's Health. Women's Health was down 16%, ex-FX, for the fourth quarter and down 2% for the year. Sales of Nexplanon decreased 20%, ex-FX, in the fourth quarter and 4% for the full year, in line with what we discussed in November when we re-guided on the product. As we've talked about in previous quarters, in 2025 Nexplanon was impacted by several headwinds. Let's break it down between those we expect to continue versus those that we believe are one-time in nature.

Starting with the one-time item. As we talked about last quarter, we expected an approximate $17 million negative impact in the fourth quarter related to the cessation of certain identified US wholesale wholesaler sales practices identified in the audit committee's internal investigation disclosed in late October. The impact from that practice is contained to 2025.

Now what do we think is likely to persist in 2026? We see four drivers. The first driver is in the US and is macro in nature. Government policy related access restrictions have impacted Planned Parenthood and federally qualified health centers where Nexplanon on has a leading market share among LARC, incorporated in our guidance is that this policy environment persists in 2026.

The second driver. In 2025, we saw a developing weakness with smaller, independent commercial clinics who are tightly managing their buy and build purchasing, with some choosing to switch to specialty pharmacy claims for each patient via assignment of benefits. While we expect this change to remain, we are actively engaging customers in this segment to support sustained and improved access to Nexplanon.

Third driver. As we've discussed previously. In 2026, we will have a volume headwind from loss of reinsertions as we transition to the five-year label.

Fourth and final driver is an offsetting positive. We expect strong ex-US growth to compensate for the US, particularly in Latin America where we are seeing improved access.

Turning to fertility. Our fertility business declined 6%, ex-FX, in the fourth quarter of 2025, primarily related to sales performance in China where we are holding share, but socioeconomic trends are weighing on the broader

fertility market. For the full year, the fertility business grew 8%, ex-FX, driven by performance in the US, particularly in the first half of 2025 as well as geographic footprint expansion, which together offset declines in China.

Fertility will likely be a headwind for us in 2026 as we expect an increasingly competitive environment in the US, brought on by a competitors agreement with the administration's new direct access program.

And finally, the JADA system delivered $74 million of revenue in 2025. We completed the divestiture of JADA in January of this year, so that will represent a headwind of about 120 basis points to Organon's consolidated revenue in 2026.

Turning now to biosimilars on slide 6. For the fourth quarter and full year, the drivers in biosimilars are largely the same. Performance was driven by Hadlima, which grew 61%, ex-FX, globally for the full year, reflecting the strong clinical profile of Hadlima and the effectiveness of our pricing strategy as well as expansion into Canada and Puerto Rico.

To a lesser extent, biosimilars also benefited from our new denosumab biosimilars, which were approved by the FDA in August and launched in the US in late September. And Tofidence, which the company acquired in the second quarter of 2025.

In 2026, we expect biosimilars to deliver flat to modest growth, with Hadlima and the contribution of new assets expected to at least offset the expected decline in Ontruzant and Renflexis, consistent with the maturity of those assets. As regards to future launches, we've entered into a settlement with Genentech that grants us a license to start launching our pertuzumab biosimilar asset in [indiscernible] (00:12:01) in 2027 and in the US in 2028.

Wrapping up the franchise discussions with Established Brands on slide 7. Established Brands revenue declined 5%, ex-FX, in the fourth quarter of 2025 as well as for the full year. We've always said that the CAGR in Established Brands should be about flat, ex-FX, with some years above and some years below. In 2025, we navigated through the LOE of Atozet which itself was an approximate 400 basis point headwind to established brands revenue. In 2026, we expect to return to flat performance. Contributions from Vtama and Emgality together with lapping LOE of Atozet should offset expected continued pressure in a respiratory franchise.

Turning now to the fourth quarter revenue bridge on slide 8. Revenue in the fourth quarter was $1.507 billion, down 8% at constant currency. Loss of exclusivity was about $20 million in the quarter, the lowest of the year and was related to lapping the Atozet LOE in the EU, which occurred in September of 2024. VBP was negligible for the quarter. Organon product were not included in any new rounds in China's national VBP program during 2025. We lost approximately $80 million on price in the fourth quarter. About $30 million of this was related to four separate gross to net adjustments that were one-time in nature. The remainder was primarily driven by pricing revisions in respiratory, expected competitive pricing pressures in fertility and biosimilars and the LOE of Atozet. Additionally, there was an increase in the US rebate rate for Nexplanon in the quarter related to a change in patient mix tied to Medicaid usage claims.

Volume declined about $10 million in the quarter, and that was mainly driven by lower volume for Nexplanon and in the respiratory portfolio, which was largely offset by volume growth in Vtama, Hadlima, Emgality, and Arcoxia.

In supply other, here, we capture the lower-margin contract manufacturing arrangements that we have with Merck, which have been declining since the spin-off as expected. And lastly, foreign exchange translation had an

approximate $35 million favorable impact for the quarter, which reflects the weaker US dollar against the majority of foreign currencies in which we transact.

Let's look at these same drivers now on a full-year basis on slide 9. Loss of volume from LOE was about $200 million, consistent with the range we've outlined all year and that was primarily related to the LOE of Atozet in the EU. As I mentioned, there was essentially no VBP impact in 2025.

There was about $180 million of negative impact from price in 2025 or about 2.8%. Pricing headwinds for the full year were primarily in the respiratory portfolio, with rate pressure in the US for Dulera and mandatory price reductions in China for Nasonex and Singulair. To a lesser extent, we also felt price impacts stemming from the competitive environment in biosimilars and fertility in the US. Volume grew $200 million in 2025 or 3% for the year, with contributions from Vtama and Emgality and growth in fertility biosimilars offsetting declines in the global respiratory portfolio and Nexplanon in the US.

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 and amortization and one-time items from cost of goods sold, which can be seen in our appendix slide. Non-GAAP adjusted gross margin was 56.7% for the fourth quarter of 2025, compared to 60.6% in the fourth quarter of 2024. Pricing pressure and unfavorable product mix were notable drivers in the decline of non-GAAP adjusted gross margin. Adjusted gross margin for the full year, 2025 was 60.1%, compared with 61.6% for the full year 2024, with pricing pressure being the primary unfavorable driver in the year. Non-GAAP adjusted EBITDA margin was 25.4% in the fourth quarter of 2025, compared with 28.1% in the fourth quarter of 2024.

The year-over-year decline in the fourth quarter 2025 adjusted EBITDA margin was primarily driven by the lower adjusted gross margin that was partially offset by a 5% reduction in non-GAAP operating expenses. Adjusted EBITDA margin was 30.7% for full year 2025, consistent with prior year as the decline in adjusted gross margin was substantially offset by lower R&D expense.

Net loss for the fourth quarter of 2025 was $205 million or $0.79 per diluted share, compared with net income of $109 million or $0.42 per diluted share in the fourth quarter of 2024. Net loss for the fourth quarter of 2025 include the non-cash goodwill impairment of $301 million or $1.16 per share, related to the decline in the company's stock price and underperformance in the US. For the fourth quarter of 2025, non-GAAP adjusted net income was $165 million or $0.63 per diluted share, compared with $235 million or $0.90 per diluted share in 2024. Non-GAAP adjusted net income was $954 million for full year 2025, or $3.66 per share, compared with $1.065 billion or $4.11 per share in full year 2024.

Turning to free cash flow now on slide 11. For full year 2025, we delivered $960 million of free cash flow before one-time costs consistent with prior year. One-time 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, which were together about $270 million for 2025.

For 2026, we expect costs associated with manufacturing separation activities to be about $100 million. We do expect an increase in CapEx associated with these activities as well as an increase in net working capital consumption driven largely by inventory in established brands and biosimilars, which means our free cash flow in 2026 will likely resemble what we delivered in both 2024 and 2025. Below the free cash flow line in 2025, we paid

about $170 million related to contractual milestones for Vtama, Emgality, and the biosimilar programs with Shanghai Henlius, and made another $66 million in upfront payments, primarily related to acquiring the licensing rights for Tofidence, and to a lesser extent, the purchase of the Oss Bio manufacturing site. In 2026, we expect the commercial milestone payments will be similar to 2025 at approximately $170 million.

Turning now to leverage on slide 12. Net leverage at year-end was approximately 4.3 times. Consistent with our priority to reduce leverage, during the year, we retired approximately $530 million of debt, which included the open market repurchase and cancellation of $419 million of Organon's 5.125% notes due in 2031, including $177 million retired in the fourth quarter. The prepayment of a portion of a long-term debt assumed as part of the Dermavant acquisition and normal quarterly term loan payments.

Given our outlook for approximately $1.9 billion in adjusted EBITDA in 2026, together with approximately $390 million of net proceeds from the JADA divestiture, we expect to be able to achieve net leverage below 4 times by the end of the year.

Now turning to the 2026 full year revenue bridge on slide 13. For full year 2026, we expect revenue of about $6.2 billion. We expect LOE to be about $40 million, related to a collection of smaller LOEs, for example, Clarinex in Japan as well as the potential for a generic of Dulera in the US.

We expect VBP impact to be about $30 million and related to the inclusion of Fosamax in Round 11. We expect headwind from price to be about $75 million or about 1.2%, which is lower than what the portfolio has experienced in prior years. And that's driven by several factors. First, lapping of the approximate $30 million in one-time gross to net adjustments in the fourth quarter of 2025. Second, we expect stability in US gross-to-net in the US in 2026. And three, less pricing erosion internationally, particularly in the EU as we lap the LOE of Atozet. And in Japan, as the majority of our portfolio there has already reached pricing parity with generics.

We expect volume growth of about $150 million or about 2.4%, will be driven by continued contribution from Vtama and Emgality and growth in biosimilars and Nexplanon ex-US. And finally, we're estimating that a modest FX tailwind offsets the loss of JADA revenue.

Turning to slide 14, we expect adjusted gross margin in 2026 to be about 75 basis points to 100 basis points lower than prior year. And while price will be a headwind as it has been in prior years, the main driver of the adjusted gross margin decline in 2026 is higher cost of goods sold related to the release of accumulated foreign exchange translation on inventory that is subsequently matched to revenue when the inventory sold.

For OpEx, our range for SG&A as a percentage of sales remains in the mid 20% area and we expect the range for R&D spend to be in the mid-single-digit area. For below the line items, our estimate for full-year 2026 interest expense is about $500 million in line with 2025. In 2026, we expect to refinance certain 2028 maturities, which will offset the benefits of recent voluntary debt repayments and lower variable interest rate. We expect depreciation of about $140 million for full year 2026 and expect approximately, $265 million of our fully diluted share count.

For 2026, we estimate our non-GAAP tax rate to be in the range of 27.5% to 29.5%. The uptick from 2025 is largely due to the full year impact of the implementation of OECD's Pillar 2, 15% Global Minimum Tax. The absence of a tax amortization benefit and an increase in our non-deductible interest expense, offset by use of additional foreign tax credits. Pro forma for any divestitures, we expect cash taxes to be similar to 2025.

As we think about the phasing of the quarters in 2026, we expect revenue growth to build throughout the year, but OpEx is more evenly spread through the quarters. So that means Q1 margin is likely to have the lowest margin of the year and Q1 could wind up looking a lot like the quarter that we just reported in Q4 2025.

In 2026, our primary objective is to maintain performance that aligns with last year. At the same time, we are committed to continuing to manage operating expenses and capital deployment in a disciplined fashion to achieve progress on our deleveraging efforts.

Carrie Smith Cox

Executive Chairman, Organon & Co.

This is Carrie. Before we go to Q&A, I'd just like to say that we won't be able to answer any questions today regarding the topic referred to in our press release under other matters that was brought to the attention of the Audit Committee yesterday.

With that operator, we are ready to begin Q&A.

QUESTION AND ANSWER SECTION

Operator: Thank you. [Operator Instructions] We ask that you please limit yourself to one question and follow-up. Thank you. Your first question comes from Umer Raffat with Evercrore ISI. Your line is open.

Umer Raffat

Analyst, Evercore ISI

Q

Thanks for taking my question, guys. And Carrie, I want to be respectful for what you just said. But not relating to that specific issue on what exactly the specifics are of the purchasing. My question is more higher level, remember last quarter, I asked you, how can one – anyone know that the channel behavior issues were limited to Nexplanon? And why was the audit committee investigation so limited in its scope only to Nexplanon? And I remember at the time you said it did span beyond look through other product areas and found nothing else. Today we're learning there was another issue and this time it's biosimilars purchasing. And that too because it was brought up meaning five other things could be brought up. How can we know that a comprehensive review has been taken? It almost looks like there's an unwillingness by the board and the leadership to actually solve this for once and do it the right way. So we can move on and look at fundamentals and pay down all the $9 billion in debt.

Carrie Smith Cox

Executive Chairman, Organon & Co.

A

Yeah. Thanks, Umer. I'm sorry we can't provide any additional color at this point.

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

Michael Nedelcovych

Analyst, TD Cowen

Q

Great. Thanks for the question. I have two. My first is on the biosimilar portfolio. Back in October, as you know, FDA released draft guidance limiting the requirement for comparative efficacy studies for biosimilars. So, I'm curious what you consider to be the status of this policy in the US? What's your interpretation of that guidance and

what impact should we expect it to have on Organon's business? For example, does it open the biosimilar floodgates [indiscernible] (00:27:21) margins or is it more of an incremental change?

And then my second question is on your 2026 guidance. Can you provide any more detail on the Nexplanon contribution as contemplated in your 2026 sales guidance? And will launch of the longer acting Nexplanon implant be accretive to total Nexplanon sales this year? Thanks.

Joseph T. Morrissey
Interim Chief Executive Officer, Organon & Co.

A

Mike I think the first issue – the first question on the biosimilars, we thought it would be more incremental. So we think our strategy with biosimilars is the right one and picking the right partners that are positioning their biosimilars in the right order of the ability to launch and building out those partnerships. We're excited about our opportunities in the US continuing to grow Hadlima as well as with our launch of the denosumab biosimilars and expanding that in other markets around the world and continuing to grow in that way. So we see that more incremental.

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

A

And on the second part of the question for 2026 and guidance on Nexplanon. We believe that Nexplanon will be roughly flat year-on-year. We've got pushes and pulls on the Nexplanon business ex-US. The business will continue to grow nicely. We talked about improved access to Nexplanon in Latin American markets.

In the United States we'll have – consistent with the launch of the five-year label. We will have a bit of a dip, due to [ph] no reinsertions (00:28:59) roughly and we said 10% to 15%, let's call it 13% of insertions annually are actually reinsertions. So now with the move to three to five years, that will create a bit of an inflection point in volume there. And some of the channel issues that we experienced the second half of the year we'll annualize.

So net-net the contribution of Nexplanon to our 2026 guidance is, to summarize, roughly level with 2025. But we remain optimistic that the attractiveness of the five new label, especially for high BMI patients and now with the duration making the product more attractive versus other long-acting reversible contraceptives, bodes very well for the long-term growth of the product, both inside and outside the United States.

Operator: The next question comes from Jason Gerberry with Bank of America. Your line is open.

Q

Hey, guys. This is [indiscernible] (00:30:11) for Jason. Two questions from us. So the first is regarding to a flat 2026 adjusted EBITDA of $1.9 billion and you've $275 million in annualized cost savings from the reset going into the P&L. So I guess if we strip out those savings, the underlying EBITDA performance appears to be declining. Maybe if you can help us bridge where that $275 million benefit is being absorbed. Is it purely the 75 bps to 100 bps of gross margin deterioration or are there massive one-time reinvestments into Vtama and Nexplanon REMS program?

And then my second question is to double click on this REMS program that launches in a couple of weeks with a six-month grace period ending in August. So those are 2026 Nexplanon outlook [ph] assume any (00:30:58) volume bottlenecks or certification friction in the second half of the year, once that mandate is fully enforced and

maybe the REMS mandated [ph] this year (00:31:09) registration, potentially provide you with like a cleaner data to monitor the wholesaler days of coverage? Thank you.

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

A

So I'll take the first part of the question. Juan Camilo can take the REMS question. So on the operating expense savings, the $275 million we referred to when we spoke earlier in the year was all related to gross takeouts that we were going out after and sort of the base, administrative and structural elements of our cost structure. That was the gross number we were going after. That enabled us in fact to take a portion of that and reinvest it, for example, in increased enhanced promotional activity for Vtama. So when you asked the question, you essentially answered it, by saying that some of that $275 million would be redirected to revenue growth opportunities.

I'll take a step back and say that the management team here continues to go after OpEx very aggressively. We've built another round of expense – OpEx savings into our 2026 guidance. Not quite as large as the 2025 effort, but certainly in the same ballpark. And it's just essential that we continue to right-size the operating expense footprint of the company, in light of what's happening, in terms of our gross margins being compressed.

Now, I'll turn the question over to Juan Camilo for REMS.

Juan Camilo Arjona Ferreira
Head-Research & Development & Chief Medical Officer, Organon & Co.

A

Yeah. Thank you, Matt. And thanks, Jason. Yeah, we are pretty confident that with this window that we have and the efforts that we've already planned. We will be able to recertify the prescribers that constantly use or are loyal to use of Nexplanon [ph] these physicians (00:33:11) that have been already certified before will have a very small requirement that will take them around [ph] 15 to 20 minutes (00:33:20) to be certified. So we are pretty confident that we'll be able to maintain the volume based on the retraining that I believe was your question. The other factors are the ones that Matt and Joe already commented.

Operator: The next question comes from Chris Schott with JPMorgan. Your line is open.

Ethan Brown
Analyst, JPMorgan Securities LLC

Q

Hi. This is Ethan on for Chris. Thanks for taking our questions. Maybe just building on the margin commentary. Just maybe taking a step back, what are your latest thoughts on what operating costs and margins can look like over time from here? And then on Nexplanon, very helpful commentary on the headwind going to the five-year indication. Just maybe, how long should we think about that headwind, about the duration of that headwind? And are there any potential offsets [ph] to your price there (00:34:15)? Thank you.

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

A

So, the first part of the question relates to OpEx. And I think the challenge for the company, as we've seen gross margins compress since the spin is to continue to streamline, make the business more efficient, get economies of scale where we can. And I just make the broad comment that it's incumbent upon us to continue to do that. But at the same time, make sure that we are not sacrificing OpEx where it can draw a clear line to revenue growth and value creation in the top line. So I don't have a numerical answer to the question. What I have is the philosophy here that we are deploying, have been deploying as we try and manage a bottom line that optimizes what our opportunity is. On the five-year and the reinsertion, I think this year will be the most pronounced for 2026. We

might be talking about reinsertion risk in 2027, it should be at a fairly significantly lower level than what we're talking about this year.

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

Q

Hi. Good morning. This is [ph] Alex (00:35:47) on for David. Thanks for taking our questions. The first one is, can you talk to the pressure on Established Brands and how we should think about key Established Brands segments not only in 2026, but also beyond and how you're thinking about potential trouble spots such as respiratory? And then on Vtama, how are you thinking about competitive dynamics for the products given that growth has been lower than topical [ph] roflumilast (00:36:15) so with that in mind, how are you thinking about your support of the product? Thank you.

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

A

So the first part of that, go ahead Joe.

Joseph T. Morrissey
Interim Chief Executive Officer, Organon & Co.

A

Yeah. Thanks, Matt. I think [ph] Alex (00:36:26) the first thing with the Established Brands, I mean, Matt said in his commentary, right? We do think Established Brands are going to have some years where you have somewhat of a reset like we did with the respiratory in 2025, and then remaining [ph] that we're flat (00:36:40) I think when we look at it, a lot of the respiratory risk, it may – it will pull into this year, but it's largely – we're getting past that as well as some of the declines we had over the year and the prior year in Japan. And so, when we look at them, the growth of – with products like Emgality plus Vtama and so forth, that's where we see stabilization in Established Brands. But it's still going to be somewhat chunky, I would say, in the future where we'll have some challenges and then opportunities to offset that with growth. Matthew, do you want to take Vtama?

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

A

Yeah. So from a Vtama perspective, as it competes against steroidal, non-steroidal options, we see that 2026, the product is likely to grow in line with the other non-steroidal topical. So in the 20%, 25% range year-on-year for Vtama. The only other thing I would add to Joe's comment on Established Brands is that we continue to add products there that capitalize on the global infrastructure that we have. So there was – we – the company made an announcement tail end of last year that we will be marketing Nilemdo in the EU. Not a big product but it can slide right in, it's similar to Emgality, very little in the way of incremental operating expense necessary and once again, capitalizes on what's a unique asset and feature for Organon's business, which is this global infrastructure that enables us to sell either directly or directly into 140 countries around the globe.

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

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

Q

Hey. Thanks for taking the question. Two for me. I was just wondering if you can give us any update on the search for a permanent CEO. And then the second one relates to the denosumab biosimilar that I know you guys

launched end of December. I think Amgen has talked about being able to, on the Prolia side at least, hold on to more share, given they have EVENITY as another option. So I guess as you think about your go-to-market strategy on the denosumab biosimilar specifically for the osteoporosis setting, anything you're doing differently to try to capture more share there? Thank you.

Carrie Smith Cox

Executive Chairman, Organon & Co.

A

So I can take the one on the CEO search. You might recall there was a special committee the board formed last year. We've had a very robust process underway, but there's no public update to share right now. Thank you.

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

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And as far as the denosumab question. I think let's just talk about what we should be modeling and how investors should be thinking about Organon's opportunity for that product. And like a lot of the biosimilar partnered opportunities that we have, we'll be competing against highly competitive markets, both from a volume and price perspective. When we think about what the peak revenues might be for that denosumab product over both reference products, it's on the order of $100 million in total, let's say, over about a five-year timeframe.

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