16-Feb-2023

Organon & Co. (OGN)

Q4 2022 Earnings Call

CORPORATE PARTICIPANTS

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

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

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

OTHER PARTICIPANTS

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

Umer Raffat
Analyst, Evercore Group LLC

Navann Ty
Analyst, Exane BNP Paribas

David Amsellem
Analyst, Piper Sandler & Co.

Chris Schott
Analyst, JPMorgan Securities LLC

Steve Scala
Analyst, Cowen and Company

Gregory D. Fraser
Analyst, Truist Securities, Inc.

Bhavin Patel
Analyst, Bank of America

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 2022 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 like now to turn the call over to Jennifer Halchak, Vice President, Investor Relations. Please begin your conference.

Jennifer Halchak

Vice President-Investor Relations, Organon & Co.

Thank you, Dennis. Good morning, everyone. Thank you for joining Organon's fourth quarter and full-year 2022 earnings call. With me today are Kevin Ali, Organon's Chief Executive Officer who will cover strategy and operational highlights; and Matt Walsh, our Chief Financial Officer, who will review performance, guidance and capital allocation. Dr. Sandra Milligan, Organon's Head of R&D, will also be joining us for the Q&A portion of this call.

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

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

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

I 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. Welcome to today's call, where we'll talk about our fourth quarter and full-year 2022 results.

To begin with I'm exceptionally proud of Organon's performance and our first full year as a standalone company. For the full-year 2022, we delivered a 4% increase in total company revenue at constant currency. We also demonstrated strong profitability, generating an adjusted EBITDA of $2.1 billion, representing a 33.8% margin. We delivered strong growth in our Women's Health and Biosimilars portfolio, as well as we grew our Established Brands business.

Starting with Women's Health. For the full-year 2022, the Women's Health franchise delivered 7% growth on a constant currency basis. This includes $834 million of revenue from Nexplanon, which grew 11% in 2022 at constant currency. This marks Nexplanon's second consecutive year of double-digit growth. That is a significant achievement for a product that has been around for over a decade and relies on continually attracting new patients to the product.

We are seeing particular strength outside the US, where Nexplanon grew 17% in 2022, especially in our LAMERA region, where improved access is helping to drive demand. In the US, Nexplanon grew 8% in 2022, and continues to gain share in the lark of a long-acting reversible contraceptive market. In 2022, we also trained more than 20,000 healthcare providers to insert Nexplanon, and we will continue to train more providers in 2023. Importantly, we continue to hone our go-to-market strategy, emphasizing follow-on reviews with healthcare providers actively prescribing Nexplanon for whom additional training may strengthen their comfort in prescribing Nexplanon.

We continue to monitor the impact of the overturn Roe v. Wade on the contraception market. Since July 2022, we have seen demand growth for Nexplanon in the most restrictive states, as well as protected and semi-restrictive states. This speaks to the need, now more than ever, for highly efficacious forms of contraception. In real-world use, Nexplanon is over 99% effective in preventing pregnancies compared with some forms of short-acting contraceptives, where efficacy is less than 80%. That is in part, because when women use a long-acting contraceptive, like Nexplanon, it takes the patient-dependent aspect out of it.

Nexplanon is inserted within minutes and currently provides efficacious – continuous efficacy for up to three years. We also believe we will be successful in demonstrating the five-year efficacy through our ongoing study. But, importantly, it wasn't just Nexplanon that continued the growth in Women's Health in 2022. We continue to

see good contribution from the fertility portfolio which, in 2022, grew approximately 9% at constant currency, despite the impact of COVID in China, which limits patient's ability to begin or continue treatment at fertility clinics.

The US and China are large fertility markets, and together represent more than half of our current fertility business. China is a particularly important fertility market for us, with the potential to grow to more than 1 million IVF cycles a year over the next decade. The number of cycles in China is already three times the number of cycles in the US. And as we have discussed many times before, fertility is a therapy area with strong demographic tailwinds. Women are waiting longer to start their families, resulting in higher prevalence of infertility, and more governments are realizing that they need to take action to address the associated low birth rates.

More than 100 countries around the world have a fertility rate or the number of births per woman that is significantly below the replacement rate that is required to sustain a population and its GDP growth. Countries are offering more monetary incentives for households to expand their families, and many are offering better fertility access and benefits. Organon is one of the few companies with a portfolio to help serve this growing market. The Women's Health franchise is also benefiting from our business development activities. As we think about business development, we are striving for balance between commercialized assets and earlier stage assets that could become significant growth catalysts for Organon in the longer term.

Since spin, through business development, we've added three assets to our Women's Health portfolio that are already contributing, or will soon be contributing to revenue growth. You will recall that, last year, we reacquired the rights to Marvelon and Mercilon, which are combined oral contraceptives in selected territories in Asia, including China and Vietnam. Together, Marvelon and Mercilon grew 20% in 2022. The success from the repatriation of these assets is just another example of how Organon is applying its own methodologies to maximize the performance of assets that may have been underprioritized in other companies in the past.

We are also very excited about the Jada System, which we added to our portfolio in 2021 with the acquisition of Alydia Health. Jada is a device indicated to provide control and treatment of abnormal postpartum uterine bleeding or hemorrhage, and postpartum hemorrhage is one of the most common complications of birth, requiring pharmacologic treatment in up to 10% of mothers. At last week's annual meeting for the Society for Maternal-Fetal Medicine, researchers unveiled the results of the RUBY study, which examined Jada's efficacy and safety in real-world use. In the RUBY study, researchers analyzed a large population of 800 women, who were treated with the device from October 2020 to April 2022 at 16 hospitals across the United States.

Researchers concluded that Jada worked quickly and was highly effective in controlling postpartum hemorrhage after both vaginal and cesarean births. Researchers also found that the device successfully treated postpartum hemorrhage in 92.5% of vaginal births, and 83.7% in cesarean births. In addition, the device was safe and only had to remain in place for a few hours after placement, allowing for a more efficient postpartum care experience. Our goals in acquiring Jada included the opportunity to speed up access to this innovation in the US and to leverage our global capability to bring this product to markets around the world. We continue to add accounts and are now in about 1,000 hospitals in the US, with more than 15,000 mothers having been treated with Jada. Additionally, in 2022, we made our first ex-US shipments, and had also submitted to the EU for approval.

We're also pursuing earlier stage assets that address the areas of highest unmet medical needs and have the potential to expand our portfolio in Women's Health. Since then, we've added four earlier stage assets in the Women's Health portfolio at different stages of development. The farthest along is OG-6219, a unique new mechanism of action, which is a candidate to treat endometriosis locally instead of systemically. In October 2022, we enrolled the first patient in our Phase 2 ELENA study, which is expected to be completed by the end of 2024.

Turning to Biosimilars. Our Biosimilars franchise grew 17% on a constant currency basis in 2022, marking its second consecutive year of double-digit growth. Biosimilars are an important growth driver for the company and, in 2022, we underscored our commitment to the business by adding a second R&D partner with Shanghai Henlius. All five of our biosimilars contributed to the strong performance in 2022. Renflexis, our largest selling biosimilar grew 22% last year, driven by solid performance in the US and Canada, despite already being on the market for five plus years.

Ontruzant, our second largest biosimilar, grew more than 40% in the US, but that growth was offset by competitive pressures in Europe. Hadlima, our biosimilar for Humira, had a very strong performance in 2022, reflecting its successful 2021 launch in Canada and Australia. We expect that our success in those markets will help with provider confidence when we launch Hadlima in the US in July of this year. Because Humira is the largest biologic to face biosimilar competition in the US, we are frequently asked about the competitive position with Hadlima. To reiterate our messaging, we believe that the best-positioned biosimilars will be those that share the same attributes as the originator. That includes the option for high-concentration, citrate-free formulation, as well as a low-concentration formulation, and we expect to have both at launch.

We also believe that real-world evidence and experience in other markets will be something that providers will appreciate. We have that data through our collaborator, Samsung Bioepis from their experience with Hadlima in EU, as well as from our own successful launches in Canada and Australia. And finally, we believe our pen design can be a differentiator for patients. Samsung is an expert in device design and manufacturing and has designed a pen with the aim of providing a frictionless experience for new patients and those transitioning from Humira. That said, with multiple parties launching mid-year, we have also conveyed our belief that 2023 will be a modest ramp-up year, with the market for biosimilars really forming in 2024 and 2025 and beyond.

Finally, let's talk about Established Brands, which currently represents about two-thirds of our overall business and generate significant free cash flow. The portfolio continues to demonstrate the sustainability and untapped potential of these brands. Over the longer term, given the maturity of the portfolio, we expect close to flat performance for our Established Brands business. In 2022, we benefited from some one-time events, as well as from delayed VBP implementation that helped the franchise deliver growth of 3% at constant currency for the full year. In the near term, as we think about 2023, we believe we will be able to offset the expected impact from round seven of VBP with continued focus on maximizing the potential of these well-known brands through continuous demand generation, and we expect the Established Brands to achieve generally flat performance in 2023 on a constant currency basis.

Briefly, turning to geographic performance, there are two important takeaways here. One, geographic risk in our revenue is well distributed; and two, each of these geographic regions grew in 2022. That includes China, which faced significant challenges related to COVID in 2022. As we think about 2023, we believe that strength in the retail channel growth and fertility, as well as the benefits from the reacquisition of Marvelon and Mercilon will together offset the expected VBP impact to our China business in 2023. We are extremely proud of our 2022 achievements, and I want to thank our 10,000 founders worldwide for rising together, for living our purpose, and for delivering the success Organon had in our first full year as a standalone company.

I'd like to now turn the call over to Matt. Thank you.

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

Thanks, Kevin. Before I talk in more depth about our results, I'll remind you that we haven't completely lapped the June 2021 spin transaction as far as financial reporting is concerned. So, while our 2022 third and fourth quarters

are apples-to-apples with the prior year periods, first half of 2022 comparability is impacted by the carve-out basis of accounting that we needed to employ for pre-spin-off accounting periods. And that really applies more to expense items and the full-year income statement, rather than revenue, and I'll call that out as necessary.

So, with that opener, we'll move to slide 7 and discuss fourth quarter revenue. Fourth quarter revenue was approximately $1.5 billion, down 7% as reported, but up 1% at constant currency, and this marks our fourth consecutive quarter of constant currency growth. We'll spend more time talking about the individual drivers when we get to the full year, but isolating the fourth quarter for the moment, we had solid volume growth in the period. Our key growth franchises, Women's Health and Biosimilars were the main drivers of growth, but Established Brands also contributed.

For example, recently, we've seen particular strength in Atozet in France and Spain, and with some generics still out of the market in Japan, we're getting some pickup there as well. In the fourth quarter, we had about a $15 million impact from volume-based procurement or VBP in China, which reflects the implementation of round seven in November. The Organon product that's impacted in this round is Ezetrol, which is sold as Zetia in markets outside of China. The biggest number on this walk across is foreign exchange translation, which represented an 800-basis-point headwind to revenue growth in the fourth quarter. This is the largest FX translation reporting impact of any quarter in 2022.

This might seem counterintuitive, because of everyone's most recent memories of the US dollar weakening versus most foreign currencies, but the numbers show that trend started at the very end of 2022. And given that north of 75% of our revenue is outside the US, FX translation was a significant theme for Organon in 2022. Our portfolio faced a significant financial reporting headwind from the strengthening US dollar and, unfortunately, that dynamic masked the operational growth in local currencies that we delivered in the fourth quarter and in the full year.

And speaking of the full year, we have an identical revenue bridge on slide 8. For the full-year 2022, revenue was approximately $6.2 billion, down 2% as reported, but up 4% at constant currency when compared to prior year. Starting with loss of exclusivity or LOE, for the full-year 2022, LOE impact was modest at about $30 million and it's coming mainly from NuvaRing's LOE in the United States. We didn't have any LOE impact in Established Brands this year. And as we've said before, the most significant LOEs facing the Established Brands portfolio washed out prior to the spin-off, and what we expect going forward is a cumulative few hundred million dollars of impact over the next several years.

The full-year impact from VBP of about $20 million primarily reflects the November implementation of round seven as I just discussed. We saw an approximate $140 million impact coming from price for the full-year 2022, and that's consistent with our expectation that we'll continue to see low-single digit price erosion on a company-wide basis. The majority of pricing pressure continues to come from Established Brands, where products are subject to mandatory annual price reductions in some markets, as well as from Biosimilars. For volumes, we expected to see strong volume growth during 2022 across our franchises, and that indeed happened.

We saw volume increases coming from, what we call, our growth pillars; Nexplanon, fertility, and Biosimilars, but Established Brands also grew volume as well. For example, Nasonex and Singulair drove strength year-on-year, Atozet grew in Europe, and we continue to see significant growth in the China retail channel. When looking at supply/other, the approximate $70 million impact primarily represents supply sales to Merck and other third parties, which consist of relatively low-margin sales of pharmaceutical products under contract manufacturing arrangements. Last year, we signaled that the volumes under these arrangements would decline in 2022, which has been the case. And finally, you can see the significant financial reporting headwind we had in foreign

exchange translation, 600 basis points for the full year which, again, is a function of more than 75% of our revenue being generated outside the US.

The next few slides lay out our performance by franchise. Kevin covered very well the highlights, and the quarterly and full-year details are provided in the supporting earnings materials. So, I'll focus on topics that may be relevant to your modeling, as we think about 2023. We'll start with Women's Health on slide 9. As Kevin mentioned, Nexplanon had a strong performance in 2022, was up 8% ex-FX in the quarter and 11% for the full year. In fact, we set two new sales records for Nexplanon in 2022; first in the third quarter, and then again in the fourth quarter. As you think about quarterly phasing for next year, it's worth reminding you that in the fourth quarter of last year, Nexplanon also set a sales record, which was then sequentially followed by a weaker first quarter, due in part to the buy-in/buy-out dynamic we tend to see around the timing of price increases in the US. This is a dynamic we would expect to see again in the first quarter of 2023.

Turning to Biosimilars on slide 10. As Kevin mentioned, this franchise continues to be an important growth driver for us. We know investors are focused on the potential revenue contribution from our US launch of Hadlima this year. Based on our expectations for a gradual market formation in 2023 and only a partial year of revenue contribution, given our July 1st launch, we expect that, globally, Hadlima will represent no more than about 1.5% of our consolidated 2023 revenue.

Turning to Established Brands now on slide 11. Here, I want to drill down into the fourth quarter because, in addition to VBP implementation, there was another item that impacted Established Brands fourth quarter performance. In January 2023, we initiated market actions for sterile suspension injectables with Diprospan and Celestone Chronodose. This was related to a purchase component used in the sterile filling process at Organon's Heist facility in Belgium that was determined to be non-conforming. To be clear, no product quality complaints or adverse events have been reported nor are any expected. Due to the compliance aspect, it was prudent to exercise these market actions and discard inventory deemed to be impacted. And for reference, combined, these two products represented about $165 million of revenue in 2022.

Turning to slide 12, you can see that this action had the effect of reducing fourth quarter revenue by $8 million for potential sales returns, and we recorded a one-time inventory charge of $36 million that shows up in cost of goods sold. We're breaking out the issue in this manner to show that, excluding the total $44 million that flows through to adjusted EBITDA, our fourth quarter adjusted EBITDA margin would have been 28.4%, very much in line with what our expectations were for the fourth quarter when we last provided guidance in November. We're also showing the full-year impact for reference. Since spin-off, we've been very pleased with our ability to forecast our business. So, while events like a market action were always a potential risk in this industry, we're confident about the durability and diversity of our business as it relates to forecasting it.

Let's now turn to key P&L line items on slide 13. For non-GAAP gross profit, we are excluding from cost of goods sold, purchase accounting, amortization and one-time items related to the spin-off. The market action I just discussed was the major driver of the change in gross margin in the fourth quarter compared to the prior year periods. For the full year, adjusted gross margin was 65.7% compared with 64.7% for the full-year 2021. Keep in mind that full year comparisons for items below the revenue line are less meaningful, because they're only truly comparable for the second half of the year.

That said, the year-over-year increase in adjusted gross margin is primarily a result of lower supply sales in 2022, which carry lower margins, as well as pre-spin allocated costs related to the separation of Organon that occurred in the prior year. Adjusted EBITDA margin was 25.6% in the fourth quarter compared to 29.3% in the same period

of last year. Adjusted EBITDA margin was 33.8% for the full-year 2022 compared with 36.1% for the full-year 2021.

The decline in the fourth quarter and full year was a result of costs associated with the market action at Heist, as well as expenses related to positioning the company for future growth. We've been talking about the importance of reinvestment in the business to create a pipeline of new products to drive revenue growth for a while now, and you see that in higher selling and promotional costs, as well as research and development spend associated with our prior acquisitions.

As we look at debt capitalization and leverage on slide 14, as of December 31, 2022, we have gross bank debt of $8.9 billion, netted against cash and cash equivalents of $706 million. We ended the year with a net leverage ratio of about 3.8 times, which ticked up from the 3.6 times we reported at the end of the third quarter. That primarily reflects the combination of the strength of the euro and the impact of the fourth quarter 2022 results. Given our adjusted EBITDA guidance for 2023, which I'll discuss in a moment, together with the currency impact on our euro-denominated debt, leverage is likely to be stubborn in 2023. In fact, given the inevitable math of this past quarter's inclusion in our LTM EBITDA calculation during the upcoming quarters, we could see leverage tick higher before leveling back down by the end of the year. This doesn't have a significant impact on our capital allocation priorities, given the strong cash flow characteristics of the business.

So, let's turn to slide 15 for a moment and take a closer look at cash flow. When we reported our third quarter financials, there was still a lot of noise in the September year-to-date cash flow numbers stemming from some transient spin-related items. This is washing out and you can see that in the fourth quarter, our free cash flow generation was very strong. In the full-year 2022, there was about $300 million related to non-recurring spin-related working capital build early in the year. And if you recall the discussion from last quarter, we said that a good portion of that $300 million was actually expected in late 2021, but instead landed in early 2022. With the spin-related build largely behind us and reaching what we expect to be a more normalized ebb and flow to our working capital position, we saw a significant improvement in Q4 cash generation.

The other driver was foreign exchange translation. Consistent with weakening of the US dollar, we had a positive impact of $100 million in the fourth quarter from foreign currency cash balances within our global liquidity management program and that partially offset the $160 million headwind we had experienced year-to-date September. But the key message here is that, putting aside the $300 million of working capital build that should not repeat in 2023, our free cash flow ex-one-time costs related to the spin-off is in that north of $1 billion range that we communicated at the time of the spin.

Our capital allocation priorities remain consistent with past communications. We will continue to prioritize servicing the current dividend, followed by pursuing organic growth through lifecycle management opportunities within our current portfolio of products. Capital expenditures in the range of 3% to 4% of revenue remains a good estimate for forecasting purposes, with that capital going to modernizing and growing our production capacity, standup-related investments like our global ERP implementation, and other strategic investments in the business.

With these priorities satisfied, we expect to have significant remaining cash flow available as we continue to balance external growth opportunities against our commitment to our BB/Ba2 rating. Having a higher leverage ratio at points during 2023 likely raises the bar on business development as it competes for capital. But even without discretionary debt repayment, which we've done twice as a standalone company, we can still get deals done and stay within the parameters of our rating, much as we have been doing since the spin-off.

Now turning to 2023 guidance on slide 16, where we highlight the items driving our 2023 revenue guidance range of $6.15 billion to $6.45 billion. Beginning with LOE, we expect an approximate $50 million to $75 million impact for full-year 2023, which reflects the continued impact of generic competition for NuvaRing. This also includes an impact from Atozet which will go LOE in Japan in 2023, as well as a provision for Dulera, where we expect a generic entrant sometime in late 2023 after not seeing one in 2022 or 2021.

We expect impact from VBP to be in the range of $125 million to $175 million in 2023, driven mostly by the inclusion of Ezetrol in this latest round. We expect approximately $75 million to $125 million of price erosion in 2023. On a total company basis, we've been able to stem pricing pressure a little better than we thought at the start of last year. Over the longer term, we would expect pricing erosion to be in the range of 200 to 300 basis points of headwind, and that is mostly related to mandatory pricing decreases in certain markets and smaller LOE impacts, but also due to product mix. So, for example, as Biosimilars becomes a bigger business within Organon, that will put more pressure on price.

And for volume, we expect growth of approximately $500 million to $600 million for the full year in line with what we saw in 2022. The majority of the volume increase is expected to come from our multiple growth pillars; Nexplanon, Biosimilars, fertility, China retail, and to a smaller degree, recent business development activity including Jada. Given where FX spot rates are trending, we would expect a more modest impact from foreign exchange translation in 2023 compared with 2022. We're estimating an approximate $50 million to $100 million impact from FX for the full year, which would represent about a 1 percentage point headwind. That means that our guidance range implies constant currency revenue growth of approximately 3.5% at the midpoint.

Moving to the other components of guidance on slide 17. We expect adjusted gross margin to be in the low to mid-60% range, which is modestly lower than where we finished 2022. As I've talked about previously, much of the inflationary impacts from 2022 were held in inventory and, therefore, have a greater impact to our cost of goods sold this year in 2023. On operating expenses, our ranges for SG&A and R&D as a percentage of sales are in line with what we guided to and delivered in 2022 and reflect continued investment in the business as we position it for future growth.

Our estimate for R&D expense includes line of sight to about $40 million of IP R&D expense that's tied to the $8 million investment we made in Claria Medical in January, plus an estimate for a milestone achievement for ebopiprant in 2023. Any upfront payments related to future business development will be incremental, and we would call that out in our announcement of any such transactions. Those OpEx assumptions would bridge you to an adjusted EBITDA margin in the range of 31% to 33% for 2023.

For below the line items, given the increasing interest rate environment, we have increased our estimate of interest expense for 2023 to approximately $510 million. The knock-on effect of higher interest expense also means that we hit a cap with regard to interest expense deductibility for tax purposes. For 2022, we actually finished on the low end of our tax expense guidance range. So, for 2023, our non-GAAP effective tax rate range reflects a normalization of expectations for tax expense, plus the incremental expense for limitation of interest expense deductibility.

Wrapping up the financial discussion, 2022 was a very solid year for the company. In addition to all the operating accomplishments Kevin mentioned, as we advance Organon's mission in Women's Health, on the financial front, we delivered constant currency revenue growth of 4%, which is well-aligned with the mid-single digit expectation we had for the year. We deployed over $200 million of capital across four promising transactions to drive future revenue growth. We proactively retired $100 million of debt. And we returned $290 million in cash dividends to

shareholders. We're looking forward to 2023, where we expect to deliver continued growth and strong capital performance based on the earnings guidance we're providing today.

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

QUESTION AND ANSWER SECTION

Operator: [Operator Instructions] Your first question is from the line of Terence Flynn with Morgan Stanley. Please go ahead.

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

Q

Good morning. Thanks for all the color and thanks for taking the questions. I guess, just as we think about Nexplanon for 2023, can you just walk us through how you're thinking about what's embedded in guidance, both on the US side and ex-US? And then Follistim was somewhat soft this quarter. Was just wondering if there's anything of note there, and then how we should think about that product on the forward as we go into first half of this year? Thank you.

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

A

Yeah. Thanks for the question, Terence. I'll take that. Look, as we start to think forward in terms of what we're doing with Nexplanon, we're very pleased with two consecutive years of double-digit performance. Of course, we had somewhat of a strong buy-in in the fourth quarter of last year. So, we expect the first quarter, as usual, to be a little bit soft, but ultimately, going forward, we see really very strong – at least in the US as well as ex-US, very strong demand growth coming. In terms of physician demand growth, we're able to kind of pick up and monitor now that we feel very good about the fact that the chances of Nexplanon continuing to grow – growing in a very solid way is something that we feel very good about.

Our ex-US business continues to grow because of the fact that it was very deprioritized in years past, and we have opportunities to really continue to drive access and, ultimately, awareness of Nexplanon throughout the world. And, of course, when we start to go outside of the US, you start to see more, kind of a lumpiness to the overall orders, because there's a lot more tender business that's being involved here. But when you look at the US, we're really very happy with what we're seeing in terms of our DTC campaigns, our social media campaigns, and all the things that we're doing in terms of our clinical training programs and continuing focus on really kind of driving prescription depth in physicians who are currently very comfortable with Nexplanon.

In terms of Follistim that you asking in terms of the – I guess, was it fourth quarter softness in terms of Follistim? Look, we have very strong In terms of Follistim growth in the US performance but, ultimately, the softness came in Q4 from China. As you can well imagine, when China started the lockdown, and then ultimately after the lockdown, when you started to have a real increase in terms of COVID infections, it really started to inhibit the opportunity for couples to go to the IVF clinics in order to be able to get their therapy. But we expect that to ultimately turn around in this year. We expect a very strong Follistim business in China for this year, as we start to rebound from all the COVID lockdowns and, ultimately, the COVID infections that are essentially kind of burning through China as we see it today. Hope that answers your questions.

Operator: Your next question is from the line of Umer Raffat with Evercore. Please go ahead.

Umer Raffat
Analyst, Evercore Group LLC

Q

Hi, guys. Sorry. Thanks for taking my question. Maybe a couple, if I may. First, on 2023 guidance, could you clarify how much Humira in the number or not, as well as sort of the ongoing China reopening and sort of what you've baked in? I think that'll be very helpful.

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

A

Well, we don't – Umer, it's good to talk to you, but we don't usually kind of talk about exactly sales numbers from individual products from Humira or for Hadlima, but we feel very good that this coming year will be a solid year for Hadlima on a few fronts. One, Canada and Australia continue to do very well in terms of their overall continuing progression, in terms of their performance, strong double-digit growth outside of the US for Hadlima. And second, we'll have half of the year of Hadlima sales, Umer, in the US. I've been saying this for some time, 2023 will be more of a race to get on formularies of the top PBMs in the country, as well as potentially some of the closed systems like Kaiser, other HMOs and also [indiscernible] (00:36:44) the VA. So, it is something that we feel very comfortable about that we'll do well because of the product presentation.

As I mentioned in my commentary, in terms of the introductory commentary, you really want a product, and we believe the products that are going to win are ones that are the closest to the originator. We are about as close as one can get in terms of having the high concentration, citrate free, low concentration. We're talking about the frictionless experience with the device and pen, our strong ex-US real-world evidence, so that PBMs can feel comfortable about the safety and security of what they're using in terms of this product. So, we feel very good about Hadlima going forward in terms of what we're doing there.

And regarding China coming back, look, we've got really good growth drivers in China. As I mentioned earlier to Terence, we've got fertility recovering. We've got the Marvelon business that is continuing to really ramp-up very well. We've got the retail business starting to come back online, because people are coming back to that. We've got the online business going very well. So, that will offset some of the big headwinds that we're facing with the seventh round and, ultimately, hopefully, we'll see what happens in the eighth round that is estimated for the Q2 period.

But, we feel very good that we'll be able to offset and we've never had a year right now recently with the recent rounds of VBP, where we've actually started to see a decline. We continue to grow in China and, as we get through 2023, we estimate anywhere between 70% to 80% of our business will have gone through the volume-based procurement business [indiscernible] (00:38:27) procurement impact. And then, we see growth, really strong robust growth after 2023. So, 2024 and beyond, don't be surprised if you start to see high-single digit, low-double digit performance coming out of China.

Umer Raffat
Analyst, Evercore Group LLC

Q

Kevin, sorry, if I may just clarify, I think on China...

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

A

Sure.

Umer Raffat
Analyst, Evercore Group LLC

Q

...what I was referring to was, so I understand most of the products have gone through VBP. I guess, what I was getting at was, the pace of the VBP rollout got paused during COVID in China. So, with Zetia...

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

A

Yes.

Umer Raffat
Analyst, Evercore Group LLC

Q

...sort of still at about $300 million run rate, Vytorin at $100 million, et cetera, I'm just trying to understand how are you guys thinking about step down on these sort of $400 million franchises in China as rollout resumes on the previously conducted VBP, and what's in the guidance?

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

A

Yeah. Well, look, I mean, you bring up a good point. The round seven was delayed by a few quarters. And so, ultimately, that benefited us last year from our Ezetrol business in China. Now, it effectively went into effect November. So, we are seeing the expected erosion of Ezetrol as we speak right now, probably about a $90 million headwind this year from volume-based procurement for Ezetrol in China. The remaining products that we expect to go through volume-based procurement, round eight and round nine, essentially are much smaller products. They are somewhere in the $40 million range.

So if that – as you say, if there is the opportunity that those get delayed because of further ongoing COVID infections or whatever, could be the things that come as a result of what's happened last year, then the upside will be greater, say, for example, the delay that we saw with Ezetrol. But, that's why I mentioned, it could be anywhere between, say, 70% and 80%, depending on those rounds happening in the second and fourth quarter, but they're much smaller products. So, we went through most of the rounds that have kind of hit the big products have already happened.

Does that answer your question, Umer?

Umer Raffat
Analyst, Evercore Group LLC

Q

Thank you so much, Kevin.

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

A

Kevin, just to quickly revisit, for Umer's benefit, in the prepared comments back to Hadlima for a second. Umer, we did say worldwide sales would not exceed about 1.5 points of Organon's consolidated revenue. And while Canada and Australia are important markets, there are a lot smaller than the US. So, you can assume that that number is weighted towards the United States a bit.

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

A

Very good.

Operator: Your next question is from the line of Navann Ty with BNP Paribas Exane. Please go ahead.

Navann Ty
Analyst, Exane BNP Paribas

Q

Hey, good morning. Thanks for taking my questions. I have a few, starting on Nexplanon. In the US, do you expect to continue to take market share following the Dobbs news and from both the oral pill and IUDs? And can you share how many healthcare professional do you expect to train this year? And also, am I right there was no Nexplanon tender in the fourth quarter outside of the US, and do you expect a tender in Q1? And then separately, do you have a net leverage target that you can share, and could we see some term loan prepayment in 2023? Than you.

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

A

So, let me let me start with the Nexplanon questions. You're right, Navann. In Q4 of 2021, we saw a big tender from Mexico. That tender came through in Q3 of 2022. So that's why you didn't see really the tender business for the ex-US business in Q4. We do expect, probably in the Q3, Q4 timeframe, more of the tender business kind of ramping up in the emerging markets, whether that be in Mexico or Brazil and others. So, you look for that. Probably, in the second half of this year, we'll start to see bigger tender activities coming through in the year. In regards to Nexplanon and kind of the post Roe v. Wade opportunities, we do see and I've been able to see that, actually, with Nexplanon in the US, what I would call those states that have restrictive policies around abortion or around access, we're seeing about high-single digit growth for Nexplanon in those states.

Those that are kind of more kind of protective of the opportunities are probably mid-single digit growth rates right now. At least, that's what we saw post the decision versus pre. So, I do see that there's opportunities to continue to grow. I've always felt that that when we think about what physicians and patients are going to be wanting in states where it's quite restrictive, I would think that real-world efficacy, and I mentioned 99% effective, you take the decision making out of the daily issues in regards to their contraception needs, and I do feel that we'll continue to see additional growth kind of accelerating from some of these states that ultimately have the restrictive policies. And the last question in regards to clinical training programs, we did, as I mentioned, in 2022, we trained 20,000 healthcare providers.

Now, that could be physicians, nurses, PAs. Many of those – some of those, actually, were retraining for people that needed to kind of get refamiliarized as the COVID lockdown started -or as people started to come back into the clinics. But, we'll continue to invest in clinical training programs going forward. I would say, there's going to be an average of anywhere between 15,000 and 20,000 per year that we'll be averaging going forward for healthcare providers, both new to prescribing Nexplanon, and those that need refresher trainings in order to be able to feel more comfortable with inserting and using Nexplanon with follow-on reviews.

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

A

And I can take the part of the question related to leverage. So, since the spin-off, we've been soft targeting a net leverage figure of 3.5 times. The business had worked its way down to that level during the course of 2022, mainly related to the favorability we saw on the euro-denominated debt as the dollar strengthened and that will – that's one of the dynamics that's reversing in 2023. We called that out in the prepared comments. But around that 3.5 times leverage target, as we think about 2023, we will be balancing the benefits of voluntary debt reduction

against what we see as the business development target landscape, and our ability to increasingly self-fund our own deals. As the year goes on, our cost of debt has risen. So, we will continue, I think, Navann, to behave as we've done since the spin, and we'll look to bring balance to that. As I said in the prepared comments, the hurdle – sort of the bar has risen as business development competes for capital against the near term and certain benefits of debt reduction.

Operator: Your next question is from the line of David Amsellem with Piper Sandler. Please go ahead.

David Amsellem
Analyst, Piper Sandler & Co.

Q

Many thanks. So, I had a few; first, on the revenue bridge for 2023 guidance. Regarding the volume growth, can you talk about the extent to which that's coming from Established Brands, and maybe talk in more detail about where the drivers are in Established Brands, as you think about volume? That's number one.

Number two is, apologize if I missed this, but just remind us, when you think you can get interchangeability in the US for Hadlima and just talk about progress towards that?

And then, lastly, on business development, I think you talked about a lean towards the acquisition of EBITDA-generating assets. I wanted to pick your brains on that and see what your appetite is in terms of commercial-stage assets vis-à-vis development-stage assets and how you're thinking about that? Thank you.

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

A

So, I can address the first two questions in regards to volume. Where's the volume growth coming in 2023 to the bridge? We definitely see non-volume-based procurement products. So, these are out. They're not part of the list. So, that will continue to be a driver. The retail sector in China will continue to be a driver. Atozet continues to grow very well for us in Europe, and now in China as well. Respiratory products continue to grow very nicely in terms of our overall volume growth. So, you see that – and then we've got some of the other smaller countries. And from regional perspective, our Latin America, Middle East, Africa and Russia business continues to grow pretty robustly in terms of our own volume growth opportunities. So there are continuing volume growth chances that we'll see that continue for Established Brands. And then, of course, we talked about some of the downsides in regards to the China VBP around that can ultimately offset some of the growth opportunities that we have in volume.

The second question that you had was, I believe, around – what was it? Oh, the interchangeability, yeah. So, interchangeability, we expect that to come probably Q2, Q3 2024. So probably, literally, one year after launch as of July of this year, which is really around the range of where everybody, at least many of the major competitors are going to have their interchangeability come through. But I want to be clear though. In my discussions with many of the PBMs, at least in the first year or two, interchangeability was not a key point of differentiation. As long as you had it in process, as long as you had it within that you could kind of make sure that everybody understood that you were going to be able to deliver interchangeability within a reasonable timeframe, that would kind of put off the table. Then, we started to get into many other concepts or product delineations that ultimately means that we're much more compelling for them.

David Amsellem
Analyst, Piper Sandler & Co.

Q

And then on biz dev, M&A?

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

A

Yeah. So, Matt, do you want to take that in terms of EBITDA...

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

A

Yeah, sure.

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

A

...question that David has?

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

A

Yeah, yeah. So, David, we've been seeking balance in the program between early, mid, late-stage assets. We have had a preference to be looking at more latter stage or currently marketed opportunities. So, as 2023 unfolds, don't be surprised if you see our capital deployed for business development [ph] sling (00:50:10) towards things that are more near term, especially since the last deal we did was Claria Medical, which is certainly early stage.

David Amsellem
Analyst, Piper Sandler & Co.

Q

Okay. Helpful. Thank you.

Operator: Your next question is from the line of Chris Schott with JPMorgan. Please go ahead.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

Ah, great. Thanks very much. Just two for me. Maybe first on Hadlima, can you just talk at all about how you see the market evolving in 2024 and beyond? I guess, specifically, have there been any changes in terms of how you think about the size of the biosimilar market you're ultimately going to see here, as you kind of think about where price is going to land, and how much volume is ultimately going to be accessible for the biosimilars?

And then my second question and, Matt, I know I've asked this in the past, but when we think about the EBITDA margins you're laying out for 2023, can we kind of think about these as starting to represent kind of a trough level of margins, and that as maybe top line growth continues over the next few years, we could start to see margin expansion from here? Or is there more investment that needs to go in the business to kind of really fund that longer-term kind of growth ambition that you have, and that maybe we need to think about margins still kind of under pressure over time? Thank you.

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

A

Thanks, Chris. I can deal with the Hadlima question, and I'll turn over the other question to Matt. Look, as I mentioned before, we believe the 2023, as you've seen from – a couple of the PBMs are basically saying that they're going to allow, obviously, the originator. There's no preferential treatment there for biosimilars. And so, as a result of that, when you're able to choose whatever you want, people will likely go with the originator, at least in

2023. And so, I believe that 2023 is going to be about which two to three biosimilars are going to get on to those formularies.

And then, we believe that our profile in terms of the high concentration, citrate-free, and the low concentration, having the full profile, real-world evidence, a patient-centric device experience by the way with the immunology organization or rather immunology business, and our deep, deep knowledge of rheumatology business across – a rheumatologist across the country, positions us in incredibly strong position to be one of those two to three products that are going to be listed on formulary.

Now, what will likely happen? Obviously in 2023, as I mentioned, this will be a lighter ramp-up year. You're going to be trying to fighting for formulary position. There will be obviously discounts that will be offered. I'm sure that the originators will be doing that in terms of kind of being more aggressive with discounts. Going forward, I do believe that volume will not retract. I think there'll be opportunities not only for the switching of the Humira volume, but also I do believe that PBMs will look at this opportunity for other such products, whether you're talking about other anti-TNF where the opportunity is there to go to a biosimilar first. So, the potential for volume and also, by the way, because of the lower price, you will be able to get patients who weren't really essentially thought of for anti-TNF treatment to be using now anti-TNF treatments.

And so, with high-quality anti-TNF biosimilars on the market, I think volume will be there. But the question is, what kind of rebates, what kind of discounts will be provided? Clearly, as we go forward in 2024 and 2025, there's going to be more of an expectation that the originator, the Humira will start to move off of formularies, as we see in the rest of the world. And then, you'll ultimately see bigger discounts being provided but also, ultimately, the volume opportunities will still exist. That's the way I see it. 2023 is a lighter ramp-up year, formulary accession. And then, 2024 and 2025, it'll start to open up. Bigger rebates, bigger discounts, but more volume opportunities for biosimilars. Matt?

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

A

I'll take the second part of the question. So, this is a dialogue that has been ongoing with investors really since the spin. When we launched, our P&L had really zero space in it for product development type expenses that could drive ongoing future revenue growth. And so, we've been slowly and steadily reintroducing those as the quarters have evolved. And, Chris, in direct answer to your question, when I think about the 31% to 33%, I think – and how much lower that might go, it depends on how and what kind of business development that we do.

But, I would say, as we look at the range for 2023, the low side of that range is starting to feel like the nadir, because at EBITDA margins like that, we've got R&D as a percentage of revenue that's right in that 9% to 10% range. We've got promotional type expenses built into our SG&A that start to feel sustainable and ongoing. And so, at this point in time, with the kind of scenarios we've been running on what future business development might look like, the low side of that range is starting to feel like the nadir, as we think about five-year strapline horizon.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

Great. Thanks so much.

Operator: Your next question is from the line of Chris Shibutani with Goldman Sachs. Please go ahead.

Q

Hi. This is [ph] Dan (00:55:47) on for Chris. Thanks for taking our questions. Just a couple [ph] of those (00:55:50). First on just business development with regards to Biosimilars. I guess, should we think that you guys are as potentially competing on some of the other biologics [indiscernible] (00:55:59) over the course of the decade? And if so, doing deals similar to the Samsung deal, kind of the 50/50 split. And then just on cash flow for 2023, I just want to confirm, should we think of this year as still kind of somewhat one-time impacted, but close to the $1 billion plus number, and then $1 billion plus starting 2024, or is the 2023 kind of above in kind of the $1 billion plus range of that? Thank you.

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

A

So, [ph] Dan (00:56:28), let me address the business development strategy for Biosimilars. Look we're very much committed to Biosimilars. Obviously, we're launching our Humira biosimilar in a few months from now. But we're also – we made the deal with Shanghai Henlius to bring in two other biosimilars and with potential opportunity to get into the Yervoy biosimilar race as well. Look, for us, it is a key. The key is order of entry. And so, rest assured, we are looking at every major potential opportunity when it comes to doing business development, and we've got a lot of ongoing discussions as we speak. So high probability of success in terms of getting to market.

As long as your order of entry is in the first tranche of launches, you can do very well and that sales curve can last anywhere between three and six years. Look at Renflexis, we still grow double-digit with Renflexis after five years of launch in the US, and that's our largest biosimilar to-date in terms of our sales. We expect Hadlima to, ultimately, when peak starts, to emerge for Hadlima sales to be the second largest product for Organon. So, you can kind of see that we see an opportunity. And in terms of profit sharing or rather margins, we're going to do our best – as you can well imagine, to continue to do the best we can for our shareholders, and the best we can for what we bring to the market. So, we'll continue to swing away at bringing more and more to the market for what we do with Biosimilars.

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

A

And then on the subject of free cash flow, we spent some time talking about it in the prepared comments. When you look at our performance this year, were it not for that working capital build that was spin related, you would've seen us in the north of $1 billion range before one-time items. We think that improves a little bit during the course of 2023, but we will still have one-time cost of about the same magnitude as we saw them in 2022. And that, as we're moving into the latter stages of the TSA agreement with Merck, we are right on target. We are kicking off and standing up all the activities we need to. The biggest driver now of one-time cost is our global ERP implementation. That's one of the biggest drivers of the one-time cost in 2023.

Operator: Your next question is from the line of Steve Scala with Cowen. Please go ahead.

Steve Scala
Analyst, Cowen and Company

Q

Well, thank you very much. I have two questions. Nexplanon missed double-digit growth expectations set early in 2022. Those expectations were reiterated at mid-year and never stated to be a constant exchange. You mentioned some pushes and pulls, but presumably, they were anticipated six months ago. So, what factors led to the shortfall in 2022 for Nexplanon? So that's the first question.

The second question is similar to questions I've asked in the past, so apologies for asking again. But with the view that the future of the company is in Women's Health, the pace of Women's Health business development deals is strikingly low, seven deals in seven quarters of public existence. I know you won't do all 140 deals originally identified, but if you did, it would take three more decades to complete them all. Was this pace that we've seen always the plan, or have things been more challenging than expected? In my humble opinion, I think the pace of activity in Women's Health needs to increase exponentially. Thank you.

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

A

Good to talk to you, Steve. Let me address Nexplanon. We always basically signal to the world that we expect a double-digit growth. We achieved 11% growth in 2022, and that is always at a constant currency, or rather ex-exchange basis, because we don't know what's going to happen with currencies on a month-by-month basis. And it was kind of hard if you're talking about at the beginning of, or rather at the end of last year to see what would happen with the dollar strengthening to the point where it was throughout the year. So, on an ex-exchange basis, we did grow 11%; 8% in the US, the remainder outside of the US. Ex-US business was responsible for 50% of our growth. So, we're feeling very good about where we landed with Nexplanon. It's consistent to what we essentially have guided and the language that we've used.

And, in terms of your second question in regards to the opportunities that exist right now in the Women's Health space. As I mentioned earlier days, we look at Women's Health from three points of view. One, with therapeutics. Two, with potentially devices. We're agnostic of whether it's a device or a therapeutic, and those are focused primarily uniquely for Women's Health-related conditions. But we're also looking at conditions that, what we would consider, disproportionately impact Women's Health and women, and that would be anything from celiac disease, lupus, migraine, osteoporosis, the list goes on and on and on, chronic cough. So that's always potential opportunity for us to use our capital allocation, our business development dollars.

Now, I will say to you, though, this is rare, because most of the time that when I say we've done eight deals in literally a year-and-a-half, that's almost a deal every two months. I would say that we feel very comfortable. And as you start to layer on some of these assets with the business – organic business that we're driving, with the opportunities that we have, not only in lifecycle management opportunities which are really plentiful, but also with the biosimilar businesses that we're bringing in, we see an opportunity to really continue to grow the growth momentum for the company going forward in the future.

Steve Scala
Analyst, Cowen and Company

Q

Thank you.

Operator: Your next question is from the line of Greg Fraser with Truist Securities. Please go ahead.

Gregory D. Fraser
Analyst, Truist Securities, Inc.

Q

Good morning, folks. Thanks for taking the questions. Following up on BD, you've done a number of deals to expand the pipeline with assets for new indications beyond your core Women's Health business, like endometriosis and preterm labor, and I know you're bullish on the potential of those programs. Are you looking to add additional programs for those indications, so you have more shots on goal? Is that something investors should expect? Or are your BD efforts in Women's Health more focused on new here? Thank you.

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

A

Well, I got to say that shots on goal is always a nice thing. The acquisition we had for Forendo has got a couple of molecules. Our OG-6219 asset is one that is furthest along, but they also have other backup compounds as well. We like the mechanism of action of this new product, of this new mechanism. It has great promise. So, yes, I mean, wherever possible in terms of we're making acquisitions, we'll see whether there's backup molecules that we potentially can take to the clinic, if our primary molecule fails. But we're also expanding, as you said. We went from essentially being in contraception and fertility to add a number of different therapeutic areas; postpartum hemorrhage, preterm labor, endometriosis, polycystic ovary syndrome, bacterial vaginosis; now, with our device with Claria for minimally-invasive laparoscopic hysterectomy. So, there's a number of different areas we continually identify as opportunities that both, meet a need in the market and need innovation in the market. And we believe that we're really very well primed to take on that leadership role.

Operator: And today's final question will come from the line of Jason Gerberry with Bank of America. Please go ahead.

Bhavin Patel
Analyst, Bank of America

Q

Hey, guys. Good morning. This is Bhavin Patel on for Jason Gerberry. Just two questions. First, I wanted to get a sense of Nexplanon growth outlook that's assumed in the 2023 top line guidance? Given that something you've provided in the past, I guess, it is still double-digit growth. And then the second question is whether it's safe to assume that Organon plans active in M&A this year? Given that leverage ratio considerations, do you expect to do a big deal in 2023? Thank you.

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

A

Thanks for the question. Look, I'd say that, first of all, I'm very happy and satisfied with the performance since we spun-off two consecutive years of double-digit performance. Our focus in 2023, we're really going to be increasing our focus on patient demand. We'll, of course be – we'll be pushing for as more robust as we can for the product. We continue to see ex-US business growing faster than the US business. We're continuing our clinical training programs, follow-on reviews, our DTC campaigns.

So, we believe that Nexplanon; A, will continue to grow robustly over the years. And second, we are also focusing on the fact that this is going to be our first $1 billion product essentially by the end of 2025. That's the run rate that we're going forward. We feel very good about that. And so, this is going to be a long-term asset for us. January demand is strong in terms of our overall physician demand. So, we feel really good about Nexplanon.

I'll hand over the last question to Matt for answering.

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

A

Yeah. So, we fielded this question a few times on deal size, and we've obviously had very good success with the smaller deals that we've been doing. They're plentiful. They're a little bit easier to integrate. The rising interest rate environment; our leverage ticking up does, I would say, make deals incrementally more challenging at the margin. But, with respect to big deals, we've always been in the same place, which is, we're not necessarily out hunting

them, but we are aware of possibilities, we think creatively, and we would not shy away from a larger opportunity, if we really felt it was a compelling shareholder value creation.

But we've got a lot of organic growth plans in place for 2023, as well as execution of the eight deals that we've already done. So, 2023 is going to be an exciting and busy year. But, like I said, as far as big deals go, we are aware of them, we're open to them, but it's not necessarily something we see as either necessary for our success or a priority.

Bhavin Patel
Analyst, Bank of America

Q

Thank you.

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

A

Thank you.

Operator: This concludes the Q&A session. I would now like to turn the call over to the company's CEO, Kevin Ali, for closing remarks.

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

Well, thank you for all the thoughtful questions. I do want to close by saying, look, today marks our seventh quarter of earnings as a standalone company. With the fourth quarter of 2022, we've continued our track record of delivering exactly what we set out to achieve. Our vision of a sustainable, growing business is being realized. We have confidence in the portfolio we have in our hands today, and we believe in the potential of our growing pipeline of assets with the promise to address significant unmet medical needs, especially for women. I want to thank you for joining us today, and we look forward to communicating our progress with you in 2023. Thanks, everyone.

Operator: Thank you, all for joining the Organon fourth quarter and full-year 2022 earnings conference call. We thank you for your participation. You may now disconnect.