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Organon & Co. (OGN)

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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 First 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. 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-Investor Relations, Organon & Co.

Thank you, Mike. Good morning, everyone. Welcome to Organon's first 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, guidance and capital allocation. Dr. Sandra Milligan, Organon's Head of R&D, will also be joining the call today at the Q&A portion.

Today, we will be referencing a presentation that will be visible during this call for those of you on our webcast. This presentation will also be available following this call on the Events & presentations section of our Organon Investor Relations website at www.organon.com.

Before we begin, I would like to caution listeners that certain information discussed by management during this conference call will include forward-looking statements. Actual results could differ materially from those stated or implied by forward-looking statements due to risks and uncertainties associated with the company's business, which are discussed in the company's filings with the Securities and Exchange Commission, including our 10-K and subsequent periodic filings.

In addition, we will discuss certain non-GAAP financial measures on this call, which should be considered a supplement to, and not as 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'll now turn the call over to our CEO, Kevin Ali.

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 first quarter 2023 results. 2023 is off to a very solid start. For the first quarter, revenue was \$1.5 billion, up 3% at constant currency. Adjusted EBITDA was \$518 million, representing a 33.7% margin. Given this solid performance, together with our visibility into the remainder of the year, we are firming our financial guidance for the full year.

The first quarter of 2023 represents the sixth consecutive quarter of product sales growth with all three franchises positively contributing to our performance. At constant currency, the Women's Health franchise grew 3%, the Biosimilars franchise grew 20%, and the Established Brands franchise, which represents approximately two-thirds of our business, grew 1%. The Established Brands franchise continues to demonstrate its durability. The franchise generates sizeable and predictable free cash flow, which is an important factor in our ability to take a balanced approach to capital allocation.

During the first quarter, we made progress toward reducing our outstanding debt with a voluntary \$250 million prepayment on our US dollar-denominated term loan. Reducing our leverage over time is an important goal for us. We are committed to maximizing profitability in order to generate cash flow that supports that objective, as well as to pursue business development strategies that enhances our growth profile.

We will continue to look at business development through two lenses: tuck-in opportunities that have the potential to drive near-term revenue as well as longer-term bets that could be transformative for Organon and for patient care. We are especially focused on building out our capabilities in Women's Health as we did in the first quarter with our strategic investment in Claria Medical, which is developing an investigational medical device being studied for use during minimally invasive laparoscopic hysterectomy.

Now, let's move on to review the quarter in a bit more detail. Let's start with Women's Health. Women's Health grew 3% on a constant currency basis this quarter. In the first quarter of last year, we acquired rights to the oral contraceptives, Marvelon and Mercilon in the People's Republic of China, including Hong Kong and Macau and Vietnam. Since spin, we've generated strong demand for these products, which grew 65% in the first quarter. This transaction has been very successful and it's just one example of how Organon is leveraging its expertise to maximize the performance of assets that may have been under-prioritized in the past.

Staying on contraception for a moment, let's look at the trailing 12-months performance of Nexplanon, which is the more informative way of evaluating the product's performance because customer buying patterns introduce noise on a quarterly basis. We have changed the growth trajectory of Nexplanon since the product has been in our hands. This long-acting reversible contraceptive is a product that has been around for over a decade and relies on continuously driving new patients to the product. Still, with the managerial focus we have put on Nexplanon, we continue to deliver very strong growth for the product.

Nexplanon is one of the most effective forms of contraception. It is an arm implant and therefore it does not require daily self-administration like an oral contraceptive. We are seeing rising patient preference for these

attributes in their choice of birth control, and that is leading to increasing physician demand. In fact, this quarter, physician demand in the US was up 6% versus last year, driven by women increasing their usage of Nexplanon. Our strategic focus in the US during 2023 is to continue to grow that physician demand by driving patient request for Nexplanon and increasing the depth of use among the 35,000 providers currently prescribing Nexplanon.

Outside the US, we continue to expand access and see strong payor, physician and consumer demand. We anticipate particularly strong growth in both Brazil and Canada, two of the more relevant contraception markets in the world and where Nexplanon is still somewhat in the launch phase. We are also making good progress with activity to expand Nexplanon production. This is subsequently enabling increased supply to parts of Africa and Asia Pacific where payors are expanding access to the product. We also continue to believe that Nexplanon can achieve \$1 billion in revenue by 2025, which implies strong growth for the product over the coming years.

Continuing our discussion on Women's Health, we remain very encouraged by our opportunity in fertility. Families are delaying parenthood due to many social and demographic factors, including education, career goals and financial barriers. This contributes to the prevalence of infertility, which in turn drives demand for IVF treatments. The use of assisted reproductive technologies, like in vitro fertilization is growing 5% to 10% annually. It is a large market impacting an estimated 190 million people around the world. Globally, the top five markets with the highest rates of infertility are in the Asia Pacific region, where a number of births per woman is significantly below the replacement rate required to sustain a population and GDP growth. Countries like South Korea are offering cash incentives for households to expand their families, and Japan, Australia, Thailand and Singapore are expanding fertility access and/or other benefits.

Over the next few years, these markets will represent the largest opportunity for Organon's fertility business. These dynamics, combined with our significant presence in the Asia Pacific and Japan region, represent an attractive opportunity for Organon and allows us to grow the fertility portfolio in markets outside the US, where we are focused on expanding market share and must, therefore, price our products competitively.

China, where we currently hold the number two market share position in fertility, will also continue to be an important market for us. Early in the first quarter, COVID-related disruptions were hampering demand for fertility treatments in China. However, we have seen solid recovery with sequential growth in both February and March. We are optimistic about getting back to normal in China and the positive impact that will have on our fertility business. Over the intermediate term, we believe fertility can grow in the high-single digit to low-double digit range and we expect 2023 to deliver a similar growth profile.

Moving now to our Biosimilars business, which continues to perform very well. Renflexis, our largest selling biosimilar, continues to grow more than five years after launch, driven by solid performance in the US and Canada. Ontruzant, our second largest biosimilar, had strong growth in the US, but that growth was offset by a very competitive pricing environment in Europe.

There is great interest centered around the July 1 US launch of Hadlima, our biosimilar for Humira. At launch, we will have the option for a high concentration citrate-free formulation as well as a low concentration formulation. We have also now the benefit of real-world evidence from our own launch of Hadlima in Australia and Canada, as well as through our collaborator, Samsung Bioepis, from their experience with Hadlima in the EU. We're excited about our pen design which was created with the patient in mind to ensure simple administration. So, we feel good about the attributes of our product and our positioning.

That said, with multiple product launch mid-year, we will also convey our assumption that 2023 will be a modest ramp, with the market for biosimilars really forming in 2024 to 2025. And then rounding out the discussion with

Established Brands, which we believe continues to be the most underappreciated part of Organon's story. The Established Brands franchise have a number of hurdles to overcome this quarter, primarily the ongoing impact of volume-based procurement initiatives in China and supply constraints associated with market action we took earlier in the year on Diprosan and Celestone. We also had a significant one-time benefit in the first quarter of last year related to some Japanese generics [Technical Difficulty] (00:10:40-00:10:50) constant currency in the first quarter.

The Established Brands franchise is comprised of products that are generally beyond LOE, but still have opportunities for growth, especially in markets outside the US. This was a portfolio that was in double-digit decline prior to the spin. With major LOE risk behind us, together with the entrepreneurial focus we have put behind managing this brand, we have seen an inflection in growth rates. We've stabilized the portfolio and expect to achieve another year of flat or better performance in 2023 at constant currency.

Within Established Brands, China is an important market, representing about 20% of the Established Brands' revenue. Despite multiple rounds of VBP in the last two years, the Established Brands revenue in China has not declined since then. We expect to achieve similar flat performance in 2023, despite the continuing VBP impact this year on our largest product in China, Ezetrol. By the end of 2024, the majority of VBP impact will be behind us and we expect growth in Established Brands in China to accelerate in line with the expectation we have for our total company business in China.

I think for some, it's a difficult proposition to understand how a portfolio of off-patent brands can demonstrate continued stability. So, let me share a few examples. Since then, we had a renewed focus on Atozet, a cardiovascular drug. We have intensified our commercial promotional effort to grow that business. We have pursued many lifecycle management actions on the product and have also added production capacity, and there was a response.

Atozet had sales of \$457 million in 2022, represent 11% growth ex – exchange. Another example is Nasonex. Nasonex is a respiratory drug that was launched in 1997. It's been off-patent in key markets for almost a decade. In 2022, it delivered \$260 million in revenue, growing about 17%. We are pursuing a number of lifecycle management opportunities to address global demand that exist for Nasonex, and we are investing in manufacturing capabilities to support those plans.

These are just two examples of ways we are unlocking the value that remains in these Established Brands. There are many more opportunities to do so among the 49 products in that franchise. So, across the business, the year is off to a very good start, thanks to the hard work of our people around the world, the business is performing the way we thought it would and each of our franchises is contributing to the success of Organon.

I'll turn it over to Matt now to go into some more financial detail. Matt?

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

Thanks, Kevin. Beginning on slide 9, let's walk through the drivers of the 3% constant currency revenue growth in the quarter. Starting with the impact of loss of exclusivity, LOE was negligible in the first quarter and the small amount that we did realize was related to generic competition for NuvaRing in the US. In the first quarter, we had about a \$30 million impact from VBP in China, and that was related to the fourth quarter implementation of round seven, which for Organon included Ezetrol, which is sold as Zetia in some markets outside of China.

Moving across to price, we saw approximately \$30 million of price erosion in the quarter. This was primarily driven by customer mix and pricing in US fertility, which was exacerbated by an unfavorable comparison to Q1 of last year when we had a more favorable customer mix in fertility. In addition, the Established Brands portfolio is subject to mandatory pricing reductions in the first quarter of 2023, and that was particularly the case in Japan and in some EU markets.

We continue to see strong volume increases across all of our franchises, about \$100 million in the first quarter. The majority of the volume increase came from Established Brands, particularly in China, and the APJ region, but also from Biosimilars, fertility and contribution from Marvelon and Mercilon. The bar for supply/other represents revenue to Merck and other third parties, which consists of relatively low margin sales of pharmaceutical products under contract manufacturing arrangements and which are expected to decline over time.

And finally, you can see the financial reporting headwind we had in foreign exchange translation, about 450 basis points for the first quarter, which is a function of more than 75% of our revenue being generated outside the United States. While we're on that topic, let's turn to slide 10, we'll take a look at revenue by geography.

In the first quarter, as Kevin mentioned, China grew at constant currency, primarily due to strong performance in the retail channel, and this growth was achieved despite the impact of VBP and despite the impact that COVID had on the fertility business in China early in the year. Asia Pacific/Japan grew 12% in the first quarter, driven by contraception, namely Nexplanon and Marvelon, Mercilon, as well as from Established Brands. For Marvelon and Mercilon in this region, just a reminder that this was a marketing rights acquisition that we did in February of 2022.

In Established Brands, we do continue to benefit from generics being out of the market in Japan, but at a significantly lower level than we saw in the first quarter of last year. Established Brands' strength for this region was mostly realized in countries outside of Japan, where we saw a pickup in demand for respiratory products associated with seasonally poor air quality.

The impact of the market action for injectable steroids, Diprosan and Celestone was most pronounced in the LAMERA region, but this was offset by better pricing in some Established Brands products. The Eucan region on the other hand, has a more competitive pricing environment, which tends to pressure results in that region. In addition, EUCAN's results also reflect some of the supply disruption from the market action on Diprosan and Celestone.

With regard to the market action we described in the last earnings call for Diprosan and Celestone, it's worth noting that we restarted production earlier than anticipated and we are already resupplying key markets such as Mexico, China and the United States, which are in the top five markets for these products. Overall, the financial impact of the market action is being realized within the parameters that we incorporated into our 2023 annual guidance that we previously provided and that we're affirming today.

And last, in the United States, what you're seeing here is the strong performance of Biosimilars, Ontruzant and Renflexis, fully offsetting unfavorable customer mix in the fertility business this quarter and also covering a \$10 million benefit we had in the first quarter of last year related to a one-time milestone payment we received for Nasonex.

The next few slides in the presentation lay out performance by franchise. I think Kevin covered very well the highlights 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.

There are three important takeaways on this slide for Women's Health. First, in contraception, Nexplanon sales in the US in the first quarter have tended to reflect customer buying patterns around announced price increases more than they have underlying patient demand. So, the first quarter is not indicative of the rest of the year.

Second, we will lap the Marvelon and Mercilon transaction next quarter, so you won't see the pronounced growth we saw here in the first quarter, but these products have performed very well for us. We are pleased with the way this acquisition is operationalizing with Organon and we do expect solid performance from Marvelon and Mercilon for the remainder of the year.

Our third and final takeaway on this slide, we expect to see good growth from fertility driven by the reopening of China, as well as strong demand in the United States, where volume growth should outpace the pricing pressure that we're seeing domestically.

Turning to Biosimilars on slide 12, clearly a good quarter in Biosimilars with 20% of revenue growth year-on-year in constant currency, but what I would like to focus is on our upcoming launch of Hadlima. As Kevin mentioned, we continue to believe there will be a gradual market formation for Humira biosimilars in 2023, and because Hadlima revenues will only be a partial-year contribution, we expect that globally Hadlima will still represent no more than about 1.5% of our consolidated 2023 revenue. And this is consistent with what we said last quarter when we provided 2023 guidance.

Turning to Established Brands on slide 13, as Kevin mentioned, this franchise is performing very well, and in 2023, our expectation is that we should achieve at least flat performance of last year on a constant currency basis.

Let's turn now to key P&L line items on slide 14. For gross profit, we're 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 65.2% compared with 66.5% in the prior-year period. The year-over-year decline in gross margins is primarily due to product mix, as well as inflationary cost pressure that impacted distribution and employee-related costs.

Adjusted EBITDA margin was 33.7% in the first quarter compared with 41.3% in the same period of last year. Higher product promotional costs for new and existing products, as well as increasing R&D spend associated with recent acquisitions of clinical-stage assets were the primary contributors to the decline in adjusted EBITDA margin year-over-year.

I should also point out that in the first quarter of last year, operating expense was at a low point because we were still staffing up positions that were vacant as of the spin-off. Contrast that now to the current quarter where we are essentially at steady state from a staffing perspective.

Non-GAAP adjusted net income was \$276 million or \$1.08 per diluted share compared with \$420 million or \$1.65 per diluted share in the first quarter of 2022. The year-over-year decline in net income was a result of, of course, lower adjusted EBITDA, but also attributable to increased interest expense. Our variable rate debt, which comprises 38% of our total debt balance, is subject to higher rates compared with last year, and we also recorded \$5 million of accelerated amortization of debt issue costs in conjunction with the \$250 million voluntary prepayment on the US dollar variable rate term loan that we completed in the first quarter. We also experienced \$9 million of foreign exchange translation losses driven by fluctuations in certain foreign currencies which are impractical to hedge. So, together, that's about \$14 million or about \$0.04 of tax affected EPS that likely wouldn't have been in anyone's models.

Turning to leverage on slide 15, as Kevin mentioned at the outset, during the quarter, we made a \$250 million voluntary prepayment on our US dollar variable rate term loan. Since the spin-off, we've now made \$450 million of voluntary debt repayments, which demonstrates the priority replacing our managing debt and leverage as a core component of overall value creation in Organon.

That said, I will reiterate the comment from our last earnings call about our leverage ratios being stubborn during 2023. Our net debt-to-adjusted EBITDA ratio is likely to end 2023 close to where it was at the start of the year. This is the impact of the inevitable math around this metric, given our strong ex-US revenue base and two dynamics this metric faces this year. The first dynamic is relatively smaller and more technical, relates to FX translation around the US dollar that has been weakening since the start of the year. As this happens, the numerator of our leverage ratio, the debt figure, trues up immediately in terms of the increased translated value of our euro denominated debt on the balance sheet. The denominator, however, is a trailing 12-month figure, which exhibits a more lagged response to FX translation. This results in a leverage ratio that is slower to show improvement when the US dollar weakens, and that's exactly what we saw this quarter.

The second dynamic is more impactful, fundamental and cuts right to the strategy that we're executing. We're reinvesting in the business to create a pipeline of future revenue opportunities. The eight transactions that we've done since the spin have all required reinvestment of some kind and that shows up on the income statement as either increased R&D expense or commercial launch and promotional expenses on the SG&A line. In the near term, this weights down our LTM adjusted EBITDA, but over the intermediate and long term, we believe this reinvestment is essential for Organon to more reliably deliver sustainable revenue growth.

Turning to slide 16, we provide a closer look at our cash flow for the quarter. What probably stands out to you is the \$200 million of working capital use of cash. Like many companies with December fiscal year ends, Q1 free cash flow is impacted by the timing of annual incentive payments and in addition, we also typically see cash cycle working capital ticking up in the first quarter and that absorbed approximately \$80 million or about a 4% increase relative to year end. Over the course of the full year, these two effects normalize.

The key takeaway is that first quarter cash flow is not indicative of our full year expectation, that we will be able to generate north of \$1 billion of free cash flow before one-time items this year, which is consistent with our expectations when we issued 2023 guidance. One-time cash costs related to the spin-off transaction are trending in line with our expectation of about \$350 million for the full year of 2023. The single biggest component of separation costs relates to the implementation of standalone IT systems, the largest of which is our own global single instance ERP system with SAP. With this complex project well underway and the finish line in sight in mid-2024, we now have a clearer picture of one-time costs and the timeframe which approximates \$950 million over 3.5 years post-spin. So, for those of you modeling these one-time costs, this would imply that we see approximately \$125 million of spin-off cash outlays remaining beyond 2023 with essentially all of that figure occurring in 2024. We expect that the composition of these remaining cash outlays will be split about 70/30 between expense and CapEx, respectively.

The free cash flow we're able to generate on a quarterly basis allows us to continue to service the dividend and take a balanced approach to capital allocation. In fact, the \$450 million of discretionary debt payments that I referenced earlier compares with approximately \$500 million of capital deployed into M&A-related activity, and this evidences the balance that we have said we would be targeting.

Looking ahead into 2023, CapEx for PP&E of 3% to 4% of revenue remains a good range for modeling purposes, as we continue to deploy that capital into our internal manufacturing and packaging capabilities, as well as our IT infrastructure to help drive cost efficiency and productivity.

Now, turning to our full year guidance on slide 17, this bridge is identical to the one we showed in February. The ranges on these various drivers still hold, driving us to affirm our 2023 revenue guidance range of \$6.15 billion to \$6.45 billion. Though LOE was minimal in the first quarter, we still expect an approximate \$50 million to \$75 million impact for the full year, which reflects the continued generic competition for NuvaRing, Atozet's LOE in Japan, which happens midyear 2023, and the expectation for a generic entrant for Dulera towards the end of the year in the United States.

We expect the impact from VBP to be in the range of \$125 million to \$175 million, driven mostly by Ezetrol's inclusion and the implementation of round seven in November of last year, as well as round eight implementation in the second half of this year, which will include for Organon the products, REMERON and Hyzaar.

On a total company basis, we continue to expect approximately \$75 million to \$125 million of price erosion this year, representing about a 200 basis point headwind, mostly related to mandatory pricing decreases in certain markets we operate in, as well as some pressure from US fertility. We still expect strong volume growth in 2023 of approximately \$500 million to \$600 million. The main drivers here will come from our multiple growth pillars: Biosimilars, fertility, China retail, and Nexplanon, as well as some contribution from Established Brands.

We're currently estimating an approximate \$50 million to \$100 million impact from foreign exchange translation for the full year, which would represent about a 1 percentage point headwind. So, that means that our guidance range implies a constant currency revenue growth of approximately 3.5% at the midpoint. If foreign exchange rates remain where spot rates are currently, this could be a factor in driving us to the higher end of that revenue range.

Moving to the other components of guidance on slide 18, we expect adjusted gross margin to be in the low- to mid-60% range, which is modestly lower than where we finished 2022. And as I've talked about previously, much of the inflationary impacts from 2022 were held in inventory and therefore, have a greater impact to our cost of goods sold this year in 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 year and reflect continued investment in the business as we position it for future growth.

Our estimate for R&D expense includes \$40 million of IP R&D expense that's tied to the \$8 million investment we made in Claria Medical, which we recorded in the first quarter, plus the \$25 million estimate for a milestone achievement for ebopiprant tied to the acceptance of the IND filing. Because we know it's important to your modeling, we will make a public statement upon achievement of that milestone so that you can factor that payment into your quarterly phasing.

The remaining approximate \$8 million of IP R&D is tied to other milestones in the portfolio that could possibly be achieved this year, so we continue to incorporate that into the guidance. These items [ph] bridge you to (00:30:14) an adjusted EBITDA margin in the range of 31% to 33%. First quarter adjusted EBITDA margin was 33.7%, just above the high end of the guidance range. In our short operating history, first quarter margins have been the highest of the year with fourth quarter being the lowest. We're starting to see that smooth a bit as we get further from the spin-off.

So, for 2023, we do expect first quarter margins still to be the highest of the year, as you think about the remaining three quarters, they do not look markedly different on an ex-milestone basis, though the second quarter does bear some incremental promotional costs related to upcoming product launches in the back half of the year. Additionally, the \$25 million milestone for ebopirant could be triggered as early as the second quarter.

For interest expense, we're nudging up our estimate slightly to reflect the accelerated debt amortization expense recorded in the first quarter actuals associated with our term loan prepayment. We now expect about \$515 million of interest expense in 2023.

Our range for effective tax rate remains in the range of 19% to 21%. In the first quarter, our rate was 22.8%, which included a discrete item related to a true-up of a 2022 valuation allowance. We expect our tax rate to trend downward over the rest of the year.

The last point I'll make on this slide is, due to the impact of employee share awards that vest in 2023, we've increased our guidance for fully diluted weighted average shares outstanding by 2 million shares.

As Kevin said, and I will reiterate here in closing, 2023 is off to a solid start. The business continues to perform well. Capital allocation is on track with a meaningful debt repayment in the first quarter, as well as the completed pipeline transaction in Women's Health where we continue to invest in our already strong market position. Overall, we're pleased with the first quarter and we remain confident about the diversity and durability of our business.

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

QUESTION AND ANSWER SECTION

Operator: Thank you. [Operator Instructions] Your first question comes from the line of Umer Raffat at Evercore ISI. Your line is open.

Q

Oh, hi. Good morning. This is [ph] Jen Chan (00:32:45) on for Umer. Thanks for taking the question. So, first on Humira biosimilar. [ph] So, Hadlima (00:32:49) reported \$50 million in the first quarter and the majority of it is inventory. So, just wondering what is your expectations on the end user demand for Humira biosimilars.

And secondly, on Nexplanon, what is the trend now [indiscernible] (00:33:04) level? Thanks.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Thank you for the question. I can address that. So, first question in regard to our Hadlima launch, we believe, again, as I mentioned a number of times in previous settings, that 2023 will be a modest ramp-up year. It's a year of essentially competition to get on formularies and our discussion with various PBMs, they still hold to the fact that there will probably be two to three – or two to three biosimilars for Humira on formulary during this period of time. And so, I think they're playing a wait-and-see game and as we speak right now. And so, 2024 and 2025 will be the formative years where we see more and more kind of Hadlima uptake and essentially the market for biosimilars for Humira will start to really form in that sector. So, we're still fairly conservative in our view in terms of

what we can do this year because it's really getting on formularies and then the years past that we'll start to see a more aggressive, robust ramp-up.

Now, in regards to your second question about Nexplanon, right now what we see is essentially a focus on expanding demand generation for Nexplanon. We see good physician growth in terms of overall demand. We see a lot of bright stars in terms of ability to be able to continue to drive this product. We've mentioned already that 2025 will likely be the milestone point where we reach \$1 billion in overall, so it's really essentially our blockbuster product. We continue to see a lot of signals that this product is getting a lot of momentum throughout the country in terms of some of the demand signals that we're seeing out of physicians and various other sectors. So, we feel very, very enthusiastic, very bullish about what's going on in terms of consumer demand, consumer market access, and what we see going forward. Nexplanon is really a healthy product. As you saw, the trailing 12 months, its double-digit growth if we look backwards and we still feel that this is a product that will be very important for us.

Operator: Thank you. Your next question comes from the line of Jason Gerberry from Bank of America. Your line is open.

Jason M. Gerberry

Analyst, BofA Securities, Inc.

Q

Hey, guys. Thanks for taking our questions. So, I just had a couple. So, OGN has a couple of Phase 2 readouts from your in-licensed endometriosis asset. How important are the 2024 pipeline updates to driving BD strategy as those assets will hopefully replace Nexplanon when it goes LOE?

And then a second question, you mentioned the year-over-year decline, 1Q gross margins, due to product mix and inflationary cost pressure, but the guidance for the full year is flat. So, do you expect any pressures there in the upcoming quarters? Thank you.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

So, I can address the first question, Jason. In regards to ebopiprant, as well as OG-6219, our endometriosis product, as you know, last year fourth quarter, we essentially initiated our Phase 2 trial. We'll see what happens in 2024. But so far, that is a product that we believe strongly in, new mechanism of action, treatment of endometriosis in a way that hasn't been essentially achieved before. Endometriosis continues to be a major, major issue across the world with almost nearly 200 million women of reproductive age suffering from some of the debilitating effects of endometriosis. The field needs innovation, it needs a new mechanism of action that does not work centrally, that's more locally acting. And so, we will see what happens, but clearly that's one of our strategies. If that product makes it across the finish line in the 2028 timeframe, we'll be able to deal with that.

But on the other topic of Nexplanon, the LOE in the United States is 2027. But as I mentioned a number of times before, the entire kind of erosion model for Nexplanon, I would probably look and start to look at a benchmarking, say, for example, Mirena from Bayer as kind of the situation, because it's a device that has drug-eluting device, it's a very difficult product to manufacture, and all of the other downstream investments that need to be made in terms of training, in terms of pharmacovigilance, in terms of all the other things that go along with the complexities of managing something like a Nexplanon in terms of your own applicator device. So, we still believe that Nexplanon is not going to essentially resemble what you might have in your models in terms of the standard kind of historical erosion rates. And so, those two together, I think, kind of signal that we're on the right path going forward.

Matt?

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

A

So, for the gross margin part of your question, just to elaborate a bit more on the commentary, just due to the production timeline cycles for our products, most of what we sell in the first half of the year is – was actually manufactured last year. So, any inflationary impacts from 2022 are already in inventory, comes out in COGS as we sell product. Any product that we're making this year is likely to be sold next year. But anything that happens within the year where it's made in the year, sold [ph] within the (00:38:54) year will continue to reflect the inflationary cost that we've been seeing. But as we think about the gross margins for the rest of the year, obviously, the biggest driver of our gross margins is going to be product mix. And so, we think we have reflected, based on the revenue forecast, everything appropriately, the gross margin line and all – what all that boils down to is that gross margins are likely to be net-net lower than last year by 100 basis points or 200 basis points, most of that driven by inflationary cost pressures that were either already reflected in inventory when the year started, or we will continue to realize for activity this year.

Jason M. Gerberry

Analyst, BofA Securities, Inc.

Q

Thank you.

Operator: Thank you. Your next question comes from the line of Navann Ty at BNP Paribas. Your line is now open.

Navann Ty

Analyst, Exane, Inc.

Q

Hi. Good morning. Thanks for taking my questions. On Women's Health, could you tell us more about the change in customer mix and discounts in the US for Follistim?

And on Nexplanon, were the distributors' buy-in, buy-out pattern is more pronounced than expected, and how do you see demand during the year on both Follistim and Nexplanon?

And then another one on Established Brand (sic) [Established Brands] (00:40:19) if you could tell us which drugs drove the strong performance in China? Thank you.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Yeah. So, let me try to take those questions, Navann. So, first and foremost, in regards to fertility, we continue to, as I mentioned in my opening remarks, see the fertility business ramping back up for the second through the fourth quarters of this year. The first quarter, we started to see essentially some COVID effects in China that were coming through. We see February very strong and March very strong and ultimately Q2 strong. So, will ramp very nicely back up.

And when you look at the Follistim business in the US, as we start to expand our share – and believe me, we're starting to expand our share in terms of our volume share in the US – we're having to get into some competitive pricing scenarios in regards to some of the accounts that we're putting on board. And so, as a result of that, there's more pricing competition. But everything we see – again, in Q2 right now and we're midway through Q2,

shows me that it's being very – it's going to be a very successful year for our overall fertility business. As I mentioned earlier in the – in the high-single digit, low-double digit rate for the intermediate period in terms of the coming few years, it's not going to be any different in 2023. So, all the signs, all the signals that we see for our fertility business in our two most important markets, that being the US and China, continue to be, I think, very solid.

In regards to the second question in regards to Nexplanon, specifically in the US, the Nexplanon business continues to act in a very kind of a predictable manner in the sense that typically in the fourth quarter of any given year, we have a buy-in and then ultimately in the first quarter, we kind of work through that process in terms of the buy-out. So, typically, when we see Nexplanon business in the US, Q1 is always kind of our lowest quarters. Everything that we see though in downstream demand, what we see from physician demand, which is essentially sales from the distributors over to the physicians, shows us mid to actually growing higher-single digit demand growth. So, everything that we see from Nexplanon tells us that in 2025 we'll surpass a \$1 billion of physician demand, continues to be very bullish, very strong in the US, ex-US business is coming along as well. The buy-in, buy-out, I think, noise that you see can be rationalized when you look at the kind of a moving annual total of the business and what's happening to those dynamics we still see some very, very good solid growth and has been the case since we took over the product, and we feel very strongly about that.

In terms of Established Brands, specifically in China, retail growth continues to do very well. We have really good opportunities with Arcoxia in respiratory. It's been a strong respiratory season. We do see the retail sector – as I mentioned a number of times, we're kind of working through all the various stages or the rounds of VBP, and we start to see the business now almost 60% in the retail sector for our Established Brands business. So, we'll go through – we'll kind of funnel through all of the rounds of VBP sometime in 2024, and then you'll start to see really more bullish growth coming out of China as we work through all the various rounds. Currently, by the end of this year, we'll have seen probably about – close to 70% of our brands kind of gone through the volume-based procurement process, and it'll be essentially fair sailing thereafter when we start to see both the retail sector really take over and do very well for us.

Navann Ty

Analyst, Exane, Inc.

Thank you.

Q

Operator: Thank you. Your next question comes from the line of David Amsellem from Piper Sandler. Your line is now open.

David Amsellem

Analyst, Piper Sandler & Co.

Thanks. So, had a question about biz-dev, M&A and the cap structure. I think in the past, maybe a few months ago, you talked about potentially adding commercial-stage assets. So, I guess the question is, how do you think about that in the context of also debt pay-down? And maybe it's not an either/or, but what are you prioritizing in terms of bigger acquisitions versus cleaning up the cap structure? Thank you.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Well, I think, Matt and I will kind of tag team on this. What I will, just from a high level, point out, David, is, as I said, we made a \$250 million pay-down of our debt in the first quarter. So, we are clearly focused on kind of some balance sheet hygiene actions that we need to take, but it never kind of detracts away from what we're doing now

A

in terms of building out a pipeline of assets for Organon, especially in the Women's Health space and Biosimilars space. We continue to look – and we're – continue to open and we continue to field a lot of incoming as well as us kind of reaching out to various parties. We are focused on more nearer term more accretive tuck-ins that I've said earlier and that's what we look at. For example, the Claria Medical system, if all things go well, which we believe very strongly in this device, we're talking about a second half 2025 launch. So, it's not a long term kind of proposition.

And so, as time goes forward, you'll start to see more and more of opportunities to talk about the things that we're doing in BD. But we are open to all – various forms, whether it's a large deal that we're looking at, but obviously, given the current environment that we are competing in, we've got to be, obviously, very careful in terms of what we're doing in regards to what we're bringing into the company. But I'll turn over to Matt for any additional comments.

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

A

That's a very complete answer, Kevin. I have nothing to add.

Operator: Thank you. Your last question comes from the line of Greg Fraser at Truist Securities. Your line is now open.

Gregory D. Fraser*Analyst, Truist Securities, Inc.*

Q

Good morning, [ph] folks. Thanks for (00:47:01) taking my questions. On the fertility business, how are you thinking about your business [ph] – I'm just talking about (00:47:08) bigger picture in terms of the commercial organization and portfolio? Is your footprint there sufficient to drive the high-single digit to low-double digit growth that you've talked about? And are you interested in BD opportunities that would expand your business and your portfolio in China? Thank you.

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

A

Yeah, Greg. Look, as I've said on a number of calls that the future of our fertility business is really the growth component is going to come – a lot of it will come from the Asia Pacific region. You start to look at the overall fertility rates in the Asia Pacific region, China doesn't publish it much, but we understand that it's somewhere around probably 1 when it should be 2.1 per couple per woman. When you look at Korea, another very large market, it's less than 1. When you look at Japan, it's around 1, 1.2. This is becoming a major issue for many countries in the Asia Pacific region.

Now, let's kind of drill down on your question in regards to China. China, we do have – we've stood up and we do have a fertility sales force. We've got good footprint in China in terms of, especially the provinces that we believe have the highest return of investment in terms of what we're doing there. Two, we're the second leading product – group of products in fertility in China, and we're competing there. We see an opportunity to really do well there. The China fertility market is clearly still not reimbursed within the China market, but there are signals that reimbursement is not so far off in the – in the distant – not too distant future. So, that will really kind of signal that there's opportunities to really expand and grow our business in China.

The first quarter was characterized by kind of working through the COVID lockdowns, but February and March were much stronger sequentially. What we're seeing right now in the second quarter is even stronger double-digit

potential expectations in the second quarter and going forward for the year. So, China will be a key market focus for us. We've got the right footprint there. We're looking – and also, to your point, we're looking at business development tuck-ins within the fertility sector in China and we're also looking for China for China as well, because we see opportunities there, given the size of the market, given the growth of the market, given the expectation that potentially we're going to see potential – some form of reimbursement potentially coming down the pike in the not too distant future.

Gregory D. Fraser

Analyst, Truist Securities, Inc.

Q

Thank you.

Operator: There are no further questions at this time. Mr. Ali, I'll turn the call back over to you.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Very good. Thank you. Thank you. Today, we've conveyed to you that we're focused on two things: balance and execution. We remain committed to creating sustainable, long-term business with growth from value-creating business development. This will be balanced against good financial hygiene, which for us means maximizing profitability and lowering our debt leverage. I'm proud of the continued business execution and our growing track record of delivering on our commitments. Thank you. We'll speak to you soon.

Operator: This concludes today's conference call. You may now disconnect.

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