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Organon & Co. (OGN)

Q2 2025 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Hello and welcome to the Organon Second 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. Thank you for joining Organon's second quarter earnings call. With me today are Kevin Ali, Organon's Chief Executive Officer; and Matt Walsh, our Chief Financial Officer. Juan Camilo Arjona Ferreira, Organon's Head of R&D, will also be joining for the Q&A portion of this call.

Today, we will be 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 at www.organon.com.

Before we begin, I would like to caution listeners that certain information discussed by management during this conference call will include forward-looking statements. 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, including our 10-K and subsequent periodic filings.

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. A reconciliation of these non-GAAP measures to the comparable GAAP measures is included in the press release and conference call presentation.

I would now like to turn the call over to our CEO, Kevin Ali.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Good morning, everyone, and thank you, Jen. Revenue for the second quarter was $1.6 billion, down 1% at constant currency, with our growth pillars and contributions from new assets mostly offsetting the loss of exclusivity of Atozet in the EU. Given year-to-date operational performance and our current view of movements in various foreign currencies, we are raising our revenue guidance range by $100 million at the midpoint. Additionally, we generated strong adjusted EBITDA this quarter of $522 million, representing a 32.7% margin. Year-to-date, our adjusted EBITDA is $1 billion or 32.4% margin.

Strength year-to-date was primarily due to favorability in adjusted gross margin, investment prioritization behind our growth pillars, and the realization of savings from our restructuring programs to become a more fit-for-purpose organization. As a result, we are affirming our adjusted EBITDA margin guidance range of 31% to 32%. The strong focus on EBITDA generation underpins our objectives to deliver more than $900 million of free cash flow before onetime costs in 2025. Year-to-date, we're tracking well against that goal.

As we signaled to you last quarter, we are committed to reducing our debt burden. To that end, in the second quarter, we repaid approximately $350 million of principal on long-term debt instruments, which sets us up on a path to achieving net leverage below 4 times by year-end. Midterm, we'll aim to drive further improvements in net leverage with the goal of achieving net leverage of 3.5 times or below by the end of 2026.

Let's now talk about franchise performance beginning with Women's Health. The Women's Health franchise grew 2% at constant currency in the second quarter of 2025, compared with the second quarter of 2024. The company's fertility business grew 15% in constant currency in the second quarter. This was driven by a favorable year-over-year comparison in Follistim related to the late 2023 exit of a spin-related interim operating model with Merck and increased demand. We expect continuous growth in the US, along with geographical expansion, to deliver high-single digit growth in our global fertility business in 2025.

Within Women's Health, Jada also grew double digit in the quarter and year-to-date. Among hospitals that have the highest adoption rates, Jada is used in nearly half of all postpartum hemorrhage care situations. We're focused on driving similar usage rates across more hospitals and are driving to have Jada incorporated into the standard postpartum hemorrhage readiness and response protocols in US hospitals.

Sales of Nexplanon declined 1% at constant currency in the second quarter. Revenue declined by 5% in the US, while outside the US, Nexplanon grew 10% at constant currency. For the first six months of the year, Nexplanon has grown 6% globally at constant currency. In the US, customers relying on federal- and state-subsidized programs are now facing potentially constrained funding. That is factoring into their purchasing decisions for contraceptive products.

Despite these headwinds, we anticipate continued global growth for Nexplanon, building on its strong double digit expansion achieved in 2024. Current policy issues notwithstanding, we remain committed to building Nexplanon into a $1 billion franchise in the very near future, reflecting our confidence in its long-term growth potential. For

Nexplanon's five-year duration indication, we have made our submission to the FDA, putting us in a position to be ready for launch later this year. As we have reiterated each quarter, we believe this indication is attractive to a much broader addressable market, and we believe Nexplanon can continue to grow until the end of the decade.

Turning the discussion to General Medicines, which is our refresh term for our business outside of Women's Health, we believe it is a better characterization of the innovation we are introducing with products like Emgality and Vtama. We will continue to discuss our biosimilars products separately, given their collective importance to the growth driver for the company.

So, then let's start with biosimilars, which is performing better than our expectations. Year-to-date performance is largely driven by Hadlima, which has generated almost $100 million as of June, up 68% compared with the prior-year period. In the US, Hadlima continues to rank among the leading biosimilars in terms of total prescriptions. This performance reflects the strong clinical profile of Hadlima, which includes the recent interchangeability approval. Hadlima has also benefited from the effectiveness of our commercial strategy and our market access teams, which have expanded availability to a broader patient population.

We've also added Tofidence, the first biosimilar approved for Actemra to the portfolio in the US. Immunology is a market we know well in the US, notably the physician administered business. And as a result, we are uniquely positioned to drive Tofidence sales.

Finally, we will begin to launch a portfolio of Henlius products in late 2025 with the denosumab biosimilar in the US. So, with better performance in the base business, together with our outlook for new assets coming on line, that have improved our view of performance in the biosimilar business for the full year.

Wrapping up the revenue discussion with established brands with a focus on Vtama. Vtama had strong performance in the second quarter with revenue of $31 million, up 35% sequentially and up 70% versus a year ago, when it was still under Dermavant. In the second quarter, NRx and TRx each grew mid-teens over Q1, representing the strongest quarterly performance among the peer set. Since launch, we have added over 20,000 new Vtama prescribers. When Organon acquired Dermavant, Vtama was accessible to about a third of the addressable population, and broader access had significant barriers.

We have achieved meaningful improvements in our access objectives to date and are on track to achieve 80% of the addressable population covered in both national and regional healthcare plans by early 2026. We've only just begun to unlock the potential of this asset. Vtama is approved for patients as young as two years of age. This unlocks the pediatric segment, where treatment options are limited and safety concerns with existing therapies are significant. Other competitors in this space have labels approved for six years of age and up. So, this is a subset of pediatrics where we have a significant advantage.

As we reflect on the first half of 2025, we're proud of several key accomplishments that have set a strong foundation for the remainder of the year. Our portfolio is performing well, overcoming and mitigating the negative effects of the LOE in the EU of our second largest product, Atozet. We have created efficiencies in our expense base, which are reflected in our year-to-date results and in our adjusted EBITDA margin guidance.

We took action on our capital allocation priorities in order to accelerate the reduction of our net leverage, paying down principal on long-term debt, and we have a clear pathway to achieving a net leverage ratio below 4 times by the end of this year. And, finally, we acquired a new growth catalyst in Vtama. Year-to-date, we're right where we want it to be with Vtama, making significant progress on our access objectives, which gives us confidence in our ability to deliver on our 2025 Vtama revenue objective.

I'll now turn the call over to Matt, who will review the financials in more detail.

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

Thank you, Kevin. Beginning on slide 8, where we bridge our second quarter revenue of $1.594 billion year-on-year. Overall, revenue was down 1%, both as reported and at constant currency, which aligns with our guidance expectations at the halfway point. Starting on the left, loss of exclusivity was about $60 million for the quarter, which primarily reflects the impact of the LOE of Atozet in Europe, which occurred in September 2024. Six months year-to-date, we are at $120 million of impact from LOE, meaning we are about two-thirds of the way through our full year estimate. We will see that [ph] headwind (00:16:15) mitigate in the fourth quarter when we start lapping the LOE of Atozet in the EU.

VBP in China was de minimis in the second quarter and year-to-date, and we expect only a nominal impact on a full year basis for 2025. Our potential exposure this fiscal year will be more back half weighted as we expect Fosamax will be included in Round 11. There was an approximate $40 million impact from price for the second quarter or about 2.5%. Pricing pressure was primarily from the LOE of Atozet as well as from certain mature products in the US like NuvaRing, Dulera, Renflexis, and Ontruzant. We also continue to face expected mandatory pricing revisions in certain regional markets, for example, Japan.

Volume increased $90 million in the quarter, representing growth of about 5.6%. Fertility, Hadlima, Emgality, and Vtama were the largest contributors to volume growth in the quarter. 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 $10 million favorable impact in the quarter, which reflects the weaker US dollar versus the majority of foreign currencies in which we transact.

Now let's turn to slide 9 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 from cost of goods sold, which can be seen in our appendix slide. Adjusted gross margin was 61.7% for the second quarter, compared with 62% in the second quarter of 2024. The modest year-over-year decrease in adjusted gross margin primarily reflects the favorable impact of foreign exchange on our inventory turns in the period more than offset by price, as I discussed.

Year-to-date, our operating expenses are down 2%, which reflects operational discipline and an element of favorable timing of spend in both SG&A and R&D. Year-to-date adjusted EBITDA margin was 32.4%, which is running above the high end of our 31% to 32% guidance range for the full year. We expect second half adjusted EBITDA margins to moderate and expect the full year to land within our existing adjusted EBITDA margin guidance range as we continue to invest in the Vtama launch and the timing of clinical spending in R&D catches up with our full year expectation. On the full year, we expect total OpEx, which we define as the sum of SG&A and R&D expenses, to be generally flat with prior year, based on our objective to achieve $200 million of operational savings in 2025 that would help offset investment in our growth drivers, especially Vtama.

Turning to free cash flow now on slide 10, we delivered $525 million of free cash flow before onetime costs in the first half, ahead of where we were this time last year. This is a function of active cash cycle working capital management, lower interest expense on our debt, and favorable first-half timing of cash tax payments. Onetime costs related to the spin-off were completed in 2024, following the rollout of our global ERP system. And as a result, these costs are zero in the first half of 2025, compared with $117 million in the prior-year period.

Six months year-to-date, we recorded $175 million in other onetime costs broken out as follows: approximately $75 million relates to cash payments associated with the restructuring initiatives we're executing to deliver $200 million of operating savings this year, as I mentioned earlier; $20 million relates to the final payment on the Microspherix legal settlement; and the remaining $80 million relates to the planned exits from supply arrangements with Merck. We've discussed in past quarters these costs would be ramping up. 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.

Our original estimate for these restructuring and manufacturing separation activities was $325 million to $375 million in 2025. While we are tracking to the midpoint of this range at the halfway point, our view into the second half is pointing to lower cash outlay. As a result, we are improving our estimate by $75 million at the midpoint. Our updated estimate for restructuring and manufacturing separation activities for 2025 is now $250 million to $300 million, with the improvement being realized in lower restructuring costs.

We slightly increased our estimate of business development cash investments for 2025, from approximately $200 million to approximately $230 million, with the increase being driven by the modest up-front payment to acquire commercial rights for Tofidence. On an absolute basis, the majority of the $230 million pertains to commercial milestone payments tied to the sales of Vtama, Emgality, and the biosimilar programs with Shanghai Henlius. Through the first half of the year, we've paid about $150 million towards that total. The achievement of these milestones means we are realizing value for business development deals already signed and validates the path to low- to mid-single digit revenue growth rate post 2025 that we've been saying Organon should be able to deliver.

Turning now to leverage on slide 11. In the first quarter, we've revised our capital allocation priorities, increasing the retention ratio of our free cash flow with the stated goal of applying that cash to debt repayment. In the second quarter, we took immediate action and started to put that cash to work. During the quarter, we made principal payments on long-term debt totaling $345 million. We repurchased and canceled $242 million of our 5.125% notes due in 2031 prior to maturity, which resulted in a pre-tax gain on extinguishment of debt of $42 million at an average purchase price of 82.6% face value.

We also paid off and terminated a legacy funding agreement with Dermavant valued at $103 million, which resulted in a pre-tax gain on extinguishment of $4 million. On an after-tax basis, the $46 million gain across both retirements added $0.14 per share to our GAAP earnings per share in the second quarter. The return on the debt repurchase was compelling, and we advanced our revolver to prudently maximize the trade. We intend to pay off the balance on the revolver by year-end as discretionary cash builds in the second half of the year.

As a result of these actions, we were able to maintain net leverage ratio flat to Q1, despite the impact of a weakening dollar, which increased by approximately $250 million, the translated US dollar value of our euro-denominated debt. We continue to see a path to achieving net leverage below 4 times by year-end. And over time, the capital preserved with a higher retention ratio creates a compounding improvement in financial flexibility, which offers us the opportunity to achieve faster and more meaningful deleveraging over the next few years.

Now turning to 2025 full year revenue guidance on slide 12. We are raising our estimate for full year revenue based on year-to-date favorability and foreign exchange translation in our belief that this favorability will persist at or close to current spot rates for the remainder of 2025. In summary, we are raising our revenue guide by $100 million at the midpoint of the range. The operational components of this revised revenue bridge look very similar to the one we provided in May, following Q1 earnings. The only change of any significance is on FX.

In May, we had said that currency could be as much as a $200 million headwind in 2025, but should a weakening dollar persist, we would see upside, and that appears to be occurring. Given current rates, we are now estimating a $50 million FX headwind year-on-year or approximately 75 basis points on our full year revenue growth driven by the euro, the Mexican peso, Canadian dollar, Chinese yuan, and Korean won.

Within the operational bars, we've modestly revised our ranges on LOE, VBP, and volume. For volume, we narrowed the range and took down the midpoint a bit to reflect conservatism with regard to some risk in the General Medicines-based business, specifically as it relates to the respiratory portfolio. Those products have been under pressure in the first half of the year due to a mild respiratory season in certain markets.

The 6% growth rate midpoint of the volume guide implies very strong volume growth in the second half of the year, which will mainly be driven by continued uptake of Vtama, but also Emgality, biosimilars, and Nexplanon. Taken together, the midpoint of our constant currency revenue guide is still about flat versus prior year. We expect the uptake of Vtama, continued solid performance in Emgality, Nexplanon, and Hadlima will help to offset the LOE of Atozet in Europe, along with typical pricing headwinds in other parts of the portfolio.

From a quarterly phasing perspective, we expect Q3 revenue should be flat with last year on a reported basis with some modest growth year-over-year coming in the fourth quarter. That will be driven by lapping the LOE of Atozet, which occurred in September 2024, as well as the continued uptake of Vtama.

Turning to slide 13 where we show all components of our earnings guidance. We continue to expect adjusted gross margin to be in the range of 60% to 61%. Adjusted gross margin was strong year-to-date, given favorable FX changes on our inventory turns. We expect adjusted gross margin will be lower in the second half, but we believe we will land the year closer to the high end of the range at 61%.

With regard to tariffs, the industry does not yet have the clarity required to be able to talk about specific impacts. For Organon, we can say that our guidance incorporates documented tariffs related to Canada, Mexico, and China. As a hypothetical sensitivity, we can also say that the EU is our most significant exposure from an import standpoint to the US, and we're comfortable saying that an EU tariff on pharmaceuticals of up to 15% alone would not cause us to lower our range on adjusted gross margin for 2025.

Moving on to OpEx. As I mentioned earlier, we still expect the SG&A and R&D expense to land the year within the ranges we've been providing, with favorability in the first half attributable to timing. We continue to expect our adjusted EBITDA margin to be in the range of 31% to 32% for the full year. If you do a second half implied P&L calculation using the midpoint of our guide, you're probably modeling adjusted EBITDA margins in the neighborhood of 30.5% in the back half, which is a pretty good estimate for both the third and fourth quarters individually.

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 capitalized fees related to the debt retirement. As we think about next year, we would expect interest expense to be closer to $475 million run rate as a result of the voluntary debt repayments completed this quarter, all else held equal. 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 full year 2025.

In summary, our year-to-date results were solidly aligned with our expectations at the start of the year. We see a very realistic path of maintaining total revenue about level with prior year, which is noteworthy given the LOE of Atozet, our second largest product, that we're facing this year. Vtama will play an important role in achieving this result. From a profitability standpoint, we are tracking well to our cost reduction goals, and we continue to improve our OpEx efficiency metric. 2025 is likely to be our strongest OpEx efficiency since the spin-off. If we achieve the midpoint of our adjusted EBITDA margin guidance range, that would represent almost a full point of improvement over last year.

And, finally, we're on the right path with regard to deleveraging. Following our reprioritization of capital allocation, we were quick to act in the second quarter and were successful in repurchasing debt in the open market, yielding a very attractive return. Combined with free cash flow, which we expect will be in excess of $900 million for 2025, we continue to see a path to sub-4 times net leverage ratio by year-end, which is an important mile marker on our way to even lower leverage in 2026.

And with that, we'll now turn the call over to Q&A.

QUESTION AND ANSWER SECTION

Operator: Thank you. [Operator Instructions] Your first question comes from David Amsellem with Piper Sandler. Your line is open.

David Amsellem

Q

Hi. Good morning. Thanks for taking our question. This is [ph] Alex (00:31:26) on for David. Just one on Vtama from us. Looking further ahead, can you talk to incremental sales and marketing investment, whether it's DTC or sales force expansion or both? And can you also remind us how many practitioners you are currently calling on and how many reps you currently have supporting the product? Thank you.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

So, thanks for the question, [ph] Alex (00:31:50). So, yes, as a matter of fact, in July, we started new telehealth and DTC campaigns, coupled with pediatric initiatives and programs to penetrate into the pediatric segment. And so, currently, we feel very comfortable with where we're going in terms of the investments for the second half of the year. They're more weighted or loaded towards the second half. And so, things are moving along exactly where we thought they would be at this period of time. And we feel good in terms of overall positioning of where we are with Vtama right now and we're expanding. And, currently, in terms of your question around reps, so we did add more reps. And I talked about DTC, so we added more sales force, and we've got now a total of more than 125 reps in the field.

Jennifer Halchak

Vice President-Investor Relations, Organon & Co.

A

Thank you. Maybe next question.

Operator: Thank you. 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 questions. I have two. The first is on Nexplanon. Can you elaborate on the federal funding headwinds you cited in the US? To what extent was the decline in US Nexplanon sales this quarter related to purchase timing versus underlying crushers that might persist through the rest of the year and beyond? And then my second question is on capital allocation. As you approach and then exceed your leverage ratio targets, how do you expect your capital allocation priorities to change what might become the top priority? Thank you.

Kevin Ali
Chief Executive Officer & Director, Organon & Co.

A

Yeah. Mike, I can get started with that. With Nexplanon, it's a combination of both. Look, I mean, with the most recent Big Beautiful Bill, there were some effects in terms of overall on Planned Parenthood and Medicaid-related funding. And so, there's a lot of kind – there's some nervousness in the market, especially when it comes to purchase of contraception as well. Remember that in the first quarter, we saw a – essentially the movement on USAID by the administration. But, overall, we're seeing a lot of pickup ex-US in countries like Brazil, Egypt, and many other countries that are starting to pick up the slack. And we have a lot of confidence that the USAID numbers will start to – or investment will start to pay off with regards to other sponsors coming in, picking up the tab on that.

Now, in regards to where we are with the US, still feel very confident that we'll grow this year with Nexplanon. But clearly, there's a lot of confusion in the market. We've got, I think, good news on Title X unfreezing in certain states that are key for us like California and Texas. But there is a little bit of hesitancy, especially around the Planned Parenthood issues that are there that needs to be dealt with. But we feel very confident that it's just a matter of, yeah, in the near future, we'll reach that $1 billion threshold and we'll see growth this year going forward.

Whether it lasts for the long-term – remember the Planned Parenthood issues were really 12 months in total. So, once that's up and running, then ultimately, we'll be able to get back to it. But feel very good about Nexplanon being our key product. And remember that we're going to be launching the five-year indication sometime at the end of this year, so we feel good about that.

In regards to leverage, well, ask us when we get down below 3.5 times, and then we'll have a discussion on that. But right now, our focus is to de-lever. We did that with regards to the payment on principal debt in terms of the first quarter, what we just came right out with, and we'll continue to do that.

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 question and thanks for all the clarity on the call. You guys mentioned that 15% tariff in the EU would not have an impact on 2025 margins. Just wondering if you can look out to 2026 and give us some idea what kind of impact it might have on 2026? And then, similar question, as you look out to 2026, how should we think about free cash flow conversion and some of the onetime items? I know you've guided to those continuing to decline, but can you give us any sense of the magnitude there? Thank you.

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

A

Yeah. So, I'll take that one. It's a little bit too soon to be talking about tariff impacts out in 2026. It's not the right time for that. Just investors should know that our largest import exposure into the United States comes from the EU. It's approximately two-thirds of our imported value. So, investors, knowing that, can make some of their own math. But it's just too soon for us to speculate about 2026, whether we're talking about tariffs or anything else.

Kevin Ali
Chief Executive Officer & Director, Organon & Co.

A

And free cash flow?

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

A

Yeah. Free cash flow should be growing in line with the business. We'll continue to see a reduction in onetime costs. So, we've needed to make a differentiation between gross free cash flow and free cash flow excluding onetime items. Those onetime items are declining. They've been declining this year. They will continue to decline into next year. So, that will be a reason why you might see, in addition to normal growth of the business, discretionary cash flow increase pretty significantly next year.

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

Umer Raffat
Analyst, Evercore ISI

Q

Good morning, guys. I was just looking at Vtama volume data. I recall you guys obviously got the atopic derm approval in December. So, a couple of months into the launch, I think around end Feb/March timeframe, it was generally hovering around 6,000 TRx a week. And it's kind of in that same ballpark right now, few months later. And I'm just trying to think about how you're looking at the volume data, because I feel like sometimes we do the year-over-year and it can mask what's happening more near-term. And is there something you want to do differently to turn the trajectory around?

Kevin Ali
Chief Executive Officer & Director, Organon & Co.

A

Hey, Umer. Good to hear you. Listen, in regards to Vtama, I mean, there's a tug of war week by week. But overall, what I can tell you is the following, that we just started the investments right now. We need it to settle down. Obviously, we just took over the product and get it launched and get it out there and do the right things in the initial stages. And now we have a very, I think, effective and full force behind our DTC campaign and our telehealth campaign and expanding in terms of sales force, in terms of what we're doing regarding penetrating into the pediatric segment as well as, obviously, continue to maintain our focus on the adult segment. But more importantly, the gross to net and lives covered continue to move in the right direction.

Look, when access starts to open up in each individual physician's offices, whether it's a dermatology office or others, they know that when they start to hear that, ultimately, PBMs start to accept it and – for AD. You have less hesitancy about using, say, coupon cards. You have more fluency, more openness to be able to use the product on a more routine basis. And so, now, as we predicted, our access teams are working incredibly hard to make huge strides, huge strides to get to 80% of the lives covered by Q1 of next year. We're making incredible movements in that space. As well, gross to net is precipitously dropping in the right direction real quick.

So, once those two things happen, it's funny how that affects volume. Volume starts to pick up because people understand it's being covered. In addition to that, you add our DTC and telehealth as well as our expansion in sales force, and I think you'll see good solid volume getting picked up. But more importantly, that every script will mean more net revenue for us as we start to get the gross to net in the right place.

Umer Raffat
Analyst, Evercore ISI

Q

But, Kevin, just to maybe expand on that, the new-to-brand is not so bad, it's kind of growing, which sounds to me like there's a duration issue more so than an access issue?

Kevin Ali
Chief Executive Officer & Director, Organon & Co.

A

Well, I think, right now, what you see is an uptick in TRx, so you've got some refills coming in as we speak. You'll start to see more and more TRx uplift as the volume starts to move. But I agree with you. Look, I mean, we've added a number of physicians right now who are new-to-brand. And we see these kind of seasonalities, but I feel really good about the second half of the year based on where we landed in terms of exiting Q2. Q2 in terms of the last month was a very strong exit. It gives me a lot of confidence in terms of where we're headed.

Umer Raffat
Analyst, Evercore ISI

Q

Thank you.

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

A

Thank you, Umer.

Kevin Ali
Chief Executive Officer & Director, Organon & Co.

A

Yeah, Umer.

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 Schott. Thanks for taking our questions. Just starting off on Vtama, can you remind us what's driving the ramp in the second half of the year to get to the $150 million in sales? And how much of that is driven by volume versus price? And then, on Nexplanon, as we think about the launch of the five-year indication, can you remind us on how we should think about the impact to growth in 2026 and 2027? And, specifically, what portion of current volumes are coming from implant replacements? Thank you.

Kevin Ali
Chief Executive Officer & Director, Organon & Co.

A

Okay. Let me try to address those, Ethan, one after the next. So, second-half uplift in terms of Vtama, we got this – it is global, obviously, the $150 million. We've got $56 million in and another $90 million something to go, $94 million to go. And so, I believe very strongly that where we are right now in implementing our new activities

around DTC, around telehealth, around expansion of sales force, around some of the things that we're doing around volume is really a very important lever to believe in for at least for me going forward. We're getting obviously a launch in Canada soon. We've got continuous implementation or rather contribution from Japan as well. But, overall, in the US, that's the key market and we feel really good about where we landed in terms of exiting Q2.

And I think the ramp in terms of where we see it, gets us to the $150 million, especially if you look at how we exited Q2 and especially you look at, see, where gross to net is falling in the right direction, the gross to net issue was not great under the psoriasis indication, but the team has done a phenomenal job of both adding significant lives in terms of PBM additions as well as lowering our gross to net range because of less usage and reliance on the coupon card. So, I think, overall, get the volume where it needs to be, get a better gross to net picture, invest in expansion of the sales force as well as DTC, and I feel really good about the second half of the year, especially how we've exited Q2.

Now in regards to Nexplanon, yeah, I mean, that's still working its way out in terms of Planned Parenthood and Medicaid. But we've got opportunities in Title X on funding or rather being unfrozen in key states like Texas as well as California. And remember, we launched the five-year duration indication by the end of this year. That will be a little bit of a small headwind in 2026. But then, ultimately, it expands our ability for exclusivity and through 2029 with the five-year indication. And I don't want to get into – I can give [indiscernible] (00:44:23) in terms of the issues on being able to try to continue to penetrate into this market.

But what I can tell you is ex-US is growing double digit robustly. US continues to be a growth driver for us, but we just got to get through this year. We got to launch the five-year indication, and I think all signals point to the fact that, okay, a little disruption in terms of federal funding, but we feel good about where we are in terms of the patient cohort, in terms of expanding, and where we are in terms of the performance year-to-date. We've got 6% growth year-to-date, which is very solid.

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

A

Thanks, Ethan.

Operator: Your last 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 squeezing me in. So, maybe firstly on the OG-6219 endometriosis setback announced in July. Do you still expect to invest in the space? I think there was some commentary in the lead up to that readout that there was a backup molecule. And if you saw at least a signal with OG-6219, you might pursue that. So, I'm just kind of curious where things may stand on that front?

And then, secondly, I know there were some efforts through citizens petition to modify the generic product-specific guidance for developing a generic Nexplanon, more around the applicator similarity. But I'm curious, when you get the five-year approval, do you expect the FDA to have the real-time release study updated to mandatory five years? Or do you think there'll still be an option to have a three-year and a five-year release time – or I guess time release study to be done by the generic supplier? Just curious your thoughts on that. Thanks.

Kevin Ali
Chief Executive Officer & Director, Organon & Co.
A

Juan Camilo, would you like to take that – those questions?

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

Yeah. I can handle both, Kevin. Yeah. So, first, regarding to OG-6219, as we shared in our press release, we did not see a signal for efficacy for OG-6219. And, therefore, to your question on the backup molecule and second asset, which was targeting the same mechanism, we have decided to discontinue that program as well.

And now, second, with regard to the citizens petition and on the overall FDA guidance, we don't comment on the decisions the FDA may make about their guidance of how to develop a generic. We are working closely with the FDA to get the right labeling for the five-year indication in Nexplanon. And as you saw on the citizens petition, we've provided our perspective of what is required and have been required for Nexplanon to be used safely in patients. So, with that information, the FDA will make their own assessment and determine what is the right appropriate guidance they'll provide to generic manufacturers.

But as Kevin pointed out, we are really excited and looking forward to bringing this new indication and a new labeling for Nexplanon through the finish line before the end of the year.

Kevin Ali
Chief Executive Officer & Director, Organon & Co.
A

Okay.

Jason M. Gerberry
Analyst, BofA Securities, Inc.
Q

Thank you, guys.

Kevin Ali
Chief Executive Officer & Director, Organon & Co.
A

What I will say, though, is that patients and providers both clearly prefer the longer duration of five years. It just gives them much more flexibility, especially for different segments like, for example, the family complete segment, the older cohort in terms of – because a lot of our business comes from the much younger cohort. And so, this will open up a completely new segment for us. And so, to the question of can we see a three-year and a five-year coexisting in the market? Very difficult. I think by the time that all plays out, I think the market will have moved securely into the five-year segment, just another hurdle to essentially for any potential generics to actually deal with and managing to get into this business.

Jason M. Gerberry
Analyst, BofA Securities, Inc.
Q

Okay. Okay. Thanks, guys.

Kevin Ali
Chief Executive Officer & Director, Organon & Co.
A

Sure.

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

A

Thanks, Jason.

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.