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Organon & Co. (OGN)

Q4 2021 Earnings Call

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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 Fourth Quarter and Full Year 2021 Earnings Conference Call. All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question-and-answer session. [Operator Instructions] As a reminder, this call is being recorded. Thank you.

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

Jennifer Halchak

Vice President - Investor Relations, Organon & Co.

Thank you, Mary. Good morning, everyone and thank you for joining our fourth quarter and full year 2021 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 today for the Q&A portion of the 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 Form 10 registration statement and subsequent periodic filings.

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

I would now like to turn the call over to our CEO, Kevin Ali.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Good morning, everyone, and thank you, Jen, and welcome to today's call, where we will talk about our results for the fourth quarter and full year of 2021. Let me start by saying that our team of 9,500 employees, our founders, did what we said we would do in 2021. We achieved all the financial objectives we laid out at the time of the spin and also began to build on our existing portfolio to fulfill our vision of becoming a leader in women's health.

In 2021, we delivered on our financial commitments. Full year revenue of $6.3 billion and adjusted EBITDA of $2.4 billion equating to just below 38% adjusted EBITDA margins, and are above the high end of the tightened guidance ranges we provided last November. Importantly, in 2021, our growth engines Nexplanon, Fertility, and Biosimilars, all grew double-digits and we continue to expect double-digit performance from all three again in 2022.

We exited 2021 on a very positive note. In fact, the fourth quarter marks the first time in our product portfolio as a whole has grown. Sales of our portfolio products, that is, ex-supply sales grew 1% in the quarter, overcoming the headwinds from loss of exclusivity and the impacts from the volume-based procurement or VBP initiatives in China. We're encouraged by the progress we see in several key areas. First, let's look at our Established Brands franchise. This is a portfolio of 49 products that includes brands with significant customer loyalty. We have said, once the impact of the most significant LOEs were behind us that we can stabilize this business such that revenue would decline in the very low single digits and that we would use a significant and durable cash flow to further invest in our growth engines. And that is exactly what is happening. In 2021, declines in the Established Brands business moderated and the franchise ended the year down 2% on both nominal and constant currency basis in the fourth quarter. In fact, all the therapy areas, including the Established Brands portfolio grew in the fourth quarter with the exception of cardiovascular, where the LOEs in the ezetimibe family are still washing through. Going forward, we will have significantly less LOE exposure weighing on our Established Brands business. But beyond that, there are several other reasons to believe in the durability of this portfolio. First, we have been successfully managing our business in China. China is an important market for us, representing about 20% of our Established Brands revenue. VBP is a business reality in China, and like other competitors, we must find ways to manage our business in China accordingly. Already, about 50% of our established brand's portfolio has been put through the process with an estimated 40% in 2022 and the remaining 10% in 2023 and 2024.

Despite the impact of VBP, the Established Brands revenue in China was down only 2% for the full year 2021 and was up 7% in the fourth quarter at constant currency. This performance is primarily due to our successful efforts of moving the business out of the hospital channel and into the retail channel, which started in earnest in 2017 and is paying dividends for us today, as that channel has been growing double-digits and now represents about half of our Established Brands business in China.

There's also strong demand for our products in the hospital channel that are currently not subject to VBP and those products have been growing double-digits as well. Across all geographies we operate in, stabilization of the Established Brands is supported by the entrepreneurial attention we have given this portfolio since the spin increased management focused, often initiated at an individual country level, has delivered growth through launches into new geographies and secondary retail channels across our dermatology, respiratory, non-opioid pain and cardiovascular portfolios. To-date, we have implemented a dozen of these lifecycle management opportunities worldwide.

Another milestone in the fourth quarter was Nexplanon's performance. Nexplanon posted its highest sales in the history of the product, with $226 million in revenue. Now, I want to caution everyone that this is not Nexplanon's new run rate. Nexplanon's growth can vary quarter to quarter. There are a few very important reasons driving this. And I want to remind everyone, Nexplanon is not a product for chronic disease, which means we need to engage new customers and patients to drive sales rather than relying on regular script renewals. Also, in our emerging markets where our business is largely tender-driven, volumes are dependent on government budget cycles. That said, we believe our efforts to modernize the brand with our go-to market approaches while significantly ramping up the number of healthcare professionals trained in the insertion and removal of Nexplanon are having a positive and durable impact on physician and patient demand.

Now let's talk about Biosimilars, another growth engine for the company. With about half of the Biosimilar business outside of the US subject to tenders, we will see growth rates vary quarter to quarter, but we expect Biosimilars to continue to deliver double-digit performance on an annual basis. We remain very well positioned as a commercial collaborator with Samsung, and we are particularly encouraged by the planned US launch of our HUMIRA biosimilar in mid-2023 for which we will be undertaking an interchangeability study. We remain committed to pursuing the sizable Biosimilar opportunity, which includes an estimated $100 billion of blockbuster biologics going off-patent over the next decade. We will evaluate these pipeline opportunities with Samsung, as well as other Biosimilar developers.

In addition to achieving our financial commitments, we have laid out a bold vision of becoming the global leader in Women's Health. We plan to do this by building on our established and leading positions in contraception and fertility and expanding our scope to include some of the most underserved conditions in Women's Health, including maternal and peripartum illnesses and other diseases impacting women. And since the spin, we have executed four transactions in pursuit of that vision. As we told you, you can expect our business development activity to include a mix of pipeline-stage assets as well as those already commercialized. This week alone, we announced that we have reacquired the rights to Marvelon and Mercilon, both combined oral hormonal daily contraceptive pills in the People's Republic of China, including Hong Kong and Macao and we have entered into an agreement to acquire the rights to these products in Vietnam as well.

From a commercial perspective, this was a very attractive transaction for us as Organon already owns, manufactures and markets these products as prescription oral contraceptive in 20 other markets. Additionally, we were able to transact at a valuation that makes this immediately accretive to Organon's adjusted EBITA profitability.

In December, we closed on our acquisition of Forendo, a clinical stage development company whose lead investigational asset FOR-6219 is being studied for its ability to reduce endometriosis-related pain. Endometriosis is a high-priority unmet need for women globally. This is a large and underserved market. Endometriosis affects up to a 170 million patients or up to 10% of all women of reproductive age. Currently, approved therapies target the pain associated with endometriosis, but optimally the systemic estrogen depletion which impacts bone mineral

density and triggers menopausal symptoms. Such treatments are therefore unsuitable for long-term use in patients.

Forendo has completed the pre-clinical and Phase 1 study supporting the progression of FOR-6219 into Phase 2. We expect Phase 2 development work to start this year and to read-out in 2024. Those Phase 2 results will further determine the potential for a Phase 3 program. And last July, we also announced the licensing of the global development, manufacture and commercial rights to another investigational asset, ebopiprant from ObsEva. Ebopiprant is currently being studied as a potential first in class innovation for the treatment of pre-term labor, which impacts an estimated 15 million babies or about 11% of all babies born globally.

This investigational agent has demonstrated biological activity in a small Phase 2A study performed in select European countries. Our aim is to study this agent more globally, and to do so, we will be investing in additional preclinical studies and technical work to enable IND submission in the US and continue Phase 2 development. Phase 2 is a critical development phase involving pregnant women and requires close collaboration with regulatory authorities to ensure that our studies meet the relevant safety criteria for both baby and mother. And our first acquisition right after the spin was Alydia Health and its JADA System, which is already commercialized in the US. The device is aimed at controlling abnormal postpartum bleeding or hemorrhage in one of the most common complications of birth. To-date, over 3,000 mothers have now been treated with our product. We anticipate continued growth of the brand into 2022, given our investment in the commercial infrastructure necessary to satisfy the significant unmet need and demand.

Overall, Organon is off to an exciting start. We are well positioned for a solid 2022, which Matt will speak more about as he discusses guidance. Over to you, Matt.

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

Thank you, 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, which is a GAAP convention, and it'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 was June 2nd, it won't be until the third quarter of 2022 that we can draw true apples-to-apples comparisons to prior year results where all P&L line items represent post-spin standalone financials for Organon. So until that time, revenue is where we'll have the best comparability to prior-year periods and that's where we'll start the financial discussion.

So turning to slide 7, fourth quarter revenue of $1.6 billion was down 1% both as reported and at constant currency. We saw solid performance from our growth franchises in Women's Health and Biosimilars, and it was offset by the decline in Established Brands, as well as a decrease in supply sales.

As Kevin mentioned, the underlying portfolio of marketed products performed well: it grew 1% in the fourth quarter, with volume and price contributing favorably and offsetting headwinds from LOE and VBP. And on slide 8, you can see this depicted graphically on the revenue bridge. So in the fourth quarter, the year-over-year negative impact from LOE was approximately $50 million. The impact from LOE moderated in the back half of the year as the erosion curves continue to flatten for Zetia in Japan and NuvaRing in the US. And going forward, our LOE risk is very limited with remaining total exposure of about $350 million to $450 million over the next four years combined.

Continuing to read across the waterfall chart, as Kevin mentioned, the Established Brands portfolio has exposure to VBP in China. The impact of fourth quarter sales was approximately $35 million compared with the fourth

quarter of last year (sic) [2020] and was associated with the third round of VBP. And that's the largest one so far and that included four of Organon's products: Singulair Pediatrics, Proscar, Propecia, and Arcoxia.

We saw COVID-19 impact to our business in the fourth quarter. And while that was a drag on our business relative to where we believe our run rate should have been, the impact was actually less than what we saw in the fourth quarter of 2020. So this ends up being a slight favorable comparison year on year.

Volume grew in the fourth quarter, and that mostly offset LOE and VBP impacts. Volume growth came from Nexplanon's strong performance as well as continued growth in Biosimilars and growth in Established Brands in China for those products not impacted by VBP. 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 full year 2021, supply sales contributed about $80 million to revenue growth, but was down about $30 million in the fourth quarter. Full year 2022 supply sales will look much more like an extrapolation of the fourth quarter and will contribute an even smaller amount to total revenues than we saw in 2021 mostly because we expect volumes under these arrangements to decline. And finally, foreign exchange translation added about 0.5 percentage point of favorability for the quarter.

So now let's take a look at performance by franchise. We'll start with Women's Health on slide 9. Our Women's Health business was up 6% both as reported and at constant currency in the fourth quarter. For the full year, the franchise was up 4% as reported and 2% at constant currency. Nexplanon had a remarkable fourth quarter: revenues of $226 million, up 37%. But for the reasons Kevin explained, Nexplanon's quarterly growth in 2022 will most likely vary quarter-to-quarter, primarily based on how the impacts of COVID and the timing of tenders influence the individual quarters of 2021. And this will be most prominent in the first quarter of 2022, which will be lapping a tough comparison to the prior year period when we saw some initial vaccination optimism driving physician demand in the beginning of last year.

For the year just completed, Nexplanon grew 12% in constant currency: we expect similar growth in 2022, with more than half of that growth expected to come from outside the United States. Fertility was flat in the quarter. The US Fertility business grew 10%, but that was offset by China and Europe, which had very strong fourth quarters in 2020 as Fertility patients outside the US and especially in Europe returned to clinics relatively faster than US patients did. For the full year, the Fertility portfolio grew double-digits on a percentage basis. Volume growth came from an increase in demand from new accounts as a result of increased selling efforts as well as from the macro trend of patients returning to fertility clinics for this time-sensitive treatment. Overall, the global Fertility market has very attractive fundamentals, including global macro trends towards advanced maternal age, as well as an increasing number of government initiatives around the world to address future negative economic consequences of lower birth rates. Together with our increased focus on this portfolio, these trends set us up nicely to expect another year of double-digit growth from Fertility in 2022.

Now turning to Biosimilars on slide 10, in the fourth quarter, Biosimilars grew 14% in constant currency and grew 25% for the year. Renflexis and Ontruzant are our two largest offerings globally, and they're both offered in the US as well. Globally, Renflexis grew 29% ex-FX in the quarter and 36% for the year. The infliximab market in the US itself is growing about 10% per year, and biosimilar acceptance and unit growth within the market is also increasing, driven by some recent payer updates and increased physician comfort with transitioning stable patients.

Ontruzant, which was launched in the US in July of last year, was down 30% in the fourth quarter, but up 7% for the full year ex-FX. Ontruzant continues to have good uptake in the United States, but in the fourth quarter, growth in the US was offset by a decrease in EU due to increasing competitive pressures in that region and Latin America's timing of tenders in specifically Brazil. With about half of our Biosimilars business outside the US and also depending upon the timing of tenders, we expect some volatility quarter-to-quarter in the Biosimilars franchise. But for the full year 2022, we expect that our portfolio of five Biosimilar offerings will continue to deliver double-digit growth over the full fiscal year.

On slide 11, you can find details for the Established Brands portfolio for the quarter and the year. And Kevin largely covered the highlights for Established Brands, but two points I would add. First, Established Brands was down 13% for the year on a constant currency basis. Now broken up by volume and price, 10% of the decline was volume and 3% was price. And if we exclude volume loss associated with LOE, that volume decline is cut in half to about 5%. As we move out of 2021 with significant LOE risk behind us, combined with the renewed investment management focus in the Established Brands portfolio, we believe we can significantly flatten Established Brands revenue CAGR to the point of being almost flat over the intermediate term, and our fourth quarter performance provides support for this view.

Second point is on slide 12. About 75% of Organon's business is outside the United States, and within Established Brands it's even higher, about 90% ex-US. The LOE of Zetia in Japan influenced our Asia-Pacific performance, as did the termination of a contract for Rosuzet in Korea, but to emphasize Kevin's earlier point, almost flat performance in China for the year is a win given the pressures of VBP.

Now turning to our non-GAAP income statement on slide 13. This slide shows our summary income statement for Q4 and full year versus the respective prior year periods across a range of GAAP and non-GAAP P&L line items. We already cautioned against the limited usefulness of comparing post-spin periods to pre-spin periods, so I would choose to focus attention on the full year 2021 column and on the key metrics circled in green. Revenue of $6.3 billion, adjusted gross margin of 64.7%, and adjusted EBITDA margin of 37.7%. For these key metrics, we completed 2021 positively either in the middle or the high end of the guidance ranges we provided before the spin. The point here is that we launched Organon with a very good sense of the business that we have and the business that we're trying to build, and we delivered on that in our first few quarters.

A few words on debt capitalization on slide 14. As a result of the spin-off in June, we separated from Merck with a pro forma net leverage ratio of approximately 4.0 times. One of our capital allocation priorities is to reduce this figure down below 3.5 times. We plan to do that through EBITDA growth, combined with reduction of debt via voluntary prepayments. During the fourth quarter, we made a $100 million voluntary prepayment on our US dollar term loan B. So with 2021 adjusted EBITDA of $2.4 billion, bank debt of $9.1 billion and cash on the balance sheet of $737 million, that would put our net leverage ratio just above 3.5 times, which is a modest improvement over last quarter and overall solid progress towards our net leverage goal.

And having just mentioned capital allocation, let me reiterate Organon's capital allocation priorities. Our first priority is servicing the dividend. With a target of 20% of free cash flow, the dividend strikes an appropriate balance between reinvesting for growth and delivering near-term value to 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 an ongoing basis, excluding separation costs. Now, 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: and it's a tie between the execution of external growth plans to develop a

pipeline of new product opportunities, and we're balancing that against discretionary debt reduction just like we did in the fourth quarter.

We're committed to maintaining our BB/Ba2 parent rating when we'll continue to make progress towards a net debt to adjusted EBITA ratio of below 3.5 times, once again balancing debt reduction with capital deployed prudently for growth through business development. As I head into the 2022 guidance discussion, to set context for that I think it will be helpful to first review again how we landed full year 2021 relative to the guidance we had provided. So the full year 2021 revenue bridge on slide 15 illustrates what we've said since the spin-off that 2021 would be an inflection year and the last year for which our product portfolio would be subject to significant LOEs. You can see that in the first bar that LOE was clearly a significant headwind to growth in 2021 with approximately $300 million of impact compared with 2020. VBP was also substantial at approximately $170 million over last year. COVID remained a factor in 2021 with about $400 million of impact to the business during the year, higher than 2020 by about $20 million. Also, as we expected, pricing erosion modestly offset volume growth. But the key takeaway from this chart is that we had good visibility into the business, and all of these bars fell squarely within the ranges that we had communicated.

On slide 16, we bridge 2021 revenue of $6.3 billion to our 2022 guidance range of $6.1 billion to $6.4 billion. At first glance, 2022 revenue guidance looks very similar to 2021, but the underlying business is actually much better positioned than it was a year ago. Beginning with the first bar, in 2022 we expect about a $100 million impact from LOEs, or a third of what it was in 2021, and this is related to NuvaRing, as well as the potential for a generic competitor for DULERA in the US.

Volume-based procurement in China will continue to have an impact, about $100 million in 2022 and we're managing that by strategically moving exposed brands into the retail channel. And given the majority of our revenue is outside the United States, we expect about $200 million of price erosion in 2022, and this level of price movement is aligned with historical pricing trends for the global markets that we've been selling into for many years. If you look at the green bar, you see that we're expecting very solid growth in volume in 2022, between $600 million and $700 million that would more than offset the other business factors I just mentioned.

So that means we expect volume growth to grow by about 10%. And by the way, we estimate that less than 20% of that growth is coming from COVID recovery. The majority of the volume increase is coming from growth across multiple pillars: Nexplanon, Biosimilars, Fertility, China retail, and to a smaller extent recent business development activity which is primarily the JADA postpartum hemorrhage device acquired as part of Alydia Health. And as an aside, the incremental contribution from requiring the marketing rights to Marvelon and Mercilon in certain Asian countries that we just announced, that's really immaterial to our consolidated financial reporting, and especially so for 2022 since we'll only see a partial year impact there.

As we keep moving to the right, you'll see a fairly sizable headwind from foreign exchange translation of $100 million to $200 million, which equates to a 200 basis point to 300 basis point headwind to revenue. This is largely a financial reporting dynamic. On an economic basis we have natural hedges in place, including having the majority of our employees and all of our manufacturing plants outside the US, as well as a meaningful portion of our debt denominated in euros. And these hedges help us manage our true economic currency exposure.

Our guidance range of $6.1 billion to $6.4 billion implies nominal growth of negative 3% to positive 1.5%, but adjusting for FX translation, let's call it 250 basis points FX translation headwind at the midpoint, revenue growth on a constant-currency basis would be more in the range of down less than 1% to up 4%.

Moving to the other components of guidance on slide 17, you can see 2021 actual performance side by side with what we expect in 2022. As we move down the P&L, you'll notice consistency between the years. Guidance for gross margin in the mid-60% area – and that's in line with what we said and delivered in 2021. We're again guiding to mid-20s percentage of sales for SG&A in 2022. And I'd point you more towards our second half of 2021 non-GAAP SG&A spend as a percentage of revenue, since that's the time period for which we were operating as a standalone company, and it's more indicative of a go-forward run rate.

Where you will see an uptick is in R&D expense, where we're expecting mid to upper single-digits as a percentage of revenue. We are building a pipeline of assets that will set-up the company for future growth: and we need to invest to support those programs, and a key element of that investment shows up on the R&D expense line. That would bring us to adjusted EBITDA margin of 34% to 36%. And then you'll see that below the line items, have remained very much in line with what we guided to in 2021.

So wrapping up the financial discussion, the business performed well during 2021, very much in line with how we thought it would. This is a durable, predictable product portfolio with solid cash flow. We saw in 2021, growth in Women's Health and Biosimilars supported by the significant cash flow generated from Established Brands. And going into 2022, we see these trends continuing in these franchises. The overall portfolio is significantly de-risked with most LOE risk behind us, and we're really just getting started in terms of maximizing the potential within this portfolio, whether it's through uncovering opportunities in currently marketed products through the lifecycle management programs that Kevin spoke of or through strategic business development that leverages our therapeutic expertise. And if for any reason, the pace of acquisitions slows in 2022, we can always redirect surplus free cash flow to accelerate debt reduction.

And with that, we'll now turn the call over to Q&A.

QUESTION AND ANSWER SECTION

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

Jason M. Gerberry
Analyst, Bank of America Merrill Lynch

Q

Hey, guys, good morning. Thanks for taking my questions. First one for Matt. Just curious, talking about EBITDA margins, I guess, as we look out over the next several years, you've got some pipeline investment ongoing. I'm just curious if you see kind of the next few years as a period where margins should continue to erode a little bit, or do you have more of a flattish margin outlook in that period before we'd expect the pipeline to start contributing?

And then, if I heard correctly, just on the modeling side I think you're expecting a DULERA generic – although I always kind of assumed this was probably too small of a brand for a generic to make the investment. So just curious, do you have a specific line of sight on a DULERA generic? And can you just clarify how much the China Marvelon or – and Mercilon contributes to 2022 guidance? Thanks.

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

A

Okay. So I'll work backwards there. The most recent deal announced for Marvelon and Mercilon really add to de minimis amount to 2022. It's within the error bars of the guidance that we would have created, Jason. So, it's just

not material. On a percentage basis, right, return on capital, valuation metrics, this was an outstanding deal for the company. It's just not that large. I think it's a great example of what sort of justifies the spin-off and that there's lots of terrific opportunities that were just too small for Merck to focus on if the business stayed within Merck. But this is just – it's a very sensible deployment of capital. It's not large in terms of return on capital. It's well in excess of our benchmarks. When you look at the acquisition multiple in terms of enterprise value to EBITDA, significantly below where the company trades. So it's just a sensible deal. Over time, we expect this to be a solid contributor on a return on capital basis. But the absolute dollars are small: like I said, Jason, especially so for 2022 because it's only a partial year impact.

Jason M. Gerberry
Analyst, Bank of America Merrill Lynch

Q

Yeah.

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

A

As far as DULERA goes, it's always challenging to try and time the entry of a generic competitor. So, we take the – just the sensible path of assuming a mid-year convention and a typical erosion curve for a product of that kind. You could be right in terms of estimating that the product may not draw much generic interest, but it's hard for us to tell. And so, we've been somewhat conservative as we think about DULERA and we're assuming a mid-year convention and typical generic erosion curves around that, and maybe we'll be surprised to the upside. On EBITDA margin, so we have said that as we are looking to develop a pipeline that would include both near-term and longer term products in terms of where they are in clinical development, that our R&D expense would be likely to grow: and you're seeing about two points of R&D growth in 2022 over 2021. And as those clinical programs progress and as we introduce new clinical programs into the pipeline, that will continue to happen. Now, the benefit for shareholders is, we expect to be able to feather in revenue growth out beyond the 2025 timeframe in a way that will deliver sustained revenue CAGR performance well into the future.

That said, let's talk about what some of the other balancing effects are on margins. Let's start with gross margins. We expect that product mix will be one of the bigger drivers of margin improvement over time. We think that the product mix will generally favor our higher margin products and higher margin geographies. So, we believe that will be an area of potential margin upside. We launched with a good sense of what our operating costs needed to be. And on top of that, we shouldn't need to add much as we either commercialize products from the pipeline, or for example with the deal we just announced: Marvelon/Mercilon, there's very little incremental cost – SG&A cost, basically fixed operating cost associated with a deal like that. So, as volumes grow, we'll get operating leverage over those, and that provides a pretty substantial opportunity to us for margin accretion over time.

Where we think we might see cost inflation – and we believe that we will be more or less countering that with operational excellence and productivity improvement programs – and that's one of the elements that's baked into our 2022 guidance. For anyone that's going to be asking the question: how well is the company positioned for inflation, where do you – where might you have risk, we'd locked in a pretty substantial portion of our spend under annual purchasing arrangements or it's under contracts: we're not expecting that we've got significant exposure there, but to the extent we do, we believe it will be offset by productivity improvement programs either in our plans or just as we get more efficient in the separation from Merck.

Jason M. Gerberry
Analyst, Bank of America Merrill Lynch

Q

Okay. Thank you.

Operator: Your next question comes from the line of Chris Schott from JPMorgan. Your line is open.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

Great. Thanks so much for the questions. I guess my first one is kind of a two parter, but I'm just trying get some more color around the $600 million or $700 million year-over-year volume growth that's reflected in the guidance. I guess on the surface, it seems like a big number. I'm just trying to get my hands around what exactly is driving that. So how much is Nexplanon and Biosimilars, some of the growth drivers you talked about versus how much of that is coming from the Established product division. So any color there would be appreciated.

And maybe just kind of linked to that, as I think about the longer term Established product division, you're talking about almost flat sales over time. Can you elaborate on the price versus volume dynamics that you need to assume to get there? So, is the 3-ish-percent price erosion that we saw in 2021 like a good run rate and you're going to need to see pretty healthy volume just to get to flat, or do you think over time we can get a more stable price dynamic as well as we think about the components that go into that longer term guidance? Thank you.

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

A

Yeah, thanks, Chris. So, that number that you just cited, that 3%, that has been our recent history in terms of the average price decline that we've seen across the Established Brands portfolio and a number approximating that is what we have factored into 2022 guidance. And if I was sitting down to do the 2023 budget with the company right now, that we would probably use a similar figure. So that's a good number I think for a price impact in Established Brands.

With respect to your first question on where the volume growth is coming from, I think one of the best things about this guidance and the company's internal budget as we've prepared it is that growth is pretty evenly distributed among those pillars that I mentioned. So, Nexplanon, double-digit growth, Biosimilars double-digit growth, Fertility double-digit growth: we're not overly dependent on any one of those items, and it's just one of the things that I think is confidence-inspiring in the – in the forecast is, we've got a lot of pans in the fire this year to be able to deliver volume growth along the lines of the 10% that we've -- that we're guiding to.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

And if I could just follow-up on that – oh, sorry.

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

A

No, Chris, the one thing I wanted to just kind of articulate around Established Brands is, you know China is very important for us. It represents about 20% of our overall Established Brands globally. By the end of 2022 – by the end of this year, 90% of the portfolio will have been through the volume-based procurement process. So we do see potentially obviously growth coming from China with the Established Brands business given the success of our pivot to retail since 2017. So, that's one of the areas where we're going to be able to take volume – not necessarily price – but definitely volume growth will be very strong in China and other parts of the emerging markets. And when I start to turn my attention to Europe, we've dealt with pricing erosion in Europe for years: it's been basically priced out, so now it's stabilized. So when you start to think about – in my introductory comments

what I said is, all the therapeutic areas in the Established Brands then just grew in 2021, in the year of the pandemic and all the volume-based procurement stuff except for cardiovascular where we're still washing out from the LOE effect in Japan for the ezetimibe franchise. But once that washes out, when I say that – you're talking about two-thirds of our business, high margin business that is essentially flat. Without really a lot of price and good volume growth, it really will give us the oxygen to reinvest in many of the other portfolios that are growing double-digit as Matt mentioned.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

Excellent. And just my follow-up for that was that, on that number I think you mentioned only about 20% or so is COVID recovery. If I then look at the remaining piece of growth, is that kind of like a reasonable assumption as we think about the longer term model about how much volume could contribute in any given year? So, let's take that $600 million or $700 million less 20% is kind of like a – is there anything [ph] that's (00:41:34) unusual about 2022 versus a typical year in terms of volume growth?

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

A

When you go pillar-by-pillar, as I've described them, I don't think that there's anything unique about 2022. Nexplanon has a lot of runway for growth, given its relatively small market share in the United States and around the world. Fertility has the favorable macro trends that we spoke of in terms of increasing maternal age, as well as governments feel like they need to address low birth rates. And Biosimilars business, as Kevin described in his prepared comments, is large and growing. So, off the top, I would say, absent that small piece that we believe is assigned to COVID recovery, the volume growth we're seeing in 2022 should have legs to it out into future years. How many is hard to say, but for the near-term, it does look repeatable.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

Great. Thanks so much.

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

A

And Chris, there's nothing specific about 2021. It is – essentially, we expect the same type of volume growth going forward. It is a new normal for us.

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

Gregory D. Fraser
Analyst, Truist Securities, Inc.

Q

Good morning, and thanks for taking the questions. On the Fertility business, how much market share do you have in China and where do you hope to grow share [ph] too (00:43:13) over the next few years? And will you need to bring in additional products to maximize your Fertility business in China or are you well positioned with your current portfolio? And then, just one other question on business development. Do you plan to remain focused on assets within reproductive health and conditions unique to women in the near-term or are you also looking at – more broadly at the products for conditions that disproportionately impact women? Thank you.

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

A

Thanks for the question, Greg. So, in regards to China, we saw some really good growth this year, 23% growth actually in 2021 versus 2020 and that's due to the fact that there was obviously some pent-up demand, but also we're seeing a lot of movement in China with regards to Fertility given the fact that there is some – a lot of news around the three-child policy and there are rumors out there that obviously the government is already starting to take kind of notice about the fact that maybe they need to start to do things to keep tourism in – medical tourism inside the country. So, there's lot more investment in that area. So, currently, our share in terms of China is very strong and is growing actually very nicely. When I start to talk about – in China – I don't have the number exactly off the top of my head, but it's close to – closing in on almost a third of the – a third – in terms of the third of the business, split between us and the other two – the other two manufacturers in the space.

And we're adding more sales force as we speak to overall China business. So we do see China as being a very major contributor. If I start to look at the contribution of overall – the business, US is about 40% of the business for Fertility and China is about – closing in on 18%. So, it is a fast growing business: it's a business that we want to invest in. And when I think about business development there as well as globally what we want to do in Fertility: products, diagnostics, there's some really interesting things happening in the space. So, we are – we are busy right now speaking to various companies right now in terms of partnering up. And as I said to many of you before that we're going to have a very balanced business development approach, both stage assets in terms of development, as well as commercialized products like the Marvelon/Mercilon example that we just did in China.

And in regards to your last question in regards to where we do capital allocation, do we focus on specifically those conditions unique to women or do we start to expand disproportionately to women, we're looking at all areas. Right now, because of the focus of being able to kind of look at those areas of significant unmet need: postpartum hemorrhage, pre-term labor, endometriosis, polycystic ovary syndrome – significant unmet need in the space, and that's why we did those three deals. We did the fourth deal as a commercialized product for Marvelon/Mercilon. But we are looking in the space of – and there's some really interesting assets, both commercializable as well – right now, as well as kind of late stage development products. So we're looking at that, but we're also got our nose – and looking into things that disproportionately impact women. Of course, then the list gets much broader. But imagine the kind of synergies that we have with those unique to women, because that's exactly in the area we're in now, and so lot of synergies there that we're going to be looking at. So overall, it looks good. We're excited of the deals we've done so far. And more to come: look forward for that in the coming quarters.

Gregory D. Fraser
Analyst, Truist Securities, Inc.

Q

Great. Thanks for the color.

Operator: Our next question comes from the line of Umer Raffat from Evercore ISI. Your line is open.

Umer Raffat
Analyst, Evercore Group LLC

Q

Hi, guys. Thanks for taking my question. Kevin, I've been thinking about some of the commentary you guys have been sharing on the four growth pillars, how they are all sort of evenly driving that $600 million in volume this year. But then I'm also looking at consensus into next year, which is 2023 where there's only $100 million worth of growth being modeled in. And I'm almost wondering, how do you – do you guys expect the momentum to continue? I'm not necessarily asking about 2023 guidance, I'm just saying, is there any reason you see why some of the growth numbers you've talked about on the base business should dampen? And how do you think about

the magnitude of first year ramp on a HUMIRA biosimilar, knowing that as much as you guys will have the high concentration, there are Amgen, Alvotech, Celltrion – there's few other players that will have it too: so would really help understand sort of the direction things are heading?

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

A

Yeah. So, Umer, thanks for the question. Good to hear you again. Listen, in regard – let's start with the last one and then we'll work backwards. Look, HUMIRA – the [ph] biosimilaries (00:47:46) for HUMIRA is, it's going to be an exciting period of time. We're going to be second to market. You know as well as I do that there are some conditions essentially for succeeding in that business. Speed to market is critical: we'll be second just after Amgen's. We're coming in to that market with our collaborator, Samsung, really focusing scientifically what payers need. You know, they want the high – high concentration, they want the citrate-free, they want an easy to use, innovative pen mechanism. We have all that, plus we have real-world evidence because of the Biogen launch of HUMIRA Biosimilars and – and because that's [ph] your (00:48:20) partner in Europe, as well as our own launches in Australia and Canada. So we've got all of that as the package that we're bringing to market, and we've initiated the interchangeability study so that we'll be able to report out and have that as well available to us in the 2024-2025 timeframe.

So we feel very, very, very excited about the opportunity to compete in that space, given the fact that it's going to be a $20 billion LOE at the time of LOE for the HUMIRA Biosimilars. So, I think it's going to be rather quick. 2023, I think at this point, PBMs are kind of doing the strategies in regards to understanding what it is that they want to do. But however – and I do think that in the 2023 and 2024 timeframe, it's going to be a full out very competitive marketplace. I think you're going to see not small molecule price erosion, but also not the earlier stuff that we saw in the hospital launches. Like the REMICADE all patent stuff, you're going to start to see more, kind of movement on price pretty quickly. And we've got really good position in that stage as well. So, I think we're going to do very well. I would tell you right now, with the consensus that I see out there for what we can do with HADLIMA, our HUMIRA Biosimilar, we are in agreement that we'll be in that neighborhood.

And in regards to going forward what kind of indicators in terms of – for the 2023 timeframe. Look, we've got HADLIMA: JADA will start to really be a contributor to our growth. China retail will continue to be a contributor to our growth. China VBP will have essentially flattened out. Nexplanon will be a continued growth story for us, and Fertility will continue to be a double-digit growth story.

So, I think we've got a lot of good news on that front in the Marvelon/Mercilon acquisition. You'll see – you'll start to see – I mean, the whole value proposition of an Organon is that we take assets that weren't necessarily important and germane to the strategy of other companies like a Merck. Put it in our hands with our attention and our focus and our people, and we can do much better. And so we can – we feel the same way about the Marvelon/Mercilon business. So those are really, really good drivers for us in a stable, of course, Established Brands business going forward. We feel very good about 2023.

Umer Raffat
Analyst, Evercore Group LLC

Q

Thank you.

Operator: Our next question comes from the line of Navann Ty from Citi. Your line is open.

Navann Ty
Analyst, Citigroup Global Markets Ltd.

Q

Hi, good morning. Can I please ask about Nexplanon run rate, please? Can we assume that Mexico represent most of the increase ex-US, and is higher demand the US from DTC and physicians training? So overall, do you see Nexplanon sustainably decoupling from lower wellness visits? And then I have a quick follow up on DULERA. Could we see upside from looking delayed generic? Thank you.

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

A

Yeah. When I look at the performance of Nexplanon, in 2021, it was really an amazing year, even in spite of the pandemic. I mean, you're talking about essentially 12% growth for the franchise in spite of, as you mentioned, wellness visits not popping back up. We're still seeing a 20% decline in wellness visits as we speak today. So there is somewhat of a decoupling, as you very rightly put it. We do see opportunities because of the fact that we've – working on a new go-to-market – let's just focus on the US for the time being, and I'll expand my comments to being outside of the US. We do see opportunities in the US given that we're working on new go-to-market models. We're working on essentially digital processing in terms of what we're doing. We've really put a lot of efforts in terms of our clinical training programs to certify physicians – almost 20,000 physicians in a pandemic year. That's way – far more than what we've ever done pre-pandemic years. And so, we've got rep visits back up to where it used to be pre-pandemic. So all that put together, plus our DTC campaigns and all the things that we're doing, we've almost got 350,000 visitors to our Internet site on nexplanon.com. That's also starting to work. So we feel very bullish and very good about Nexplanon in the US.

Now going outside of the US, that's the exciting part: because while there was attention on Nexplanon in the US pre-spin, there was literally very little at all attention paid to Nexplanon outside of the US pre-spin. And to that end, just before spin it was 75% of our business – Nexplanon was in the US and 25% was outside of the US. Today, as I speak to you, it's changed: so two-thirds in the US and one-third outside of the US. So business outside of the US is growing faster, but its choppier. The reason it is choppier is because a lot of these markets are single payer systems, or for that matter in the emerging markets where you start to see very much kind of these government tender procurement processes that makes it kind of a saw tooth type of performance. So that's why we don't look at Nexplanon in any single quarter defining what happens in a given year. We have to look at Nexplanon as a kind of a longer view – of a year view. And I do believe strongly – I know that Nexplanon will be a billion dollar business. It will be a business that will continue to grow, at least to what you saw in 2021 and we are going to be doing everything in our power to continue the growth outside of the US, where our managing directors are focusing on it as well as in the US of which I've just detailed some of the things that we've done.

Operator: The next question comes from the line of Stephen (sic) [Steve] (00:54:08) Scala from Cowen. Your line is open.

Steve Scala
Analyst, Cowen and Company, LLC

Q

Well, thank you. Two questions, first on Nexplanon, was there any change in inventory levels in the fourth quarter versus the third quarter? And then secondly, I appreciate that any business development needs to make sense. But you did four deals since the IPO out of what I think was the 140 potential deals that Organon says are out there. So rather than four deals, it seems the number should have been 10 or more deals to build this business at a decent pace. So why haven't there been more transactions than we have seen so far? What has been the reason why transactions have not gone through that you have kicked the tires on? Thank you.

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

A

So let's start with your first question. In regards to Nexplanon and inventory management, essentially there was a buy-in in terms of price protection by the end of the year in the US. There was – so there was a little bit of volume buildup in the US in the fourth quarter. As well, of course, we had the Mexico tender, which was nearly $40 million. So, that also was coming kind of in a one-off in the fourth quarter in Mexico that was delayed from Q3 to Q4. So there was a little bit of inventory, but this is not a product – because a lot of the business in the US is buy and build, it's a lot of clinics, and so you don't have the inventory mechanisms that you have in other businesses. So, it's not a product where we really have large inventories being developed and being in any given place. So, we've got very healthy inventories. We're managing it very well in that respect.

Now, in regards to your second question...

Steve Scala
Analyst, Cowen and Company, LLC

Q

Kevin?

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

A

Yes.

Steve Scala
Analyst, Cowen and Company, LLC

Q

Kevin, may I ask? Can you quantify the build in the US? Was it $20 million or more?

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

A

Yeah, it's about $15 million that essentially was the buildup in the US. So, not a great – not a great number.

Steve Scala
Analyst, Cowen and Company, LLC

Q

Okay. Thank you.

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

A

Now, in terms of your second question regarding business development, if I told you the number of deals we looked at – I mean, we looked at a number, but we – you know, we have a high bar. We looked at 60 – over 60 potential deals that we looked at. We're ongoing right now. There's a – there's more than probably a dozen we're looking at and we're in deep discussions with. So, we wanted to make sure that the four deals that we did, the first four did the following: one, they either met significant unmet needs and really new mechanisms of action like the Forendo deal as well as the ObsEva deal; or two, they had deals that we could count on today, like a launch product like JADA as well as the Marvelon/Mercilon. As we start to build that out – sure, I mean I definitely would have liked 10, but we're going to start to increase the pace of business development. We've got a lot of things we're looking at in the Biosimilar space. We've got a lot of things we're looking at in the Women's Health space unique to women health – to women's health, as opposed to those conditions that disproportionately impacted women. So that's another level that we're going to be looking at. So look for more, because we are trying to make

the best deals that both fit the unmet needs that we talk about and that are good valuations that our shareholders and investors can look at us and say, look, that was a good deal, that was the right price, we didn't overpay for assets that we believe that we needed to get into. So I think we're taking a very balanced view. And I would tell you, look, in a pandemic, first six months of our life after launching out and we do four deals. I'm very proud of the team that they were able to get that done in that type of chaotic timeframe.

Steve Scala
Analyst, Cowen and Company, LLC

Q

May I follow up?

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

A

Sure.

Steve Scala
Analyst, Cowen and Company, LLC

Q

Yeah. So on the 56 deals that you didn't do, which of the three criteria most often was the reason? Was it, they didn't fulfill a significant unmet need? Was it that you couldn't count on them today, or was it valuation?

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

A

I think a combination of all the three: there were some deals essentially that we didn't feel really met the unmet need. There wasn't really a unique mechanism there that we could stand behind or some other deals essentially where the valuations – where essentially we didn't think it was worth it. And number of other reasons. It's quite a number of reasons we were looking at in terms of what we were doing. But look, we've got a fantastic Business Development Head in Daniel Karp, who has long years of history both at Pfizer as well as Biogen and he's got a team of 29 people who are really focused on this and doing some outstanding work.

Steve Scala
Analyst, Cowen and Company, LLC

Q

May I follow up?

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

A

Sure.

Steve Scala
Analyst, Cowen and Company, LLC

Q

So there was 140 deals I think initially and you've looked at 60: does that mean there's 80 to go?

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

A

No, no: the 140 deals that we were looking at were in – specifically unique to Women's Health. Now the 60 were now outside of that where we looked at devices, we looked at femtech, we looked at diagnostics: so, we've got a lot more to go down that list and we are actually in the later stages of doing some pretty interesting deals that you'll hopefully see coming your way in the very near future.

Steve Scala
Analyst, Cowen and Company, LLC

Q

Thank you.

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

A

Sure.

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

David Amsellem
Analyst, Piper Sandler & Co.

Q

Thanks. So, just a couple. So on Nexplanon, can you just remind us how you're thinking about the exclusivity runway in the United States? That's number one. And then number two, regarding just the overall product mix, do you have a long-term target in mind in terms of the percentage of Established Brands as a portion of the overall mix? I mean obviously Established Brands is a pretty high portion of the mix. How are you thinking about diversifying down from that? And do you have a target in mind in terms of portion of the mix over say the next several years? Thank you.

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

A

So, David, just real briefly about Nexplanon, we lose exclusivity in 2027 in the US and 2025 in Europe and outside of the US: that's one issue. But as I mentioned earlier on previous calls, we have an indication we're working on essentially to get an extension so that we're – we have a five-year efficacy of indication. And those studies started at the end of 2020. We expect to report out by the end of 2024. So that gives us three years more of exclusivity in terms of marketing exclusivity, which essentially means if we launch in 2025 timeframe, we could potentially and theoretically take it to 2028. Now remember, generics can come in and market for a three-year indication in 2027, but they can't market for a five-year indication. Essentially, you can rest assured we'll do everything in our power to move everything over to the five-year indication because that's what women want. They want a longer potential [indiscernible] (01:01:20) availability to them that can take one minute to insert in the upper arm. So we're very excited about that five-year indication. We feel very good about it. And so that's essentially the status of that.

In regards to the contribution of the Established Brands, look, it's two-thirds of our business today, somewhere in that vicinity – that range. But given the fact that it's flattening out and we're stabilizing that business – and I mean stabilizing, right? It'll start to come down over time to probably half of our business. But good cash generation from there. And the other products – the businesses that we have, Biosimilars, Fertility, Contraception, JADA, all the other things that we're doing will ultimately start to contribute more. And so you'll see a 50% split for everything else. And then of course, in the later stages, if we're lucky enough to be able to turn the cards over and launch FOR-6219 for endometriosis, it's a whole different game: that's an exciting new future to think about.

David Amsellem
Analyst, Piper Sandler & Co.

Q

Okay. And if I may just sneak in a follow up question – and I may have missed this. Can you just talk about deal size? I know you're looking at quantity, but what's the extent to which you could do something more transformational? And I know that might have implications for the credit rating, but how are you thinking about that in terms of size and ultimately where you would go in terms of the rating?

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

A

Yeah, David, so you know, right now we're – as we screen deals, we're really not – one of our screening criteria is not the size of the deal. My experience has been, if you find a compelling target, you can make a good investment case around it. You can always find a way to finance it. And we have to – we're operating under some, I'll call it goalposts from the Tax Matters Agreement with Merck as part of the separation, but those are pretty wide. And so, we can use a number of financing pockets to make attractive deals happen. So, we're not looking any significant governors – or, we're not turning away deals – let me put it that way. We're not turning away opportunities because of size.

David Amsellem
Analyst, Piper Sandler & Co.

Q

Okay. Thank you.

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

So if I can just – yeah, if I can just summarize – thanks everybody for your questions – your thoughtful questions. And just a summary comment: our separation from Merck and our launch as an independent company has really involved a great deal of effort from every one of our employees who we consider as founders. Some like myself had really been working on this transaction for several years to see the realization of our conviction that this portfolio in a different set of hands with management focus and attention can deliver the financial and operational commitments we set for 2021 is a proud moment for our team. And we look back we can truly take stock of our many accomplishments. We delivered double-digit growth for Biosimilars, Fertility, and Nexplanon. We stabilized our Established Brands business, which generates significant cash flow. We established a dividend and we have wasted no time in building out a Women's Health portfolio that tackles the areas of profound unmet need. All of this has been accomplished during a major pandemic, which should tell you something about how special the team we have at Organon. And I want to tell you that we're equally committed and energized about doing the same in 2022.

So with that, I want to thank everyone for your time, and we'll speak with all of you soon. Thank you.

Operator: This concludes today's conference call. Thank you for participating. You may now disconnect.