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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 Third Quarter 2022 Earnings Conference Call. [Operator Instructions] 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 like now 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, Michelle. Good morning, everyone, and thanks for joining Organon's third quarter 2022 earnings call. With me today are Kevin Ali, Organon's Chief Executive Officer; and Matt Walsh, our Chief Financial Officer. Dr. Sandra Milligan, Organon's Head of R&D, will also be joining us for the Q&A portion of this call.

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

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

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

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Good morning, everyone, and thank you, Jen. Welcome to today's call where we will talk about our third quarter 2022 results.

Beginning on slide 4, Organon continues to perform very well. For the third quarter of 2022, revenue was $1.5 billion, up 3% at constant currency. This marks our third consecutive quarter of revenue growth at constant currency rates. And if we exclude supply sales and just look at product sales, it is the fourth consecutive quarter of product growth on a constant currency basis. We also demonstrated strong profitability. Organon generated adjusted EBITDA of $546 million in the third quarter, representing a 35.5% margin.

Turning to slide 5. We're building a company that we believe can deliver sustainable growth driven by the contributions of each of our three key franchises. During the third quarter, the Women's Health franchise delivered 23% growth on a constant currency basis. This includes $229 million of revenue in Nexplanon, which beat the record we set in the fourth quarter of 2021. This was also the first quarter during which we delivered more than $150 million of Nexplanon in the US, where the product grew 26%, and that is driven primarily by increased physician demand.

Execution of the promotional strategy continues to support the Nexplanon growth trajectory this year. This includes training. We continue to train more physicians across the US. And year-to-date, we have trained over 16,000 providers. It also includes educational and direct-to-consumer campaigns, which are reaching millions of women and driving more patients to the product.

The steady penetration of this product is evident when you look at Nexplanon's global performance on a trailing 12-month basis, which takes out the noise of the timing of tenders and pricing actions. We've added a slide in the appendix to illustrate the steady pickup in growth we have seen in this product since it has been in our hands. We should see a continuation of that trend into the fourth quarter.

Fertility also grew double digits during the quarter as well as year-to-date. We expect double-digit performance for this portfolio for the full year 2022. The US and China are large and important fertility markets and together represent over half of our current fertility business. Revenue increased in both of those markets during the third quarter, and that was despite slower-than-expected recovery from the COVID lockdowns in China. China is a particularly important fertility market with over a million IVF cycles a year, that is five times the number of cycles in the US.

As you've heard us discuss many times before, fertility is a therapy area with strong demographic tailwinds. Women are waiting longer to start a family, resulting in higher infertility prevalence, and more governments are realizing that they need to take action to address the associated low birth rates. Globally, the top five markets with the highest infertility rates are in the Asia-Pacific region, where the fertility rate or the number of births per woman is significantly below the replacement rate required to sustain a population and a GDP growth.

Countries like Korea are offering cash incentives for households to expand their families, and Japan, Australia, Thailand and Singapore are expanding fertility access and/or their benefits. These dynamics represent an attractive opportunity for Organon given our already significant presence in that region.

The Women's Health franchise is also benefiting from our business development activities. We've added three commercialized assets to our Women's Health portfolio since spin that are already contributing or will soon be contributing to revenue growth. You will recall that earlier this year, we reacquired the rights to Marvelon and Mercilon in selected territories in Asia, including China and Vietnam.

Both Marvelon and Mercilon are combined oral hormonal daily contraceptive pills. These contraceptives were already owned, manufactured and marketed by Organon in 20 other markets. Since we have taken ownership of Marvelon, growth has outpaced the market, and we increased market share of the product by two points in China. We also made our first shipments to Vietnam. The success from the repatriation of these assets is – but one additional example of how Organon is applying its own methodologies to maximize the performance of assets that may have been under-prioritized in the past.

The third quarter also includes the contribution from the JADA System, which is a device intended to provide control and treatment of abnormal postpartum uterine bleeding or hemorrhage. Our goal in acquiring JADA included the opportunity to speed up access to innovation in the US and to leverage our global capabilities to bring JADA to markets around the world. We continue to add accounts and are now in about 800 hospitals in the US, where more than 10,000 mothers have been treated with JADA.

Additionally, we recently made our first ex-US shipment for the JADA System and have also submitted to the EU for approval, with that review process set to begin in December. And finally, together with our partner, Daré Bioscience, we look forward to a first half 2023 launch of XACIATO, an FDA-approved medication for the treatment of bacterial vaginosis in female 12 years of age and older.

We continue to balance our business development activity between commercial-stage assets and pipeline-stage assets, particularly with regards to potential opportunities in the US market as we seek to further enhance the growth profile of Organon.

With respect to the clinical assets we have added to our portfolio, we took an important step forward last week when we enrolled the first patient in the Phase 2 ELENA study to evaluate the safety and efficacy of OG-6219, a candidate for endometriosis. We are proud to have achieved this milestone as it is Organon's first molecular entity to enter this phase and signifies our dedication to developing novel alternative therapies for patients suffering from endometriosis.

Endometriosis is among our highest priority areas of focus. It's a common and chronic condition that effects up to one in 10 women of reproductive age. And yet despite increasing awareness of this condition, there are currently no long-term approved treatment options. The compound we are studying is different than currently available treatments because of its potential ability to act locally in the target tissues without impacting systemic hormone levels.

This potentially selective activity allows for its evaluation as a long-term treatment option for endometriosis. We are proud to be moving forward with this research in the hopes of addressing this significant unmet need.

Turning to Biosimilars. We continue to have solid uptake of ONTRUZANT and RENFLEXIS in the US. While the phasing of tenders will show up in quarterly results, year-to-date this business is developing or delivering double-digit growth, and we expect results for the full year to demonstrate double-digit growth as well.

Our next biosimilar launch will be mid next year with our launch of HADLIMA in the US. There are other biosimilars launching along with us in July, but here's why we think HADLIMA will be successful. We believe that biosimilars that will be best positioned to succeed are those that share the same attributes as the originator HUMIRA. That includes the option for a high concentration citrate-free formulation and a low concentration formulation, and we expect to have both at launch.

We also believe that real-world evidence and experience in other markets is important for provider uptake and product confidence. Our collaborator, Samsung Bioepis, has data from their launch of HADLIMA in EU, and we have data from our own launches in Canada and Australia.

And finally, our pen design. Samsung is an expert in device design and manufacturing. We believe our pen design can deliver a frictionless experience for patients transitioning from HUMIRA and we think will be a true differentiator among our other offerings.

And before I turn the discussion over to Matt, which should not go underappreciated, on slide 6, is our Established Brands business. That franchise currently represents about two-thirds of our overall business. The portfolio continues to demonstrate the sustainability, and untapped potential of these brands can generate significant free cash flow.

Year-to-date, Established Brands has delivered 6% growth on a constant currency basis. Given its strong year-to-date performance, we expect the Established Brands franchise to deliver modest revenue growth for the full year 2022, even with some expected impact from volume-based procurement in China in the fourth quarter.

As strategic owners of this business, we are staying nimble so that we can capitalize on dislocations in local markets, like competitor stock-outs. Our policy and market access teams have worked to minimize price erosions where possible, and we have been strategic about extracting value from long-standing brands with planned life cycle management activities.

With these initiatives and programs, we believe we can manage this franchise to a very low single-digit rate of erosion over the longer term. And this, in our opinion, is a significant early win for a business that was experiencing double-digit decline prior to the spin.

With that, now I'd like to turn over the discussion to Matt. Matt?

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

Thank you, Kevin. I'm pleased to go into further detail on our results for the third quarter, not just because the performance was solid but also because we reached an important milestone in financial reporting this quarter.

Organon as a standalone entity in both the current and prior year periods, which means this is the first earnings call that we can discuss performance with apples-to-apples comparability to the prior year period without being obstructed by the carve-out basis of accounting that we needed to employ for pre-spin-off accounting periods.

And with that opener, we'll start the financial discussion on slide 7. I'm showing this slide for two reasons: first, to highlight operational performance by geography; and second, and really more important, to provide a basis for understanding just how much Organon's results are subject to foreign exchange translation.

On an operational basis, our best performance in the third quarter came from the United States and Asia-Pacific, Japan regions. The US is an important market, representing a quarter of our business, so the 6% growth in that market during the quarter was meaningful and was primarily driven by growth in Nexplanon and also ONTRUZANT and RENFLEXIS, the two biosimilars that we offer in the United States.

On a constant currency basis, the APJ region grew 13% during the quarter. We continue to benefit in Japan where generics, really since the start of the year, have been having structural supply issues related to GMP conformance and quality issues. Now this presents an opportunity for Organon, and we've been able to flex our manufacturing and supply chain capabilities to meet market demand.

We've also seen growth in Southeast Asia and Thailand. And as Kevin mentioned, we shipped our first order of Marvelon to Vietnam in the third quarter. Our remaining regions were level with prior year during the quarter on a constant currency basis. We had very strong performance in China during the third quarter of last year related to resupply of key products from long back orders. So it was a tough comparison point in China for Established Brands, but growth in fertility and in other Women's Health, namely Marvelon, offset the modest decline in Established Brands.

We're seeing strong demand for Nexplanon and HUMIRA, but that was offset by the phasing of an ONTRUZANT tender that we received in the third quarter of last year, but moved to the second quarter of this year.

In EU/CAN, we had good volume growth in Biosimilars and Established Brands, but that was offset with annualized pricing erosion in Established Brands in Europe. As we think about foreign exchange, other than the US dollar, which represents about 30% of our revenue exposure, we have most exposure to the euro, which is about 20% of our revenue; the Chinese renminbi, which is about 15%; and the Japanese yen, which is less than 10%.

But my main point here is that with about three quarters of our revenue outside the US, our portfolio faced a significant headwind from FX, not unlike a lot of other multinational companies. But in our case, it amounted to a full 7 percentage point swing in revenue growth for the quarter, but unfortunately masked the operational growth in local currencies that we delivered.

Turning to slide 8, which bridges our year-over-year quarterly revenue performance by key driver. Revenue for the third quarter was approximately $1.5 billion, down 4% as reported, but up 3% at constant currency when compared to the third quarter of last year. These are the components of the 7 percentage point swing in revenue that I was referencing.

The impact of loss of exclusivity or LOE during the third quarter compared to last year was negligible. In the first half of this year, the majority of LOE exposure in the portfolio was coming from NuvaRing, but that was countered this quarter by favorable volume demand in the United States, and NuvaRing revenue actually grew modestly year-over-year in the third quarter.

In addition, we didn't have any LOE impact in Established Brands this quarter. The most significant LOEs facing the portfolio washed out prior to the spin-off, and we expect only modest new LOE exposure going forward. Now

since the spin-off in 2021, we have been expecting a generic entrant in the US for DULERA. That did not happen in 2021 and now looks very unlikely for the remainder of 2022.

Continuing to read across the waterfall chart, the impact from volume-based procurement in China was also negligible in the third quarter, which is also the case year-to-date as the implementation of the next rounds of VBP have been delayed. That said, we expect the VBP implementation to resume in the fourth quarter and that it will primarily impact EZETROL.

Moving across, we saw an approximate $30 million impact coming from price in the third quarter, which is consistent with our expectation that we'll see low single-digit price erosion on a company-wide basis. This is mostly coming from Established Brands where products are subject to mandatory price reductions in some markets.

We had good volume growth in the quarter. That came mostly from our growth pillars, Nexplanon, particularly the United States and Latin America; biosimilars in the US; respiratory and cardiovascular products in the APJ region; and just overall growth in fertility.

And finally, foreign exchange translation continues to be a significant headwind for us. As I introduced on the last slide, and here you can see the translation impact of approximately $100 million on the top line.

Now let's take a look at our performance by franchise, and we'll start with Women's Health on slide 9. We had very strong growth in the United States in Women's Health during the quarter, driven by 34% growth in Nexplanon. We did have a favorable comp in Nexplanon in the third quarter of last year as annual patient well visits were depressed, and there was also a tender in Mexico that would normally hit the third quarter but moved into the fourth quarter of last year.

In addition to volume growth, our Q3 2022 performance also reflects our ability to secure a modest price increase in Nexplanon, but that had a lesser impact relative to volume. And as Kevin mentioned, we also saw a double-digit growth in fertility this quarter. We had better performance in NuvaRing and in other Women's Health, which reflects the reacquisition of Marvelon rights in China.

Turning to Biosimilars on slide 10. Biosimilars declined 7% as reported and 4% ex-FX in the quarter, which really reflects timing of revenues. Year-to-date, Biosimilars has grown revenues double digits and is on track to grow double digits for the full year. What we're seeing here in this quarter is the tendency for the Biosimilars business to be lumpy due to timing of tenders.

Both ONTRUZANT and RENFLEXIS performed strongly in the US during the quarter, and overall, the US Biosimilars business was up 23% on a constant currency basis, but year-over-year tender phasing and, in this case, in Brazil for ONTRUZANT offset those increases in the quarter.

Turning to Established Brands on slide 11. With close to 90% of the revenue in Established Brands coming from outside the US, FX translation impacts are most prevalent in this franchise. Revenue for Established Brands was down 11% as reported and down 2% ex-FX in the third quarter. We've seen very strong year-to-date performance with revenue up 6% at constant currency.

And given the strong nine-month performance, we now expect that revenue for Established Brands will land in modestly positive territory for full year 2022 on a constant currency basis. The question we receive most from investors is, what can the Established Brands franchise do next year and over the longer term? So since the spin-

off, we've said we could manage this business to very low single-digit erosion on the top line at constant currency. We think we can deliver at least that performance over the intermediate term.

And there's three reasons why we believe this. First, our actual revenue performance in the first five quarters since the spin-off has exceeded our expectations. Two, more than half of our Established Brands portfolio will have already gone through VBP in China by the end of this year. And three, there's very modest LOE left in the portfolio.

So now turning to our income statement on slide 12. We've already discussed revenue, so we'll move down the P&L. For gross profit, we're excluding from cost of goods sold, purchase accounting amortization and one-time items related to the spin-off. Making these straightforward adjustments in the third quarter of 2022, non-GAAP adjusted gross profit was $1.032 billion on revenues of $1.537 billion, representing a gross margin of 67.1%, which was up from 64.9% in the third quarter of last year.

The year-over-year improvement in gross margins is primarily due to favorable product mix and the $24 million charge in 2021 related to a long-term vendor supply contract conveyed as part of the spin-off.

Adjusted EBITDA margin was 35.5% in the third quarter of this year compared with 38.2% in the third quarter of last year. And just a quick reminder that we've revised our presentation of adjusted EBITDA to conform with industry-wide SEC guidance to include IP R&D and milestone payments within any adjusted income reported. And in our case, adjusted EBITDA margin this quarter includes $10 million of acquired IP R&D and milestones compared with $25 million of similar costs in the prior year period.

Higher selling and promotional costs as well as R&D spending associated with recent acquisitions of clinical-stage assets contributed to the decline in adjusted EBITDA margin year-over-year. As we have been communicating consistently since the spin-off, expenses to develop new products, to support commercial product launches and to build core capabilities are going to be drivers of our adjusted EBITDA margin in the intermediate term.

As we look at debt capitalization and leverage on slide 13, as of September 30, 2022, we have debt of $8.7 billion netted against cash and cash equivalents of $500 million. Our bank covenant calculations provide for the add back of acquired IP R&D and milestones to our last 12-months EBITDA calculation, which is how we have been presenting leverage ratios in prior slide decks and on prior earnings calls.

Now on that basis, net leverage was about 3.6 times as of September 30. Recall that at the time of the spin-off in 2021, we had a pro forma net leverage ratio of about 4.0 times. And we said then that we were targeting a leverage ratio of less than 3.5 times on a sustained basis. So we've made progress on leverage reduction, which has been aided by $200 million in voluntary prepayments of our US Term Loan B since the spin-off.

Turning to free cash flow on slide 14. Part of the Organon investment thesis for stakeholders is that the standalone business generates significant free cash flow. We set the dividend at a rate that would imply that we expect Organon to generate north of $1 billion of free cash flow per year, and that basic math still holds. The recency of the spin and related timing of some payments to Merck, coupled with unfavorable foreign exchange translation, obfuscate this important characteristic of the business on our year-to-date free cash flow calculation.

So on this slide, I'm going to walk through a few of the issues, most of which are transient in nature. This simplified year-to-date free cash flow on this slide starts with $1.7 billion of adjusted EBITDA, which as I mentioned earlier, includes the impact of acquired IP R&D and milestones. The biggest change relative to what

we had expected at the start of the year is the working capital line item highlighted in green. And there are three components making up this $764 million use of cash.

First is the timing of about $300 million of working capital build related to the spin-off and separation from Merck. We expected this figure to be built during the prior year period, but it slid into 2022. Second is an increase in normal course cash cycle working capital of about $250 million.

About half of that is related to intentional, strategic growth in inventory where it can drive revenue performance in our growth pillars, and that's mainly in Biosimilars and the completed acquisitions in Women's Health, with the remainder in line with volume growth across our businesses. And the third driver is foreign exchange translation, and the reporting impact there is about $160 million.

So the working capital build associated with the spin together with the FX impact has been significant year-to-date. We wouldn't expect items like these to be of this magnitude in future years.

Our capital allocation priorities remain consistent with past communications. Our first priority, of course, is servicing the dividend. Our second priority is organic growth, which would include life cycle management opportunities for existing products within our portfolio, supported by capital deployed in our manufacturing plants.

On the latter, we expect to see annual CapEx in the range of 3% to 4% of revenue on an ongoing basis, excluding separation costs, although we're very likely to finish below this level in 2022. That should leave significant self-generated cash flow for our third capital allocation priority, which is really a tie between execution of external growth plans to develop a portfolio of new product opportunities with an increased focus on immediately accretive or imminently accretive acquisitions, we'll balance that against discretionary debt reduction. We're committed to maintaining our BB/Ba2 parent rating balancing debt reduction with capital deployed for externally sourced growth initiatives.

Turning to revenue guidance on slide 15. Here, we bridge our expected revenue change year-on-year. The impact of foreign exchange translation has increased throughout the year to where we now expect an approximate $400 million or an approximate 650 basis point headwind based on where spot rates are today. And given where we are in the year, we're able to narrow our guidance range for full year 2022 revenue from $6.1 billion to $6.3 billion to $6.1 billion to $6.2 billion, consistent with the movements we've seen in foreign exchange translation.

For LOE at this stage in the year, a generic in DULERA is looking unlikely. So together with recent favorability in NuvaRing, we expect LOE impact for 2022 will be about $25 million for the full year. For VBP in China, the implementation of rounds seven and eight have been delayed. So again, we've not had any year-to-date impact from VBP this year. However, the inclusion of EZETROL is likely in the fourth quarter, so we're now forecasting just under $50 million of impact from VBP for the full year of 2022.

We continue to expect about $150 million of price erosion in 2022, in line with historical pricing trends for global markets that we've been selling into for many years. Our teams across the world are focused on improving profitability and delivering profitable growth. You can see that in our estimates for price erosion, those have actually improved by about $50 million from our original 2022 guidance back in February.

And for volume, we're tracking to approximately $550 million of growth for the full year, which has come down from the $600 million to $700 million of growth since we last guided, and that's primarily related to two factors.

First, given the protracted nature of lockdowns in China, we've seen slower-than-anticipated recovery, particularly in the fertility clinics and the overall retail market. In spite of this transient headwind, we still feel very good about our business in China and in our ability to grow our business in China.

Second, in order to meet emerging demand trends we're seeing for certain Established Brands products, we've strategically aligned our supply priorities to more timely meet those demands, and that has resulted in different shipment schedule for the fourth quarter that we anticipated in prior volume guidance.

The majority of our year-over-year volume increase is coming from our multiple growth pillars: Nexplanon, Biosimilars, Fertility, followed by favorable one-time items like the competitive issue in Japan and, to a lesser extent, recent business development activity. We do expect net volume growth across our product portfolio and Established Brands as well, which is supported by our year-to-date results.

Turning to other guidance metrics on slide 16. As I mentioned, we're recasting our revenue range to incorporate the continued strength in the US dollar. We're also tightening our estimates on depreciation and interest expense given where we are in the year.

The other range we're modifying this quarter is for adjusted EBITDA margin to reflect the operational favorability we've seen year-to-date. So we're adjusting upward the range accordingly from 32% to 34% to 33.5% to 34.5%. That includes $107 million of acquired IP R&D year-to-date.

Taking the midpoint of our guidance, that would imply second half margins – EBITDA margins just north of the 30% area. As we said last quarter, second half 2022 margins are a directional indicator for what 2023 adjusted EBITDA margins could look like in advance of Organon's formally releasing 2023 guidance, which we will do when we report our full year results in February.

The movement in our EBITDA margin is a function of reinvestment in our business, primarily in new clinical programs, new commercial product launches and in our R&D and commercial capabilities that position the company very well to deliver sustained revenue growth in the future.

Wrapping up the financial discussion. On a constant currency basis, the business has performed very well in the third quarter and nine months year-to-date, really as we expected. Actually better-than-expected in Established Brands, which is over 60% of our total revenues. And together with Biosimilars and Women's Health, our guidance range implies annual revenue growth of about 3% to 5% on a constant currency basis, which is right where we thought we would be.

At this point, I'll turn the call back to the operator for questions.

QUESTION AND ANSWER SECTION

Operator: [Operator Instructions] Your first question comes from the line of Terence Flynn with Morgan Stanley. Your line is now open.

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

Q

Great. Thanks for taking the questions. I guess two for me. Maybe, Matt, you can help us think about what your outlook is for China heading into 2023. You mentioned some of the variables you've seen here playing out over the last couple of quarters. But as you think about 2023, how are you thinking about the growth outlook there?

And then the second question I had is on your Biosimilars, HUMIRA or HADLIMA. I'm assuming you've had some initial conversations with US payers at this point. I know you're not launching until July. But maybe just how are you thinking about second half of 2023 in terms of both share and then price point? Thank you.

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

A

Okay. I'll take the first part of that question, which relates to China. So we expect to see growth in China in 2023. That's mainly coming from the strategic shift that we've been executing from the hospital channel to the retail channel. We do expect VBP will certainly be at play and will limit the growth that we expect, but we do expect growth in China in 2023. So directionally, I can give you that much.

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

A

And Terence, I can address the second part of your question in regards to Biosimilars. I personally met with a number of the larger PBMs in the US. And I think that 2023 will obviously be kind of a light ramp-up year as people are – PBMs are kind of locking in some of the contracts for 2023, as we speak now. And so I do believe that where you have closed systems like government business, VAs, large HMOs, like Kaiser, they could be potentially more aggressive in terms of the switch.

But I think in terms of overall on the PBM side, you'll see more of that business start to fold in, in 2024. And then ultimately, really open up in 2025. But we feel very, very good after discussing with those PBMs that our product profile and our offering, everything from the real-world evidence to the low and high citrate-free concentrations that we have got coming, plus, they were very excited about, obviously, our pen device and I keep using the term frictionless experience for many patients.

And so I think the general assumption is that, what I'm hearing is that they'll accept maybe two, at best three, but probably more likely two biosimilars on formulary. And ultimately, I think we're in good shape when it comes to that.

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

A

We can take our next question, operator.

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

A

Next question?

Operator: Your next question comes from the line of Umer Raffat, Evercore SIS (sic) [ISI] (35:02). Your line is now open.

Umer Raffat
Analyst, Evercore ISI

Q

Hi, guys. Thanks so much for taking my questions. Maybe a couple here, if I may. I wanted to – there's one of your pipeline programs which looked very interesting based on its prior data, ebopiprant. But the pace of development really confuses me, especially since it looks like there's been almost no progress since you guys in-licensed it mid last year, and my understanding is you're trying to file an IND. But I'm more confused sort of over the course of 12 to 18 months as the IND is not filed, is there something more significant that's holding it up, just so we understand it better?

And then secondly, just on the comments on Biosimilars, HUMIRA, you said it will be a light ramp-up year. PBMs are locking up contracts. But it looks like the estimates and the Street expectations are all over the place. On some players, there's as much as $2 billion plus in a Biosimilars, HUMIRA.

I think in your case, you're talking it down and you're implying more of a 2024, 2025, and most investors read that as more of a sort of $300 million to $500 million type of opportunity. Could you just list some parameters for us? Because I feel like this is one of those line items that could get mismodeled, especially in the context of the overall pipeline you guys have. Thank you

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

A

Thanks, Umer. I can start with the second part of your question, and then I'll hand it over to Sandy to address the issues that you brought up on ebopiprant. In regards to Biosimilars, look, it is going to be a kind of a lot of dust, a lot of things throwing up in the air, because it's hard to really understand right now, because PBMs are still trying to develop their strategies. And overall, I think what we're guiding to is essentially what you've seen out there, and you're right, we're guiding to a lower number versus the billions that you see out there.

I do think there's going to be some pretty aggressive discounting taking place. Obviously, nothing on the level of small molecule discounts that you see, but obviously – but there will be some. And I think because it's a pharmacy dispensed product and it's the largest biologic coming off patent, there's a lot of questions, obviously, as you can imagine in that area.

But again, Umer, we feel very good about where we are. We've got – we've checked all the boxes off. A lot of the PBMs we're talking to feel that 2023 will be kind of a light takeoff in terms of the fact that the originator will still be there, obviously, in full force. But then 2024, it will start to open up, and 2025 be much more aggressive.

And over the years, you'll see price erosion starting to hit. We feel very good about the consensus that's been put out there on HADLIMA. It is going to be a successful product for us, and we'll have to see what 2023 brings. But I do think it will be a light glide path and then ultimately, it will open up in 2024 and 2025. Sandy?

Sandra Milligan
Head-Research & Development, Organon & Co.
A

Sure. Thanks for the question. So as you probably recall, we brought over the ebopiprant asset from ObsEva close to spin. And to your point, ObsEva initially did a Phase 2 study against atosiban as an add-on therapy in select European and other countries. The preclinical data package that was put together by ObsEva satisfied these individual country requirements for the clinical trial application. However, we anticipated would not satisfy the requirements to pass the muster of the FDA in order to get a move forward on IND submission.

Therefore, right after we acquired the asset, we started out contracting and doing our preclinical work with our providers. And it has taken a little bit longer in the sense of the contract and we were just starting up as a company, but we're fully online, and we have the initial results from many of those studies.

We've already had a pre-IND meeting where we've discussed not just the preclinical data, but our development plan initially. And we had a very robust interaction with the FDA to think about that clinical development program ahead. So we are anticipating, after the finalization of the data readout on the study report, that we will be able to file this IND and pass muster early in 2023.

Umer Raffat
Analyst, Evercore ISI
Q

Thank you.

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

Next question? Thanks, Umer.

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

David Amsellem
Analyst, Piper Sandler & Co.
Q

Thanks. So just had one question on Nexplanon and one on Established Brands. So on Nexplanon, I'm trying to get a better sense for how we should think about adoption growth in a more normalized post-pandemic environment. And more specifically, what portion of OB/GYNs have already been trained? And how much remaining is out there to train going forward? So that's number one.

And then on Established Brands, you cited cardio and respiratory as being particularly resilient. I'm just wondering how sticky those products are. And even just beyond those therapeutic verticals, just thinking about these ex-US markets, what's your view on, I guess, for lack of a better term, brand loyalty or relative stickiness of these products going forward? Thanks.

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

Sure. Thank you, David, for the questions. Let me start with Nexplanon. I do believe that the pandemic, clearly, as we've seen, has created a lot of confusion in the market. I mean we still see a 25% reduction in regards to Women's Health visits that have never bounced back versus pre-pandemic, and so – pre-pandemic level. So I would say to you that it is a slow-moving process in terms of getting everyone back. That's kind of an issue that needs to be addressed, obviously.

And – but when you speak about long-acting reversible contraceptives, Nexplanon is gaining share because what we do is – what we see is the IUDs are losing favor. We see that. Obviously, it's hard to get that from IQVIA data because it's a buy-and-bill model. But nevertheless, we see that from other companies' report-outs that large IUD manufacturers are seeing declines in that business, but we continue to see increases. I see – we see increases in physician demand quarter-by-quarter. We had a really strong quarter, as you said – as I mentioned earlier, in terms of the third quarter with 26% growth in the US alone. And we do see that we're starting to gain share there.

So I do agree with you that some of the noise is going to have to come out of the system. And I believe as we go forward in 2023 and 2024, you're going to start to see more stickiness to use your vernacular in terms of Nexplanon kind of really getting more into the mainstream of a lot of OB/GYNs using that product because there is a demand.

I mean, when you start to think about it, what is the need? The need is the fact that we've got nearly a 45% unintended pregnancy rate in the US and a fact that people – a little fact that people don't really recognize is that 40% of those unintended pregnancies, patients were – women were using some form of contraception.

So it clearly shows you they need more real-world high efficacy, and that's where Nexplanon, it's really an insert and forget. And you've got among the highest, if not the highest level of protection against unintended pregnancies. So I do believe that profile will gain more traction as we start to see more women come back. And ultimately, the things that we're doing around clinical training programs as well as direct-to-consumer advertisements and things that we're doing with that nature.

In regards to Established Brands, I do believe the ex-US business is sticky. You see that -- you see in China, for example, our business continues to grow in spite of VBP rounds as well as lockdowns. We still see retail growth. We see e-commerce growth. I do believe that in many of these markets, especially in the emerging markets, you see a lot of brand loyalty, especially around cardiovascular and respiratory products, our respiratory products especially in markets that have very high seasonal allergy seasons do extremely well.

And so products like NASONEX, products like SINGULAIR continue to do very well and are very robustly accepted and people pay out of pocket for that. And at the same time, in many of these emerging markets, they want a reliable, high-quality supplier that has good science, good manufacturing know-how, and people feel very tied to their brands.

So I do believe, going forward, as I mentioned, that we will see a very, very low single-digit erosion. There are going to be some years like this year where we see a lot of upside in certain markets where we see growth. And it's been pretty robust growth for Established Brands, which is unique. You'll get other years where you get very low single-digit erosion, you get other years where it's flat. So overall, though, for the long term, I think it's a really good thing to say about this business, which is two-thirds of our business and a large part of our free cash flow. Thanks, David.

David Amsellem
Analyst, Piper Sandler & Co.

Q

Okay. Thank you.

Operator: Your next question comes from Chris Schott with JPMorgan.

Q

Hi, this is [ph] Katerina (44:45) on for Chris. Thank you so much for taking our questions. So the question is on margins. So can you just help us or rather elaborate on some of the drivers of the better-than-expected kind of margin trends this year? How much of that is delayed spend versus something that you think can carry over to future periods? And then you've talked a little bit about 2023, but more wondering, should we be thinking about 2023 as kind of a floor for margins? Or is there kind of potential for another step-up in operating cost as we think about 2024 or 2025? Thank you so much.

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

A

Yeah. So the better-than-expected performance on margins this year is a function of a few things. You can't just tie it to one driver. But what we have seen is better-than-expected price performance, right, price still went down across the portfolio, but not by as much as we had thought at the beginning of the year. Our product mix has been a little bit more favorable than we thought in our overall manufacturing performance in the plants.

Now in terms of margins going forward, I think I've – the sort of early directional indicator that we gave about margins, second half margins being a directional indicator for 2023 encompasses everything we know at this time about the amalgamation of forces that will be impacting us in 2023.

So in that directional indicator that includes, at least to the extent we know now, right, we're in the middle of our budgeting process for the company, which has yet to conclude, but product mix will always be one of the most significant drivers of our margins year-on-year. What we know about that now is baked into that directional indication.

On a margin up basis, we continue to improve productivity in our manufacturing plants. What we do expect to see some hits on, of course, is inflation for next year. That is impacting our numbers this year, but to a lesser extent, we expect to see a bigger impact of that next year. And once again, we've got the steady drumbeat year-over-year of price pressure across the portfolio given the age of the products. But all of that has been considered in the directional indicator that I provided.

Q

Great. Thank you so much.

Operator: Your next question comes from the line of Chris Shibutani with Goldman Sachs. Your line is now open.

Q

Hi, this is [ph] Dan (47:35) on for Chris. Thank for taking our questions. I guess just first on HADLIMA. Could you guys maybe talk about how impactful you see interchangeability being once you ultimately received it both being on formulary and commercially versus other biosimilars?

And then second on capital allocation. I know you guys discussed maybe more potentially near-term accretive deals. Could you maybe just give kind of the current thinking on views across segments and areas of focus in Women's Health? Thank you.

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

Sure, [ph] Dan (48:05). I can address the first question on Biosimilars on HADLIMA. In my discussions with all the PBMs that I've interacted with, and they're large ones, interchangeability does not come up as a key point. It is something that I think they'd like to see that is underway, and we will have our interchangeability indication likely in the 2024 timeframe. So that's fine. That's kind of checked the box. They're more focused on a number of other issues.

Number one is, do you have the manufacturing capability to make sure that whatever is ordered, because they're large volumes, will be met? Do you have a pen? Again, I use the term frictionless experience. Look, you don't want – they don't want to give their healthcare providers a reason to move off because patients don't have the ability to be able to inject seamlessly. And so we feel really good about the device that Samsung has put forward for us.

Do you have real-world evidence? Because we don't want to be the first country that you actually sell and provide and commercialize your product.

And then finally, do you have the high concentration citrate-free and the low concentration? Because there are some customers, approximately about 20% of customers in the US, do – or rather 20% of the business in the US is moving towards a low concentration form. So both of them, we've got that boxes well checked off. So we're fairly very comfortable with our position in terms of the profile.

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

And regarding capital allocation, what we have been seeking to do since the spin really is to bring balance in our capital allocation between innovative assets that address large areas of unmet needs in Women's Health where the commercial opportunity is also strong. Those tend to be longer-duration product development cycles. And so we've been trying to match that with either immediately accretive or imminently accretive deals that can effectively keep the business and the operating margin we're posting within a range that is just representative of a well-run business.

So we've recently put in some longer – some more early phase assets. And so as we think about balance, that would suggest that some of the next deployments that we do should be either immediately accretive or imminently accretive, once again, just to bring balance to the overall program.

Operator: Your next question comes from the line of Jason Gerberry with BofA. Your line is now open.

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

Oh, hey. Good morning. Thanks for taking my questions. Just wanted to come back, one question on HUMIRA. You mentioned that PBMs are locking in contracts now. We heard from Teva earlier this morning that per the settlement agreement, you can only contract when you launch. So just trying to reconcile those discrepant viewpoints.

And ultimately, another thing I was curious about, your one-month order of entry advantage versus that sort of next wave of biosimilars, I realize it's kind of a small time differential. But wondering mechanically, does this potentially give you a leg up that you think investors might be under-appreciating and that could be potentially, from a contracting perspective, an advantage that could be material? Thanks.

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

Thanks for the question, Jason. What I was saying, at least in my script and ultimately, in the discussion with Umer is the fact that PBMs are now kind of looking at their business for 2023. They're not kind of locking it in now. And you're right, I mean what Teva said earlier is correct that we can't start to really negotiate and contract based on the agreement that we have with AbbVie.

But nevertheless, what I will tell you is the fact that we believe that 2023, the glide – the ramp – kind of the ramp-up will not be as dramatic, because it's – you're coming in half the year. By that time, the contracts will obviously be in place, the originator will be on formulary, obviously, there will be kind of a fight in terms of getting on formularies. So there's a lot of that kind of tactical – set of activities.

But I do believe that 2024 will be a much – what I'm understanding from all the PBMs that I talk to as well as government business like the VA as well as the Kaiser system, those closed systems will move faster to replace and potentially have business switched over in more of an aggressive fashion. PBMs will take their time. And ultimately, that's what I'm signaling is that it's going to be more of a 2024 and 2025 timeline where you really start to see a lot of movement, we believe, away from the originator and essentially what happens to pricing in the marketplace.

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

Okay. Fair enough. Thanks so much.

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

Operator, I think our last question.

Operator: Your last question comes from Greg Fraser with Truist Securities. Your line is now open.

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

Good morning. Thanks for taking the questions. My first one is on the LARC category. Curious how much of the pressure on IUD demand has been tied to temporary COVID-related headwinds versus drivers that could be more durable over time? And then on Established Brands, as we think about 2023 and beyond, where do you still have exposure to VBP? You commented on longer-term growth. Should we expect greater pressure on 2023 sales tied to VBP versus future years? Thank you.

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

Yeah. So Greg, let me address some of those questions. And so in regards to your second question, regards to VBP, we do believe that VBP round seven will happen in November of this year, this month. And essentially one of our cardiovascular products EZETROL will be on that list for round seven. But by the end of 2023, we see that more than three quarters of our business will have gone through the volume-based procurement process.

And so you offset that with the growth that we have, right now, where more – almost 50% of our business is going through the retail channel and more and more of that business is now starting to go through the e-commerce channel. We will still see basically China with a high single-digit growth opportunity and potential going forward into the 2023, 2024, more 2024 timeframe where we see that there's opportunities to actually grow the business.

Sorry, your first question – IUDs – on the stickiness of IUDs and what's happening in regards to the pandemic. It's hard to – look, I can't answer the question in terms of what physicians and patients are thinking in regards to their acceptability of IUDs. But I can say that the unique thing about Nexplanon is it literally takes one or two minutes to insert and it takes the same amount of time to remove. It is much more convenient in terms of being able to use it as a long-acting reversible contraceptive that can fit in so many different settings.

In addition to that, it has the same basic efficacy as an IUD does. The difference is that you're talking about a product that currently works at efficacy for three years. We're working on the five-year extension. So that means we'll have efficacy for duration for five years. That will be launched in probably the 2025 timeframe. So we do see a long and productive runway for us for Nexplanon. And we do see more and more patients coming online and higher demand for Nexplanon as a reasonable alternative when a woman wants to have a long-acting reversible contraceptive.

And currently, there's all the signals, all the signs that we see in the marketplace, especially in the US and ex-US, which is growing actually even faster than US is that it is a method or a form of contraception that people are getting much more attached to it, because, again, back to the basic principle, in our hands, we've been able to give it the right type of attention, the right type of senior management attention, the resourcing to ultimately kick start and get that business to be $1 billion business in the very near future. It will be our first $1 billion blockbuster for Nexplanon probably in the 2024, 2025 timeframe.

Gregory D. Fraser
Analyst, Truist Securities, Inc.

Q

Thank you.

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

So, I think Kevin has a couple of closing remarks.

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

Yes, just in closing for all those – thanks for the questions, by the way. And just in closing, Organon has really had a strong third quarter with all three franchises continuing to make really important contributions. We're building a business, as you all can see, that is sustainable, and it's a sustainable growing concern. Our track record to-date supports what we have said from the very beginning of the spin, that in our hands, this portfolio of assets can generate sustainable growth.

So I want to thank you for joining us today, and we look forward to continuing to communicate our progress with all of you as time permits. Thank you very much.

Operator: Ladies and gentlemen, this concludes today's call. Thank you for attending. You may now disconnect.