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MANAGEMENT DISCUSSION SECTION

Operator: Ladies and gentlemen, thank you for standing by. At this time, I'd like to welcome everyone to the Organon Second Quarter 2022 Earnings Conference Call. All lines have been placed on mute to prevent any background noise.

After the speakers' remarks, there'll be a question- and-answer session. [Operator Instructions] As a reminder, this call is being recorded. Thank you.

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

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

Thank you, Chantal. And good morning, everyone. Thank you for joining Organon's second quarter 2022 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 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 & Presentations section of our Organon Investor Relations website at www.organon.com.

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

In addition, we will discuss certain non-GAAP financial measures on this call, which should be considered a supplement to and not a substitute for financial measures prepared in accordance with GAAP. A reconciliation of these non-GAAP measures to the comparable GAAP measures is included in the presentation and conference call presentation.

I would 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 will talk about our second quarter 2022 results. Our second quarter 2022 results round out one full year as a standalone, publicly traded company. And today, I'm proud to be reporting our third consecutive quarter of product sales growth and solid progress against our stated objectives.

Despite a challenging global macroeconomic and geopolitical environment, during the second quarter, we delivered growth across all reportable geographies and in all three franchises. We even saw growth in China despite the negative impact from the COVID-related lockdowns. And in our LAMERA region, where growth in Latin America offset the negative impacts associated with the war in the Ukraine.

For the second quarter 2022, revenue was $1.6 billion, up 5% at constant currency, and adjusted EBITDA was $512 million. That includes $97 million of acquired in-process R&D, otherwise known as IPR&D, and milestones in the quarter. So on a basis we're all accustomed to, our EBITDA would be over – our adjusted EBITDA would be over $600 million in the second quarter of 2022. During the quarter, Biosimilars continued its double-digit growth trajectory and grew 42% ex-FX. All five of our currently commercialized biosimilar assets had a strong second quarter and year-to-date 2022 compared with the previous reporting periods.

Our next Biosimilars launch will be mid next year with our launch of Hadlima in the US. We believe that biosimilars that will be best positioned for success are those that share the same attributes as the originator, Humira. That includes the option for a high concentration of citrate-free formulation and a low concentration form, which we expect to have at launch. We also believe that real world evidence and experience in other markets is important for provider uptake. And our collaborator, Samsung Bioepis, has data from the launch of Hadlima in EU, Canada, and Australia. These critical product attributes differentiate Hadlima from other offerings.

Also in Biosimilars this quarter, we demonstrated our commitment to the business by adding a collaboration with Shanghai Henlius Biotech, who, like Samsung Bioepis, will be an R&D and manufacturing collaborator with us, and I'll talk more about that in a minute.

Women's Health grew in the second quarter, driven by 8% growth in Nexplanon and continued demand for our fertility products. Outside the US, Nexplanon grew 16% in the quarter as access continued to expand in key markets like Latin America and Canada. Nexplanon growth in the US was 4% in the second quarter compared with the prior year period and 14% sequentially versus the previous quarter.

In the US, the long-acting reversible contraception market, also known as LARC, continues to face a macro trend that OB-GYN office visits continue to lag behind pre-pandemic levels. This has translated into a sustained level of telemedicine visits, which are not often conducive to prescribing a LARC. Since our spin, we've accelerated our efforts to adapt to this environment and have developed and executed marketing campaigns to meet her where she is. We've added a telehealth capability at Nexplanon.com to enable women to immediately talk to an

independent healthcare professional about her contraception options and about Nexplanon. And we are training and certifying more physicians each quarter on the insertion and removal of Nexplanon. All of these efforts are helping Nexplanon to outperform the high-single-digit decline we have seen in the overall LARC market in the US year-to-date.

Despite this dynamic in the US, we still see a path to double-digit growth globally for Nexplanon for the full year and this is based on four drivers. First, in the US, physician demand per week increased over the last three months with a meaningful increase in July. Second, continuing strong momentum outside of the US. Third, the visibility we have into customer buying patterns for the remainder of the year. And finally, in the third quarter of last year, Nexplanon was heavily impacted by COVID, so that presents an easier comparison for us next quarter.

But let's talk longer term about Nexplanon and the LARC market. There is much progress to be made when it comes to all dimensions of Women's Health, and this includes unintended pregnancies. Just this year, a United Nations Population Fund report estimated that nearly 50% of all pregnancies worldwide were unintended. Data from the Guttmacher Institute report also estimates that a large share of these unintended pregnancies, more than 40%, are a result of inconsistent or incorrect use of contraceptives. On the other hand, long-acting reversible contraception methods like Nexplanon do not require daily self-administration and are subsequently very effective at preventing unintended pregnancies.

To consider, with just weeks after publishing our inaugural ESG report, in which we outline our vision of creating a healthier every day for every woman, Roe v. Wade was overturned, an important moment in history. We expect that now more than ever, women together with their health care professionals will be seeking information about the most efficacious methods of contraception. Not necessarily the option that in the short term may seem more convenient, like an oral contraceptive that doesn't require an initial in-office doctor's visit, but the most effective methods for preventing unintended pregnancies, which wind up being more convenient because LARC, like Nexplanon, do not require that daily self-administration. We believe that over time we can help with the education process and to be a resource for those women and health care professionals looking for an efficacious and long-acting reversible contraceptive option.

Turning to fertility, where we also expect to see double-digit growth for the full year, this past quarter, the fertility business was affected by strict COVID-related lockdowns in China, which has since eased. 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 rate. This is increasing demand for IVF treatments and, in turn, our fertility products.

Trying to Established Brands franchise, which again demonstrated very solid performance and grew 4% ex-FX this quarter. Established Brands showed growth in almost every therapeutic area, demonstrating the sustainability and untapped potential of these brands. With the strong performance in the first half, we now expect this franchise to achieve flattish revenue growth in 2022. This is stronger performance compared with the low-single-digit erosion that was expected of this franchise at the time of our spin.

We have been very successful at creating opportunities locally and globally for the Established Brands franchise. This has included developing new commercial models and new digital approaches, focusing on consumers; repatriations of our business in certain emerging markets; and building flexibility to capitalize on market opportunities like competitive stock-outs and later-than-expected generic entries. The Established Brands business represents approximately two-thirds of our revenue, and its sizable cash flows are critical to our ability to execute on investments that will help to grow our top line over time. And in that regard, we've been very active on the business development front.

We are striving for balance in our business development program, adding already commercialized or soon-to-be commercialized assets, as well as pipeline stage assets that will set up Organon for future growth. In the commercialized assets column, we are focusing on a distinctive way of working that allows us to unlock value quickly beyond what others have the capabilities to do and apply it to new assets from the start of integration. An example of this is JADA, where we could apply our expertise in regulatory manufacturing and leverage our commercial footprint. We plan to do the same for Xaciato. And replanning Marvelon and Mercilon with the People's Republic of China, including Hong Kong and Macao and in Vietnam, made a lot of sense since we already manufacture these products and commercialize them in 20 other markets.

In the second column, our pipeline assets, these earlier bets are important to get a foot in the door with potential treatments that could be significant catalysts for Organon in the longer term. An example is our acquisition of Forendo. Just this week, we received the safe-to-proceed notification from the FDA for the OG-6219 asset for endometriosis, which enables the team to start the initiation of our planned Phase 2 study. And during the second quarter, we added Shanghai Henlius Biotech as our second R&D and manufacturing collaborator for Biosimilars. This is the first Biosimilars deal we have completed since our spin. The global agreement includes two biosimilar candidates, one representing Perjeta and one for Prolia/Xgeva in seven markets in Europe and in North America. The agreement also includes an option to negotiate an exclusive license for the global commercialization rights for our biosimilar candidate referencing Yervoy.

Our strategy in Biosimilars remains the same, namely to bring our commercial expertise to collaborations where we expect to have a very favorable launch position and competitive pricing. This transaction expands on our existing collaboration with Samsung Bioepis and further emphasizes our commitment to growing our Biosimilars franchise. It also demonstrates that we recognize the importance of delivering treatment options that are aimed at reducing spending pressures on health care systems and enable a greater number of patients to access these important medicines. Also in business development, we recently announced the research and collaboration agreement with Cirqle Biomedical to develop a non-hormonal on-demand effective contraception candidate, a category preferred by many women but with limited available options.

From the start, Organon has been an advocate for access to a broad range of effective contraceptive options and comprehensive counseling in partnership with health care providers. There is no one-size-fits-all solution when it comes to family planning. Women need more and different efficacious options that better reflect their very needs and preferences. And as a leader in contraception, Organon is focused on driving innovation and bringing forward more of these types of options.

Overall, this was another solid quarter of progress. In just one year, we have focused on our Women's Health business to modernize the Nexplanon franchise, while ensuring that our fertility business returns to a sustainable growth rate. We broadened our therapy area to focus on women's health from two with contraception and fertility to seven with the addition of postpartum hemorrhage, pre-term labor, endometriosis, polycystic ovary syndrome, and bacterial vaginosis.

We've expanded our Biosimilars portfolio and continued to accelerate revenue growth. And finally, we've demonstrated that with the right entrepreneurial focus that Organon is applying to these brands. Established Brands does not have to be a business in steady decline. This was a big achievement. Our ability to arrest the steady decline in that portfolio following legacy loss of exclusivity patents was probably the biggest open question in investors' minds at the time of the spin. These accomplishments are all due to the remarkable dedication and effort of our team of over 9,000 founders. We have made tremendous progress and the team has much to be proud of.

Now I would like to turn it over to Matt to review our financial performance in greater detail. Over to you, Matt.

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

Thanks a lot, Kevin. As I've done in previous quarters, I'll remind you that our results prior to spin-off are presented on the carve-out basis of accounting. That's a GAAP convention that's not intended to present results as if Organon were a standalone company. So I want to be clear as we discuss results that because our spin date was June 2 of last year, it won't be until next quarter, the third quarter of 2022, that we can draw a true apples-to-apples comparison to prior-year results where all P&L line items represent post-spin standalone financials for Organon. Until then, as I've said over the past few quarters, the revenue line is where we'll have the best comparability to prior-year periods and that's where we'll start the financial discussion.

Turning to slide 6 revenue for the third quarter was approximately $1.6 billion, down 1% as reported but up 5% at constant currency when compared to the second quarter of last year. In this graphic, we break out the change in revenue according to key drivers and I'll highlight some of the more significant impacts. The impact of loss of exclusivity or LOE during the second quarter compared to the second quarter of last year, approximately $10 million, is primarily related to NuvaRing's LOE in the United States. We didn't have any LOE-impacted 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. 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 has not happened thus far in 2022.

Continuing to read across the waterfall chart, the impact from volume-based procurement in China was negligible in the second quarter, which is also the case year-to-date as the implementation of the next rounds of VBP have been delayed. Moving across, we saw an approximate $60 million impact coming from price in the second quarter, which is consistent with our expectation that we will see low-single-digit price erosion on a companywide 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. You may recall we had some one-time favorability in Established Brands last quarter. We continue to see some benefit in Japan where certain competitors are out of the market because they didn't receive good manufacturing practice or GMP certification. But the impact of that in this quarter is about half of what it was in Q1.

In addition to volume growth in Established Brands, we also saw volume growth from our key growth drivers, including the China retail sector, biosimilars and Nexplanon. The other bucket primarily represents supply sales to Merck and other third-parties, which consists of lower margin sales of pharmaceutical products under contract manufacturing arrangements. For the quarter, supply sales were down about $25 million year-on-year, and that's consistent with our view that we expect volumes under these arrangements to decline.

And finally, foreign exchange translation continues to be a headwind for us, and FX represented about 500 basis points of headwind for the quarter, which is not really surprising given the fluctuations in the global currency markets and the composition of our business, with approximately 80% of our revenues derived outside the United States during the second quarter.

Briefly on slide 7, this depicts the geographic mix of our revenues. As Kevin mentioned, all of our geographic regions grew versus prior year at constant currency. EU/CAN benefited from volume growth in the Established Brands franchise, most notably from respiratory and cardiovascular products. Strong performance from Renflexis and Ontruzant drove growth in the US along with increased Nexplanon sales in the quarter. Asia Pacific and Japan, as we mentioned earlier, had some help from a near-term competitor supply issue, however, to a much lesser degree in the last quarter. In China, growth in retail as well as the recently repatriated brands Marvelon and Mercilon offset the decline in fertility that was due to strict, protracted COVID lockdowns. Finally, the LAMERA region showed strong results on a constant currency basis, primarily from growth in Nexplanon as well as benefiting from the timing of an order of Ontruzant in Brazil.

So, now, let's take a look at performance by franchise and then we'll start with Women's Health on slide 8. Our Women's Health business was down 2% as reported, but up 1% at constant currency in the second quarter. Nexplanon grew 8% ex-FX during the quarter and that strong performance was partially offset by NuvaRing, where we continue to see pressure from generic competition. Fertility was down low-single digit this quarter and that was due to the impact of COVID lockdowns in China. In the United States, Follistim had some unfavorable channel mix this quarter, but that was partially offset by other products in the fertility portfolio. Year-to-date, fertility is up mid-single digits on a constant currency basis. We expect the fertility business to deliver double-digit growth in 2022, driven by recovery in China and strong demand across our markets.

Turning to Biosimilars now on slide 9, Biosimilars grew 39% as reported and 42% ex-FX. Renflexis grew 39% ex-FX in the quarter, driven by strong performance in the US. The infliximab market continues to grow and biosimilar adoption for infliximab also continues to grow, with biosimilars now representing close to 40% of the infliximab market share in the US. Ontruzant was up 61%, driven by continued uptake in the United States since its launch in July 2020 as well as the timing of a government contract in Brazil that hit the second quarter this year compared with the third quarter of last year. And those factors were partially offset by competitive pressures in Europe.

Turning to Established Brands on slide 10, revenue for Established Brands was down 2% as reported but up 4% ex-FX during the quarter. As Kevin mentioned, this franchise is performing very well. It's a sizeable and stable source of revenue for us. In addition, the sequential revenue trend in this franchise is fairly steady, as you can see on slide 18 in the appendix. In the second half of the year, we expect that we'll see impact from next rounds of VBP in China. But still, with minimal LOE risk expected until we see a generic entrant for Dulera, together with the strong performance year-to-date, we now expect that revenue for Established Brands will be flattish for full-year 2022 at constant currency.

Now, turning to our income statement on slide 11, our GAAP income statement for the second quarter is available in our earnings release. I encourage investors to look at that important information. Here on slide 11, we'll be looking at our non-GAAP income statement for the second quarter. 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, the second quarter of 2022 non-GAAP adjusted gross profit was $1.047 billion on revenues of $1.585 billion, representing a gross margin of 66.1%, up from 65.6% in the second quarter of last year. Year-to-date 2022 gross margin is tracking a bit ahead of the prior year period on both an adjusted and as reported basis.

And underlying that is really product mix. We have less lower margin supply sales in 2022, as we expected would be the case. There were also allocated costs related to the spin in the 2021 financials that are not in 2022 and impact apples-to-apples comparability, as I mentioned at the outset. Adjusted EBITDA margins were 32.3% in the

second quarter. I'll draw your attention to the R&D line in this P&L. That $203 million of R&D expense in the second quarter includes IPR&D in milestones of $97 million related to the Biosimilars transaction with Shanghai Henlius Biotech. So as Kevin mentioned, that would be $97 million, but in prior quarters, we would be adding back to our adjusted EBITDA calculation, driving adjusted EBITDA to $609 million or 38.4% margin on a like-for-like basis with prior quarters.

SG&A costs were modestly higher in the second quarter of 2022 compared with prior year, primarily due to standing up Organon as an independent company as well as commercial expenses associated with business development transactions completed in the last year. R&D expenses increased in support of a growing pipeline, for example, OG-6219 and ebopiprant. Spending of this kind to develop new products, support new product launches and to build capabilities, they're going to be drivers of our adjusted EBITDA margin in the intermediate term.

On that topic, it's important to take another look at the business development slide that Kevin showed. As Kevin mentioned, we're looking for balance in our BD program. That includes adding immediately accretive or imminently accretive deals to the portfolio. Together those commercialized deals that we've done to-date shown in the first column of this slide, they're expected to contribute about a point of revenue growth in 2022.

Our pipeline assets in the second column are longer cycle and require years of investment in order to realize their significantly larger commercial potential relative to the immediately or imminently accretive deals that we've completed so far.

Our goal is to construct a suitably-sized portfolio of these longer term pipeline projects to enable Organon to sustain attractive revenue growth well beyond a five-year planning horizon when we need to be launching new products that can more than offset any revenue declines we might see related to Nexplanon's LOE. All of our business development projects, whether near-term accretive or pipeline, compete for capital. We analyze all of these opportunities on a risk-adjusted basis, set against the baseline of a next best use of capital, which in our case is reducing outstanding leverage.

That happens to be a good lead into the next slide. As we look at debt capitalization and leverage on slide 13, as of June 30, 2022, we have bank debt of $8.9 billion, netted against cash and cash equivalents of $545 million. Our bank covenants allow us to add back acquired in-process R&D and milestones to our LTM EBITDA calculation which is consistent with how we've been showing you leverage on prior earnings calls. And on that basis, net leverage was about 3.5 times as of June 30. Recall that at the spin-off in 2021, we had a pro forma leverage ratio of about 4 times and we said that we were targeting a leverage ratio of less than 3.5 times on a sustained basis. We made solid progress on debt reduction that was aided by another voluntary $100 million repayment of the US term loan B during the quarter.

This is the second voluntary repayment of debt that we've completed since the spin-off, $200 million in total. Our capital allocation priorities remain consistent with past communications. Our first priority, of course, is servicing the dividend, which we're targeting at a low-20s percentage of free cash flow, which we believe strikes an appropriate balance between reinvesting for growth and delivering near-term value for shareholders. Our second priority is organic growth, which would include lifecycle 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 ongoing basis excluding separation costs.

So because these first two priorities are not big absorbers of capital, that leaves 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, balanced against discretionary debt reduction, just like we did this quarter. 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 14 now, here we bridge our expected revenue change year-on-year. Compared with our last guidance update, the biggest difference on this slide is the FX translation impact, which has gone from an approximate $200 million to $300 million impact, or a headwind of 300 to 475 basis points, to an approximate $350 million to $400 million impact, or now 550 to 650-basis-point headwind based on where FX spot rates are today. Accordingly, we're adjusting our guidance range for full-year 2022 revenue from $6.1 billion to $6.4 billion to $6.1 billion to $6.3 billion, consistent with the movements we've seen in foreign exchange.

We feel comfortable maintaining the low end of the previously guided revenue range because the view on a few of our key drivers has improved modestly, for example LOE. But given the volatility in currency markets, I'll employ language here as I did last quarter, and signal that if exchange rates don't improve from here, we would likely be at the lower end of our revised guidance range. For LOE, at this stage in the year, generic of Dulera is looking unlikely. So we expect LOE impact for 2022 will be less than the approximate $100 million full year impact we communicated last quarter. And that remaining exposure is mainly tied to NuvaRing.

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, but we think that remains likely to occur in the second half, which could result in approximately $50 million of impact in 2022.

We continue to expect about $200 million of price erosion in 2022, in line with the historical pricing trends for global markets that we've been selling into for many years. And for volume, we're tracking to $600 million to $700 million of volume growth for the full year. The majority of that volume increase has been coming from our multiple growth pillars – Nexplanon, biosimilars, fertility, China retail, followed by favorable one-time items like that competitive issue in Japan and to a lesser extent recently completed business development transactions. We do expect net volume growth across our product portfolio in Established Brands as well, which is well supported by our first half actual performance.

Turning to other guidance metrics on slide 15. As I mentioned, we are recasting our revenue range to incorporate the continued strength in the US dollar. The other range that we're modifying this quarter is for adjusted EBITDA margin. Operationally, there are no changes in our outlook. In fact, on an absolute dollar basis, EBITDA is less impacted by foreign exchange relative to revenue. So if not for these adjustments, we and our industry peers are making to incorporate in-process R&D and milestones, we would be keeping our full year margin range identical to prior guidance, but giving effect to the now approximate $110 million of IPR&D, we now have a view for 2022 that impacts margins by just under 2 percentage points. So, we're adjusting the range accordingly from 34% to 36%, to 32% to 34%. And by the way, that approximate $110 million nudges our R&D expense as a percentage of revenue into the upper-single-digit range from mid- to upper-single-digit range. And to remind you, our criteria for inclusion of an IPR&D estimate attached to a business development transaction will be to have a signed contract.

Business development is a strategic priority for us, and future M&A activity that involves upfront and/or milestone payments could impact our guidance ranges. And while we will work to provide details on those relevant payments when we announce the transaction, we do not plan to update our guidance between quarters based solely on those associated payments alone.

Wrapping up the financial discussion, on a constant currency basis, the business is doing very well. Operationally, the business is performing as we expected. We believe Biosimilars and Women's Health should deliver solid

growth in 2022, paired with a revenue trajectory within Established Brands, that's meaningfully better than we expected prior to the start of the year.

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

QUESTION AND ANSWER SECTION

Operator: [Operator Instructions] Our first question comes from Jason Gerberry with Bank of America. Your line is open.

Jason M. Gerberry
Analyst, BofA Securities, Inc.

Q

Hey, guys. Good morning and thanks for taking my questions. Matt, just this one for you. First, just in terms of the business model, it seems like more likely than not going to do a couple of license deals per year. So, should we be thinking about this year's kind of EBITDA margin as more likely the go-forward EBITDA margin, I'm seeing Street at like 35% next year, but it seems like maybe prudent to kind of factor in some deals.

And then just secondly, on the commentary about the impacts of the [ph] Roe (00:33:50) decision. Just curious, have you guys done any work just looking at states where there's automatic trigger laws banning abortion, if you're starting to see women embrace contraception at a higher rate. Just curious, I know that was sort of flagged as a tailwind, but if there's anything tangible that you could tie to that, that would be helpful. Thanks.

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

A

Thanks, Jason. I'll take the first part of that question, and Kevin can take the second. So we've been saying, since even before the spin, that to position the portfolio for sustained revenue growth beyond a five-year horizon, we would need to be reinvesting. That reinvestment would show up not just in cash outlays, but it would be showing up on the P&L in our R&D line as well as our SG&A line specifically for commercial expenses to support.

So when we think about the long-term trend in margins, it would be below the 35% full-year number that we've been guiding to on a pre-IPR&D basis. And so I think if you look at the implied second half performance versus our full year guidance as compared to our year-to-date results, that might be more representative of what the near-term future might look like beyond 2022. And actually, the numbers that we see, in fact said, pretty much reflect that.

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

A

Yeah. And Jason, it's Kevin. So thanks for your question. And in regards to the change of the landscape post-op, we don't see any effect in terms of overall view of how contraception is going to go forward. Right now, it's still up in the air. You saw what happened in Kansas a couple of days ago in terms of what's going on. And so as a result of that, it's far too early to determine what exactly is going to happen. What I can tell you though is, we're getting more and more interest by consumers as well as health care professionals, asking a lot of questions about long-acting reversible contraceptives, about trying to get more information.

You can well imagine that if you're a physician right now in what you considered or what you termed a trigger state, you're going to start to be much more careful in terms of your counseling of your patient in regards to make

sure you do not have an unintended pregnancy. And I made that comment earlier about the fact in my opening that there's almost a 50% unintended pregnancy rate around the world, and 40% of those was actually folks or women on some form of contraception.

So as a result of that, you can see there's inconsistent or inaccurate or incorrect use of contraceptives. And so as a result of that, I think that the focus going forward will definitely be on efficacy. Efficacy should and, I believe, will rule the day at the end of the day in terms of getting women the kind of options they need to make sure that they do not have an unintended pregnancy.

Jason M. Gerberry
Analyst, BofA Securities, Inc.

Q

Great. Thank you.

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

Umer Raffat
Analyst, Evercore ISI

Q

Yes. Thanks for taking my question. I guess, first, I'm just trying to understand Nexplanon growth trends better. I'm a little puzzled by sort of the performance in the first half, especially in the context of the broader landscape around abortion laws, et cetera. So I'm just curious in general, what's going on there? And should we reasonably expect this product to be growing sort of mid-teens, which is how folks expect it to be growing in 2022, 2023, et cetera.

The second one is, I was quite intrigued by the Cirqle deal for the vaginal gel. But I was not quite sure sort of what was the thought process around differentiation versus a lot of the other pH-raising vaginal gels that are out there. I was just curious if you'd share your thoughts there.

And then finally, maybe quickly, Kevin, I feel like in the branded sort of innovative product territory for pipeline assets, it looks like there's a very large swath of biotech that's looking to raise capital or collaborations, whatever the case may be. And it might be a very opportune time for you guys to be more active. And it seems like between the deal last December and then this new one with Cirqle as well, they're very early stage, very early stage to the point where over the next two to four-year horizon, they're not needle moving from a numbers perspective. And I'm curious how you're thinking about sort of branded biotechy drugs in a more mid-to-late stage as well. Thank you very much.

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

A

Well, thanks, Umer, and great to hear your voice again and hope all is well. And I just wanted to – first of all, let me address some of these questions that you have regarding Nexplanon. So it's been a little bumpy in terms of the comparator quarters. Last year, our year of spin, there was a number of things that were happening in terms of the pricing movements and some of the issues around kind of name changes and other things that were going on in terms of our spin logistics. And right now, we feel that right now going forward you're going to get a much more predictable pattern of demand. And right now, what we can see is that every month post – and we had a large buy-out ultimately in January and February. But every month subsequent to that, we have actually seen an increase in demand. And we're seeing very, very strong increase in demand in July – double-digit increase demand in July. And that's going to be a significant quarter. But keep in mind there are two things that are really important with regards to understanding Nexplanon.

As I mentioned to you almost a year ago, we expect the international business to grow faster than the US business, and that has held true. We see robust double-digit growth going forward with the international business. It has now started out as a 75/25 contribution. Now, it's more like 65/35. And that's moving in the favor of a faster growing ex-US market. But within the US, we do see some things, I think, that are coming in in our favor. I mentioned earlier to Jason we feel that there's going to be more of a focus on efficacy, more of a focus on convenience, given the fact that you're talking about a three-year efficacy. And ultimately, we're outperforming the market.

The LARCs right now are in decline, single-digit – high-single-digit decline and we're growing. So I feel very confident, as I mentioned earlier in my opening, that we're going to see double-digit growth of Nexplanon this year globally. And that ultimately over time will settle things down in the US as things start to clear up in regards to the kind of Roe v. Wade decision in terms of going forward. So we're very confident about Nexplanon going forward. We've got all cylinders kind of moving in the right direction there.

In terms of your second question, in regards to Cirqle, we believe there is a distinguished nature here, because in the preclinical work that we've seen, this is a kind of a dual mechanism of action that this product has, which at least in the initial trials that we've seen has – at least in animal trials has shown nearly 100% – actually, 100% efficacy, so much so that we really wanted to kind of collaborate with them in order to be able to understand whether there is a possibility, because, as you say, some of the other agents on the market to-date don't have that type of efficacy. We're looking for exceptionally high efficacy products in the space, always been focused on non-hormonal on demand. But I'll let Sandy jump in after I finish the last point with regards to BD, especially in the biotechy space as you say.

Clearly, as I have mentioned and as Matt mentioned, Umer, we are taking a very balanced approach to our business development and capital allocation strategy. Think about the deals we've done. I mean, when you include the Cirqle deal, it's been balanced. There's been probably four commercialized or near-to-be commercialized assets and there are three kind of earlier stage assets that will report out, as you say, in the later periods.

As we go forward, we're definitely going to be doing. We'll continue to be doing more business development because we see some really interesting assets out there for us to act on. We'll definitely be looking at continuing that balanced approach in the way that we generate accretive deals in the near term and then ultimately for the longer term, we're looking at some blockbusters. I mean I'll come back to OG-6219 from Forendo. We believe that to be a significant mover in the long term, a real catalyst for us.

But Sandy, did you want to add anything to the Cirqle deal?

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

A

Yes. That would be great, Kevin. Thank you for the opportunity to respond. So, Umer, we do believe that with today's currently available on-demand and non-hormonal products, there is room for improvement for women in wanting increased efficacy and maybe some differences in just some of the product characteristics. And so we think that this is a very interesting opportunity, albeit it's very early and we're looking forward to the partnered collaboration that we have with Cirqle.

But basically, as Kevin mentioned, it's a two-pronged approach in the product. It's a cytosine that creates a barrier that prevents sperm from entering the cervical canal, plus a pH modulator that immobilizes the sperm. And so

we're really focused on augmenting our contraceptive portfolio with such an on-demand non-hormonal approach. And so this is just the first one that we're tucking into our pipeline, and we look forward to finding other opportunities to expand the differential product offerings that we can have for women as they proceed along their reproductive journey and decide how to do their family planning when it's right for them.

Umer Raffat
Analyst, Evercore ISI

Q

Thank you.

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

David Amsellem
Analyst, Piper Sandler & Co.

Q

Hey. Thanks. So just a couple. So, number one, wanted to get your thoughts, and I apologize if I missed this, but your thoughts on China just with lockdowns and our emerging from lockdowns, how are you thinking about the mix of hospital versus retail and just the overall trajectory of that business?

And then secondly, just on the theme of business development, what is the extent to which you would do something transformational? I know you said you're sensitive to leverage and the credit rating, but is that something you're willing to revisit if the price is right, particularly in the context of asset prices having come down? Just wanted to get your thoughts philosophically on that. Thank you.

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

A

Sure. David. I'll address the first question regards to China. So, clearly, look, we've got a good outlook for China right now. There's two things happening. In the lockdowns that are just finally easing up, it affected our fertility business clearly because the clinics were closed down. But it also slightly affected our Established Brands business. But remember that, right now, in terms of our year-to-date business versus prior, we're essentially 8% growth in the overall market, 13% on retail sector. And by the way now, retail for June was at 50% of our Established Brands business, is coming through the retail channel. So it is as I've always said that we've done the right things to really invest in the retail channel and expanding quickly. So the headwinds were essentially in the area of fertility and some established brands. But the tailwind is the fact that they delayed some of the rounds of the VBP specifically round seven and eight timing have been delayed a bit.

So, ultimately, we feel that the EZETROL business, which is one of our biggest cardiovascular products, will happen much later in the year versus our original anticipation in terms of VBP update, so I look for a positive outlook for the remainder of the year. We're continuing to invest in retail. Our Women's Health business now is starting to unlock because fertility is coming back, clinics are open, as well our Marvelon/Mercilon acquisition or repatriation back from Bayer has started out like gangbusters and doing exceptionally well in the women's health space. So we feel very strong in the in the China sector.

Matt, do you want to take the second question?

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

A

Yeah. Thank you, Kevin. And just to close out on China, China is an important geography for us. We have well over $900 million of revenue in China. We have over 1,000 people there. So it is a key geography for us in terms

of growth for the future. But moving to BD, so, David, we're not out hunting for those big deals, but we certainly are assessing the landscape and the possibility for them as a potential part of Organon's future.

Right now, especially as we're standing up, the company fully separating from Merck and putting all of our own systems in place, these smaller deals are digestible and with a high degree of probability of value creation. So that makes sense for now. And once we get across the other side of all the agreements that we have in place with Merck, with most of them have about a two-year duration to them, the potential for larger deals just becomes wider. But as I said, we're not out hunting for them, but we are planning for their possibility.

David Amsellem
Analyst, Piper Sandler & Co.

Q

Okay. Thank you.

Operator: Your next question comes from [Technical Difficulty] (00:47:50-00:47:58)

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

A

Sorry. You dropped off. We didn't hear you. Who's the question coming from?

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

Q

Hi. This is [ph] Dan (00:48:09) on for Chris. Thanks for taking our questions. Just two from us. First, I guess your commentary on Nexplanon in the LARC market suggests you're taking share from IUDs. And if so, can you maybe talk a little more about the drivers of that and if you expect that to continue? And then second, just looking at your volumes year-to-date, it looks like you're tracking ahead of the $600 million to $700 million guidance. So we know you touched on this, but could you talk a little more maybe about the outlook for volumes in the second half and maybe how much of a benefit in first half was from some of the Japan dynamics in Established Brands? Thank you.

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

A

Sure. Dan, I can take the first question in regards to Nexplanon. We don't have data. I mean [indiscernible] (00:48:49) data in terms of the overall market is not very robust because we have the direct-to-physician buy and bill type of phenomenon happening. But what we can see is that there is obviously in terms of LARCs, IUDs are moving in terms of the decline section and essentially Nexplanon is moving up.

So I think you're right. You're clearly seeing that what's happening in terms of the fact that although albeit it's mid – for the quarter, it's mid-single-digit growth, but nevertheless all the signs according to the fact that we're going to see continuing robust growth going forward for this product and we're doing very well outside of the US. But our focus really is on combined oral contraceptive pills. That's essentially the biggest area for us because that's the area that ultimately is most used. And our focus again is on reducing unintended pregnancies. And so really, we need to go where the greatest need is, which is essentially conveying the information and educating physicians on the benefits of Nexplanon. We feel good about that product for the future.

Matt, do you want to take the second question?

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

A

Yeah, sure. So, Dan, if your intuition says that we're running a little bit hot in the first half on what our full-year volume guidance would be, I think you are right about that, and I can point to a few things. I would say none of these are particularly large individually though. But for example, on a timing basis, we had more Ontruzant volume in the first half actuals that we had thought might come in the second half. We had some one-time favorability for the Japan competitor GMP issue that happened in the first half. It's likely to be transitory in nature. And then we've been anticipating since the start that the VBP would be more of a back-end loaded phenomenon for 2022, we thought we might see some of it in the first half, but that number actually turned out to be really, really de minimis because of the delays. So on a full-year basis, we still feel very good about the volume growth in the business, but we did have a little bit of ultimately frontloading of it per your question.

We're ready for the next question, operator.

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

Gregory D. Fraser
Analyst, Truist Securities, Inc.

Q

Good morning, guys. Thanks for taking the questions. On Nexplanon, you mentioned visibility on customer buying patterns in the second half. Can you help us with how to think about the potential benefit from those patterns in the third quarter and the fourth quarter? Also on Nexplanon, are there important ex-US markets where you're working to secure reimbursement that could be important future growth drivers?

And then just one on the fertility business, if you could just speak about [indiscernible] (00:52:02) products based on your prior experience in challenging macroeconomic conditions, that would be helpful.

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

A

Yeah. So in terms of buying patterns, when I made the comment in my introductory comments, it's really about looking at understanding the tenders that we see outside of the US. We know when they're coming through. We know what the sale – what the level is and we know what to expect. And so when we think about, for example, Canada, it's still a launch market with sales doubling from $1 million to $2.1 million. Public access coverage has been attained across all provinces. France, additional sales reps have been put on. And so ultimately we're seeing double-digit growth in France as well. UK, our second largest business outside of the US, is doing well. And then Mexico, our third largest market globally, has very strong sales with over 100% growth.

So we're doing – we see just overall, across the board, really good ex-US business. Inside the US, what we see is opportunities in terms of, as I mentioned earlier, that we continue to see more and more interest in LARCs and especially for Nexplanon. We see more and more visits to our Nexplanon.com specifically increasing, and we're certifying more and more physicians and health care providers by the day on the successful insertion and removal of Nexplanon. So again, like I mentioned, that's our key product for Organon. It has patent protection until 2027 and with the five-year indication, hopefully coming in the near term, we'll be able to extend that to a few years longer than that. And we feel very good about the solid growth of this product going forward.

In regards to – I'm sorry – I didn't get the question regards to fertility. You wanted to understand kind of robustness of fertility going forward in terms of whether we can deliver the double-digit growth that I mentioned earlier?

Gregory D. Fraser
Analyst, Truist Securities, Inc.

Q

Asking more about just how sensitive that business and demand for those types of products could be in sort of a recessionary environment.

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

A

Well, one of the things to keep in mind that two-thirds of our fertility business is outside the US and one-third is in the US, and both are growing very nicely. I think – I believe what I can tell you is that the demographics in terms of our tailwind for us right now, we are currently seeing significant demand across the world. There is clearly, as you start to see, things from COVID in terms of the lockdowns. You still see a rebound where these couples, irrespective, I believe, of the recessionary pressures that we potentially might feel, are very motivated and extremely committed and passionate about starting the process. And then you see also more and more governments like Japan investing in essentially reimbursement for IVF therapies [indiscernible] (00:54:58) starting at the beginning of the year. And you see other countries doing the same. So I think that what you see is that ultimately more and more – there are going to be more and more tailwinds behind the fertility business. We feel very good about it and we'll continue to have double-digit growth going forward.

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

A

Chantal, [indiscernible] (00:55:28)

Operator: Thank you. We have reached the end of the question-and-answer session. I'll turn the call back over to Kevin for closing remarks.

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

Thank you. Thank you, operator. Well, we hope we came across today in that we are delivering on what we have committed to deliver. Our growth franchises, Biosimilars and Women's Health, are performing really well and we're enthused by the stabilization in our Established Brands business. We do continue to demonstrate that these products are in the right set of hands and we're tapping into their potential with attention and resources.

Additionally, we continue to be smart with capital allocation, with the business development approach that balances more immediate opportunities with future growth prospects. We're proud of the solid track record we're building and we're confident in our ability to deliver on our objectives for the remainder of the year. I want to thank you for joining us today and thank you for your interest in Organon.

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