Organon & Co.

Moderator: Ali, Kevin

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OPERATOR: This is Conference # 2594964

Operator: Ladies and gentlemen, thank you for standing by. At this time, I would like to welcome everyone to the *"Organon Third Quarter 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. To ask a question during the session, you will need to press star one on your telephone keypad. 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: Thank you, Polly. Good morning, everyone. Thanks for joining our Third Quarter 2021 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. Today we will be referencing a presentation that will be visible during this call for those of you on our webcast. This presentation will also be available following this call on the events and presentation section of our Organon Investor Relations website at 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 the 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'd now like to turn the call over to our CEO, Kevin Ali.

Kevin Ali: Good morning, everyone and thank you, Jen. Welcome to today's call where we will talk about our first full quarter as a standalone company. Also, as today is Veteran's Day in the US and Remembrance Day in other parts of the world, we would like to thank all of those who have served, especially our own employee veterans.

Let me start by saying I continue to be inspired by the commitment of our employees across the world. They are unified in the dedication to our vision, creating a better and healthier everyday for every woman. Already, less than six months after spinning into an independent company, we are delivering on our corporate and financial goals. Our year-to-date results have shaped up very much in line with our expectations with third quarter revenues of $1.6 billion and adjusted EBITDA of $636 million and with about seven weeks left in 2021, we have good visibility into the performance of each of our key 3 franchises for the remainder of the year.

Accordingly, we affirmed our guidance and narrow the ranges for revenue and adjusted EBITDA margin for full year 2021, which Matt will discuss with all of you shortly.

Importantly, we have been active on the business development front. As we told you we would be, we have executed 3 transactions in the last six months. This underscores our stated commitment to deliver health care interventions that address unmet and undermet needs in Women's Health.

We're partnering with or acquiring companies to advance true innovation, something that has been willfully lacking in the area of Women's Health. Today, we announced our proposed acquisition of Forendo, a clinical stage drug development company focused on novel treatments in Women's Health. This acquisition brings a pipeline of candidates, including a lead candidate for endometriosis and a secondary candidate in polycystic ovary syndrome or PCOS.

Endometriosis is a high priority unmet need for us. It affects up to 170 million patients or up to 10% of all women of reproductive age. In current therapies and development, candidates target the pain associated with endometriosis, but do not address disease progression. Existing treatments also often lead to systemic estrogen depletion, which impacts bone mineral density and triggers menopausal symptoms. Such treatments are therefore unsuitable beyond short term use in premenopausal women.

Completing the acquisition of Forendo will be another step in building our end-to-end Women's Health portfolio. It joins our other recent editions including Alydia Health and its Jada System, which Organon acquired in June of this year.

The Jada System is aimed at controlling abnormal postpartum bleeding or hemorrhage. One of the most common complications of birth impacting up to 10% of mothers and potentially resulting in emergency interventions such as hysterectomy and blood transfusions. In July, we also announced the licensing of the global development, manufacturing, and commercial rights to an investigational agent Ebopiprant from ObsEva.

Ebopiprant is currently being studied as a first in class innovation for the treatment of preterm labor, which impacts an estimated 15 million babies or about 11% of all babies born globally. These acquisitions are tightly aligned with our goals to be the leader in Women's Health by addressing the significant unmet needs of women. We have quickly expanded beyond contraception and fertility where we are well-established and already hold leading market share positions.

I want to turn my attention to fertility where we saw revenue growth of approximately 30% year-to-date ex-FX. We don't believe the opportunity for the products in our fertility portfolio Follistim, Orgalutran and Elonva are always well understood. These products are used in the patient-friendly GNRH antagonist protocol which requires fewer injections and is favored in conjunction with egg and embryo freezing. Globally, and fertility rates are increasing. We've seen the average age for giving birth to a first child increase from 21 years old in 1970 to 29 years old today. About 15% of couples worldwide experience infertility, impacting almost 190 million people. These figures are impacted by women proactively choosing to delay

parenthood until an optimal time due to advances in modern fertility protocols and egg and embryo freezing technology.

Governments are recognizing. Fertility rates are not just a personal family planning issue, but also have an impact on GDP. In 100 countries, birthrates are now below 2.1. The level needed to maintain the population. Low birth rates are a growing threat to some very large economies such as China, US, and Japan triggering public sector responses that serve as structural tailwinds for fertility treatment.

Recently, China introduced the three child policy. Next year, Japan will introduce reimbursement for IVF treatments and the French, Swiss, and Spanish Governments recently passed bills allowing egg freezing and IVF treatments for same sex couples.

These recent changes are just the beginning of providing equal access to reproductive assistance. Government interest in increasing fertility rates and changing laws on access to reproductive assistance makes us optimistic for the growing prospects of our fertility portfolio.

Let's talk now about contraception, NEXPLANON. The #2 contraceptive worldwide by revenue. We believe NEXPLANON or LARC (Long-Acting Reversible Contraceptive) has blockbuster potential. Historically, there has been a sustained shift in the hormonal contraception market away from the daily combined oral contraceptive segment towards LARCs. LARCs are highly efficacious and considered to be one of the most effective forms of hormonal contraception.

Nexplanon or Implanon NXT as it's known in some markets is differentiated even within a large segment. It is the only single rod subdermal Long-Acting Reversible Contraceptive comprised of a progesterone only rod inserted in a woman's upper arm. Average insertion time takes about a minute. Historically, NEXPLANON sales have been highly correlated with well visits, and logically the pandemic dampened our ability to reach health care providers and patients, especially in US. However, as the pandemic is slowly receding, we are seeing improvements in recent weeks.

Additionally, since NEXPLANON has been in our hands, we have been aggressively working to modernize the brand's marketing and our operating

model. This has included a direct-to-consumer education campaign and television and social media with digital campaigns to drive traffic to our revamped websites where patients can find healthcare professionals by ZIP code trained in NEXPLANON insertion. This was complemented by targeted Bespoke campaigns aimed at specific patient segments.

Additionally, our clinical training programs ramped up quickly once providers offices reopened. We trained over 7500 health care professionals in the third quarter alone, which is above our pre-pandemic baseline levels and we trained over 6000 health care professionals in Q2. This is a steep ramp up from the 2000 that were trained in Q1 and we believe it's contributing to increasing demand and we are very encouraged by the results of these programs, especially given we're less than six months into this journey. We continue to feel very positive about NEXPLANON path, particularly now, midway through the fourth quarter.

Now, let's talk about biosimilars, which has grown 30% year-to-date and where we are well positioned with our commercial strategy. In US our two offerings are RENFLEXIS or infliximab biosimilar or ONTRUZANT, our trastuzumab biosimilar. The Infliximab market continues to grow every year, and RENFLEXIS had benefited from that tailwind with sales still growing even four years after launch. The trastuzumab market has some of the highest adoption rates, about 70% among biosimilars and the uptake of ONTRUZANT in the US continues to show unit growth since its launch last year.

Outside of the US, our recent launches have had LIMA in Australia and Canada have been performing exceptionally well. We also continue to evaluate other potential pipeline opportunities with Samsung as well as other developers as we pursue the potential opportunity to present it by the estimated $100 billion plus a blockbuster biologics going off patent over the next decade.

As we now turn our attention to establish brands, I'll repeat what I said last quarter. Part of the strategic timing of our spin is that 2021 is an inflection year. It is the last year during which the portfolio is subject to significant new LOE risk.

Beyond 2021, the impact from the LOE decreases significantly. This portfolio of 49 products to comprised of brands with significant customer

loyalty that tend to respond well to promotion. For example, in China, our retail business now representing almost 50% of our China established brands revenue continues to grow strong double digits because of brand loyalty, offsetting the impact of the Volume-Based Procurement program or VBP and positioning Organon for sustainable growth in China post VBP.

Importantly, we are taking a very entrepreneurial view of this portfolio and have uncovered a number of accretive opportunities within our existing portfolio. For example, we anticipate taking Nasonex OTC in Russia with that launch plan for early next year. All three franchises are global businesses as you will see on Slide #7.

There are several areas I want to highlight about our business geographically. The decline in Asia-Pacific is primarily related to Zetia's loss of exclusivity in Japan. In the US, the LOE from NuvaRing as well as NEXPLANON performance through the pandemic were factors. However, importantly, we continue to grow in China despite four of our products being included in the Volume-Based Procurement process in the fourth quarter of last year.

Revenue from China is up 4% ex-FX. This quarter driven by the respiratory market recovering from the COVID impact in 2020. The favorable positioning of our fertility portfolio and continued contribution from the retail channel. Overall, we are very encouraged by our performance in this very important market.

Now, I'd like to turn it over to Matt to discuss our third quarter performance in more detail.

Matt Walsh: Thank you, Kevin. Before we dive into the specifics of our financial performance, let's start briefly with basis of presentation and make sure we align on exactly what numbers we're looking at, where we have apples-to-apples comparability, and where we may have something less than that.

On the plus side, our third quarter results marked the first time that Organon is reporting an entire corridor of standalone results. As I discussed in last quarters, call our results prior to the June 2nd spinoff date are presented on the carveout basis of accounting. Carveout accounting is a GAAP convention which has a lot of positives; however, it's not intended to present results as Organon were standalone company. So I want to be clear as we

discuss results for this quarter and for the next three quarters that any comparisons to prior year periods will be somewhat apples-to-oranges, and that we will be comparing Organon's standalone performance to pre-spin carveout basis of accounting.

With that said, where we'll have the best comparability is at the revenue line, so I'll be focusing attention at the top line as we discuss our performance. So turning to Slide #8 revenue for the third quarter was $1.6 billion, down 1% as reported and down about 3% at constant currency exchange rates when compared to the third 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 third quarter compared to the third quarter of last year is approximately $70 million, and it's primarily related to the LOE of Zetia in Japan and NuvaRing's LOE in the United States.

Continuing to read across the waterfall chart. The established brands portfolio has exposure to VBP in China. The total impact of sales for the third quarter compared to the third quarter of last year was approximately $60 million and was associated with the third round of VBP, the largest round so far, which occurred in the fourth quarter of 2020 and that included four of Organon's products. Singulair Pediatrics, PROSCAR, PROPECIA and ARCOXIA.

In the third quarter of 2021, the negative impact of COVID-19 was estimated to be approximately $100 million, which is about $20 million above Q3 of last year. Our product portfolio is comprised of physician-prescribed products which have been infected by the shortage of qualified personnel, social distancing measures, and delayed medical visits.

In the third quarter, we continued to see lingering effects from COVID as compared to the year ago quarter, including as Kevin just mentioned a slower return of well visits, which particularly impacts NEXPLANON. We continue to observe restrictive measures which vary by country and region, so we expect to see some further lingering negative impacts from COVID persisting into the fourth quarter. Although we believe we're starting to see encouraging trend developments in US NEXPLANON early in the fourth quarter, which could be pointing to stronger sequential performance in Q4 versus Q3.

Foreign exchange translation had about 200 basis points of favorability for the quarter. Year-to-date that impact is more pronounced at about 350 basis points, which is not really surprising given the impact of COVID-19 on global currency markets in the prior year period and also understanding that about 75% of our revenues derived outside the United States.

And finally, on the plus side, we saw volume growth in Q3, mainly driven by growth in China in US biosimilars and in Europe with established brands.

So now let's take a look at performance by franchise and we'll start with Women's Health on Slide #9. Our Women's Health business was down 10% as reported an 11% constant currency in the third quarter versus the prior year. NEXPLANON declined 8% ex-FX in the quarter. As Kevin mentioned, well-visits are not yet back to pre-pandemic levels in the US and NEXPLANON site sales are largely tied to that metric, so we know the question on investor's minds is, can NEXPLANON have a $200 million revenue quarter in Q4? And while we don't provide specific guidance by product, this question is important enough to address and provide you with at least a directional answer and based on current visibility into the data that we're looking at, we do see fourth quarter as being favorable for US NEXPLANON.

There's three reasons why. Reason #1 goes back to the quarter just completed. Third quarter negative growth should be considered in the context of Q3 2020 being a tough comp from the standpoint that in September of last year, even though we were in the pandemic, we saw a short-lived resurgence in patient well-visits that positively impacted third quarter 2020 NEXPLANON sales.

There has been volatility in the trend of patient OB-GYN well-visits over the last year, but for the third quarter of last year, those visits were almost back to a pre-COVID baseline and Q3 2020 NEXPLANON sales were the highest since the start of the pandemic. So the message here is that the third quarter of 2020 was a tough comp for NEXPLANON.

Second reason goes to phasing of revenues within this year. There was a tender that we were expecting in the third quarter in Mexico that was delayed and has now become signed business for us in the fourth quarter.

Third and final reason goes back to what Kevin said about our NEXPLANON DTC campaign in the United States, which began running this summer. It's starting to show results now as well as other new digital campaigns that are raising brand awareness for NEXPLANON and driving sizable increases in our website traffic by potential new users.

Beyond NEXPLANON, also pressuring Women's Health this quarter was the continuing and expected decline in NuvaRing, down 17% ex-FX in the quarter related to increased generic penetration as a result of the products LOE in 2018 in the US.

On a positive note, our fertility portfolio continues to show strength. Follistim grew 18% ex-FX in the quarter. Volume growth came from an increase in demand from new accounts as well as from patients returning to clinics and our observation has been that patients seeking fertility treatments are more motivated to return to doctor's offices than those patients seeking normal course OB-GYN well-visits.

Turning to biosimilars on Slide #10, biosimilars grew 41% as reported in the third quarter and 39% ex-FX. We have 5 assets in the portfolio, 3 in immunology and 2 in oncology. RENFLEXIS and ONTRUZANT are our two largest offerings, and both are offered in US. Globally, where RENFLEXIS grew 43% ex-FX in the quarter, driven by strong performance in the US and ONTRUZANT which was launched in US in July of last year, was up 47%.

The biosimilars business outside the US, which represents about half of our total biosimilars revenue, is tender-driven, and therefore it's more price sensitive, and timing of tenders can also make this business somewhat lumpy, and we benefited from that in the third quarter. So while we are coming off two quarters of about 40% year-over-year revenue growth in biosimilars, we see some moderation of that growth rate for the remainder of 2021, resulting in solid double digit revenue growth year-over-year.

I am now turning to establish brands on Slide #11. Revenue for established brands was down 6% as reported and 8% ex-FX in the third quarter of 2021. Excluding the impacts of LOE revenue was down 4% ex-FX. Volumes were up incrementally, mainly driven by COVID rebound, although not as strong as it was in Q2 as well as growth in China retail.

Price was down about 5% across the established brands portfolio. Now, given that this is a portfolio of medicines that for the most part are well beyond their LOEs, it may be counterintuitive to investors to hear that in the third quarter more than 50% of established brands revenue came from products for which volumes grew. These brands are well known. They respond to promotion and were actively managing lifecycle opportunities across the portfolio. These factors support our May Investor Day discussion that we expect erosion in this portfolio to be in the low single digit area ex-LOE over the intermediate term.

China– China is an important market for established brands and part of our strategy in this market has been to drive volumes into the retail channel versus our historical presence in the hospital channel. And this effort continues to be successful. The retail channel in China grew 20% in the third quarter versus prior year and now represents almost 50% of established brands revenue in China, up from approximately 35% year ago.

Now turning to our income statement on Slide #12. Our GAAP income statements for Q3 and year-to-date are available in our earnings release and I encourage investors to look at that important information. Here on Slide #12, we will be looking at our non-GAAP income statement for these same time periods.

Our gross margins were excluding purchase accounting amortization and one-time items related to the spinoff from cost of goods sold. So making these straightforward adjustments in the third quarter of 2021 non-GAAP adjusted gross profit was $1 billion, representing gross margin of 64.9% compared with 68.6% in the third quarter of 2020.

The decline reflects costs associated with standing up Organon as an independent company, including certain costs related to manufacturing agreements between Organon and Merck, which have lower gross margin percentages compared to product sales. Those manufacturing agreements had an approximate 180 basis point negative impact to gross margins in the third quarter.

Also included in the cost of goods sold this quarter was a $24 million one-time cost related to estimated losses associated with the vendor supply contract, conveyed as part of the spin, which had a 160 basis point negative

impact to gross margins. There were some spin related accounting items that partially offset this unfavorability, but this quarter's gross margin is a good example actually of where we have apples and oranges comparability issues with prior year comparisons, and why our 2021 guidance becomes a much more useful yardstick for investors.

That said, our gross margin for the third quarter was squarely aligned with the guidance that we've communicated in the low-to-mid 60% range. Adjusted EBITDA margins were 39.8% in the third quarter, which brings year-to-date margins to 38.9%. We had told you last quarter that we expected second half EBITDA margins to be lower than the first half. The reason why our EBITDA margins are running stronger than we forecasted is driven by lower operating expenses, and this is mainly timing related.

We are onboarding our standalone operating expenses of a bit more slowly than we thought in headcount costs as well as promotional spending in certain markets. And if you're doing back in the envelope math, you'd likely draw the conclusion that Q4 adjusted EBITDA margin would have to be markedly lower than year-to-date for us to finish within the EBITDA margin guidance range that we will be discussing shortly. So we do expect operating expenses to increase sequentially in the fourth quarter relative to the third quarter as the pace of onboarding some of these expenses speeds up going into year end.

Given the strong EBITDA performance in Q3, we did consider raising the adjusted EBITDA margin guidance range for the full year, but it would have been by a relatively small amount, so instead we elected to just narrow the range and communicate to you a high and improved level of confidence in the guidance that we are affirming.

A few words on debt capitalization on Slide #13. At September 30th, our bank debt was $9.3 billion against cash and cash equivalents of $1 billion. Now embedded in that cash balance is approximately $320 million that is earmarked for finished goods inventory purchases from our former parent that's really related to the spinoff transaction. So a more representative net debt number as of September 30th is close at $8.6 billion. If we had used– if we use the implied midpoint of our 2021 EBITDA guidance just for illustrative purposes that would put our pro forma net leverage at about 3.7 times, which is a modest improvement in leverage ratio compared sequentially to last quarter.

And one more item here our imputed cash flow for the third quarter is a good indicator that we are meeting our pre-spin forecasting and is a representative of the cash generating power of this business. Our capital allocation priorities remain consistent with what we laid out in our pre-spinoff communications and we are reiterating them today.

Now that our board has established a dividend, the dividend becomes our first priority. We're targeting the dividend at a low 20's percentage of free cash flow, excluding one-time cost of the separation, a level of which we believe is very manageable.

Our second priority will be organic growth and that would include lifecycle management opportunities for existing products within our portfolio supported by capital deployed in our manufacturing plants.

And on the latter, we expect to see annual CapEx in the range of 3% to 4% of revenue on an ongoing basis, once again, excluding separation costs.

Our third priority for capital allocation is really a tie. It's a tie between (a) execution of external growth plans to develop a pipeline of new product opportunities like you've seen us announced already. Alydia Health and the Jada System investigation of Ebopiprant for preterm labor, and now Forendo targeting endometriosis. We will balance that against be debt reduction and our commitment to maintaining our BB BA2 parent rating. We are targeting a long-term leverage ratio below 3.5 times net debt to adjusted EBITDA.

Turning to guidance on Slide #14. Consistent with previous communications, this guidance is all non-GAAP and pro form as if the spinoff happened on January 1st of this year. The beginning with revenue this is a chart we showed at Investor Day and changes since then have really been at the margin. Based on where we are in the year, we're narrowing our full year 2021 revenue range from $6.1 billion to $6.4 billion to $6.2 billion to $6.3 billion. And this revenue is essentially all organic. We do include a de minimis partial year revenue contribution from the acquisition of Alydia Health.

The biggest component to the year-over-year change in revenue is the expected LOE impacts. Impacts from LOE were approximately $280

million year-to-date are primarily related to the loss of patent protection for Zetia in Japan and NuvaRing in the US.

We continue to expect a full-year LOE impact of approximately $300 million to $400 million. As we've been careful to describe previously, 2021 is an inflection year for Organon as regards LOE impacts. After 2021, oue LOE exposure dissipates to approximately $300 million cumulatively over the next four years combined, 2022 through year end 2025.

We now think our VBP exposure in China for the year will be on the low end of the $200 million to $300 million range we previously communicated. Year-to-date exposure has been about $150 million and we have a fairly good understanding of what will be included in the next round of VBP, which is likely to include Ezetrol, Hyzaar, and Nasonex.

Now COVID is something that we're obviously watching very closely. We updated our view on COVID impact last quarter to expect that our total year impact from COVID in 2021 would be about even with what we experienced in 2020, which was about $400 million. Year-to-date 2021 impact from COVID was $320 million and given the recent trends that we've seen in NEXPLANON prescriptions, which is the product where we see the most lingering COVID impact we are comfortable with that implied estimate of about $80 million of COVID impact in the fourth quarter.

On a yearly basis, we expect foreign exchange translations to be a modest tailwind based on year-to-date currency performance and where spot rates are currently. And finally, for performance, we've tweaked this bucket [down a hair], and this is mostly tide to my earlier commentary on biosimilars, and the lumpiness of tenders quarter-to-quarter.

Taken as a whole, year-to-date revenue performance is largely as we expected despite the uncertainties introduced by COVID. The key themes that we've been talking about in our public communications prior to spinoff and since the spinoff remains very much intact and those are LOE issues that are waning, Women's Health, especially fertility, and biosimilars that are delivery and growth and China, that's performing very well despite VBP headwinds.

Turning to other guidance metrics on Slide #15. The message here is that for all the items shown were affirming prior guidance for most metrics and

for revenue and adjusted EBITDA were simply narrowing the ranges in light of where we are in fiscal year.

Reiterating a point I made earlier, during 2021, we've on boarded operating expenses more deliberately than we had forecasted. We're not yet at our run rate for SGA expenses and independent company. We know R&D expense will be increasing in 2022 and beyond as we add pipeline assets, and I say this more as we start to look forward to next fiscal year and we will provide quantitative guidance for 2022 when we report our full-year 2021 results in February.

Wrapping up the financial discussion, the franchises are progressing as we had expected and given our outlook for 2021, we continue to believe that we are well positioned for feature[?] organic revenue growth in the low-to-mid single digits on a constant currency basis. This will be driven by stabilization in the established brands portfolio and continued growth in both Women's Health and biosimilars, each of which has the potential to grow at low double digit CAGRs in the intermediate term. At this point, I'll turn the call back to Kevin for closing remarks.

Kevin Ali: Thank you, Matt., Again, we are very pleased with how our year has been taking shape. Organon is very well diversified geographically and therapeutically. Our mix of business is uniquely aligned to our future vision. Additionally, timing is in our favor as we move out from the negative impacts of the LOEs and can focus on building out our vision. Further, as the pandemic starts to recede, we have doubled down on our operational investments behind NEXPLANON in the US to ensure that we meet her where she is and we have started to see very positive impact of those investments in the first weeks of the fourth quarter.

We've been very disciplined in our business development plans and have actioned on three attractive assets, two of them are earlier stage products with significant downstream opportunities as well as a recently commercialized device Jada, which is helping to address a significant unmet need. All-in-all, we are very pleased with our third quarter performance and all the evidence points to a solid fourth quarter to finish off the year. So, now, we're happy to take your questions. Thank you.

Jennifer Halchak: Sally, I think we can queue up the first question.

Operator: Thank you. If you would like to ask a question, simply press star then the number one on your telephone keypad. Your first question comes from the line of Chris Schott with JP Morgan.

Chris Schott: Great. Thanks so much for the questions. My first one was just on EBITDA margins as we think about going forward. I guess given some of the comments you are making about the timing of onboarding and the R&D step up, can you just directionally help us in 22 formal guidance yet. I guess at a high level, I guess I'm assuming we shouldn't use Q4 as a run rate for margins, but when we think about your margins for next year, is it fair to think about us coming down a bit from 21 as again it sounds like SG&A comes up, R&D comes up, so just any directional color there I think would be very much appreciated.

Then my second question was just on the pipeline build out. You've done three deals this year. Should we think about these types of transactions, which seem like there is some R&D elements to them that seem a bit smaller in size is kind of the sweet spot in terms of acquisitions both near and long term or do we think about deal starting to skew towards larger transactions as you de-lever? So, I am trying to sense of like if there weren't capital constraints right now, would you be also mixing in some larger deals or again are these types of transactions more that go forward to think about? Thanks so much.

Matt Walsh: So, I'll start with EBITDA margin question, Chris. This is obviously sensitive territory because we're not providing 2022 guidance today, I want to be clear on that. Directionally, they were providing maybe some bumpers. I think the comment that you made -- let's back up and just repeat some of the prepared comments which were geared to start to address this question, which is we know that R&D expense will be increasing in 2022 to support pipeline assets. This is we believe very important for the future sustainable revenue growth of the company.

So, you'll see R&D expenses increasing. We've been very careful about how we are adding costs at the SG&A line to reach out what we believe our run rate is. Every dollar that we're adding, we're analyzing it very carefully. So, that said, you had said Chris, looks like 2022 EBITDA margin is likely to be below what you're guiding for in 2021. I think directionally, that's a fair statement. You also said how should we think about the fourth quarter

EBITDA margin in the context of 2022. It might not be as low as that; I think that's directionally accurate. Now, I think it probably makes sense to just stop there at this point and we'll be providing quantitative, very transparent guidance in February.

Kevin Ali: And Chris, to your second point, in regard to kind of our appetite on business development. Look, even though we're just shy of six months into this journey since we rang the bell on June 3rd, we've been working on these assets in terms of identifying and reaching out to potential targets well over probably six months a year before that. So, we've been very disciplined, exceptionally disciplined in the way that we've looked at our business development portfolio. We did signal early on in the investment day that we're going to kind of using baseball parlance kind of go after singles and doubles because we saw opportunities.

Like for example with Jada to solve a significant unmet need in post-partum hemorrhage, we saw an opportunity with ObsEva product with the preterm labor, a significant unmet need today in that world and now we're very excited about the Forendo acquisition because they bring a new mechanism of action to treat a significant issue around the world, which is endometriosis affecting only a 170 million women across the world. So, we see great opportunities there, I've mentioned before, there's about 140 assets out there in various stages of development, but having said that, let me be clear, we're not saying no to larger deals, we're not saying no to essentially anything that we believe it could be accretive ultimately down the road for Organon.

We are open to whatever is actually going to be working best for us as a company, but right now what we see as opportunities that are really what we consider low hanging fruit to go after in order to be able to really round out our portfolio to be a leader in women's health.

Chris Schott: Thanks so much.

Operator: And your next question comes from the line of Navann Ty with Citi.

Navann Ty: Hi. Good morning. Can you discuss your expectation on the recovery of contraception with NEXPLANON and when do you expect and GC and training programs to benefit NEXPLANON sales? Then my second

question is around the cash balance, which was higher than expected. Can you discuss the free cash flow generation this quarter and going forward? Thank you.

Kevin Ali: So, let me take that first question. It's a very important question in regard to the performance of NEXPLANON. Look, I mean the thing to keep in mind is the fact that we truly believe that NEXPLANON will be a blockbuster for all of us. We have patent protection until 2027 with an opportunity to extend it to 2030 as we start to round out and look at our five-year extension data that will possibly come through and report out in the 2025 timeframe.

Having said that, we've invested, really truly invested in the operational opportunities in the US, and I'd like to point out three key investments and then ultimately, I'm going to lead to answering your question after going through that. Clinical training programs: these are essentially just to keep you in mind that physicians or healthcare providers need to be certified and trained on how to insert and remove NEXPLANON in order to be able to prescribe and use the product.

Prior to the pandemic, Merck had average about 18,000 certifications per year. Since spin, that would especially be June through September, we've done 10,000 certifications. We're essentially averaging in the second and third quarters nearly 13,500 certifications. That is a significant proxy for NEXPLANON uptake and performance going forward. Direct to consumer art marketing, we've invested in the drug to consumer initiated, TV and social media campaign with a well-known celebrity and more importantly real world uses of NEXPLANON.

Two observations, unaided awareness of NEXPLANON has increased when compared to the prior three months and our organic searches for NEXPLANON information have increased as we've made significant, really significant improvements and enhancements to our NEXPLANON.com site where we expect to see about seven million visitors uniquely every year.

Finally, representative activities as the COVID pandemic recedes, over the last three quarters of 2021 versus the three quarters of 2020, our representative calls, face to face, have increased by 60%. All of that is leading to the fact that right now in the first five weeks of performance of

Q4, we see sales distributors have increased strong double digits, strong double digits.

We expect the fourth quarter to be a very strong quarter for us to NEXPLANON and ultimately as I've always been saying, as we start to invest in senior management attention, as we start to invest in some of these programs, we will see NEXPLANON just from the sheer fact of the matter of what it can represent and dealing with unintended pregnancies in the US and beyond start to really ramp up and start to go back to that double digit performance that we expect of it.

Matt Walsh: And on the second part of your question regarding free cash flow, the reason why we included slide 13 of the earnings deck in the format that we did was so that investors would be able to triangulate back to what third quarter operating cash flow was and free cash flow. So, now the question is, is that big year for operating cash flow representative, and I would tell you that there are one timers that are running through that, but they're going in both directions, some good guys and some bad guys use colloquial terms that we use within the company, but they're netting out so that the Q3 operating cash flow figure that we're looking at is really pretty representative of what the company should do when I put that in my prepared comments and say that the cash flow generating performance in Q3 is well aligned with what we had forecasted. So, that much I can say for this fiscal year, and I'll refrain from making any free cash flow commentary for 2022 at this point.

Operator: And your next question comes from the line of Umer Raffat with Evercore.

Umer Raffat: Hi guys. thanks for taking my few questions, not one question today. I kind of thought it would be helpful today to focus on the latest tuck-in that you guys announced on Forendo just given the potential optionality. So, if I may, perhaps a few quick ones, one, could you speak to endometrial thickness changes you saw on phase IB and secondly, can you also speak to any ECG changes and/or hypertension with this molecule so far. Third, perhaps just a selectivity for 17b-HSD1 versus sort of 11 beta or other ones and finally would you potentially intend to develop it in oncology indications as well? Thank you so much.

Matt Walsh: Thank you for that question. I will say that first of all, we are truly excited about the Forendo announcement and potential acquisition going forward.

I mean when you think about endometriosis, it's really under research, underfunded and misunderstood with essentially an average of eight to ten years before a woman is actually diagnosed with the diagnosis of endometriosis. In regard to your questions of endometrial thickness, we're just starting our phase II proof of concept studies.

We expect to report out in the 2024, 2025 range with commercialization of this product if all goes well knock-on wood by the 2027, 2028 timeframe. It is something that we need to get back to you as we start to kind of go down deep in terms of understanding exactly the data in that respect. We can return back to you on that, but just to say this, currently as you know, the treatment of endometriosis is really relied on pain medication and managing the symptoms in regard to endometriosis, not necessarily the underlying issues that are essentially causing the problems.

GNRH is for example, act systemically at the pituitary level cutting off all signals to the female reproductive system, which basically is plunging a woman into menopause and really causing all kinds of bone mineral density issues. So, that's why it's really short-term usage. For 6219, it's really targeting the estradiol pathway essentially targeting only impacting estrone to estradiol conversion process, and that process is exclusively responsible for endometriosis and ultimately all of the sequelae when you see in terms of the inflammation and all the things regarding the pain and bleeding all the issues go on.

So, we feel very excited about this mechanism. It is a potential, and I underscore potential, for disease modification as well as managing the symptoms of endometriosis really at the site where it really needs to be addressed. In terms of endometrial thickness and in terms of an ECG or any cardiovascular issues, we'll get back to you in terms of as we start to be able to get a better insight in terms of the data.

Operator: And your next question comes from the line of Stephen M. Scala with Cowen.

Stephen . Scala: Thank you. I have a few questions and then an observation. First, under the drug price reform proposal or reimbursement for part B drugs would go from ASP+6 to ASP+1000 dollars, this would seem to potentially encourage prescribing a biosimilars over more expensive brand drugs. Can

you put some numbers on that, to what extent could biosimilar usage increase by simply reimbursement changes or do you think that that's not correct that biosimilar use will not be encouraged by any reimbursement change?

Second question is on the acquisition of Forendo, the total consideration of 954 million seem strikingly high. How much is that attributable to the lead asset versus the follow ons and what happens with the existing collaboration with Novartis for chronic liver disease? Then lastly, the observation; for a company that has a core strategy, a business development, I'm surprised that business development is third or even last on the capital allocation priority list. That's it. Thank you.

Matt Walsh: So, let's take the capital allocation question first. So, the business generates strong cash flow today. The collective view of our former parent Merck, our board of directors, is that investors should be able to share in that cash flow in real time and that the valuation of the company at a very sensitive time around the spin was that the dividend would be an important consideration in achieving the right value on the company. So, that was the reason for the institution of the dividend and of course once it's in, it does become the number one priority.

The reason why organic growth projects come in number two, Steve, is because these are products that are already in the portfolio. They've got to demonstrate a track record of safety and performance. So, simply introducing these products in new markets or potentially for adjacent indications are generally de-risked investment opportunities and have very attractive risk adjusted returns. I would also add, it's not a big consumer of capital in the overall scheme of things.

So, with the dividend being a relatively modest and manageable number with the organic growth plans being de-risked and also modest and manageable that still leaves really a substantial amount of our available operating cash flow, free cash flow available to pursue the business development agenda. So, I hope that explanation makes sense. In terms of the economics around the Forendo deal; of the number that you cited in terms of total consideration, 600 million of that are commercial milestones.

So, the product has to be successful commercially for most of the value of the deal to be realized and the considerations about 84 million dollars up

front and then approximately 270 million dollars of clinical milestones. So, we did wait the deal to be back ended and dependent as much as we could justify a commercial success of the product, and yes most of the value has been described to the lead candidate. I think your last question was on biosimilars. We do view the current dialogue in Washington as very positive for biosimilar, Steve, and it's difficult to quantify the impact for Organon at this point. Certainly, be articulated when we provide guidance for 2022, but we do see the dialogue in Washington as being favorable for our portfolio biosimilar products.

Stephen Scala: Thank you.

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

Greg Fraser: Good morning, folks. Thanks for taking the questions. Just following up on your comments around NEXPLANON, was the intent to suggest that 200 million plus the sales in Q4 is achievable given the positive drivers that you mentioned? Then on endometriosis, clearly an area of women's health with unmet needs, Forendo appears promising, it's relatively early development. Do you say that it makes sense to have multiple shots on goal for endometriosis and is this an area that more what we're made us okay for VD? Thanks.

Matt Walsh: So, we do see a 200-million dollar plus quarter as well within the realm of a achievability for NEXPLANON. We wouldn't normally make those kinds of definitive statements on a forward-looking basis especially for the quarter that we're in, but we wanted to be responsive to any potential extrapolation of the Q3 results that we just announced on NEXPLANON. We do see it as bucking sort of counter into the trend going forward for NEXPLANON. So, we decided to put some definitive commentary around what we see in Q4 and so yes, we do see north of 200 million dollars as a real high confidence in that figure for NEXPLANON Q4 sales.

Kevin Ali: Greg, to your second question in regard to endometriosis and shots on goal, Forendo does have a backup compound to the lead 6219 compound. So, we feel very excited and extremely thrilled that we're able to work with Forendo and potentially acquire this company for this very exciting asset and we look forward to being able to continue to develop this product out

and it of course has got a very exciting earlier stage asset, not in humans yet in terms of PCOS which is another significant unmet need.

I want to reiterate the fact that we started this journey saying that there was significant unmet needs in women's health across the world that this is the right time for a company like Organon to be born to take on those challenges of being able to resolve issues like post-partum hemorrhage, preterm labor, endometriosis, PCOS and this is the beginning of the journey in that respect, but we do hear you and Forendo does have backup molecules.

Greg Fraser: Thank you.

Operator: Your next question comes from the line of Jason Gerberry with Bank of America.

Jason Gerberry: Hi. This is Ash Verma on for Jason. Thanks for taking our question. I just had one, in terms of contracting for biosimilar Humira been during 2022, do you expect to have a line of sight on this contracting as the company believe that the payers will look to some of the deals in the first half to make 2022 given the early entry of post biosimilar in 2023? Thanks.

Matt Walsh: Are you referring to HADLIMA specifically?

Jason Gerberry: Yeah.

Matt Walsh: Okay. There's ongoing right now discussions. It's early. We expect to launch in June of 2023 with our HADLIMA or our Humira biosimilar. It's going to be a busy year in 2023, but we expect to be second in line in terms of overall launching sequence, which is obviously a very important aspect in terms of sequence of launch. Right now, there are discussions. The unique thing about Organon is that the fact that the biosimilar team essentially moved over from Merck, and they've been working for a number of years and have significant great relationships with all the PBMs as well as the ongoing discussions with them. You remember that this is a pharmacy dispense product and so it's going to be controlled and it's going to move very fast, we believe, by the PBMs to essentially take advantage of biosimilar switch.

Jason Gerberry: Thank you.

Operator: And your next question comes from the line of Charlie Yang with Morgan Stanley.

Charlie Yang: So, I just have two questions please. One is, can you just talk a little more detail on the biosimilar price and volume on dynamics going forward? The second question is kind of recalling the NEXPLANON. What would that look like in terms of the growth acceleration and trend? Thank you.

Matt Walsh: Yeah. So, Charlie, I think those are good questions. Let me take the NEXPLANON first. As we said in last May in our investor day, we believe that NEXPLANON is a poise for strong double-digit growth. It was a double-digit growing product prior to the pandemic. We believe that that will continue to be the case as soon as clinic start to open up as they are reopening now, and staffs are coming back online. That's what kind of why we made the investments we did and things like us clinical training programs, direct to consumer marketing, all the rep activities that are ongoing right now and many other things that we're doing right now in the space.

Keep in mind that NEXPLANON really only has about 5% market share. So, there's a tremendous room for growth going forward and we do have patent protection for some time in order to build this product out. It will be a billion-dollar product for us. We feel very sure about that and as I mentioned, first half of the fourth quarter looks very strong for NEXPLANON which is again it's tied to the fact that as women go back into the clinics right now, there's opportunities to really be able to utilize NEXPLANON in a manner by which kind of comes along with our vision of double-digit growth for this product and blockbuster potential.

In regard to the second point, I think you were mentioning in terms of price volume activity around Humira biosimilars, look we expect unlike say for example, hospital products like infliximab and Remicade where the price tends to move kind of a lumpy fashion, hospital by hospital, account by account. We do expect that it's going to move very quickly, not like small molecule erosion, but nevertheless it's going to move fairly quickly in terms of price erosion with the loss of exclusivity of Humira and moving forward in 2023 as you start to see all the launches of biosimilars and you're going

to probably see anywhere between seven to eight biosimilar launches in the first year of opportunities for biosimilars to come in. So, we'll see, I think, significant erosion. Again, nothing like the small molecule type of erosion, but nothing like that you see for example in a hospital dispensed biosimilars that you see today.

Charlie Yang: Thank you.

Operator: And your final question comes from the line of David Amsellem with Piper Sandler.

David Amsellem: Thanks. So, just had a couple. Another question on biosimilars and this relates to HADLIMA, but it also maybe a broader question as well. With Boehringer Ingelheim getting interchangeable, how do you think about the role of interchangeability and what that means for your volume share or other products that don't have interchangeability? So, this is really not a question about price, but more of question about volume share given the interchangeability. And then the second question I have is on XUS established brands. Is there a good way to think about what may be steady state pricing erosion if there is any at all could be over the long term? It's a business that admittedly is a little more opaque. So, I'm wondering if you could help us get a window into your thinking there. Thank you.

Kevin Ali: Okay David. Let me take the first question in regard to interchangeability because I know it's coming up recently. Look, the way that we've really looked at this market and let's just take HADLIMA or rather the Humira biosimilars, you're right, Boehringer does have a low dose interchangeability study that they've done. That represents a very small segment of the market. The majority of the market is in high dose segment. So, really the following variables, we believe, are very important.

Order of entry, again, is very important and we're still planning to be the second to the market in June 2023. The high dose citrate free formulation is exceptionally important because that is essentially what the dominant form is today without these products real world experience and we have that from successful launches in Europe, Canada and Australia for our Humira biosimilar, HADLIMA where we've launched that product in those places.

Quality product from a manufacturing part and you can rest assured is got top line quality manufacturing like for example Samsungbioepis, but having said that, our thinking around interchangeability, especially interchangeability in a high dose citrate free form is evolving and we're in very active discussions with our partner in Samsung right now, and we will take a decision shortly in terms of what needs to be done in that space, but we are going to be very competitive. We're not going to be essentially a company that's going to have all the right variables to launch and succeed in this segment because it's an important area for us and not be competitive in regard to competitive pressures from other companies, but keep in mind, there are no companies perfectly positioned.

As we look today in terms of being kind of early launching with high concentration citrate free dose also having interchangeable designation for high concentration at launched, nobody's got that. So, essentially, it's going to be that we launched with what we have and then ultimately, you'll see later post launch as many of the other competitors are stating the interchangeability indication coming through. In regard to established brands, what we do see -- let's have Matt address that.

Matt Walsh: Yeah. So, just to ground you, Dave, approximately 92% of our established brand sales are XUS. Across the entire portfolio, we see, let's say, over a planning horizon, so four or five years we see price decline approximately 3 to 4% per year. We see volumes actually across the portfolio growing about 1 to 2% per year and that's what has been supporting our commentary that we see the established brands business having a low single digit CAGR in terms of glide past revenue over the foreseeable future.

David Amsellem: Okay. That's very helpful. Thank you.

Kevin Ali: Thanks everyone for your very thoughtful questions, but I just want to say as we wrap up today's call, I want to conclude by saying we are exactly where we want to be. At our first investor day in May, one month before spin, we laid out our plan for delivering low to mid-single digit organic growth. We are delivering on what we committed to. Women's health by NEXPLANON and fertility remains position delivered double digit growth over the intermediate period plus we're making the changes necessary to build the foundation for continued growth going forward. Year to date

biosimilars is already delivering double digit growth and we expect that to happen over the planning period.

We are stabilizing the established brand's business with volume increases in more than 50% of our products and we believe we have a pathway to sustain performance over the coming years. This portfolio serves as a cash generator contributing to the free cash flow that Matt referenced enabling us to build out our pipeline with targeted and disciplined business development and lifecycle management activity focused on our company's purpose to address significant unmet medical needs in women's health. With our three deals in the past six months, we have lost no time in tackling areas where new innovation is sorely needed.

We have commercialized the Jada device to address post-partum hemorrhage launched in the US with plans to bring it to the rest of the world as quickly as possible. We've licensed ObsEva in the investigational preterm labor agent, a new mechanism of action in the space with few options. Our exciting deal announced today the proposed acquisition of Forendo brings an early-stage asset with new mechanism of action being study for endometriosis plus an earlier stage asset for PCOS.

In addition, we have a number of lifecycle management opportunities under way including the potential for a NEXPLANON five-year label extension and many, many more. Overall, our company is shaping up just as we planned, sustainable, predictable and on strategy. So, I want to thank you and we'll talk again early next year. All the best.

Operator: Thank you. Ladies and gentlemen, this concludes today's conference call. Thank you for your participation you may now disconnect.