

S&P Global

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Organon & Co. NYSE:OGN

Earnings Call

Thursday, November 2, 2023 12:30 PM GMT

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Presentation

Operator

Ladies and gentlemen, thank you for standing by. At this time, I'd like to welcome everyone to the Organon Third Quarter 2023 Earnings Conference Call. [Operator Instructions] As a reminder, this call is being recorded. Thank you.

I would now like to turn the call over to Jennifer Halchak, Vice President, Investor Relations. Please begin your conference.

Jennifer Halchak

Vice President of Investor Relations

Thank you, operator, and good morning, everyone. Thank you for joining Organon's Third 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 will be referencing a presentation that will be visible during this call for those of you on the 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.

Before we begin, I would like to remind 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

CEO & Director

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

In the third quarter, we navigated some external factors impacting the business. The strength of the U.S. dollar persists. We are navigating a challenging economic and policy environment in China and -- but we have said from the very beginning that we expected the biosimilars market for Humira to be a slow formation, it has been slower than we thought. Still in the third quarter, we delivered product sales that grew 1% at constant currency. That represents our eighth consecutive quarter of product growth.

Total revenue, which includes lower-margin product sales to Merck was down 1% at constant currency compared with the prior year. In the third quarter, ex FX, our women's health was down 7%, our biosimilars franchise grew 10% and the established brand franchise which represents nearly 2/3 of our business grew 3%, again, demonstrating its continued stability.

Adjusted EBITDA was \$447 million, representing a 29.4% margin and adjusted diluted EPS was \$0.87. With these results in mind, we are lowering our revenue guidance by \$150 million at the midpoint, to a range of \$6.15 billion to \$6.25 billion, about \$100 million of this is from FX rates that have worsened since we last guided in August.

The remaining impact primarily reflects the operational factors I just described, plus changes we are making to our go-to-market model for Nexplanon. We are also revising our range on our adjusted EBITDA margin to 30.5% to 31.5% to reflect the lower gross margin stemming from the impacts of foreign exchange on revenue, unfavorable product mix and the timing of manufacturing costs.

Now let's start by reviewing revenue beginning with women's health. The women's health franchise was down 7% on a constant currency basis in the third quarter, primarily driven by NuvaRing, which went LOE in 2018 and now has 5 generics in the market.

The fertility business is flat year-to-date, but we anticipate a very strong fourth quarter, driven by identifiable market tailwinds in China as well as the onboarding of a large new customer win in the U.S. Strong finish in the fourth quarter underpins our expectation that the fertility business will deliver high single-digit revenue growth for the full year on a constant currency basis. In China, we are seeing IVF cycles pick up after a slower third quarter stemming from the Chinese government's ongoing review of health care practices which commanded significant physician attention. This is a transient issue impacting the entire industry.

The fourth quarter of 2023 will also benefit from an easier year-over-year compare, as the fourth quarter of 2022 was impacted by COVID. Year-to-date, the fertility business in China has been a growth engine, up 15% FX. We are doing very well in that important market, and we have been gaining market share in China. In U.S., the fertility market is growing and demand is very strong. Strategically, we are working on an evolution of our go-to-market strategy into the reimbursed market segment which is rapidly growing.

Over the past 3 years, the percentage of employers providing fertility benefits has increased from 30% to 40%. To compete in the reimbursed market, we have traded price for volume. We are having success, and we're excited about some of the significant accounts we have recently secured that will start to benefit the business in the near term. In fact, a recent win in the reimbursed book of business represents our largest customer win since becoming an independent company. Inventory build from this customer will help to drive what we expect to be a strong fourth quarter for fertility in the U.S. Particularly encouraging is that we -- as we head into 2024, we expect Organon's fertility products will be the preferred brands in a significant percentage of covered lives in the U.S.

Let's now turn to Nexplanon, which declined 3% ex FX in the quarter and is up 2% year-to-date on a constant currency basis. We expect a robust fourth quarter Nexplanon, resulting in full year performance in line with that low single-digit growth year-to-date. We've made some key strategic decisions to better position Nexplanon in the U.S. and to accelerate growth globally. The initiatives undertaken will position Nexplanon for strong growth in 2024, and we expect to reach \$1 billion run rate in 2025.

First, we have made some changes to our U.S. go-to-market model. We will not take effective price in Nexplanon in the U.S. in 2023. Our future U.S. pricing increases will now be aligned with when health plans update their pricing and reimbursement schedules. This timing update will make a meaningful difference to the value physicians see from carrying and implanting Nexplanon.

Additionally, we see a healthy uptick in customer purchases ahead of when a new price increase goes into effect. So by postponing our price increase until next year, we anticipate about \$20 million of customer buying will shift into 2024. Also, as we have signaled in the last couple of quarters, our Nexplanon mix in the U.S. has been skewing more heavily towards higher discounted channels. We are adapting to this industry-wide dynamic by removing voluntary discounts in these federal programs, which we believe will benefit the fourth quarter and going forward.

Secondly, we limited our participation in the annual Mexico tender on the basis of price. That represents about \$20 million of negative impact to Nexplanon revenue in 2023. Lapping this impact will be a tailwind to Nexplanon results next year.

And thirdly, overall demand outside the U.S. has been strong, Asia and in Africa. In fact, so strong that we've invested in expanding our Nexplanon supply capacity to satisfy these fast-growing international markets. We have visibility to approximately \$20 million of throughput related to that demand that we expect to be realized in 2024. So I've talked about 3 factors that will drive Nexplanon growth next year,

which together represents \$60 million or about 7 points of growth that we have high visibility into for next year.

Turning to other women's health products. Let's talk about Jada, our device for postpartum hemorrhage. This is the first time we're publicly breaking out revenue for Jada. And so you'll see that year-to-date, Jada has generated \$31 million, more than double the revenue for the same period last year. Jada is now available in over 85% of the largest birthing hospitals in the U.S. and more than 36,000 mothers have been treated with Jada since launch.

Given our progress in making Jada available in the majority of the hospitals in the U.S., our focus will now shift to supporting hospitals and users in the incorporation of Jada into their standard PPH readiness and response protocols. We believe Jada can achieve a peak of up to \$150 million in the U.S. and more than \$250 million peak when layering in the potential sales outside the U.S. Globally, there are over 100 million births annually, and less than 4 million of those are in the U.S. Jada is a great fit for our global footprint.

And finally, in October, we made our first U.S. shipments of Xaciato, an FDA-approved medication for the treatment of bacterial vaginosis in patients 12 years of age and older developed by our collaborator, Dare Bioscience. Our go-to-market strategy leverages the knowledge and experience of the Nexplanon commercial team. Our skilled market access team continues to meet with customers to review Xaciato and obtain competitive managed care formulary status in the bacterial vaginosis marketplace.

Let's move now to our biosimilars business, which grew 10% ex FX in the third quarter and 15% year-to-date. Understandably, we get the most investor questions on the recent launch of Hadlima in the U.S., so let's focus the discussion there. At an 85% discount, we priced Hadlima to enable expanded access and to bring the economic benefits of biosimilars directly to the patient. We've emphasized that's where we believe we can offer the highest value to patients. We have focused our commercial efforts on payers who want to bring lower net costs to patients. We estimate that together, those plans represent about 40% of the covered lives in the U.S.

While not as rapidly as we may have hoped for, we're having success. Among the July cohorts of entrants, we're out prescribing our next closest competitor by a factor of over 3 times. We're winning in both the commercial and managed Medicaid space across the competitive set, and we're rapidly closing in on the gap on Amgen's Amjevita despite their 6-month lead in the market.

Consistent with comments we made around Hadlima's launch, there is a market need for a simple, single price strategy, and we believe that product attributes will be a key to uptake. We're well positioned with a product that has high concentration citrate-free formulation, as well as the low concentration formulation, a user-friendly [pen] backed by the Arthritis Foundation, a wealth of real-world evidence from over 20 studies and interchangeability expected by mid-2024.

We view the slower market formation for biosimilars as a clear missed opportunity to pass on savings to patients. Right now, about 1/3 of patients on Humira pay at least \$1,000 a month. That is more than they would pay for Hadlima out of pocket without insurance coverage. We believe it is not a matter of if, but when this market starts to meaningfully form. Our very intentional focus on the low-cost segment of the market together with our product profile could very well help the market convert much faster.

Rounding out the top line discussion, let's move to established brands. Year-to-date, the established brands franchise has grown 1% ex FX. Over the past quarters, we've highlighted some fundamentals of our established brand strategy which explains why the franchise has been performing ahead of external expectations since then.

In the first quarter, we talked about manufacturing optimization for Nasonex and Atozet to meet increasing demand, resulting from heightened promotional activity. Last quarter, we talked about adapting our commercial model to compensate for payer pressure and to mitigate pricing declines in select markets through our policy work. What bears repeating this quarter is the product and geographic diversity of the portfolio, and the way we have been managing these assets has led to very stable results.

During any given quarter, we are navigating and capitalizing on geographic and competitive complexities that can vary widely across our 5 geographic regions and 49 products. The stable results in established

brands we have delivered since then, have been a testament to the diversity of the portfolio as well as the solid execution by the team.

Now let's turn to Slide 9 where we can take a look at revenue by geography. Let's focus on China because that is the region that's currently moving most dynamically this quarter. As you probably understand, the Chinese economy has had a slower-than-expected recovery post COVID. The general economic slowdown is impacting Chinese consumers, which for our business, had read through to the retail business. We've had a long operating history in China, and our experience in navigating this dynamic market. We've implemented initiatives that help us reach the consumer more directly. For example, through e-commerce.

In addition, in recent weeks, our traditional retail business that is through pharmacies has also started to improve. The other macro issue at play in China is that for the first time in recent history, the health care budget in China is in a deficit. The authorities are seeking options to offset this decline, which includes stricter enforcement of the volume-based procurement rules and investigations into prescribing patterns at the hospital level.

Our portfolio has seen a very muted impact from these particular initiatives. We have strong diversity in our China business. No product represents more than 16% of revenue in China. Also, most of our portfolio has already been through VBP and has weathered those impacts. And because we have a long operating history in China, our team has experienced and has reallocated resources to other areas less impacted by this campaign.

Overall, we believe that we will see a return to a more normal level of engagement in the hospital and retail channels by the beginning of next year. In fact, we're already seeing growth in China in the fourth quarter. Since then, we have given new life to establish brands and have expanded our pipeline in both biosimilars and women's health. As we move into 2024, we will be working to reduce leverage and maximize the power of our existing portfolio. We will also look to bring in assets that enhance our growth profile.

We are currently creating our own opportunities. We are overturning every stone to unlock value. The transient headwinds we saw in 2023 will serve as tailwinds for us next year. We believe we are well positioned to build from here and deliver mid-single-digit revenue growth over the medium term.

Now let's turn the call over to Matt, who will go into our financial results in more detail.

Matthew M. Walsh
Executive VP & CFO

Thanks, Kevin. Beginning on Slide 10, let's walk through the drivers of our 1% decline in revenue at constant currency for the third quarter. Starting with the impact of loss of exclusivity, LOE was about \$10 million in the third quarter, and the small amount that we have realized year-to-date has been related to generic competition for NuvaRing in the U.S.

In the third quarter, we had about a \$30 million volume impact from VBP in China consistent with the first 2 quarters of the year as the impact continues to be 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 as well as the July implementation of Round 8 that included REMERON and HYZAAR.

We experienced a \$25 million price erosion in the quarter. In prior quarters, established brands was the franchise contributing most significantly to this area. But as Kevin just referenced, we've been able to stem price erosion and establish brands to the low end of our expectations. What we saw in Q3 was price pressure being driven within other franchises. Given the nature of biosimilar competition, we're seeing pricing pressure broadly across that franchise. Additionally, 2 issues within women's health in the U.S.

First, customer mix in Nexplanon has been skewing towards the 340B channel. And second, within fertility, we're seeing price pressure as we competitively position ourselves to grow volume in the attractive market for reimbursed fertility services. We had about \$70 million of volume growth in the third quarter, primarily from established brands, particularly in our LAMERA region and non-VBP products in China. Setting aside the slow market formation for HUMIRA biosimilars in the U.S., which Kevin covered in detail, our

biosimilars volume was up nicely in the U.S., Canada and Brazil due to volumes from new customers as well as greater depth of purchasing from existing customers.

The bar for supply/other primarily represents sales to Merck, off \$15 million for the quarter compared to prior year. As we've discussed in the past, this revenue stream is essentially a series of lower-margin contract manufacturing arrangements 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 65 basis points for the third quarter. In August, when we last updated guidance, we raised our revenue guidance based on where spot rates were at that time. With the benefit of hindsight, late July, early August happens to be the most favorable point in the year in terms of FX spot rates versus the U.S. dollar.

Since then, the dollar has strengthened as much as 6% across some of our most significant currencies, which has caused us to give up the second half favorability we were anticipating based on August spot rates and then some. I'll remind everyone our sensitivity to foreign exchange and financial reporting is a function of more than 75% of our revenue being generated outside the United States. Now let's turn to performance by franchise. As has been our convention, I will target my comments over the next 3 slides to those areas most relevant to your modeling as we think about where we will end the year.

Let's start with women's health on Slide 11. As Kevin covered in some detail at the outset, Nexplanon is experiencing headwinds in 2023 that we don't expect will recur next year. The math on those headwinds, especially those in the second half, indicate that it's hard to envision a scenario where Nexplanon doesn't return to strong growth in the high single digits next year. Demand for fertility is solid, and that therapy area continues to have strong structural tailwinds, even if we have to continue to give up some price as we did in the third quarter in order to gain greater market share. In the area of new products, the Jada device for postpartum hemorrhage is now hitting a steeper part of its revenue curve post launch, and Xaciato is now in the channel as of last month, and we're looking forward to what that launch will yield in 2024.

Turning to biosimilars on Slide 12. Biosimilars grew 10% ex FX in the quarter and has grown 15% ex FX year-to-date. Renflexis grew 15% in the quarter and it's on track for its sixth consecutive year of annual revenue growth in the U.S. Ontruzant continues to operate in a competitive environment in both the U.S. and Europe. However, volume remains strong in the LAMERA region, mainly in Brazil, and this is offsetting competitive pricing dynamics.

With regard to Hadlima, our original expectation for global Hadlima sales in 2023 was that it would represent just under 1.5% of full year 2023 revenue. Given the slower market formation in the U.S. for HUMIRA biosimilars that Kevin discussed, global HUMIRA revenue mix will be significantly less than that in 2023 and in fact, this is one of the key factors driving our 2023 revenue guidance revision.

Turning to Slide 13. Established brands grew 3% ex FX in the third quarter and it's still in positive territory for the year at 1% growth year-to-date. We've talked about the durability of established brands. This year is a case in point that 3% growth ex FX was delivered despite 3 pretty significant headwinds. First, VBP in China which is currently capturing our largest product, Ezetrol in Round 7 and now we have Round 8 underway. Second, the economic slowdown and challenging policy environment in China. And third, we grew despite the market action that occurred at the very beginning of the year for injectable steroid products. Given year-to-date performance and the outlook for the fourth quarter, we expect established brands to deliver at least level performance year-on-year at constant currency.

Now let's turn to Slide 14, where we show key non-GAAP P&L line items, metrics for the third quarter and year-to-date performance. For reference, GAAP financials and reconciliations to the non-GAAP financial measures are included in our press release and in the appendix slides of this presentation. For gross profit, we are excluding from cost of goods sold, purchase accounting amortization and onetime items related to the spin-off which can be seen in our appendix slides. Non-GAAP adjusted gross margin was 62.6% compared with 67.1% in the prior year period. The year-over-year decline in gross margin is primarily due to foreign exchange translation and inflationary manufacturing and distribution costs. Product mix and pricing erosion were also factors, but to a lesser extent in this quarter.

With respect to the foreign exchange impact on cost of sales, third quarter adjusted gross profit margin reflects the timing of FX recognition related to inventory purchases, which has impacted us unfavorably versus the prior year, and this will continue into the fourth quarter.

Moving down the P&L. In October, we were able to reach agreement in principle on the key terms of a settlement with MICROSPHERIX to resolve patent infringement claims for Nexplanon that predated the spin-off. We reserved an amount of \$80 million to cover the settlement. The settlement will be paid out over 3 fiscal years. \$35 million in 2023, \$25 million in 2024 and \$20 million in 2025. That total of \$80 million in legal reserves was the main driver in GAAP SG&A increase year-over-year.

On a non-GAAP basis, as you can see, SG&A increased 4%, mainly due to higher employee-related costs. Total non-GAAP R&D, excluding IP R&D expense increased 7% in the quarter. The increase is primarily due to continued investments into our pipeline and higher costs associated with the development of these assets. Including IP R&D, R&D expense was actually down 2% year-on-year. We had \$10 million of IP R&D expense in the third quarter of 2022, against no such expenses in this quarter. These factors culminate in an adjusted EBITDA margin of 29.4% in the third quarter of 2023 compared to 35.5% in the third quarter of last year. Non-GAAP adjusted net income was \$223 million or \$0.87 per diluted share compared with \$337 million or \$1.32 per diluted share in 2022. The year-over-year decrease in net income was a result of lower adjusted EBITDA as well as higher interest expense.

Turning to our net leverage ratio on Slide 15. As we've previously discussed, we expected upward pressure on our net leverage ratio this year, with the peak expected to be in the third quarter, and this has played out. Next quarter, we will be lapping a low adjusted EBITDA quarter last year due to last year's market action on injectable steroids, and that should drive a decline in the net leverage ratio in Q4, all else equal.

Turning to Slide 16, we provide a closer look at our cash flow. For full year 2023, we expect to generate between \$700 million to \$800 million in free cash flow before onetime charges. At the midpoint of the range, this is about \$250 million below what we expected earlier in the year, and the difference is attributable to lower expected EBITDA as well as working capital use. On the latter, we're now deep in the implementation of our new global ERP system, that has temporarily tied up cash and current accounts to mitigate potential disruptions to normal operations. As a reminder, in 2022, we generated just over 75% of our annual cash flow in the second half, and we expect this year to follow a similar pattern.

Onetime cash costs related to the spin-off transaction are trending in line with our expectation of about \$350 million for the full year 2023. The single biggest component of separation costs relates to the implementation of the global ERP system that I just referenced, and we're on track to complete that in the second quarter of 2024. As a result, these onetime costs associated with the spin, especially those that are related to transition services agreements as opposed to the longer tail manufacturing services agreements should decline meaningfully next year.

For CapEx, 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 on Slide 17. We bridge our expected revenue change year-on-year. We have revised the number of these ranges based on how we expect to finish the year. LOE impact has been minimal so far in 2023. We expect the year to finish similarly. The small amount realized was related to the impact of generics for NuvaRing. We lowered our range to \$10 million to \$20 million, down from \$50 million to \$75 million as we do not anticipate a generic entrant for DULERA in the U.S. this year. And in addition, the impact of generic competition for Atozet in Japan on that LOE event has been lower than anticipated this year.

Turning to VBP. We now expect the annual impact to be slightly lower than what we guided to in the second quarter as we're tracking better with both EZETROL, which was in the implementation of Round 7 in November of last year, as well as the recent Round 8 implementation in July of this year, which included our REMERON and HYZAAR products.

We're lowering our estimate of potential price erosion to \$90 million to \$100 million down from \$100 million to \$150 million, an improvement from the bridge that we showed you last quarter. Here, we're seeing the momentum of our established brands portfolio, being able to manage price erosion better than expected across several markets.

We've lowered our outlook for volume growth for the year, and that underpins our revision to the revenue guidance. We lowered our range to \$370 million to \$400 million or about 6% year-on-year growth at the midpoint, down from the 9% we were forecasting last quarter as a result of changes we've made to our go-to-market model for Nexplanon, a slower-than-expected uptake of Hadlima and macroeconomic and policy headwinds in China.

When we reported our second quarter results in August, the U.S. dollar had been steadily weakening over the first 7 months of 2023, and we saw favorability in our forecast that rates simply held at where spot rates were in early August. Since then, FX has retraced, and we gave back all of those gains and then some. We're now raising our FX exposure to \$120 million to \$130 million, representing about a 200 basis point headwind for the full year 2023 compared with the 0 to 80 basis points of headwind we expected for the full year back in August. Together, these factors result in revising top line guidance to \$6.15 billion to \$6.25 billion, which represents growth of 1.6% to 3.3% growth on a constant currency basis.

Moving to the other components of guidance on Slide 18. We're revising our range on expected gross margin to the low 60% range, which reflects impacts from foreign exchange on revenue, unfavorable product mix and timing of manufacturing costs. We're in the midst of our budget planning process for 2024. So while we aren't providing 2024 gross margin guidance today, we can say directionally that the factors that have impacted gross margin in 2023, especially in the back half will be factors for us in 2024 as well. For example, inflationary pressures will likely persist at the COGS line.

Also, the Fed dialogue around higher for longer as regards its influence over short-term interest rates in the U.S., suggest that the strong dollar is likely to continue to be a headwind given our significant ex U.S. revenue exposure. For 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 year, and reflect the investments we're making in the business to position it for future growth.

In closing, bright spots in the third quarter performance included the continued steady performance of established brands, our largest revenue segment. And within women's health, the strong performance of Jada and the launch of Xaciato. The 2023 guidance revision was necessary in light of the macro issues around economic and policy conditions in China and FX translation as well as the slow market formation for HUMIRA biosimilars. Even with this, we believe Organon will post constant currency revenue growth in the low single digits. And on a reported basis, we're likely to post revenue growth for 2023 that exceeds the revenue growth rate of last year.

With that, we can now turn the call over to Q&A.

Question and Answer

Operator

[Operator Instructions] Our first question comes from the line of Navann Ty with BNP Paribas.

Navann Ty Dietschi

BNP Paribas Exane, Research Division

I have 3 questions, please. Can you hear me okay?

Kevin Ali

CEO & Director

Yes, we can.

Matthew M. Walsh

Executive VP & CFO

Yes.

Navann Ty Dietschi

BNP Paribas Exane, Research Division

Okay. Great. Yes, on the -- could you clarify an external change in the go-to-market model and what drove the change? And will it move the quarterly cadence of Nexplanon revenues? And then on fertility, have you seen biosimilar competition pressure intensifying? And also curious about what level of discount did Organon provide when onboarding accounts in Q3? And then just one overall, if you do still expect a long-term high single-digit, low double-digit growth with the current women's health portfolio?

Kevin Ali

CEO & Director

Thanks, Navann. Good to hear your voice, and I'll try to address the 3 questions you had. First question on Nexplanon. So we've it was historical that many years prespend that the increase in price for Nexplanon always happened sometime in the fourth quarter. So you'd see this very lumpy buy-in in the third and fourth quarter, taking advantage of the eventual price increase, price protection. And so you'd end up having this very difficult seesawing type of thing in the first quarter of every year.

In addition to that, physicians and systems usually just kind of get online in terms of updating their reimbursement schedules in the first quarter of every given new year. And so there was a point in time there where physicians actually were -- it's challenged -- let's call it stressed, in terms of the difference in price versus the reimbursement schedule.

So by changing into being able to take price in the first quarter, we do 2 things. We align with the rest of the LARC industry in terms of when they take price, we align with when the schedules of reimbursement actually hit with physicians at the state level. And finally, we end up taking away some of this lumpiness and get more of a smoother, more predictable forecasting trends for you all and for us as well to be able to point to.

So I think we wanted to take away some of this unpredictability and the volatility of the buy-in and buyout phenomenon that we talk to. We want to be able to speak more in terms of the opportunities that exist just to look at any given year. That's essentially why we took the change in the go-to-market model for Nexplanon, and we believe it will have an impact at the very least of which it will smoothen things out for us.

In terms of your second question around the biosimilar penetration in the U.S., we really haven't seen any additional biosimilar penetration. As a matter of fact, what we do see is clearly more of a movement of patients moving over to the reimbursed segment just because of essentially company-sponsored benefits that are uptake in terms of the fertility sector.

And so with that, you're really kind of trading off price for volume. And we've just -- we're not -- we can't announce it right now, but ultimately, what we've been able to do is secure a very large win in that reimbursement sector. We'll probably be talking more about it, obviously, in our next earnings call. And so you'll see some buy-in in the fourth quarter for inventory purposes. But that is essentially what's happening is essentially we're getting more and more opportunities to really be on some of these plans in regards to kind of the PBM-driven process with the reimbursed market segment.

And finally, yes, our long-term goal really is to see continued growth in our women's health portfolio. We see fertility, it will be high single-digit growth this year. It will likely be kind of following the same trends of next year. And we reassume that Nexplanon will have a very, very good year next year in terms of the ability to kind of course correct with regards to the go-to-market model and to be able to take price in next year -- in the beginning of next year for next month.

And finally, the issue regarding the ex U.S. business, we've got supply kind of opening up so that we can meet more demand outside of the U.S., especially in Latin America and Asia Pacific and the African regions, because the supply actually demand has been very robust. And so that gives us a lot of confidence in the future growth opportunities for our women's health business. And not to mention, Jada, now we're reporting it out, it's doing extremely well. And we'll be launching Xaciato as we speak right now. So that will continue to be a contributor in the future.

Operator

Our next question comes from the line of Umer Raffat with Evercore.

Unknown Analyst

This is [indiscernible] for Umer. Just want to ask about your China business. Previously, it was estimated that 70% to 80% of business will have gone through the VBP by end of this year. So with some of the new dynamics you just described, how should we think about the China business going into 2024, especially in the first half of the year? And also, how much impact have you seen from the government review campaign happened in the health care sector this year in China?

Kevin Ali

CEO & Director

Thanks for the question. So China is obviously our second largest market in Organon, a very important market. We've had a long history in China. It continues to be a very important market for us to focus on. The first question in regards to the VBP impact. By the end of this year, probably 3/4, 75% of our business will have gone through the established brands business, will have gone through the volume-based procurement process, which basically means now, our focus and our strategy to move the business over to the retail sector in all the various forms of the retail sector, whether it's e-commerce, whether it's actually folks going into the pharmacies, into the retail sector is really starting to take hold.

And we continue to see an opportunity to grow our business in many different sectors in the retail sector, whether it's e-commerce, whether it's pharmacy dispensing. And we're working with all the top pharmacy chains in China, and we've got good ongoing programs going with that as well.

In regards to the policy framework that you talked about in your second question, yes, I believe if you are a company that has, what I would consider, concentration risk, too much business in the public sector and the volume-based procurement process that is exposed, you will have more problems. But we actually -- no single product of ours represents more than 16% of our overall business, and we've shifted essentially most of that business to the retail sector, so out of the control of that.

So it has been disruptive. There's no doubt for the summer period of time. We're coming out of that as we speak right now. We feel we're in a very good position. We're seeing growth in the fourth quarter. We've increased access in the retail sector. And we feel that next year will be a healthy year for us in China, definitely overcoming some of the issues that we saw this year, and I feel very strongly about that.

Operator

Our next question comes from the line of David Amsellem with Piper Sandler.

David A. Amsellem

Piper Sandler & Co., Research Division

Just 2 from me. Broadly speaking, just given the headwinds you cited, are there any initiatives that you're considering to try to boost EBITDA margins as you think about '24 and longer term? That's number one. Number two is thinking broadly about biosimilars, what's the role of that segment in the organization? And is that something you might look to monetize in some way, either as a way to pivot to acquisition of brand assets or to address the debt balance? How do you think about that?

Matthew M. Walsh

Executive VP & CFO

Thanks for the question, David. On the first part, I'll take that one. So we are and have been managing the business pretty tightly. From a cost perspective, most of the increases that you've seen in our reported results, whether it's in the SG&A line or the R&D line, have been for revenue-producing activities in the future so that we can sustain our long-term revenue growth rate.

That said, as regards what you might refer to as infrastructure costs, administrative costs, et cetera, we're going after those, hard to manage those as tightly as we can. And so just -- we're rest assured that we're really examining the cost structure hard to make sure that we're differentiating from revenue-producing costs that represent investments in the future, and any costs related to running the business from an administrative perspective, we are clamping down on those.

Kevin Ali

CEO & Director

And David, in regards to your second question regarding biosimilars, I've always maintained that biosimilars is really an opportunistic -- opportunity for us in the short to medium term. I look through, I guess, the end of the decade, when you have, say, for example, IOs coming off patent, there's going to be still a very robust market there.

Hadlima, our HUMIRA biosimilar is definitely slower than we had anticipated. But when you start to think about kind of our share of total prescriptions, we're 3x greater than our nearest competitor that launched in the July time frame. So to me, it is a question -- more a question of when, not if this market will start to open up.

You're talking about the fact that 1/3 of the patients currently today are spending about \$1,000 out of their pocket every month for co-pay cost for HUMIRA, still to this day, even after LOE. And when you consider the fact that 2/3 of -- it's estimated that 2/3 of Americans today are living check-to-check. I truly believe that over time, that market will start to open up on its own, and it will be something where we are talking about more of a linearity to our Hadlima business going forward as opposed to that kind of quick peak and then on the other side coming straight down.

So it is something that we believe in the biosimilar franchise, it's very opportunistic for us, and we'll continue to treat it as so because remember, the return on invested capital is very good. We don't spend a lot of money in regards to our biosimilar franchise, in regards to boots on the ground or any other type of resources. So it is very -- it's a very healthy return on that. So we feel good about it for the time being.

Operator

Our next question comes from the line of Jason Gerberry with Bank of America.

Unknown Analyst

This is [Bhavin Patel] on for Jason Gerberry. Two questions from us. The first is on free cash flow. It seems like the lower \$700 million to \$800 million free cash flow target from \$1 billion previously is mainly due to net working capital use, as well as lower EBITDA outlook. So how likely is this net working capital use impact to carry over into next year? Do you think that we should start thinking about \$700 million to

\$800 million of free cash flow as an annual benchmark? Or do you see it possibly getting back to \$1 billion annually next year?

And then the second is on capital allocation. Notice these plans for further debt paydown in 2024. So can you frame any sort of leverage ratio target or at least how you may balance the debt paydown with business development and paying dividend?

Matthew M. Walsh

Executive VP & CFO

Okay. So we'll take the free cash flow question first. We started the year with an anticipation of in round numbers, about \$1 billion of free cash flow. We have had to take that back given developments this year, as we noted, related to lower EBITDA as well as the investment in net working capital. Now the latter is temporary. That will come back out of the business. We will be fully through the implementation of our global ERP system in the second quarter of next year. So working capital should work its way back into our bank accounts as cash, sort of more or less ratably over that time frame.

And so we do see that the business should return to a higher level of free cash flow generation next year. And when you combine that with the fact that we expect to see lower onetime costs from the separation next year, we're actually quite optimistic about what next year's free cash flow number will look like and when we guide to that in February.

In terms of capital allocation, we've been, since the spin-off, trying to achieve a balance of capital allocation between investments and growth for the future, and balancing that against the near term and certain benefits of leverage reduction. That equation has been tilted a little bit more, given where interest rates have gone, the near-term benefits of debt reduction look more attractive. So as we've said in the past a few times, it raises the bar on the type of business development and M&A transactions that we would execute. And that's one of the reasons why you've seen, relatively speaking, a lower level of activity in BD in 2023 than you saw in 2022. We continue to believe that the business -- the cash flow profile that the business exhibits supports a dividend, certainly at the level that we have. There's no plans to change that in the near term.

Operator

Our next question comes from the line of Chris Shibutani with Goldman Sachs.

Unknown Analyst

This is Roger on for Chris. Just one quick question from our end. So just given the updated statements from the FDA recommending that all labeling for biosimilars include one statement, the biosimilarity statement. Can you comment on how you view this change and whether this act as a tailwind or headwind for the uptake of Hadlima?

Kevin Ali

CEO & Director

Yes. Look, listen, that's a draft statement right now. It's in draft form. It's not necessarily going out in terms of what people need to do right now, but I think it's eventually going to take hold. What I do believe is we've already made the investment in interchangeability. We -- the data has already come on very strong with our partners at Samsung Bioepis. We believe that we'll be able to launch our interchangeability indication, probably sometime in the second quarter -- end of the second quarter, beginning of the third quarter of next year. It will definitely, I think, help us in terms of being a tailwind.

What we're seeing playing out in the market today is the fact that interchangeability, especially at the pharmacy level, will be able to have an easier switch for patients when they get to the pharmacy, they'll understand that do they want to, for example, pay \$1,000 a month for -- as a co-pay or do they want to pay \$100 or whatever it is, it's going to be in that particular plan. And so having that ability to have the interchangeability designation, I think, will help to guide pharmacists to be able to more actively switch from HUMIRA to the biosimilar specifically. And if they switch, obviously, we have a commanding market share right now in terms of total prescriptions, we'll be able to get a lot of share of that.

So it is a tailwind, I believe, for us for whoever has the interchangeability designation. And I think there's only about maybe a handful, 3 or 4 actually that will have the interchangeability designation as opposed to others that haven't initiated the studies. So that's -- I think that's where it is because it's in draft form right now, and I think people are going to want to see it, and see that you actually have it, and we'll have it end of Q2, beginning of Q3 next year.

Operator

Our next question comes from the line of Balaji Prasad with Barclays.

Unknown Analyst

This is [indiscernible] on for Balaji. Just 2 from us. I guess, can you talk a bit more about the Hadlima ramp into 2024? And I guess, elaborate on just some of the key factors impacting it. And on women's health, will you be able to reverse the weakness seen? And I guess, any further comments on what will be needed here?

Kevin Ali

CEO & Director

Yes. For Hadlima, the ramp-up of 2024 will be -- I mean, what we see right now is the fact that what AbbVie has been able to do is essentially use their bundling power to essentially exclude -- especially in the PBM world. But remember, about 40% of the lives covered right now or what we would call WAC sensitive, or what we call, low net cost sensitive, it's just going to be some time until we're able to get those plants to start opening up. There's a time lag between kind of the discounts you lose on the AbbVie business as well as kind of compared to the benefit you gain from the discounts that you get going with a biosimilar.

We'll definitely see better business next year, but at the same time -- at the same token, we do see that this is another market formation year in 2024. And then the breakthrough, I believe, will come in 2025, when kind of the floodgates will start to open up slowly and give us an opportunity. That's why see Hadlima more as kind of a longer-tail business and continued growth, double-digit year-over-year, which will help us in the outer years. There's no doubt about it.

In regards to the women's health question, yes, we found some issues this particular quarter, but it doesn't change the overall trajectory of our Women's Health business. Let's remember that in Q3 of 2022, there was 18% growth in the U.S. for Nexplanon. That was because the previous year, there were some COVID issues. So 2023 in this quarter is really a function of a few things. Lapping of very, very strong quarter of last year and second, the fact that the go-to-market model has changed in terms of taking price. Right now, people would start to kind of build their inventories in order to take advantage of the upcoming price change. Now that's not happening. So that's what you're lapping. And then ultimately, you'll see that kind of come to fruition in the first quarter of next year where people will start to take inventory at that point of time.

Operator

There are no further questions at this time. I would now like to turn the call over to Kevin Ali for closing remarks.

Kevin Ali

CEO & Director

Thank you. It's been an opportunity for us to kind of show what we've been able to accomplish a lot in a very short period of time as a stand-alone company. We're just a little bit over 2.5 years old and we've got a very talented team dedicated to continuing the growth of Organon's business. We look forward to the future. There has been some headwinds in this quarter, but we see them as more transient. China is starting to grow again in Q4, so that overhang is starting to lift, and we see China's growth opportunities as solid for next year.

We've taken some changes in regards to our go-to-market model on Nexplanon, and that will continue to show progress for next year as well. And we see opportunities for Hadlima. And it's not a question of if, it's a question of when it starts to open up and ultimately drive more incremental growth for us as a company. So we feel we're in a good position to continue our work and continue our focus, and we take the opportunity to look forward to speaking to you on the next earnings call. Thank you very much.

Operator

I would like to thank our speakers for today's presentation, and thank you all for joining us. This now concludes today's call. You may now disconnect.

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