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Organon & Co. (OGN)

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Chris Schott

Analyst, JPMorgan Securities LLC

MANAGEMENT DISCUSSION SECTION

Chris Schott

Analyst, JPMorgan Securities LLC

Good morning, everybody. I'm Chris Schott at JPMorgan, and it's my pleasure to be hosting a fireside chat this morning with the Organon management team. From the company, we have CEO Kevin Ali, as well as CFO Matt Walsh. So Kevin and Matt, Happy New Year, and thanks for joining us this morning.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Thank you.

QUESTION AND ANSWER SECTION

Chris Schott

Analyst, JPMorgan Securities LLC

Q

I thought maybe to kick things off, the company just completed its first full year as a standalone company, and in a high level, I'd love just to hear your thoughts of kind of what's gone well and maybe what are the surprises as you start the company and operate as an independent entity here.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Well, good morning, Chris, and good to be here. And yeah, I think from a high level, what I can say very briefly is the fact that we've been incredibly happy with the performance of our first full year out. We set out to do a few things at the beginning of this journey. First of all, folks didn't really recognize that the established brands business, which is 60% of our overall business, there was an assumption that it would continue to decline. And what we've been able to do, what the team has been able to do – I'm fiercely proud of what they've been able to do – is actually stabilize that business. And in this first year, in 2022, we actually saw growth in that franchise.

Secondly, we said we were going to grow our strategic pillars by double digit. We grew biosimilars by double-digit rate, and we grew our women's health franchise, including fertility and, of course, Nexplanon, our key product, by double digits. So that was actually in the midst of the traditional things that one has to do in spinning a company out with all the TSAs and all the nuts and bolts of that. So I'm incredibly proud of what the team has done. And I think that we're well on the way. And of course, now, just last week, we announced our eighth deal. So we've done eight deals in literally 18 months. So we're very serious about ramping up essentially our pipeline, both in terms of early stage, mid-stage and as well commercialized assets. So we're really excited about our pipeline that we've built in a very short period of time. And so, we're really thrilled.

I think that you mentioned what was unexpected, I guess.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Yeah, yeah.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

I think what was unexpected is I was probably a bit naïve to think that you could build Rome in a day.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

So realizing it does take time and you do have to be patient and we're only a year and a half into it. But we've met every commitment we said in terms of our guidance every quarter, we've actually met our guidance and exceeded in many instances and we're really on track.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Great, great. Yeah. I know you've talked about becoming a leader in the women's health space. And I guess just to – two other questions I get from investors is why women's health and why do you think the company can succeed in this vertical when it seems like others have maybe struggled a bit to get the type of traction they want here.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

We know they say that timing is everything. And I tell you right now, if it was 5 or 10 years ago, I probably wouldn't have decided to go in the direction of women's health. But so much of what we do in this industry is contingent upon what's available in the R&D space.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

And so over the last 5 to 10 years, there's been some really interesting developments, a lot of grass, green shoots kind of popping up all over the place, and not only in the US, but in Europe, which we've done a number of deals, as well as the Asia-Pacific region. So there's been more emphasis put on the R&D area. Secondly, there's no other company in the world today that actually focuses on being a women's health leader. So being in that space, we're actually kind of we're magnetizing it. So a lot of the folks that are working around the world on some early stage, mid-stage and late stage assets are coming to us now because we've kind of stimulated, we've kind of catalyzed the whole area of women's health. And the timing is right. I mean, societally, the timing is right, and the focus is the fact that the R&D efforts around women's health had been woefully underfunded. I mean, I don't want to go into the statistics of it in terms of what you see, in terms of what's being approved year by year, but really, really a lot of need, a huge amount of gaps and a great amount of opportunity for us to kind of step into that space and take a leadership role.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

So, if I think about where others have struggled with the lack of pipeline, is that – was that you think – or is it just more the – it wasn't as focused and it was kind of disparate assets...

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Yeah. I think if you're – so, I'll look at it this way. If you're a large company, a large pharma company, which many of us came, as all of you know, is a spin out from Merck. If you're a large company, a \$300 million to \$400 million to \$600 million peak revenue business is not going to get you out of bed, really. But for \$6.5 billion business, a number of \$300 million to \$400 million assets start to become very material and actually can become

transformative for us. So those assets – so if you're a large company, the reason that they were really enthusiastic because they didn't see the multibillion dollar opportunities and everybody of course started to migrate towards where currently they're migrating in terms of oncology, orphan and other CNS and other area. So, that's one aspect.

The second aspect, if you're a small company, you probably didn't have what we have, which is a base of business like the established brands business and the biosimilar business that sheds off a lot of cash. I mean, our free cash flow every year provides us an opportunity to do meaningful business development. As we've – as I've said, we've done eight deals, so we can be an aggregator of these assets. And finally, because there's not a rush from large pharma to get in there, valuations are reasonable. So, we can actually start to do more in that space. And so, as a result of that, I would say if you're a small company, you don't have a global footprint. We're in – we're just like big pharma, we're in 60 markets across the world, you may not have essentially other parts of the business that can fund that journey. If you're a large cap pharma, you're not really interested in \$400 million, \$500 million business. So that's a kind of a nice niche that we've been able to build for ourselves.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Great. I think you mentioned double-digit growth in 2022. I guess as we think about the women's health business for 2023, do you think the portfolio is positioned for another year of double-digit growth? And as part of that, is it coming from the core assets or do we start to think about BD being – or some of the recently acquired [ph] in-license (00:06:13) products being a bigger contributor?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Yeah. So I'll answer that, Chris, in two ways. First is that double-digit growth has been essentially what we've been experiencing with our women's health franchise. Specifically, if I split it out between our fertility franchise, which we consider a double-digit growth therapeutic area for years to come, because just the need is so incredibly great and there's not a lot of companies in that space. It's just us and two other companies that really kind of dominate a rather 85% share of that space. If I look at our biggest product, Nexplanon, we're on track to be \$1 billion product in 2025 for Nexplanon. And we've got essentially patent protection until 2027 with the opportunity to stretch it out to 2029-2030 with a lifecycle management opportunity we're pursuing right now, which we feel is highly likely of actually giving us an opportunity to stretch it that far. This will be \$1 billion franchise. It's our first \$1 billion franchise with good runway in terms of patent protection.

So what I would say is, yeah, we're going to be seeing consistently strong growth momentum from our women's health franchise. Now, that's organically. The inorganic acquisitions that we've made, the Jada system, which is doing exceptionally well, we'll start reporting on – out on the performance of Jada this year in 2023. We're going to be launching XACIATO, which is our partnership with Daré for bacterial vaginosis. That's going to be a nice little addition, maybe not in 2023, but in 2024 and 2025, you'll start to see more contribution.

And then, of course, our earlier stage assets are really starting to be very nice. Our Forendo acquisition, which gave us an opportunity for a new mechanism of action in endometriosis, OG-6219. OG-6219 has actually started Phase 2 first patient in October of last year. So we expect to report out our data probably in the 2024 timeframe for our Phase 2 data. This is a completely new mechanism of action, has tremendous growth opportunities. If that comes to the market in the 2028-2029 timeframe, it's going to be a major, major contributor for our future. So growth is really going to be there. What I would consistently say to you, Chris, is our baseline business of established brands will continue to be a stable business. Nobody thought we could do that.

Chris Schott

Analyst, JPMorgan Securities LLC

Yeah, yeah.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

And now it's stabilized. It's actually growing this year. Our two growth momentums of biosimilars, which we've added more to that franchise, as well as women's health will continue to grow double-digit. Women's health will – Nexplanon will be \$1 billion product in 2025. So overall, when you start to feather in all of these BD activities we're doing, we're signaling low to mid-single-digit growth. Actually, it's more mid-single digit growth right now that we see kind of coming up in the years to come. Start to feather all that stuff in and you start to see the opportunities exist to start to really accelerate growth.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Yeah, great. Thanks for that. You mentioned biosimilars kind of the growth pillar here. Just talk about how I guess strategic that franchise is to Organon, because I feel like the strategy now, we've got a number of partnerships. So to some point, does it make sense to more vertically integrate, how core is this to the business? Just help us a little bit on that.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Well, we started out Organon as being essentially a value-added partner, commercial partner, access partner, pricing partner, government affairs partner, regulatory partner to a number of developers. Our first relationship really was transferred over from Merck, which is a Samsung relationship that gave us five assets. Subsequent to that, in the last, we actually did deal with Henlius, a very well-known biotech company that does biosimilars in China, that has done international work already for biosimilar Prolia and Perjeta, and now basically an option to do a deal with them for Yervoy.

A

So we're starting to expand obviously in different areas. It's very strategic. I can tell you why because if you're vertically integrated, you may miss the most important point, which is that in order to participate and compete and succeed in biosimilars, you've got to be first, second or third. You've got to be in that first tranche of launches. If you missed that window, it gets to be much more difficult to succeed in the biosimilar space. So by being a value added partner, we can pick who we want to partner up with based on our due diligence to better understand where they're launching, how – are they're going to be in the first tranche or not, that's first.

Secondly, I really don't know where the biosimilar business is going to be in the next decade. After you get the IOs, after the KEYTRUDAs, and OPDIVOs, and all the others start to see the biosimilars introductions, what happens beyond that. So that's why I'd say it's a really good strategy for contribution to growth now. And on a return on invested capital is very good because we don't invest a lot of expenses on it. But for the future, we'll have to see. But by that time, we hope and we feel very confident that the introductions that we have with our women's health business will take us continuing going forward.

Chris Schott

Analyst, JPMorgan Securities LLC

So the strategy can maximize your optionality...

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Exactly, exactly.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Yeah. I know we've had a lot of conversation at this conference room, biosimilar, Humira, had this big opportunity. So we'd love to hear your thoughts about how you see this market developing as we go through 2023 and beyond.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Well, any meeting would not be complete without a question on Humira biosimilars. So, yeah, we're actually in the first tranche with our Samsung partners and the first tranche of launches we'll be launching next summer, this summer, actually, with a few others. When you look at the US market, you've got to basically say, this is a pharmacy benefit product. So what's it – what's going on with the PBMs. And essentially, as I meet with PBMs, what I understand from their point of view is put rebate structure, put pricing aside for a moment. Just talk to us about what are your needs. A, do you have high-concentration citrate-free? And by the way, do you have a low concentration dose as well? We do, so check that box. B, is this the first country you're launching your biosimilar or have you actually had real-world evidence so that we know it's safe and tolerable in other populations? Check, because we've actually launched in Canada and in Australia, and Samsung through their partnership with Biogen has launched it in Europe. So we've got plenty of safety data.

A

Three, you have a manufacturing network that can satisfy whatever demand we throw at you because it could be huge volumes you're talking about. Samsung happens to be one of the largest, if not the largest [ph] total (00:13:00) manufacturer in the world for biologics. So check that box up. Four, do you – what's your pen device like? We like to use the word frictionless. Is it easy, is it elegant? And Samsung has got a long heritage in device manufacturing. And so, it's a fantastic device as well. And finally, where are you in terms of interchangeability, when is that indication coming? So as you start to check off all the boxes and you realize many of the other competitors may check two or three, but not all of them, you start to realize that you're very strong, in a strong position to do one very important thing. Most PBMs will have 1 to 3 maximum biosimilars on formulary, plus the originator. You need – in 2023, in the second half of 2023, when you're going to see a lot of launches, you need to be one of those two or three. And then, when the dust settles in 2024, you'll be able to see, okay, he's going to win this race. So we're in a good position.

Chris Schott

Analyst, JPMorgan Securities LLC

Can I ask just when I think about 2023, it does seem like AbbVie has locked up quite a bit of formulary access that's at [ph] pathway to (00:14:06) parity to a biosimilar. Should we think about this being an interesting commercial market this year or is it more 2024 and beyond sales opportunity.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

I would guess it'll be more in 2024 and beyond.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Okay.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

I think this year, most PBMs will go to parity. So if you're a physician, you're – if you got parity, which means you can pick whatever you want, they'll go with their knee jerk reaction, which is Humira. But going forward, as things start to change in the marketplace, and I can tell you when I meet with PBMs, they want biosimilars to succeed. They don't want to see a future where originators essentially evergreen the field in terms of continuing to do that. So, if you're talking about a \$20 billion – the largest LOE in the history of the pharma industry, a \$20 billion net revenue in the US, going from \$20 billion to say, \$4 billion or \$3 billion, then it starts to become less interesting probably for the originator, because you're getting a lot of pressure on that price. So 2023, I think will be a slow ramp up year with really focus on formulary inclusion. 2024 and 2025 will open up.

A

Chris Schott

Analyst, JPMorgan Securities LLC

And with those initial formulary kind of decisions, do you expect those end up being fairly sticky? So if you're kind of there at the start, it's kind of almost like your business to lose going forward when those volume comes around, or could we see there's more changes as we go...

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

That's a great question. I think it depends on two things. One is it depends on the PBMs' appetite to reeducate physicians on how to use the pen device and what to look for and all the things associated with that biosimilar. But secondly, what it depends on what kind of discounts are provided in the early stage and is a PBM going to ship for 1 or 2 percentage points. And probably not, because if they're comfortable, they'll settle in in terms of when you're meeting their criteria in terms of the kind of discounts that you're getting.

A

Chris Schott

Analyst, JPMorgan Securities LLC

I mean, the final question is, I think you've mentioned that market compression over time. Just thoughts in general of where pricing or what kind of TAM we ultimately kind of pursuing here for the industry.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

For the bio – for the year?

A

Chris Schott

Analyst, JPMorgan Securities LLC

For the biosimilar, yes. So I think we all know about the branded sales, but what's the kind of really like the biosimilar opportunity you're going to be...

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

I think by – my view, and this is just [indiscernible] (00:16:31) one, I think by 2025-2026, you might range anywhere between 80% and 90% discounts...

Chris Schott

Analyst, JPMorgan Securities LLC

Okay.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

...potentially.

Chris Schott

Analyst, JPMorgan Securities LLC

Just given all the players involved.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Yeah. I think that's just the natural course of events.

Chris Schott

Analyst, JPMorgan Securities LLC

Yeah. Okay. Perfect. Maybe going over to the established brands division. I think as you've kind of talked about earlier, I think you were originally talking about this as a business that could erode over time. Looking at 2022, obviously a lot better performance there. So talk about just what's driven the strength in that business so far and maybe what we can expect in 2023 from the franchise.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Well, I wish I could give you, on the established brands business, which is, again, 60% of our base of our business. I wish I could give you some nuggets to say if you do these three things and you have these kind of global products, you'll succeed with established brands where others have not...

Chris Schott

Analyst, JPMorgan Securities LLC

Yeah.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

...because most of the others have actually continued to decline. What I can tell you is the following. We don't have, in our portfolio of established brands, any commoditized generics, which are – these are the originals. These are the original products like Singulair or others like [indiscernible] (00:17:42) and others, these are the original products that have gone off patent. In many countries outside of the US, that would be China, parts of the emerging markets, of course, southern Europe. They still have tremendous kind of value for patients. And it ranges from completely out of pocket. Like, for example, what's starting to emerge now in China, all the way to kind of higher co-pays in southern Europe. But people will go for it.

Now, the second point is you really have to have an incredibly entrepreneurial group in each country, because I can tell you across the world, in all the subsidiaries we have, in the 60 countries we actively participate in, no one country is like the other in terms of the contribution of the portfolio. That tells you that folks are looking under every stone to drive this business. We took a business and, again, as I said, I'm fiercely proud of what they've been able to do. We took a business that was in double-digit decline and now it's single-digit growth year to date and through Q3. So when I signal to the investment community that the long-term aspect – and people were kind of shaking their heads – long-term forecast for this part of the business, and it's important because this throws off a lot of cash that we can reinvest. It provides oxygen so that we can reinvest in women's health and some biosimilar business, is that it'll be a stable business. So one year, we might grow by 5%, one year, we might decline by 2%. Next year, we might be zero. The next year, we might be 1%. Put a line through it, put a regression line through it, and you see, oh, that's a flat business.

Chris Schott*Analyst, JPMorgan Securities LLC*

Yeah.

Q

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

Once you establish that that's a stable business that throws off good margin business, throws off a lot of cash, then you can start to say, okay, now I can start to look at their growth aspirations because they don't have this leaky bucket that's driving everything down. It's anchoring their business. So I think so far, what I understand from investors and number of other analysts, I think we're starting to believe that this is a stable business, somehow some going on different at Organon where they've been able to do this.

A

Chris Schott*Analyst, JPMorgan Securities LLC*

Yeah, absolutely. And I guess in that context, the growth that you've seen year-to-date, it does seem directionally the business is trending in a good place. Should we think of there being anything that was particularly strong this year that might be harder to replicate next year?

Q

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

Yeah. There was a couple of onetime benefits, tailwinds. In Japan, they had a number of generics that were withdrawn because of quality issues. The Japanese regulatory authorities are very conservative, so I don't know. Some of them may not come back, some of them may. So that tailwind will decrease, but it still might – a little bit of it might be there. We had a delay of a launch of an inhaled product for Dulera in the US. Generic didn't show up, so essentially we had the benefit of that. We had a couple of other kind of onetime benefits that helped us. VBP, which is essentially the volume based procurement process in China, that's their way of kind of rationalizing price and moving forward in the public sector, didn't happen the round that we thought when it's supposed to happen. So it just happened round 7 in October of last year. So now, we're starting to get back into kind of the normal routine of things. So going forward, what I can tell you is it's a flattish business.

A

Chris Schott*Analyst, JPMorgan Securities LLC*

Okay. Okay, great. You mentioned China, I know it's an important geography for this business. Can you just talk about what COVID shutdowns have meant to that kind of, I guess, region or country? And as we think about reopening, is that a tailwind for...

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

I think it will be.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Okay.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

I can tell you that, Chris, that over the years where other competitors have had these huge products, the LIPITORs of the world, \$1 billion product franchises in China, they got just massacred.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Yeah.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Where essentially, we're very diversified. There's no single product in China that represents more than 15% of our business.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Okay.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

So each round, I think we're up to round 7 now, we finished in the rounds of VBP. We've had something happen. So currently, 50% of our business has gone through by the end of this year. In 2023, 75% of our products will have gone through. In the meantime, in 2017, actually, we started – at that time when I was at Merck, we started kind of a retail business unit because we saw that there was things happening in retail sector, activity happening. And now, the retail sector represents 50% of our business, growing double digit. And that's been able to offset many of these kind of hits that we've had from the volume-based procurement. Through 2023, we'll still face some downfall, but not in a single year have we ever declined in China. So once we pass through 2023 and we start to go to 2024, we'll have gone through most of the kind of the leaky bucket sorts and we'll move on to really more solid growth.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Okay. Perfect. And you mentioned VBP some impact this year. Can you just help quantify what products and then maybe the size and scale of those they're hitting this year?

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

So in round 7, at the end of last year, essentially, our largest – one of our largest products, which is a cardiovascular lipid lowering product, ezetimibe, actually got into the round 7. So we're starting to face that, will lap that next year in November. Round 8 and round 10, potentially could take place round 8, but definitely take place in round 10. So, we're talking about essentially three products or so, maybe four that actually go through that process. That's what kind of tells me that by the end of next – by the end of this year, 75% of our portfolio will have gone through. But then it becomes – it no longer becomes 50% of our business.

Chris Schott

Analyst, JPMorgan Securities LLC

Yeah, yeah.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Starts to shrink and starts to have a less of an impact for us.

Chris Schott

Analyst, JPMorgan Securities LLC

Yeah.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

And the other retail business which includes the e-commerce side, will start to grow.

Chris Schott

Analyst, JPMorgan Securities LLC

Okay.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

And then that will overtake and then will...

[indiscernible] (00:23:36)

Chris Schott

Analyst, JPMorgan Securities LLC

And maybe last question in this division.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Yeah.

Chris Schott

Analyst, JPMorgan Securities LLC

Is established brands an area that we can think about business development, would that be something that makes sense for Organon?

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Yeah, absolutely. I mean, if – but not – I wouldn't say we're interested in a portfolio of declining products. That's somebody else's problem.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Okay. [ph] You want to do this (00:23:55)?

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

No, no, I'd rather go after a single kind of base hit...

A

Chris Schott

Analyst, JPMorgan Securities LLC

Okay. Yeah.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

...where I see a product maybe that's gone through the LOE effect that has kind of stabilized that we can start to throw into and kind of bolt into our business and then start to grow. I start to potentially look at areas that are derm, pain. There are other areas that are not necessarily as affected by the LOE events throughout the world. Yeah. So yeah, if it makes sense, if it's accretive in the near term. I'll give you an example. We brought back – I wouldn't call them – I would call them the established brands of the women's health sector.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Okay.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Bayer had – for whatever reason, had some of our contraception, combined oral contraception products in the Asia-Pacific region, specifically in China, Vietnam and other countries. And we brought that back. We actually pay them to bring it back actually. And so we were already manufacturing it, but that's almost accretive in the year – in year one.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Okay.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

And it's growing incredibly nicely. So that's the kind of thing that we would...

A

Chris Schott

Analyst, JPMorgan Securities LLC

See kind of tuck-in.

Q

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Yes.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Exactly, yeah. Maybe shifting to the P&L. I know you've talked about the need to make investments in both R&D and SG&A to generate this growth over time. How do we think about the investment that's – the impact those investments are going to have on the P&L as we think about 2023?

Q

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

Yeah. So I can take that one. So let's take a step back for a moment. So when Merck prepared Organon for spin, they sized the cost structure really to accommodate the portfolio of products that we're launching. There was no placeholder or consideration given for how Organon would grow. Merck figured, well, okay, they have their own management team, their own board, they'll figure that out. And so we have been pretty clear since even the communications right before the spin that we would be reinvesting our profits to create a pipeline of opportunities to grow revenue. And that would show up in two places on the P&L. It would show up on the R&D line, obviously, as we would be putting in place a portfolio of new product candidates. You'd also see it on the SG&A line for commercial expenses for these products that would launch if we were buying things in that were currently marketed products or imminently accretive.

A

And so that we've been steadily moving in that direction since the spin. And of course, the big investor question is as well what is the next quarter look like, what does the next year look like, is there a minimum point that we can think of before things start to turn around. So it is a question that we get a lot. And so in advance of providing formal guidance for 2023, which we'll do in mid-February when we release earnings, we decided to soft guide towards the latter part of 2022 to start to get people grounded. And so we had told folks that if you looked at the second half EBITDA margin, that would be implied by our third quarter actuals and our fourth quarter guide, that would be a good directional indication of where margins would be headed for 2023, and that's still the case.

So there's no new information today, Chris. As we finalize our budget for the year and look at where FX rates are headed, that information is still good. And that I think adequately reflects what we see as the needed reinvestment to make sure that we can deliver that low to mid-single digit revenue growth, not just out to 2025, but even well beyond that.

Chris Schott

Analyst, JPMorgan Securities LLC

Can I ask question on those margins, is that including process R&Ds? I know some companies are guiding, pulling that out...

Q

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

A

That's a very good question, yeah. So, across our industry, for those of you that aren't familiar, Chris is pointing out that as you bring in new opportunities, there are upfronts, there are milestone payments, these are lumpy type outflows. They're more related to almost business development or M&A type cash flows than they are real R&D expense and it's always been sort of a gray area. And so the SEC has mandated that we include these payments in whatever adjusted income reporting that we do. And when we gave that soft guide, there was about \$25 million of that kind of milestone type included for deals that we've already completed.

Chris Schott

Analyst, JPMorgan Securities LLC

Sure.

Q

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

And that number in 2022 actuals is about \$107 million, so people can compare.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Okay. Great. And I think I asked you this last year in a similar setting, can we think about 2023 being something that's starting to approach I won't say trough, but that is starting to get to a point where your cost base is at an appropriate level to kind of support the business going forward?

Q

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

Yeah. So, the answer I'll give there, Chris, is it reflects all the scenario, multitude of scenarios that we're running on what the future could hold for the eight deals we've already done. And it does feel like we are starting to get towards a trough there.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Okay, okay. And then obviously, as the topline starts to grow over time, we can maybe think about some...

Q

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

Yeah. So – yeah, there's always the question of, well, if we're going to be hitting the trough, then where do you think normalized margins for the business would be. And that will depend heavily on the commercial success of the eight deals that we're pursuing and whatever new ones will layer on in 2023 and beyond. So it's hard to make a commentary on that, Chris, right now.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Okay. And then maybe last one, just on FX. I know that was a huge swing factor given the exposure of your portfolio, and just any strategies just to either hedge the business out or kind of dampen some of this volatility that we're seeing from currency.

Q

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

A

Yeah. So, one of your first questions was what was unexpected or what was a surprise. And from my chair, we've got 70% of our revenues denominated ex-USD, but we report in US dollars. And so we spend and it's great, everything's going well operationally, but we've had really the strongest US dollar in the last 20 to 30 years, unexpected. And so the really strong revenue growth that we've been seeing in local currency, investors have not been able to see.

And so Kevin alluded to, we've had solid mid-single digit growth in the established brands business. Investors have gotten to see none of it because 90% of that particular part of our company is ex-US revenue. So we always get the question, well, why not hedge? And so the answer to that is we do some hedging. I would say – I would call our hedging activities – we have a balance sheet hedging program. So we hedge known exposures where we've got large trade receivables or payables, we've got dollars going out on CapEx spend or large inter-company flows. Those are all hedged to de-risk those.

We do not at the moment do anticipatory hedging of our P&L. This is largely a financial reporting issue. We're actually pretty well naturally hedged on a cash basis. All of our manufacturing is outside the United States. Half of our employees are outside the United States. So that provides a natural hedge. So this is more of a financial reporting issue than an economic issue. And we haven't found – we just don't believe it's in shareholders' best interest to be addressing a short-term financial reporting issue by putting cash out to hedge revenue. Ultimately, you're not going to outrun spot rates. They're going to catch up with you. And so, we've taken the position that let's just take our medicine as it comes. It's easier to explain to investors than trying to explain actuals plus a hedging overlay.

Chris Schott

Analyst, JPMorgan Securities LLC

Sure.

Q

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

And now, I think that the dollar, the pendulum starting to swing back, we'll actually have some of the reverse issue in 2023 hopefully. And then...

A

Chris Schott

Analyst, JPMorgan Securities LLC

Good problem.

Q

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

...I'll be having to explain why we've had higher numbers in reported than we've been seeing in local currency.

A

Chris Schott

Analyst, JPMorgan Securities LLC

Okay. And maybe one kind of last cash flow question. I know you've talked about some onetimers in the business...

Q

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

A

Yeah.

Chris Schott

Analyst, JPMorgan Securities LLC

...as we went through 2022. How do we think about kind of normalized cash flow and cash conversion for Organon as you kind of move past some of these events?

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

Yeah, yeah. So let's start with the dividend, right? It's a great place to start to answer that question. When we launched, you were launching into a spec pharma space, which is very heterogeneous and there are not a lot of comps out there for Organon.

Chris Schott

Analyst, JPMorgan Securities LLC

Yeah.

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

So, the thought was let's put a nice attractive dividend on the company and that'll provide a baseline for the valuation, and that, at the time, the dividend was sized to be low 20s percent of free cash flow before any one time items related to the spin.

Chris Schott

Analyst, JPMorgan Securities LLC

Yeah, yeah.

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

So that math is still good math.

Chris Schott

Analyst, JPMorgan Securities LLC

Okay.

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

So that would say that this business should be generating nicely north of \$1 billion of free cash flow before – and when we say onetime items, in our case, it's really separation...

Chris Schott

Analyst, JPMorgan Securities LLC

Yeah.

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

A

...related spending. We're still doing that. Most of that will be done by June of this year. But for the global ERP implementation that we're doing, which will dribble into 2024.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay.

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

A

But that investors should be expecting that this business can generate north of \$1 billion of [ph] free cash flow (00:33:33), and that really had – our thinking hasn't really changed since the time of the spin.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay. Great. Great. Can I just start on the capital deployment front? You've talked about the different divisions and some smaller acquisitions you've done. What is the, I guess, capacity and appetite to look at larger, maybe more transformational deals? And what would you want – kind of conceptually, what would you be looking for in a larger transaction?

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

A

Yeah. Yeah. So as I answer that question, we'll talk about ability...

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay.

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

A

...which doesn't necessarily imply intent.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay.

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

A

Okay. So when we were creating the capital structure, we could have lobbied for an investment grade rating. We wanted the BB rating because it gave us more flexibility to do exactly what you're talking about, if the situation ever presented itself for us to do a larger, more transformative deal and without endangering the rating. And so the conversation that we had with the rating agencies at the time was within the rating that you have, we could see leverage going up into the mid-4s with a trajectory that it could get down below 4x within a two year timeframe. That wouldn't – if you were to extend capital that way, it wouldn't necessarily endanger the rating. Our

rating is very important to us. We've got roughly \$9 billion of market value of debt out there. So it's something that we obviously pay a lot of attention to. So that's the ability, people can back into how large of a deal we could do

As far as intent goes, we – the business is doing everything we thought it would. We're not feeling the pressure to do a large deal. But that said, every now and again, you will have an opportunity to really accelerate your – the achievement of your strategic goals with a significant inorganic transaction. So we're well aware that those possibilities are out there. And we are – we'd certainly do them if the conditions were right. But we've had a lot of success with the smaller deals so far, easier to digest. We can get them done at good pace and we can execute well on those. And so that's been going great.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay. And does that – is the success you're having with those smaller deals, the stabilizing things like established brands, does that make a larger transaction less interesting for you? And certainly, the right large deal you'll always look at. But I guess it's just the framework that you're even looking at maybe changed a bit now that you have a bit more experience with the business.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

I can address that a little bit. No.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay. Okay, the right deal is there...

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

Yeah. The right deals there and I'm kind of the – of the two of us, I'm the shopper.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

And he's the one who says, no, don't think about that. So, no, I mean, we are always on the lookout for strengthening our position specifically on women's health.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Okay.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

A

If we can accelerate that timeline in terms of being a global leader, we're almost there, but essentially accelerated, take a stand on it, sure, we'll look at it. But it's not distinctly only women's health. I mean, if there are other things

out there – because remember, women's health are two different areas. One is essentially those conditions unique to women, and the other is kind of disproportionately impacting women. So that kind of opens everything up. And so, yeah, we're always in the mode.

Chris Schott*Analyst, JPMorgan Securities LLC*

Q

Okay. Sounds good. And maybe one last question. Higher interest rate environment. Can you maybe just talk about, A, what that means for your existing debt? And then on this business development kind of question, does that change the way you turn your appetite if there was a larger deal that take on more leverage?

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

A

Great, great, great question, Chris. So we are – in our debt stack, we have a fixed floating mix of 60% fixed, 40% floating. If you include cash, it's about 65% fixed. So there's really no concerns that we have from an operating perspective about operating leverage or the increase in interest expense that we'll see as a result of rates going up. So it's not really an operational issue.

What it has done is has raised the bar on M&A, that – on the M&A analysis and decision making that we do. For deals that bring near-term growth, whether it's currently marketed products or imminently marketable products, we're still going to run after those just as hard. Where we see it starting to impact is the decisions that we might make for early stage deals. Those deals are effectively riskier now because of the near term benefits and 100% probability of debt reduction. So that's kind of how we think about it.

Chris Schott*Analyst, JPMorgan Securities LLC*

Okay. Very helpful. I think we're out of time. Really appreciate the comments today and look forward to the updates as the year goes along. Thank you.

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

Thank you. Thanks, Chris.

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

Thanks, Chris.

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