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# Organon & Co. (OGN)

Q2 2023 Earnings Call

## CORPORATE PARTICIPANTS

**Jennifer Halchak**

*Vice President-Investor Relations, Organon & Co.*

**Kevin Ali**

*Chief Executive Officer & Director, Organon & Co.*

**Matthew M. Walsh**

*Chief Financial Officer, Organon & Co.*

**Sandra Milligan**

*Head-Research & Development, Organon & Co.*

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## OTHER PARTICIPANTS

**David Amsellem**

*Analyst, Piper Sandler & Co.*

**Umer Raffat**

*Analyst, Evercore ISI*

**Jason M. Gerberry**

*Analyst, Bank of America Merrill Lynch*

**Navann Ty**

*Analyst, BNP Paribas Exane*

**Roger Xu**

*Analyst, Goldman Sachs & Co. LLC*

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## MANAGEMENT DISCUSSION SECTION

**Operator:** Ladies and gentlemen, thank you for standing by. At this time, I would like to welcome everyone to the Organon Second Quarter 2023 Earnings Conference Call. 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] As a reminder, this call is being recorded. I would now like to turn the call over to Jennifer Halchak, Vice President, Investor Relations. Please begin your conference.

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**Jennifer Halchak**

*Vice President-Investor Relations, Organon & Co.*

Thank you, Audra, and good morning, everyone. Thank you for joining Organon's second quarter 2023 earnings call. With me today are Kevin Ali, Organon's Chief Executive Officer, who will cover strategy and operational highlights, and Matt Walsh, our Chief Financial Officer, who will review performance and guidance. Dr. Sandra Milligan, Organon's Head of R&D, will also be joining us for the Q&A portion of this call.

Today, we'll be referencing a presentation that will be visible during this call for those of you on our webcast. The presentation will also be available following this call on the Events & Presentations section of our Organon Investor Relations website at [www.organon.com](http://www.organon.com). Before we begin, I would like to caution listeners that certain information discussed by management today during this conference 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'd now like to turn the call over to our CEO, Kevin Ali.

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## Kevin Ali

*Chief Executive Officer & Director, Organon & Co.*

Good morning, everyone, and thank you, Jen. Welcome to today's call, where we'll talk about our second quarter 2023 results.

Our revenue for the second quarter was \$1.6 billion, up 4% at constant currency compared with the prior year period. In the second quarter, our Women's Health and Biosimilars franchises grew double digits, while our Established Brands franchise achieved flat performance again, demonstrating its continued stability. Adjusted EBITDA was \$530 million, representing a 33% margin.

Turning to the full year. Given our current view of foreign currency exchange rates, we narrowed our guidance range on revenue from \$6.15 billion to \$6.45 billion to now \$6.25 billion to \$6.45 billion, which raises the midpoint of the revenue range by \$50 million. We also raised the lower end of our adjusted EBITDA guidance based on our latest visibility into potential milestone payments. The new range of the full year is 31.5% to 33%, a quarter of a percentage point higher at the midpoint compared with prior guidance.

Now, let's review the quarter in greater detail, beginning with Women's Health. Women's Health grew 10% on a constant currency basis, primarily driven by 12% growth in Nexplanon. Performance of Nexplanon in the US was particularly strong this quarter with revenue growth of 19%. This reflects a 5% increase in US physician demand and increase in distributor inventory as well as the benefit of our pricing action in the third quarter of 2022. Year-to-date, Nexplanon is up 6%, outpacing the large market, which grew 3% over the same period.

We expect continued demand growth in the United States, especially with the more than 35,000 healthcare professionals currently prescribing Nexplanon. We also expect increasing demand outside the US, especially in Latin American in countries like Brazil and Argentina, as well as in Asia in countries like Thailand and the Philippines. We continue to believe that Nexplanon will achieve \$1 billion in revenue by 2025 and we expect Nexplanon to be a significant contributor to growth for the coming years.

Continuing our discussion on Women's Health, fertility was up 17% at constant currency. As we have discussed, China and the US are large fertility markets and together represent more than half of our current fertility business. During the second quarter, we saw significant growth in China, where there was a post-COVID rebound, as patients returned to clinics for treatment. We have a very positive outlook for the fertility business in China for the remainder of the year.

In the US, the fertility market is growing and remains an attractive business for Organon. We're seeing increasing demand from our existing customer base, but also since spin, we've worked to improve the consistency and reliability of our supply chain, which has allowed us to win incremental business from existing customers and to expand into new accounts in the reimburse market. Demand is very strong in the US market and we believe volume will continue to offset a competitive pricing environment. Over the intermediate term, we believe our global fertility business can grow in the high-single-digit to low-double-digit range, in line with our expectation for 2023.

Wrapping up on Women's Health is the Jada System, our device for postpartum hemorrhage. Year-to-date, revenue from Jada has more than doubled, albeit off a small base and is fast approaching a threshold where it will

start to disclose its revenue in our product table. During the second quarter, we added more than 300 new accounts. We are now in over 100 of the 150 largest birthing hospitals in the US and more than 28,000 mothers have been treated with Jada since launch.

The enthusiasm around Jada is palpable and ranges from a rising profile and scientific journals like the RUBY study's upcoming publication, to healthcare professionals taking to social media to talk about the product. Overall, we are feeling very good about the future prospect for Jada.

Moving now to our Biosimilars business, where today, I'll focus my discussion around our US launch of HADLIMA, a biosimilar for HUMIRA. Since launch, all major wholesalers have placed orders for HADLIMA. We're encouraged by our early traction as Organon is emerging as one of the few players earning spots on formularies and winning orders.

In approaching the launch of HADLIMA, we were very intentional in our market positioning and segmentation. Our pricing strategy focuses on simplicity. It was a deliberate choice and design so that the savings to the healthcare system would be more transparent. We price HADLIMA to enable access and to bring the economic benefits of biosimilars directly to the patients. We believe this is where we can offer the highest utility to patients.

For example, here we're showing the two PBMs who have so far announced their formulary listings, OptumRx and Express Scripts. You can see where Organon has already been able to secure access within both PBMs outside of the national formulary listings. In the case of OptumRx, we have secured more than half of the lives through UnitedHealthcare. In the case of Express Scripts, between Cigna and Prime Therapeutics, we've secured about a third of the lives.

Prime Therapeutics is the fourth largest PBM. Health plans of Prime include some of the largest Blue Cross Blue Shield plans in the nation. Many of these health plans are the dominant player in their respective states. And for both OptumRx and Express Scripts, we remain active in discussions for the custom health plan business.

While we're very encouraged by the access we've secured so far, access alone does not guarantee success, and access doesn't necessarily mean the patients will get the product. This is why our strategy is expressly focused on customers that are not dependent on rebates, but rather, the providers in the market who are focused on bringing the savings of biosimilars to the patients. And we're not done. The market is still evolving. Decisions from PBMs and insurers are still forthcoming. Product attributes will be a key in continuing to unlock opportunities. We continue to believe HADLIMA is positively positioned when it comes to its product attributes.

For example, our pen design received an Arthritis Foundation designation, which recognizes products that make life easier for those living with arthritis and other functional limitations. We also developed the HADLIMA For You patient support program that features comprehensive resources, including a copay program and dedicated nurse coaches, who engage with patients throughout their treatment journey.

One of the most important differentiators for HADLIMA is the five years of real-world evidence covering tens of thousands of patients that we have collected from Samsung's launch in Europe and from our own launches in Canada and Australia. This data should give great confidence and comfort to prescribers and patients alike, and we continue to move forward with our collaborator, Samsung, on the interchangeability designation. We recently announced that the Phase 4 study had reached its primary endpoint, which puts us on track for summer of 2024 approval.

And finally, our product formulation is high concentration, citrate-free aligned with the most prescribed formulation of the originator. A product that can create a frictionless experience for a patient is the best way to drive pull-through. That is what gives patients a better comfort level and will influence physician prescriptions.

The US healthcare system needs biosimilars to be successful. They fill a significant gap in more affordable options for some of the most chronic diseases people face. We're proud of our market positioning and pricing. We're very pleased and encouraged by the signals we are getting so far, and we believe we'll be able to secure further access as this market continues to develop.

Rounding out the top-line discussion, let's move on to Established Brands. Year-to-date, the Established Brands franchise has grown 1% ex exchange, as 2% volume growth has offset a 1% decline in price across the portfolio. Since launch, we've encountered skepticism around how a portfolio of [ph] all patent (10:35) brands can demonstrate that kind of continued stability. There are several reasons, and over the next few quarters, we will highlight a few of them in detail.

Last quarter, we talked about manufacturing optimization for Nasonex and Atozet to meet increasing demand resulting from heightened promotional activities. Today, I'll focus on our strategic approach to pricing. In some lower-priced markets, lawmakers are backing policies that propose to raise originator and generic prices, hoping to draw manufacturers back into the market and cure ongoing supply issues. This is true in select EU markets such as Germany, France and Sweden as well as some APAC markets like India and Australia.

Where this isn't the case, we have worked with policymakers to demonstrate how investments are important to ensure access to reliable and high-quality manufactured products. Further, we've been able to selectively increase our list price in many markets, subject to meeting certain conditions. An example is our LAMERA region, where currency devaluation and inflation provided a basis for all our price increases in a number of countries. Beyond increasing list price, we've also scrubbed the channel for commercial and trade discount improvements.

As we continue to look at this portfolio, we're identifying opportunity that gives us greater confidence that the five-year CAGR for this franchise will be relatively flat on a constant currency basis. This June, we entered into our third year as a standalone company. Thanks to the hard work of our people around the world and their commitment to our vision and business, each of our franchises are performing as good as or better than we thought they would. Importantly, we have grown our pipeline since launch and have added eight assets to our portfolio, which includes some very interesting molecules in the early stages of development. This investment is key so that over time, Organon evolves into a pharma company with a regular cadence of catalysts and an accelerating growth rate.

In our first two years as a company, we continue to build a track record of good operational results while also laying the groundwork for a successful future. I'll turn it over to Matt now to talk more about the solid results of the second quarter in more detail.

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## Matthew M. Walsh

*Chief Financial Officer, Organon & Co.*

Thank you, Kevin.

Beginning on slide 9, let's walk through the drivers of our 4% constant currency revenue growth in the quarter. Starting with the impact of loss of exclusivity, LOE was negligible in the second quarter as it was in the first quarter, and the small amount that we have realized year-to-date was related to generic competition for NuvaRing in the US.

In the second quarter, we had about a \$25 million impact from VBP in China related to last year's implementation of Round 7 that included our cardiovascular product, EZETROL, which is sold as Zetia in some markets outside of China. Year-to-date impact from VBP is about \$50 million, which is tracking to our expectations for the year.

Moving across the price, we saw approximately \$30 million in price erosion in the quarter. And as Kevin mentioned, through various initiatives, we have been able to do a bit better on stemming price erosion in Established Brands. But given the nature of Biosimilars, we will see pricing pressure in that franchise. Additionally, in the United States, we're attempting to gain share in fertility, especially in reimburse markets, so we have to price our products competitively in that channel.

We continue to see strong volume increases across all of our franchises, about \$115 million in the second quarter. About 60% of the volume growth came from our growth pillars, Biosimilars, Nexplanon, fertility, Jada and China retail. The remainder came from volume growth within Established Brands.

The bar for supply/other primarily represents revenue to Merck, with the plus \$5 million from this quarter bringing us to level with our expectations six months year-to-date. As we have advised in the past, this revenue stream is essentially a series of lower margin contract manufacturing agreements that have been declining since the spin-off and will continue to decline going forward.

And finally, you can see the financial reporting headwind we had in foreign exchange translation, about 250 basis points for the second quarter, which is a function of more than 75% of our revenue being generated outside of the United States. Now, this moderated from the first quarter when we saw a 450-basis-point headwind. And we expect the impact of FX translation to continue to moderate through the end of 2023.

Now, let's turn to slide 10, where we take a look at revenue by geography. The UK region grew 6%, primarily related to growth in Atozet and particularly in France as well as growth in biosimilars in Canada, where multiple provinces are executing a mandatory transition from originator drugs to biosimilars. Partial offsets in the quarter were mandatory price declines typical in Europe, as well as supply constraints related to the market action on injectable steroids, as we're steadily rebuilding supply chain inventories to our desired stocking levels.

The US grew 6% in the quarter as a result of the strong performance across most of our key growth platforms: Nexplanon, Renflexis, Jada and to a lesser extent, fertility. Asia Pacific, Japan declined 5% in constant currency in the second quarter, driven mainly by an unfavorable comparison to the very strong performance in the second quarter of last year, when certain competitors in Japan were out of the market because they didn't receive GMP or good manufacturing practice certification.

Despite VBP, China grew 2% in the second quarter on a constant currency basis, driven by the COVID recovery in fertility and modest growth in the retail channel. Constant currency growth in the LAMERA region of 11% was mainly driven by solid contributions in Women's Health across contraception and fertility, coupled with robust growth from our Established Brands products primarily in cardiovascular. This was partially offset by supply constraints related to the first quarter market action for injectable steroids, as we just mentioned in the EUCAN region.

The next few slides lay out our performance by franchise. Kevin covered the highlights very well in his opening comments, and the details are provided in the supporting earnings materials. So, I'll focus on topics that may be relevant to your modeling as we think about the remainder of 2023.



We'll start with Women's Health on slide 11. A key volume driver in both Nexplanon as well as our fertility portfolio results from expanded access, moving from traditionally out-of-pocket markets into the reimburse segments. For example, in the United States, the Dobbs decision has driven an increase in demand from patients obtaining Nexplanon through providers under the 340B program, which is a more highly discounted channel. And in fertility, while volume demand is strong, we are trying to expand access into the reimburse segments, which requires competitive pricing. Ex-US, we've seen strong performance from fertility in LAMERA and also in China, as patients return to the clinics post COVID.

Turning to Biosimilars on slide 12. Kevin covered the US HADLIMA launch, which began on July 1, but I would also highlight that the second quarter was a very solid quarter for biosimilars, which grew 15% ex-FX in the quarter and has grown 18% ex-FX year-to-date. Renflexis grew 20% in the quarter and is on track for its sixth consecutive year of annual revenue growth in the US. Ontruzant is weathering competitive headwinds in Europe and more recently in the US. But in the US, the team has been able to substantially grow volumes to offset competitive pricing dynamics.

Turning to Established Brands on slide 13. As Kevin mentioned, that franchise continues to demonstrate its durability. The team has been able to cover what was, on a companywide basis, about 1 percentage point of revenue headwind from the market action on injectable steroids, Diprospan and Celestone. And we expect Established Brands to be flat for the full year on a constant currency basis

Now let's turn to key P&L line items on slide 14. For gross profit, we are excluding from cost of goods sold, purchase accounting amortization, and one-time items related to the spin-off, which can be seen on table 4 in our appendix slides. Non-GAAP adjusted gross margin was 62.9%, compared with 66.1% in the prior year period. The year-over-year decline in gross margins is primarily due to product mix and FX translation as well as inflationary cost pressures that impacted distribution and employee-related costs.

Our adjusted EBITDA margin was 33% in the second quarter compared to 32.3% in the second quarter of last year. The increase in adjusted EBITDA margin was primarily a result of \$97 million of IPR&D and milestones in the second quarter of last year, where no such costs were incurred in the second quarter this year.

With regard to IPR&D, these milestones are subject to a great deal of uncertainty and are difficult to forecast. Based on our current view into the rest of the year, we do not anticipate any additional IPR&D payments in 2023 tied to current assets in the portfolio. That includes \$25 million tied to the IND acceptance for ebopirant.

Last quarter, we said that the IND for ebopirant could be filed as early as the second quarter of 2023. Since then, [audio gap] (20:38) additional development work that's required to inform a clinical program for this asset. As a result, we currently do not have an updated date for filing the IND and we'll plan to evaluate future development of this program as new data is available.

Non-GAAP adjusted net income was \$336 million, or \$1.31 per diluted share, compared with \$319 million, or \$1.25 per diluted share in 2022. The year-over-year increase in net income was a result of higher adjusted EBITDA compared with the second quarter of 2022, as well as a tax benefit in the second quarter related to foreign earnings. This was partially offset by an increase in interest expense related to our variable rate debt.

Turning to our net leverage ratio on slide 15. Reiterating comments I made on our last two earnings calls, I said that we would see upward pressure on our net leverage ratio through the third quarter, ultimately ending 2023 close to where it was at the start of the year. This is both a function of investments we've made to support our business development strategy that have an impact on our trailing 12-month EBITDA calculation, as well as a

debt figure that trues up immediately when the dollar weakens because it increases the translated value of our euro-denominated debt on the balance sheet.

Turning to slide 16, we provide a closer look at our cash flow. As a reminder, in 2022, we generated just over 75% of our annual cash flow in the second half of the year, and we expect this year to follow that same pattern. The biggest use of cash in the first half is working capital. There are few items in working capital that are timing-related, and we expect to be absorbing cash in the first half of the year and then releasing it in the back half. That includes certain accruals, which, for instance, include annual incentives, among others, that represented about \$110 million of that \$440 million working capital use. There's about \$130 million use of cash related to a planned first half inventory build to support the growth of the Biosimilars business, including the HADLIMA launch, and to achieve target fill rates across the portfolio.

In addition, as inventory turns, the replenishment cycles reflect the impact of both inflation and foreign exchange on our purchased raw material and labor inputs. And if you're tracking our trade days sales outstanding, or DSO, you probably noticed that metric ticked up by about five days this quarter. That was largely driven by strong sales in the month of June. We believe we will revert back to our norm of about 65 days trade DSO during the second half of the year, which alone should improve working capital by about \$100 million in the second half.

So, there are some very logical levers that will unwind a fair bit of this first half use of working capital use in the back half, and that'll drive us towards that approximately \$1 billion of free cash flow before one-time costs on an annual basis for 2023. One-time cash costs related to the spinoff transaction are trending in line with our expectation of about \$350 million for the full-year 2023. And the single biggest component of separation cost relates to the implementation of standalone IT systems, the largest of which is our standalone SAP global single instance ERP system, which is scheduled for completion in the second quarter of 2024.

Looking ahead, CapEx for PP&E of 3% to 4% of revenue remains a good range for forecasting purposes, as we continue to deploy that capital into our internal manufacturing and packaging capabilities as well as our technology infrastructure to help drive cost efficiency and productivity.

Turning to revenue guidance now on slide 17. Here, we bridge our expected revenue change year-on-year. Compared with our last guidance update, the biggest difference on this slide is the FX translation impact and that dynamic is improving. We're moving from an approximate \$50 million to \$100 million impact or a headwind of about 80 basis points to 160 basis points to an approximate \$0 to \$50 million impact, representing an 80-basis-point headwind on the high end based on where spot FX rates are today.

Accordingly, we're adjusting our guidance range for full-year 2023 revenue from \$6.15 billion to \$6.45 billion to \$6.25 billion to \$6.45 billion, consistent with the movements we've seen in foreign exchange. LOE impact has been minimal so far in 2023 and is primarily related to the continued impact of generics for NuvaRing in the United States. In the second half of the year, we still expect an approximate \$50 million to \$75 million impact related to the continuing erosion of NuvaRing, generic competition for Atozet in Japan following recent LOE in that market, as well as a possible generic entrant for DULERA in the US by year-end.

We now expect the annual impact from VBP to be in the range of \$100 million to \$125 million, an improvement from the bridge we showed last quarter. The VBP impact in 2023 will be driven mostly by EZETROL's inclusion in the implementation of Round 7. In November of 2022, as well as the recent Round 8 implementation in July, which will include for Organon our REMERON and HYZAAR products.



We're raising our estimate of potential exposure to price erosion to \$100 million to \$150 million, which is about \$25 million higher than our previous estimate. This is less about Established Brands, but rather tied to my earlier comment around expanding access for Nexplanon and commercial strategies in fertility in US Biosimilars. We continue to expect approximately \$500 million to \$600 million of volume growth in 2023, unchanged from prior guidance, with that growth coming from our multiple growth pillars, Biosimilars, fertility, China retail, Jada and Nexplanon, as well as contributions from Established Brands.

Moving to the other components of guidance on slide 18. We continue to expect adjusted gross margin to be in the low- to mid-60% range and in fact, the back half of 2023 gross margins should look much like what we saw in the second quarter. This is primarily due to product mix. The Biosimilars franchise operates as a profit share model, so growth in that franchise from the US launch of HADLIMA will be unfavorable with the gross margin line. Additionally, the inflationary cost pressures we saw in the second quarter will persist through the remainder of 2023.

On operating expenses, our ranges for SG&A and R&D as a percentage of sales are consistent with what we laid out last quarter for our expectations for the full year and reflect continued investment in the business as we position it for future growth. But I would add that typically our second half OpEx spending tends to trend a bit higher than the first half of the year.

Operationally, all of these ranges are largely in line with the financial guidance we laid out back at the beginning of the year. Consistent with our view that we no longer expect about \$30 million of IPR&D in the remainder of the year, we are raising the bottom end of our adjusted EBITDA guidance by 0.5 percentage point, so the new range is 31.5% to 33%.

We also expect to have some net favorability below the EBITDA line. Given the favorability on tax rate we had in the second quarter, we are lowering our estimate of our non-GAAP tax rate by about 150 basis points, which represents about \$20 million of net savings in 2023. We increased our estimate of annual interest expense by \$10 million due to the Fed's most recent rate hikes, but that's offset by a \$10 million decrease in our estimated depreciation for the year.

In summary, second quarter results represent solid execution against our expectations and guidance for the full year. Our businesses continue to deliver constant currency performance aligned with our long-range targets. We're looking forward to the results from HADLIMA's launch in the US as well as the upcoming US launch of XACIATO. Also important, we're starting to see moderation in the strength of the US dollar, which bodes well for near-term reported results in terms of closer alignment between our reported results in US dollars and our relatively stronger performance in local currencies.

With that, let's now turn the call over to questions and answers.

## QUESTION AND ANSWER SECTION

**Operator:** Thank you. [Operator Instructions] We'll go first to David Amsellem at Piper Sandler.

**David Amsellem**

*Analyst, Piper Sandler & Co.*

Q

Hey. Thanks. So, got a question on the capital structure. I think you've said in the past that you're looking to clean up some of the variable rate debt. So, I just want to get some more color on how you're thinking about that, what that means for 2024, how you're thinking about interest expense. I know it's a little early, but just help us better understand your broader thinking.

And then, related to the cap structure, in terms of BD M&A, how do you sort of square the two goals of deleveraging and adding assets? And how are you thinking about what to prioritize, bearing in mind that it may not necessarily be an either/or, but just give us your latest thinking. Thank you.

**Matthew M. Walsh**

*Chief Financial Officer, Organon & Co.*

A

Okay. So, I'll start with that one and we'll start with the debt piece. So, just a reminder to investors that in the first quarter, the company did make a \$250 million voluntary debt paydown of our variable rate debt. Given recent Fed increases, the cost of that debt is now the most expensive debt in our debt stack. So, as we look at future voluntary debt repayments, we'll certainly be focused on that. And when we think about the 75% of our free cash flow we'll be generating in the back half of the year, that'll be a decision that we'll be looking at in the second half in terms of capital allocation, capital deployment, further reductions in that variable rate debt.

The second part of your question, David, is really integral to it, because since the spin, we've been saying that we would be looking to bring a balance between growth, external growth source through business development, M&A type capital deployment and balancing that against the near term and if certain benefits from debt reduction. And that's exactly what we've done to this point in time. We've deployed about equal amounts of capital to growth over the eight deals we've completed and about \$450 million in total of voluntary debt repayments. And we expect to continue to do – we expect to continue that strategy.

In terms of how we think about capital deployment in the BD program, the change in the interest rate environment, we've said this before as well, has raised the bar on capital deployment through BD and causes us to think about opportunities that result in more near-term visibility into revenue and EBITDA accretion. So, with those comments, Dave, I think we've addressed that question.

**David Amsellem**

*Analyst, Piper Sandler & Co.*

Q

Yeah. Thank you.

**Operator:** We'll move next to Umer Raffat at Evercore.

**Umer Raffat**

*Analyst, Evercore ISI*

Q

Hi, guys. Thanks for taking my question. I'm still trying to make up my mind on reading all the details of the quarter. I mean, clearly tracked ahead, but I know there are some one-timers in there as well. So, could you lay those out first? Also, first perhaps on the cholesterol franchise ex-US tracking ahead relative to whether the trade receivables build was specifically focused on those cholesterol meds. And secondly, also, what exactly drove such a big tax lowering?

**Matthew M. Walsh**

*Chief Financial Officer, Organon & Co.*

A

So, I'll start with the second part of that, Umer. So, we have a global tax structure that has a significant amount of exposure in Europe, where we have a significant presence, especially in Switzerland. So, it was really a result of the international tax planning structure that we have in Europe that generated that benefit. And as opposed – to address the first part of your question, June was a strong month across the board for the company. Cardiovascular played a role in that and I think it really relates to that relatively strong global demand that we see in the Atozet franchise.

**Kevin Ali**

*Chief Executive Officer & Director, Organon & Co.*

A

Did that answer your questions, Umer?

**Umer Raffat**

*Analyst, Evercore ISI*

Q

I guess, Kevin, I just look at it as your cholesterol meds between Atozet and Zetia is about \$200 million a quarter and this quarter, it was about 25% ahead. Like, there must be some one-off in there. No?

**Kevin Ali**

*Chief Executive Officer & Director, Organon & Co.*

A

Yeah. So, we had kind of a slow kind of volume-based procurement implementation in China, which impacted one of the rounds, which kind of gave us more opportunity for the ezetimibe franchise. And Atozet is just doing exceptionally well in Europe. France, for example, is doing exceptionally well. Double-digit growth with Atozet in France is creating a lot of uplift in terms of overall volume and we don't really face a lot of price erosion on Atozet right now.

So, I think it's just very, very strong, robust quarter with regards to a couple of issues. One is opportunity with Zetia because of slowdown of implementation of Round 7 and Atozet growth in Europe. Did that answer it?

**Umer Raffat**

*Analyst, Evercore ISI*

Q

That's very helpful. Thank you so much.

**Kevin Ali**

*Chief Executive Officer & Director, Organon & Co.*

A

Sure.

**Operator:** We'll move next to Jason Gerberry at Bank of America.

**Jason M. Gerberry**

*Analyst, Bank of America Merrill Lynch*

Q

Hey, guys. Thanks for taking my question. Wanted to just ask about the interchangeability commentary on HUMIRA. It seems like in the past, you guys maybe downplayed that as important in the commercial. And I'm wondering if there's, like, any kind of revised view just given how AbbVie's contracting practices have made it difficult for biosimilar adoption and maybe now interchangeability is important. And then along those lines then, does this become a race with Teva to be the first one to get this interchangeability designation? Thanks.

**Kevin Ali**

*Chief Executive Officer & Director, Organon & Co.*

A

Good question, Jason. So, in regards to interchangeability, it was always something where a couple of years ago, when we were starting going down the path of developing, along with our partners, obviously Samsung, this asset, it wasn't something that was on the top of minds of PBMs or others. It only came about recently because one of the competitors said, oh, we've got interchangeability designation for working on it for a lower concentration business, and obviously, the high concentration citrate-free business is about 85% of the overall business in the US.

So, you probably have seen recently that our collaborator, Samsung, published essentially our Phase 4 trial that shows really kind of very positive outlook for – we met all the endpoints for the interchangeability study. So, we do expect the interchangeability indication by next summer. I can't really comment on what's going on with Teva or anybody else in terms of that matter, in terms of their race to get interchangeability.

But what I will tell you is in our discussions with the PBM folks, what they've told us is, look, what's most important to us is, obviously, let's contract on price, let's see how competitive things are, because there's kind of a duality of the market right now. There's about 40% of the lives covered in the PBM world are kind of what I would consider low WACC, low rebate in order to be able to give an opportunity for patients to have a low out-of-pocket expense experience for their biosimilar asset. And then there's the high WACC, high rebate, which really essentially is the game that AbbVie is playing in terms of being the originator.

And so, what I will tell you is that, obviously, that's an ongoing discussion and we feel very good about our success today in terms of where we're going with that. But most importantly, they look for reliability in manufacturing, they want to look at the pen design. We just got the Arthritis Foundation designation as really being a very unique pen design. They look for real-world evidence. It's a very important thing. And we have 7 million units sold since 2019 in Europe, now in Canada and Australia, with excellent real-world evidence.

So, those are the kind of attributes they want to look for in order to be able to differentiate in the market. The indication or rather getting the interchangeability indication just gives an extra added boost. And I think that most PBMs know that if the studies are ongoing and now with the Phase 4 study reporting out that we met endpoints, it's just going to be basically cost of doing business

**Jason M. Gerberry**

*Analyst, Bank of America Merrill Lynch*

Q

Got it. Thanks, guys.

**Operator:** We'll go next to Navann Ty at BNP Paribas Exane.

**Navann Ty**

*Analyst, BNP Paribas Exane*

Q

Hi. Good morning. Thanks for taking my question. A follow-up on HADLIMA. Just wanted to hear about your dialogue with PBMs and health plans on your low WACC and high discount strategy. And do you still expect most market formation in 2024 and 2025? And will the high concentration [indiscernible] (40:11) be a game changer? So it's a bit of a follow-up of the previous question. And then, can you also give us more information on the missing data on ebopiprant and the timing of the additional clinical work? Thank you.

**Kevin Ali**

*Chief Executive Officer & Director, Organon & Co.*

A

Hello, Navann. Yeah, I can give you some of the information on the first part of the question and then I'll hand it over to Sandy to update on ebopiprant. So, in regards to what's happening right now with the PBMs and with HADLIMA, as I mentioned, there's kind of a dual strategy, a dual reality that's happening in the launches as we speak. There are some, AbbVie being one of them, high WACC, high rebate and others that are kind of following that route. And then, there's the other group that is essentially following the route where we've basically staked out the claim because we've always believed that the value proposition of biosimilars is to provide savings to the system and also, more importantly, savings to patients in terms of their out-of-pocket costs. And keep in mind that most patients, obviously, their out-of-pocket costs are going to be related to what the WACC price is.

And so, that's been our formation, that's been our focus and our strategy. And so far, as I've said in my script at the beginning of this hour, we started to really see some good pull-through coming through. And I've been saying for the last couple of years that I think that 2023 and 2024 will be kind of a market-forming years as you kind of get on access to formularies. And ultimately then, the real revenue-generating and the real market formation, as it pull through, is really in late 2024, 2025 timeframe as you start to see the real uptake, because I believe by then, a number of things are going to happen.

For example, my estimate right now is that 40% of the lives covered to date essentially are what I would consider the low WACC, low rebates, low out-of-pocket expenses, lower, as co-pay in that segment, in the HUMIRA biosimilar segment. We're very strongly positioned there because of all the attributes I've listed out a number of times before. And you've seen some of the early successes we've had, whether it's Prime in terms of the one-third of the lives covered there, whether it's UnitedHealthcare, whether it's a half of the lives covered there.

Now, just this morning, we got notification of Centene, which is another 5 million lives covered. These are all areas in PBMs and areas that are focused on that low net cost and ultimately passing on the savings to patients. So, we feel really good about where we are and where we're going with this product. We've always felt really good. And I think that's kind of the way I see it going forward. We do, of course, have both concentrations, high concentration, citrate-free as well as low concentrations available for our customers. And we feel, I think, we're on the right track.

I'll hand it over – Navann, did I answer that question or did you need some more clarity on HADLIMA?

**Navann Ty**

*Analyst, BNP Paribas Exane*

Q

Yes. Thank you for the color.

**Kevin Ali**

*Chief Executive Officer & Director, Organon & Co.*

A

Okay. So, I'll hand it over to Sandy now to address the ebopiprant question, Navann.

**Sandra Milligan**

*Head-Research & Development, Organon & Co.*

A

Thank you both. So, Navann, to answer your question, as you know, we've been doing quite a bit of additional preclinical work to progress the asset. And we've been able to take a look at that data as well as the clinical data that was obtained by ObsEva during their clinical studies. And as well, looking at the technical work that is necessary to get us to a clinical formulation, and it's clear that there's additional pre-clinical work that we need to do before we take this forward to the development phase in humans, so before we get to Phase 1.

**Navann Ty**

*Analyst, BNP Paribas Exane*

Q

Thank you.

**Operator:** And we'll go next to Chris Shibutani at Goldman Sachs.

**Roger Xu**

*Analyst, Goldman Sachs & Co. LLC*

Q

Hi. Thanks for taking our question. This is Roger on for Chris. Just a quick question from us and maybe you touched a bit on this already in your earlier comments on BD, but how are you thinking about the relative scale of your Biosimilars and Women's Health businesses? Have you been seeing any more opportunities in Women's Health as of late? Thank you.

**Kevin Ali**

*Chief Executive Officer & Director, Organon & Co.*

A

I can address that, Roger. So, we made that – we announced that deal last year with Henlius to bring in two assets in the biosimilars space. We're being very optimistic about it. Wherever we see opportunities, obviously, the next kind of windfall will be the [ph] IOs (44:50), and that's in the 2028 timeframe that we see that happening. So, there's things that we're working on in that space. And so, we feel good about the fact that – the portfolio we have today, not only with Samsung but with our Henlius partners now.

And going forward, what do we see with Women's Health? Look, we've looked through a number of companies and products with our outstanding business development team. We do see opportunities in Women's Health. But I will underline the following: Where we started this journey, we were focused on exclusively to women in terms of the women's health space. And now, we're kind of opening the aperture and looking at those conditions disproportionate to women, which can include a number of different indications, a number of different therapeutic areas that we feel could be a really nice fit with our overall structure and what we're trying to do.

So, got a lot of things we're looking at right now. We're looking at some very interesting assets both in the ready to launch or recently launch space, as well as kind of the mid-stage development cycle as well. So, very committed to that as well, Roger. I hope that answered your question.

**Roger Xu**

*Analyst, Goldman Sachs & Co. LLC*

Q

Thank you.



**Operator:** And that does conclude the question-and-answer session. I would like to turn the call back over to Kevin Ali for closing remarks.

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## Kevin Ali

*Chief Executive Officer & Director, Organon & Co.*

Well, I will just say that I want to thank everybody for tuning in and we'll talk to you soon. We're very proud of the results of the second quarter, and we'll be speaking to you soon. All the best.

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**Operator:** And this concludes today's conference call. Thank you for your participation. You may now disconnect.

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