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Organon & Co. (OGN)

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OTHER PARTICIPANTS

Chris Schott

Analyst, JPMorgan Securities LLC

MANAGEMENT DISCUSSION SECTION

Chris Schott

Analyst, JPMorgan Securities LLC

Good afternoon, everybody. I'm Chris Schott at JPMorgan and it is my pleasure to be hosting this fireside chat with the Organon management today. From the company we have CEO, Kevin Ali as well as CFO, Matt Walsh. Kevin and Matt, Happy New Year. Thanks for joining us again today.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Yes.

QUESTION AND ANSWER SECTION

Chris Schott

Analyst, JPMorgan Securities LLC

Q

I thought Kevin maybe just to kick off, would be interested in just maybe some bigger picture thoughts on the business heading into 2024 and then we'll dive into the specifics of the business from there?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Sure. Well, I think Chris and thanks for the introduction and for hosting this. I think you saw – actually just yesterday we had an announcement that we made at JPM, a press release where we essentially did a few things. One is, we reaffirmed our guidance for 2023. And also we said that our cash position is probably going to be a little bit better on the high side in terms of our range for 2023. And then we kind of gave a soft nuanced guide for 2024...

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Yes.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Where we talked about low single-digit growth on the revenue line as well as, we're working towards stabilizing our EBITDA margin and maybe potentially even increasing basically you see an increase in our EBITDA going forward. So I think that's moving well. And we actually made a business development announcement recently just a couple of weeks ago with our deal with Lilly for Europe for their migraine assets in which is we're very excited about.

And so, as you go forward, we'll start to see more of a focus on delevering, a focus on doing these – more of these type of Lilly deals, where we have been very successful with bringing those kind of deals in. And ultimately we see really good growth with our biosimilars business, continued stability and growth with our Women's Health business and a stabilization and even a little bit of growth on our Established Brands. So we're in good position.

QUESTION AND ANSWER SECTION

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Excellent, excellent. Lot going on, lots to dig into here. So maybe starting off on Women's Health, I just like to talk about positioning of the Women's Health franchise and your confidence in the growth outlook there. I guess maybe as part of that, just any learnings from the past few years as you kind of [ph] stepped (00:02:24) the company that you can think about applying to the portfolio going forward?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Yeah, I think overall, we're still very focused on trying to define Women's Health in a very different meaning that the fact that Women's Health is really the health of women in the sense that it doesn't necessarily mean that we have to do business development activities around just those conditions unique to women. But like the Lilly deal, we can expand to those conditions disproportionately impacting women.

Like, for example, migraine, where three quarters of the patients or so are women versus men. So migraine, osteoporosis, number of different other areas that are tangential to Women's Health. So as we start to expand the definition of Women's Health, we ultimately have plenty of opportunities for inorganic opportunities to continue to drive the business forward.

But what we see is fertility in spite of where you see, for example, no patent protection in the fertility sector, it continues to grow high single-digit, has tremendous opportunity in the Asia-Pacific region, especially China, now that they're starting to reimburse for more fertility treatments.

So that's an opportunity for continued growth. US that business is moving now to a more reimbursed business. So PBMs are getting more involved. So price is at stake, but at the same time you get a lot more volume. So fertility is very robust. We obviously have our Nexplanon business that continues to grow. We didn't take price in 2023, but we'll be taking price in 2024. So you'll start to see really a nice solid growth for Nexplanon in 2024 versus 2023.

Jada now, our device that we had done with the acquisition of Alydia is now kind of over \$40 million for 2023. And so it's on the right track. And will definitely you'll see peak revenues for Jada of about \$150 million in US and probably \$250 million all total for global sales for Jada ultimately, as peak. XACIATO our collaboration with Daré as a unique product for the treatment of bacterial vaginosis, of which 20 million women in the US suffer from that condition.

And very – a lot of dissatisfaction in there. We launched that in November. You'll start to see more of that business start to trickle in into 2024. And this time next year, we'll hopefully be turning the card over on our OG-6219 asset, which is a completely new mechanism of action and unique new product for the treatment of endometriosis. We'll see where that goes, but we're actually looking forward to that.

So overall, I think it's a nice business to be in. There's tremendous opportunities for growth as you expand the definition of Women's Health. And we continue, I think to do the right things to really stabilize and grow that business.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Great. Touched on a lot of things there. Maybe first on Nexplanon, can you just elaborate a little bit more on your growth outlook for that one, both US and ex-US?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Yeah, for 2023, it was the year where we didn't take price in the US and the...

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Yeah.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

...US represents about 70% of our business. So it's clearly very important for us. And by doing that, we did that for a very specific reason. Most of the competition, actually the long-acting reversible contraception business takes price in the first quarter of every year.

It was historical precedent from Merck doing that and ultimately we decided to move where the competition is because that's when the state reimbursement list gets updated.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

So we wanted to make sure that customers are not really out of pocket or underwater for that short period of time. So we decided not to take price. So you'll see price be more of a factor in 2024 and the underlying volume continues to be low single-digit growth. So the direction of travel for Nexplanon is that it will reach kind of a steady state of a \$1 billion product by the end of 2025. If you annualize it at that point and we've got at least to the end of the decade to really make some good business, continuing business. And that's our blockbuster product.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Yeah. And can you latest on the timing, I know you're working on the five-year study and...

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Yeah.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

...when should we expect some updates there?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

2025 is the year we'll be able to, I think, be able to submit.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Okay.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

And then we'll probably launch that five-year indication in 2026, which will take the exclusivity period in terms of – for the five year indication until 2029.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Okay.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

That's ultimately the plan.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Yeah. Do we have to think about pricing dynamics shifting around at all as you kind of go from a three year to five year and kind of just I know it's a few years out, but how do we think about that?

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Yeah. We haven't taken a decision formally on what we do with price, but we'll likely take price with the new indication coming. And that gives us an opportunity there because a lot of work has gone into the five-year indication.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Okay. I think you mentioned the Jada System and some of the peak sales opportunities. Just elaborate a little bit more on what you're seeing with that and how you kind of get to the peak sales opportunity for that asset?

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Well, that was a real learning opportunity for us, because realizing that this is a hospital product, you need to get formulary acceptance, you need to start to train physicians ultimately to get it into the labor and delivery suite so that it's there as a default kind of for patients or for physicians. Now, 45,000 women have been treated with the Jada System since launch.

A

That's a great thing because of the fact that that means that less women would have to have other transfusions or potentially more morbidity and mortality associated with postpartum hemorrhage. And so as we start to kind of get now almost to the point where 80% of those centers that we wanted to have access and we have now access in Tier 1, Tier 2 and Tier 3 hospitals.

Now, we're talking about in 2024 and beyond getting depth of prescription in each one of those centers. So right now, it's more about driving share, driving penetration as opposed to getting new accounts lined up.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay. And then on the pipeline, you mentioned [ph] one of the (00:08:21) assets, but just holistically [indiscernible] (00:08:22) question I have is, you did this Lilly deal. How much of the incremental portfolio here should we think about things more like partnerships that you saw with Lilly versus – and you've got some internal assets, but continue to build out the internal pipeline of the business?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Look, I think the way that I would look at the business going forward holistically is the fact that 2024 is a year where we don't see really any – you never know when it can potentially be made available. Any transformative M&A activity...

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

...going forward in 2024. We've really kind of looked at everything right now. And right now the year-end 2024 is really about and we reaffirmed our commitment to pay the dividend going forward. And that's what we're going to be doing. And that's we've got plenty of cash at our disposal in order to be able to pay the dividend comfortably, but really to focus on execution, delivering, incorporating some of these new business development deals, continuing to move our Nexplanon business, fertility business, drive our Hadlima biosimilar business and really have a stable kind of year ahead of us in terms of being able to deliver the growth on the top line and hopefully on the bottom line.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

And obviously, better in terms of leverage. So as we go forward, though, we'll be looking at business development in two ways. One is, we'll do those deals like the Lilly type of deal...

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Yeah.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

... and the Marvelon, Mercilon deal and other deals we've done. We'll do those all the time.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

They are very nice, very high probability of success, low entry cost. They deliver accretive sales relatively fast. We have the scale across the world as a global footprint in order to pull those products in and really kind of do well without essentially adding more cost to the base. So we'll do those deals. Those are always things that we're looking at. Sometimes it'll be regional, sometimes it'll be like China for China deals, we're looking at as well. Sometimes they may be global in nature and then we'll always be looking for that transformative deal. And then ultimately, if we do something like that, everything is on the table. But it will be the kind of deal people will say, I get it, make sense.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay. That seems like that's maybe [indiscernible] (00:10:27)

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Yeah that's further out...

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Yeah.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

... that's further out as we start to stabilize and delever the company.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay, that's helpful. [ph] Maybe kicking (00:10:35) over to biosimilars.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Sure.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Obviously, a lot of discussion around biosimilar HUMIRA as we went through 2023. Just latest in terms of how you're thinking about market dynamics for that opportunity?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

You know, I was sitting here a year ago, and I was actually the person who was kind of signaling that it's going to be a slower uptake, people should be ready for that. And I think a lot of people were very bullish and I was more kind of being conservative that I said, the market will take some time to form because it is a hospital, rather a pharmacy-driven dispensed product. And so the PBM work – world works a little differently.

The way I look at it going forward is the following, is that currently there were about six or seven biosimilars that were launched in July of 2023 and then there was previous January Amgen launched their biosimilar of HUMIRA. We are now number one biosimilar of HUMIRA, albeit it's a smaller scale business that is growing.

We beat everybody else and clearly the value proposition that we've come to the market with has been picked up. But it's going to take time in order for those PBMs, as well as what I would call the low WACC type of businesses Medicaid, Medicare, [ph] Blue Cross Blue Shield, VA, prisons (00:11:45), all those things that kind of look for the lowest net price. We fit into that world very well.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay, okay.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

We also fit into the PBM world. You saw what's happened recently with the CVS announcement with Cordavis. So there's a lot of activity, a lot of churn in that system. All of that means that 2024 is still a year of market formation. 2025, you'll start to see more of the pickup. So what I'm signaling is if the net revenue of HUMIRA at its height, let's say, \$20 billion of net revenue, if that ultimately comes down and I said last year to \$2 billion.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Yeah.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Right. And we're one of three. It's still a very good business for us. And it will get us to the place where we want it to be in terms of what we've said about our peak revenue for Hadlima in the US.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

When I look at that 2024 dynamic, it still [ph] seems you have (00:12:37) market build. Should we expect that there is steady progress on volumes or with some of the efforts we've seen on the AbbVie side, is it still going to be a pretty low penetration year?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

I think that you'll see sequentially more penetration quarter-by-quarter, definitely.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Okay.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

There's no doubt about that because that low WACC, low net cost business will continue to churn to want to be able to get to a place where they take on biosimilars as opposed to the Originator. So it's just going to be a slower build. So we'll reach that peak revenue, I've always signaled in a couple of hundreds of millions for the US, but it's a time continuum that gets pushed out of it.

A

Chris Schott

Analyst, JPMorgan Securities LLC

All right. And then just on the competitive landscape there, you've obviously pulled away from the competition. I think in terms of the share that's available. Do you see that we're going to end up with still seven or eight relevant players, or do you think we can start to see one by one some folks deciding not to compete here?

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

I've always said that there will be two or three that emerge...

A

Chris Schott

Analyst, JPMorgan Securities LLC

Okay.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

...ultimately at the end of the game.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Yeah.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

I still feel that way. I think that even PBMs, if – and any [ph] payor system (00:13:43), if you're not getting the uptake, if you're not getting the pull through, they'll pull you off formulary because essentially you're just wasting space of which you could go somewhere else.

A

And so ultimately, I do think in the case of CVS, they've went for a system where there will be one biosimilar and then one originator, obviously, in the other case of other PBMs, they may go to two or three, but I think three is

the max. And I think that's what you'll see is kind of emerging for the market in the long run, is that there'll be three winners that come through, and that's fine for the kind of market that I'm saying is going to end up being along with AbbVie.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Yeah, yeah. Is having I guess initial share even if it's small relatively important in terms of making sure you're staked out as one of those three players or...

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

I do think so.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

I think you've got to get on formularies, you've got to get some usage, you've got to get people feeling comfortable with your form, with your presentation. I think that's what's happening to us.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay, great. Maybe just update us on status of interchangeability here.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Yeah.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

And I guess how important, I guess, is that for the market, do you think?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

That's the one area I might have missed a year ago. I didn't think it was going to be as important as it's emerging to be more important. Study is finished, we submitted for the FDA. We expect to have that indication wrapped up and launched in the summer of this year.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

And so what that will mean is that, in specialty pharmacies, when patients coming in, they get the sticker shock in terms of the out-of-pocket costs. They'll be able to move that patient over if you have interchangeability status without any issues.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay, okay. So do you think that that actually will be a...

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

I think it will help a little bit.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Yeah, yeah, okay. And then just bigger picture view on the biosimilar business. I guess, is there any takeaways from like biosimilar of HUMIRA experience that kind of inform your approach that what molecules you're looking at or what markets you want to compete in?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Well, I mean, the big group of competition was really focused on now the HUMIRA LOE event. And then the next tidal wave will come in 2028 with OPDIVO and KEYTRUDA.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay. Yeah.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

But that's a different go-to-market model.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Yeah.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

This is unique because this is the first and largest pharmacy dispensed LOE in the biosimilars or the biologic space that has ever taken place. And we see there's a very big different set of kind of perverse incentives that take place at the PBM level and the low WACC business. So that will be different when you get to more of a hospital dispense buy-and-bill type of process where it flows into something that we know.

So I do believe that 2028 will be another very serious milestone in terms of a lot of activity around the IOs. In between there is a number of immunology products as well as some cancer products coming off patent. We have an agreement with Henlius. We'll be launching in 2025 and 2026. The biosimilar of pertuzumab as well as the biosimilar of denosumab. So one for breast cancer, again, Women's Health space and one is for osteoporosis, which is again is tangential to Women's Health.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

I guess when I think about biosimilars, it seems like it's a couple of different strategies emerging, we've got some companies that are starting to vertically integrate a little bit, we've got other companies that are happy using partnerships. The other people who are looking to maybe just exit the business, kind of where do you – in terms of where you sit today, is there any desire to kind of [ph] as one of the, it goes one of those directions either (00:17:06), like, yeah, this business altogether or vertically integrated or do you think you're in a good place with the approach you're taking?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

I think we're in a good place because we're not end-to-end, so we don't have to invest capital in terms of manufacturing, research and development, regulatory pathways. We are just focused on the commercial partnership. There are a number of developers out there, including Samsung and Henlius and others that we've done business with, where we feel the return on invested capital is really good because you don't have a lot of investment on the upfront expense, in terms of commercialization...

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Yeah.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

...of these products. You just have to have really good key account processes and other things that you need to do, to get the business moving. So it's a very nice, opportunistic play. Let's see where it plays out to the end of the decade when the IOs come off and then we'll start to see what's there in the future for in the cards for that.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

In the meantime, is there a desire to further build out the portfolio in terms of number of assets?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Yeah. Absolutely. We're always looking for potential partnerships like the one with Henlius, with those two assets, and we're looking at more assets in the space.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Is there a capacity issue or is this like you don't want to do a lot of these at once or is this really just finding the right asset [indiscernible] (00:18:18)?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

It's – the key is what is – when are you coming to market? Are you among the first, say, two or three?

A

Chris Schott

Analyst, JPMorgan Securities LLC

Yeah.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

That to me is number one. If you're actually going to be in the second group of, say, three to six, it's probably not worth your while.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Okay.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

To get into there.

A

Chris Schott

Analyst, JPMorgan Securities LLC

[ph] That's key deals getting there (00:18:35).

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

[ph] First (00:18:36) to market is key.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Yeah. Established brands.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Yeah.

A

Chris Schott

Analyst, JPMorgan Securities LLC

It's been – it gives a lot of skepticism when you guys spun out in terms of your ability to stabilize this. Just talk about what's allowed the better than expected performance since the spin and how you kind of thinking about that business over time?

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Well, it's analogous to what we've done, I think in biosimilars. I mean, we're the number one, as I said, HUMIRA biosimilar and that's against a lot of folks that have been investing the [ph] end-to-end (00:18:59) folks that you're talking about.

So I think that we've proven that we can execute commercially, I think very well. The biggest test was around Established Brands. It's 60% of our business. These are originals. These are commoditized generics of course, they play very well in the emerging markets in China, in Southern Europe.

And it's done very well and the ultimately the direction of travel before we took this business over was high single-digit decline year-over-year. We've actually increased that business year-over-year. Every year that we've had that business we're two and a half years into the spin, we have grown the Established Brands business.

We foresee and that's again where I was wrong in the good way in the sense that I basically said there was going to be low decline, single-digit decline. Actually, I reverse that. It's flat to increasing year-over-year and we continue to see opportunities to grow that business depending on which country that we have an opportunity in any given year.

But it's really about the knowledge of these products. It's the knowledge of these markets. It's the entrepreneurial kind of nature of the sales force that we have, the commercial excellence. These products do have a future if you put the right type of investments in them.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

I guess on that point, is that an opportunity where you get, let's say, a couple of year bump, where there's an asset that hasn't been focused on, you focus on it, you gain some share and then it goes back to a state where it's maybe not growing that much or do you think there can be some legs to that?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Well, from a macro perspective, a lot of countries have had -- outside of the US have had issues around generic quality.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Around stock outs on certain generic, whether it's sterile manufacturing or just small molecules. And so as a result of that, there has been less of a push on price.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

So the price volume interplay that we had at the beginning was you lose more price than you were able to generate volume. We continue to generate volume better than we thought, and we're losing less price than we thought globally. And of course, I'm taking a very global perspective on this. As a result of that, we've been able to eke out growth year in and year out.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Does that – I guess that price dynamic, is that pretty broad based or are there specific markets you'd call out that have been maybe better than others?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Well, US is the most efficient at taking price in the small molecule space and then you'd follow that by Western Europe and then ultimately Southern Europe and the rest of the, what we call emerging -- the old emerging market, plus Japan, to some extent. It's not as aggressive.

Because people like, for example, in China will pay out of pocket for what they consider to be high quality products. And that's our largest established brands business is in China and it continues to potentially have growth aspirations for us for the future.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

I guess, is that -- given this dynamic you're seeing, is there a desire to continue to build up this business? It seems like if I was interpreting when you became public, it seemed like, it was -- you used the cash flow for this to really build biosimilars...

[indiscernible] (00:21:55)

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Is this in itself a business that I guess I kind of envisioned that there's a lot of assets around the industry that maybe haven't had the investment or haven't had the focus, and that you could add some value by bringing that focus to them is that an opportunity,?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Well, the Lilly deal is a perfect example of products that could potentially address tangentially the women's health space, but ultimately is in the Established Brands business definition. Those are ways that we can continue to add on these assets that from an inorganic perspective, can keep us to low single-digit potential growth.

From an organic perspective, we feel good that we've been able to stabilize that business and there's an opportunity to continue to have it stable over time. But if you're asking me, would I do an M&A, large transformative M&A focused on Established Brands likely not.

Chris Schott

Analyst, JPMorgan Securities LLC

Okay.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

I'm focusing more on growth for the future as most of us are.

A

Chris Schott

Analyst, JPMorgan Securities LLC

So these are probably more one-off kind of products and geography.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Yeah, here and there opportunistic. Exactly. Exactly.

A

Chris Schott

Analyst, JPMorgan Securities LLC

And then just kind of maybe summarizing all this, just longer term view of this business. Is this something that you think is sustainable kind of low single-digit grower or is it -- how should we be thinking about it?

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Well, I think I can say that to the end of the decade. I can give you assurance that it will be -- I love this term, flat-ish. So some years we might eke out some 1% or 2% or so growth, other years we might see minus 1% at best. But if you just put a line through it, there'll be a little bit of growth we can generate till the end of the decade.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Okay. Pretty stable?

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Yeah. Pretty stable.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Nice business for you.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Yeah.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Within there, I mean, I did mention China a few times. So talk about dynamics that we should be thinking about for China, for Organon in 2020. I guess what we see in 2023, what should we look forward to in 2024?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Yeah, so 2023 for the variety of reasons, China was a headwind because of the anti-corruption campaign that started in July, but that petered out very quickly.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

So now we're kind of looking at the position where we no longer see the effects of that.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay. Good.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

In terms of COVID in the first quarter, that was overhang in terms of kind of holding us back from kind of seeing the fruition of that fertility explosion that was happening in terms of the business that's now over. So we're able to get back and do what we need to do for fertility.

So now that headwind in 2023 will turn into somewhat of a tailwind in 2024, where we will start to see growth for China. And we're looking at inorganic opportunities because we've got over 1,000 people in China that ultimately are really good at what they do in terms of commercializing assets. And so as a result of that, we do see an opportunity to do some inorganic activity in China.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay. So that's one of the markets that you'd be looking at?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

That's one of the markets I would do China for China deals.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay. And I know VBP has been a discussion point over time. How much of the portfolio is left to go through that, how much exposure you have the next few years?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Yeah. So 75% of the portfolio has gone through.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Okay.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

25% is remaining. That'll kind of peter out over the two, three years in front of us, depending on whether they get delayed on certain volume-based procurement rounds. But right now, we're looking good in terms of where we need to do for 2024 and 2025.

A

I would tell you that fertility is not part of the VBP business. It's -- it goes through the retail channels. And so we're looking at fertility being a really -- a very nice growth driver. And we brought back in Marvelon and Mercilon, which is our oral contraceptive products from Bayer back into our portfolio in China. It's growing exceptionally well.

Chris Schott

Analyst, JPMorgan Securities LLC

Okay.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

So China is an important movement for us going forward. And then, the thing that we are most concerned about in China was the general economy. Because if you have an economy where people are perceiving there to be a recession potentially at hand, unemployment is rearing its head potentially.

A

And people tend to be very kind of restrictive in terms of that out-of-pocket spend. But then the alternative they have is to go back into the public hospitals and they see the difficulty of getting kind of long term, chronic medications as they go -- they'd spring back to the retail channels. So that is working its way through as well.

Chris Schott

Analyst, JPMorgan Securities LLC

Okay. Just on the retail piece of the business, can you just remind us how much of your business in China is in retail markets? And actually the question, I guess, is just longer term sustainability of that retail channel. Is there something -- items you worry about there that could be a less attractive market for you over time?

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Well, 55% of our business is through the retail channel.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Okay.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

And it's growing and the retail channel is growing in itself as well. It's not only retail in the sense that, the shops, the stores, but also kind of [indiscernible] (00:26:31). A number of online retailers are starting to emerge to become really an important contributor to the business as well.

I do see that as a channel that will continue on because the -- I believe the China government, Chinese government wants that to continue as optionality for their patients in terms of -- or for their population, in terms of whether they want to go to the public system and deal with the bureaucracy of it or whether they want to get the convenience of doing the retail channel. And I still see that being an important channel going forward.

And we took the decision back in the previous days when I was running MSD International to essentially build up our portfolio in 2017 in the retail channel. So we've got a lot of good experience there.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Maybe pivoting over to 2024.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Sure.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

I know you made some comments yesterday.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Yeah.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Maybe just -- and you talked a little bit in the opening remarks, but just talk about the general outlook for 2024, what kind of -- I know you can frame more formal guidance at some point, but just how are you thinking about the year shaping up?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

I do -- I feel very strongly that we'll have low single-digit growth on the top line. We'll have stabilized and start to grow our margin, our EBITDA. We are starting to essentially understand 2.5 years in what kind of expense base we're looking at. So we're being more efficient with our OpEx. I don't want to send a signal that we're declining year-over-year our expenses, but definitely we're stabilizing them and where we can actually take expense out, we're doing so.

So as a result of that, you'll start to see more margin expansion. We feel good about that. We feel good that we can over this year, start to delever a bit more than where we're going to end up in 2023, which will be just north of

four. And so I think that it's a year of growth, stability, potentially focused on delevering, paying the dividend and ultimately gaining more, I think, shareholder and investor confidence.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Excellent. Can you elaborate a little bit more? I know you talked about the cost opportunities being part of the -- what's enabling the EBITDA margins to stabilize and start to improve from here. Just a little bit more flavor of where that cost is coming from? And should we think of this as kind of a one-year event or something that could be kind of a continual process over time?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Well, I mean, we're taking -- it's everywhere, really. It's -- whether it's global business services, whether it's manpower personnel in terms of what we need to be more efficient, whether it's taking down our R&D expense of areas that we weren't investing in, in terms of, say, lifecycle management projects, that we weren't continuing to pursue, whether it's things that we're doing on a number of different fronts to really kind of look at ways of being able to squeeze down and be more efficient, because now we know exactly what we need to run this business.

Where we spun out 2.5 years ago was a function of what we didn't know, what we did know. And ultimately, I think we're able to kind of now operate in a way where it's not a one-year event and then next year we'd have pop back up. It's rather kind of a running ability to continue to drive the right expense structure.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

So is it reasonable to think about from here that we could see kind of steady progress on the EBITDA margins or is the bigger EBITDA margin expansion going to be predicated on whether it's pipeline or further acceleration of top line growth, I guess?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Well, I think that we're now stabilizing our OpEx. We haven't given really clear guidance yet. We'll do that in February with our Q4 earnings call. So at that point, I think we'll be able to get a bit more granular in terms of what we expect to go forward with it. But clearly, I mean, in the absence of any type of transformative deals, which I don't see anything in front of me right now, we'll continue to just work on the basic fundamentals of the business.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay, great. Cash flow. I think you talked about coming in above the high end of the range for 2023. Just talk a little bit about the drivers of that performance and just how -- just in a bigger picture, how representative is 2023 in terms of like a normal cash flow generation year for Organon?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Yeah. So our business is -- one of the core investment thesis of our business, it's a strong cash flow generating business. In 2023, there were a few things that impeded that and they're more or less all related to the separation process that we're still undergoing from Merck.

So, for example, we had about \$350 million of onetime costs related to separation. Most of that is in the IT space and global ERP system. That's the high watermark. We see that number improving significantly in 2024, probably on the order of 40% lower.

The other piece was and through nine months of the year, we had about \$500 million working capital build. Once again, a lot of that related to the global ERP system. And I had said in the third quarter earnings call that with our largest plants now on the system up and running, we would start to claw back some of that working capital but start in Q4 and then it would progress into Q1 and Q2 of 2024.

So we were more successful at clawing back that working capital earlier than we thought, and that's what drove the overperformance on cash flow in Q4.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Great. That's helpful. On, I guess, capital allocation, you said in the past and you reiterated on in terms of the, I guess, kind of debt repayment, business development, dividend kind of the biggest uses of that. Just first one for me is on the yield, the stock has got a very healthy yield right now, just commitment to the current dividend is that -- should we think of that as kind of a rock solid commitment to that dividend?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Yes.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay. Perfect. And then more broadly, how do you think about capital market allocation priorities, just given, I guess, the environment we're in, where your stock is trading? Like, how are you thinking about balancing the different uses of your cash going forward?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Yeah, I mean, I think, look, as we start to get a better cash picture going forward in the years to come, as we continue to grow our top line, as we continue to do these kind of very nice bolt-on deals that you see with Lilly, and we've done other deals like that and they're not de minimis. They actually develop -- they deliver really nice growth opportunities for us.

We're always looking for that transformative potential M&A opportunity. But I think that -- I believe that the stock was trading artificially too low. And I think now that people are seeing, what we're capable of doing and delivering, it's starting to kind of bounce back up to kind of more levels that we think are hopefully in the near future will be reflective of where we need to be.

But I do believe that going forward, we're committed to the dividend. We're committed to doing some of the BD that we think is very attractive. These kind of bolt-ons that we talked about. And we'll always be looking for that transformative M&A opportunity when and if that presents itself and then everything is on the table ultimately.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay. On leverage, just what's a reasonable way to think about leverage targets for 2024 and then what's the – what do you think is an appropriate leverage level for the company as we think longer term?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Yeah. So go ahead.

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

A

Kevin, I can start. So we'll finish the year leverage ratio in the 4, 4.2, 4.25 range. And I think we can delever the business in 2024, probably by a quarter point or so.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay.

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

A

When we spun and we were looking at the cash flow generating ability of the business and the stability of it and the diversification. We were thinking that a sensible place to land leverage from a total shareholder return perspective would be right around 3.5 times.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay.

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

A

And I think the market has grown more sensitive to leverage. I mean, from an operating perspective, it's no problem for us to run this business at 3.5 times. The market has grown a little bit more sensitive to leverage. So whereas we might have seen investors nodding their heads at 3.5 times around the time of the spin. They're nodding their heads that are maybe at about a half point lower than that now.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Sure. Yeah.

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

A

And so the gating issue for us on leverage is really what's the market perception of it versus any operating considerations we would have. So there are benefits to getting -- there are benefits to the equity to getting that leverage number down. And it does have, I think -- it's appropriate place in the way that we think about capital allocation priorities.

So we've always said our number one priority is the dividend now that we have it. But really sort of tied for second is business development and debt reduction. The near-term and certain benefits of debt reduction have their place in the way that we think about overall value creation.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Great. In the last minute or two here, maybe the Lilly migraine deal, is there more opportunities that you see that are near-term actionable like that or are these kind of harder to find in terms of the [indiscernible] (00:35:33).

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

I know I think that -- I think doing the deal with Lilly, I think has kind of created halo effect to some extent because, other companies are in the same situation where they're saying strategically is this the right thing to be doing and can we partner with a company that we trust and feel that are going to do good in terms of what we need them to?

And I think that was a good deal. There are more to be done. We're just kicking the tires on a number of things now. And I guess, like I said it, some are going to be regional focused, some might be country focused depending on, I think China is the key country we're looking at for China for China deals.

But we've done four of those deals so far. And they're all doing exceptionally well. So we'll continue to look at that.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

And maybe the last question here, just thoughts on the stock. I know it's -- talk a little bit about just the primary, I guess, disconnects you're seeing between how you're thinking about the business, what seems to be reflected in valuations. Just any perspective there?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

I think there was -- I think 2023 was a very challenging year. There was a lot of noise about the dividend.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Yeah.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

And that's why we had to clear that up with a clear and unambiguous.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Yes.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Language around the dividend. I think that's one thing. The second thing is investors wanted to see EBITDA start to stabilize and grow. I think we've started to signal that's the direction of travel. And I think that was the second thing that kind of took a moment for people to kind of adjust and say, oh, okay, well then, if that's the case, you're generating a lot of cash, you should be able to do more things.

And then the final thing is really about the future growth prospects. And what we're signaling is and what we've signaled and we continued to deliver, this is a business on its own organically that can drive low-to-mid single-digit growth over the long range operating planning period.

And I still believe very strongly that that's the case. We've been able to do it. You'll see that in 2023. We fell into that range in 2024, we're signaling the same. And Nexplanon is our key product. It will get to a run rate of about \$1 billion by the end of 2025. It will continue to be a very key contributor of growth through the end of the decade.

We'll get the five-year indication and launch that in 2026 likely, which will take us to 2029. And so there's a lot of reasons to believe in the strong fundamentals of the business. And we're finally, I mean, when you look at the ERP implementation, the average tenure or the average length of time it takes to get a global ERP system set up is anywhere between 7 and 10 years.

This June, will it finish it? That's 3.5 years in. That's a record. So getting those things behind us, giving us the opportunity to kind of focus on running the business in the best possible way, doing these kind of accretive deals until something more transformative comes along.

I think the right way of being able to approach the future.

Chris Schott

Analyst, JPMorgan Securities LLC

Excellent. Well, appreciate the comments today. Thanks for joining us.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Thank you, Chris. Pleasure. Thank you.

Chris Schott

Analyst, JPMorgan Securities LLC

Thanks so much.

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

Thank you.

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