29-Nov-2023

Organon & Co. (OGN)

Piper Sandler Healthcare Conference - Fireside Chat
CORPORATE PARTICIPANTS

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

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

OTHER PARTICIPANTS

David Amsellem  
Analyst, Piper Sandler & Co.

MANAGEMENT DISCUSSION SECTION

David Amsellem  
Analyst, Piper Sandler & Co.

Okay. Good morning, everyone, and let's get started. Welcome again to the 35th Annual Piper Sandler Healthcare Conference. I'm David Amsellem from the Pharma team, and with us is Organon. We have Kevin Ali, CEO; and Matt Walsh, CFO. Thanks, gentlemen, for joining us and certainly lots to talk about, so I'm going to dive right in...

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

Go ahead.

David Amsellem  
Analyst, Piper Sandler & Co.

...with questions here.
QUESTION AND ANSWER SECTION

David Amsellem
Analyst, Piper Sandler & Co.

So, I'll start at a high level and ask how you're thinking about balancing debt paydown and capital deployment to bolster the pipeline and/or commercial portfolio. So, maybe I'll start with you, Kevin.

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

You jumped right in the deep end first.

David Amsellem
Analyst, Piper Sandler & Co.

Right in the deep end. Right in the hot topics. Yeah.

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

Yeah. So, look, I mean, as we go forward, a couple of things are happening. One is that we're getting to understand now I'm going into year three in terms of what our real cost structure is required, in terms of what we need to do to be more efficient. We're winding down from some of the one-time costs to stand the company up. We've gotten past that horizon of what kind of structure, the consultants told us we should spin out with, what we need more of and less of. And so, I think you'll see more of a kind of a scrutiny on OpEx going forward. So I think we'll be able to look at more of a leverage P&L as we move forward, as we've kind of past this period of time of investing in terms of just standing up the company, that's good news.

And so, when we start to think about capital allocation for the years to come, look, we're always – we're focused on becoming a leader in women's health. But I want to be declarative on this. What that means is not only conditions unique to women, but the disproportionately impact women. So that basically, includes almost everything.

So that's why we have a very active business development group that reports to Matt. And we're constantly looking. And right now is not a bad time to be looking for assets where we're more focused on either soon to be commercialized or recently commercialized assets in the market, and there are some really interesting things out there we're looking at. But nevertheless, as we start to be able to generate more free cash flow, absent anything that's interesting in BD will definitely put it to debt paydown.

David Amsellem
Analyst, Piper Sandler & Co.

Yeah. I think you've talked about trying to get to under 4 times, net debt to EBITDA. And so, I guess the question here is what can you realistically do on the BD M&A front that would bolster the business, but at the same time not set you back too far in terms of getting under 4 times?

Kevin Ali
Chief Executive Officer & Director, Organon & Co.
I think that is the question. Absent anything, you can rest assured we'll be definitely migrating below 4 next year.

David Amsellem  
*Analyst, Piper Sandler & Co.*

Okay.

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

And that's our ambition. That's what we're focused on doing. If something comes along that's very interesting, that's commercialized out there, that's generating revenue, that just in our hands, we're more a better owner. We're more – because we have an international footprint, we've got the same footprint as most big pharma does. So, as a result of that, we can internationalize a product, let's say, for example, is only in the US. That may be one reason that we might do something, that we ultimately can do more with it. Maybe some synergies out of it. We would come and essentially might have – we would necessarily need to have a very strong narrative, very strong story as to why we're doing this and why it is that we need another year to get to where we need to go. But after that, that's what we're going to be going.

David Amsellem  
*Analyst, Piper Sandler & Co.*

So to be clear, absent any M&A, you'll get on the 4x...

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

Yeah.

David Amsellem  
*Analyst, Piper Sandler & Co.*

...at some point next year. As you think longer term and I don't want to pin you down here on targets, but do you have a steady state net debt to EBITDA that you want to get to? I mean, I can name one of your peers that said we want to be at 3x. Where do you want to be?

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

Back around the time of the spin, my answer to that question would have been 3.5 times given how the business should cash flow, excluding any separation related items. And – but really sort of the binding constraint on that answer has really been how the stock trades. Operationally, the company can function quite easily at higher leverage levels than we think investors are comfortable with right now.

Now, around the time of the spin, we would have said. 3.5 times is a good place to land. And at that time, investors were nodding like, okay, we can defend that answer. I think our impression is now just given the current macroeconomic climate, investors are roughly half a turn more sensitive to leverage than they were.

So if they were sensitive – if they were fine with 3.5 times, the dialogue we have back and forth is now 3 times. And so, we – running the company is one vector into what the leverage ratio is. But really, what – the interaction that we have with shareholders is another vector and it's generally more conservative.
Yeah, okay. Want to talk about margins, EBITDA margins. So this year lower than last year. And with that in mind, what are you doing to manage margins, prevent further margin degradation or maybe I'll ask it differently. What is within your control?

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

Yeah, so it's a great question, Dave. So the answer to that question starts with discipline. Our operating expense at the time of the spin had very little reflection of any reinvestment in pipeline. And so, our costs had gone up to accommodate that. But as we – as capital has gotten more expensive, that reads through both on the BD side, right, the M&A side, as well as our own internal pipeline. So, we have generally been speaking to balance debt reduction and external growth, and we've almost done that to the dollar since the spin.

But that same discipline that we're now applying where the hurdle is higher for M&A and not only is it higher, it's slanted more towards income-producing assets, we have to apply that same discipline to our own internal pipeline. And I think you'll see that reflected in how we're thinking about next year.

So, OpEx is where we have hands down the most ability to impact it. You've seen some of it in our last quarter Q. We announced a restructuring charge. We're incorporating more of that kind of discipline and planning into 2024. Gross margins, just reflecting some of the latency effect of foreign exchange. And it's hard to have a conversation about Organon's financial performance and not talk about FX just given that roughly 75% of our sales are outside the United States. So we will see a read through next year on some of the margin pressures that we've been seeing in the second half of this year.

On the upside, though, right, as we think about rightsizing leverage ratio, which is important to us, and we have a lot of conversation with investors that just are anxious about Organon's leverage over 4 times. So, OpEx is one piece of it, but debt reduction is the other piece. And we are going to see improved performance next year, we'll have lower costs of separation next year. It should be at least 40% lower.

Most of the working capital build that we've had to do is done. We've put even a little more working capital in, in support of an ERP. Rollout that, should moderate next year. So the ability for the business to de-lever just naturally, given all those things, David, is at least a third of a turn and can be the half a turn just within one calendar year, absent any BD. Because as hard as we can tighten down the P&L, if we do that and that looks great, the next question you're going to ask is how are you guys going to grow?

And so, we always have that in the back of our minds. It's just if we're going to do a growth deal any time in the next 12 or 14 months, it's going to be very easy to defend. People can draw a straight line as to why that makes sense for a company with our balance sheet to be doing it. And if we don't see them, we'll probably do like we did this year. We only announced one deal this year.

David Amsellem  
Analyst, Piper Sandler & Co.

Yeah. Yes. All right. That's fair. So I want to make sure we hit on specifics, within the business. And I'll start with women's health. And there were some dynamics for NEXPLANON that drove some of the weakness in 3Q. And I wanted to have a little bit of a refresher on that and talk through the extent to which you think that's going to be short lived.
Kevin Ali
Chief Executive Officer & Director, Organon & Co.

Yeah. So NEXPLANON is – look, nothing has happened to NEXPLANON at all over the last five years, excluding that you're seeing ex-US business grow more because there was no investment in NEXPLANON outside the US. And now, that's something like around 35% of our – or 30% of our business is ex-US and growing in contribution and 70% of our business is in the US.

In the US, what's happened is because we've taken it over, you start to see a tick-up of volume increases. Now, every year, Merck was getting essentially where we came from was getting their growth because of price, right? So, now, we decided not to take price in this year. There's a very good reason for that. It's based on two important factors. And one that's important to both of us, but not important to all of you, which is number one is when physicians are able to prescribe a product at the state level, they have to wait to – they basically that the states update their list, the pricing list, every kind of beginning of the year in the quarter.

If you take price in the fourth quarter, there's a very high likelihood the physician that's prescribing NEXPLANON is underwater because the price is higher than what the reimbursement price is. So what we did is we equalize that so that when a physician – so when we take price, it's along the same lines as in that – within that quarter that the price will be updated in the state list so they ultimately, they're not underwater.

And coincidentally, that's where all the other large take their price is in the first quarter, not the fourth quarter. So we align to where the competition is and we align to where states update their reimbursement list and reimbursement pricing. That's number one.

Number two, we got really a lot of questions in the 2.5 years we've been here. What's going on with the fourth quarter? Why is it so high and what's going on with the first quarter? Why is it so low? Well, obviously, people bought in to take advantage of the lower price knowing that the price is going to go up.

Now, we take all of that noise out of the forecast by moving into the first quarter so that in a calendar year, you actually see everything happening in that given period of time. And so, as a result of that, that'll move in the overall volatility of that forecast line so that you can say, oh, okay, I can see what's happening now. There's not all these violent swings in Q4 and Q1 that I need to try to make sense out of. So those are the – I think the two most important reasons why we decided to not take price.

So going forward in 2024, to put it mildly to you, it's going to be a very strong year for NEXPLANON for two reasons in the US. One, our 340B business, which is a lower priced, federally mandated business, has grown to about a third of our overall business globally. And so, that Merck – the previous company used to actually give even additional discount on top of the 340B price. We've taken all that away.

So we took that away sort of – we removed that discount in September. So, for next year, you'll see basically three quarters of overlap of benefit of that. Plus, we get the added price increase that we're taking next year, plus you get the incremental volume growth that we have. So we expect low double-digit growth of NEXPLANON next year. So it's still our strongest product going forward. Nothing has changed dramatically.

David Amsellem
Analyst, Piper Sandler & Co.

So when you say low double-digits, how much of that is price and pricing dynamics and how much of that is volume?
Kevin Ali  
Chief Executive Officer & Director, Organon & Co.

Low to mid-single-digits in the US for volume and the rest is all price.

David Amsellem  
Analyst, Piper Sandler & Co.

Yeah. I guess, and this is – I don’t mean to ask this as a loaded question, but could it be – in volumes at least, could it be better just given the penetration of the LARC category?

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

Yeah.

David Amsellem  
Analyst, Piper Sandler & Co.

Number one. And then, number two, just the dynamics post Roe v. Wade. I’m just wondering why wouldn’t volumes, trajectory be higher?

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

It’s not a simple answer, but it’s answerable. So I would say this to you, is that, first of all, the product’s been in the US for nearly 10 years. So, you get a certain wrote kind of prescription behavior from physicians that are essentially, with this product. So, it takes more time and effort to start to change that momentum so that you have, instead of low-single-digit – low to mid, you get mid-to-high-single-digit. That takes time to do. Number one.

Number two is the fact that when you think about this product, it takes – so when you think about the LARC segment, it’s declining the others in the LARC. We’re the only ones actually increasing in the LARC segment. So LARCs, in general, IUDs are starting to essentially flatten to go down where we continue to grow. We’re the growth driver of the LARC segment. And so, as a result of that, you’ve got forces at play. It’s not as if the LARC segment is just exploding and we’re on that wave, we’re actually carrying everybody else in terms of driving growth.

Finally, what I will tell you is the following. This takes a lot of effort around social media, a lot of effort in terms of being able to get people to understand that in the US, 40% of all pregnancies, even a little north of that, 45%, are unintended. And along with those comes the unintended consequences. And I don’t want to get into that, but quite a number of things. And 40% of those were on some form of contraception, most likely pills.

So when people ask me, so what happens if the over-the-counter pills start to come in line? Is that going to hurt you? No, actually, the more – we get all our business from the patients who are on pills, women who are on pills. So the more pills that are actually being distributed, the more we actually get patient influx. So that is the standard. And then ultimately, we go over to NEXPLANON. So I believe it’ll break through and we have plenty of runway ahead of us before LOE to be able to create the kind of, as you say, volume uptick that we think this deserves.
Yes. So, you touched on R&D and spend overall in the beginning of our discussion. One of the things that I think comes up a lot in my discussion is pipeline visibility. And so, with that in mind, can you walk us through some of the key deliverables on the pipeline, not just women's health, but just broadly speaking that we could expect over, say, the next 12 to 18 months?

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

12 to 18 months. So remember, we're 2.5 years old. We spent about $500 million in BD activities. We didn't spin out with a pipeline to speak of, obviously, from my previous company. And we spent about the other $500 million in terms of capital allocation and debt paydown over that 2.5 years.

So what we've been able to do is bring in about eight assets and in various stages. So, for example, JADA, which we launched a couple of years ago, it's starting to really do well. It's starting to really contribute. We broke it out in the Q3 earnings. We'll break it out more in Q4. We have high expectations for that device going forward. And then, when you talk about XACIATO, we just launched that, soft launch right now, will be full launch in 2024. That is a nice little business to get into. It's a unique product for bacterial vaginosis, one application and basically very good efficacy. So there's a tremendous need in that space.

Then the more earlier stage assets, like for example, OG-6219, which is our endometriosis product, it is exciting. It'll -- in that 12 to 18-month period, you'll see a report out of Phase 2, and hopefully, if, knock on wood, if that's positive, we'll actually be able to talk about something in terms of Phase 3 migration from a product that has a complete new mechanism of action and an exciting type of delivery in terms of safety that you don't see with the GnRH class as well as the efficacy that we're hopeful that we're able to see with the OG-6219.

And then, another 12 to 18 months, you'll see a migration of OG-7191. This is the Forendo acquisition. That asset is for polycystic ovary syndrome. Now that is an area, when you're talking about unmet need, it is absolutely screaming off the page for innovation, for investment innovation. That one will be going into Phase 1 in 2024. And probably in the end of that 18-month period that you're talking about, if we're, all things being equal, if things go well, we can potentially start the Phase 2 process at the end of that.

David Amsellem
Analyst, Piper Sandler & Co.

Let's move on to biosimilars. And I think for a long time that seems like that's all we talked about even though it's a small part...

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

I'm so -- part of me actually is happy, I'm not getting 6 million questions about biosimilars.

David Amsellem
Analyst, Piper Sandler & Co.

Well, you'll get a few here. So, I guess, I'll start with HADILIMA, [indiscernible] (19:02) biosimilar, let's talk about market dynamics in the US. And I guess, maybe, again, another somewhat loaded question is, is the business -- is that market evolving differently than how you thought?
Yes. But having said that, when I first started to signal what the peak revenues of HADLIMA would be, couple of hundreds of millions in the US and globally. I think we'll still get there. It's just going to be a time continuum. This product is going to have a longer tail than originally anticipated. Where I anticipated a faster uptake, a faster downgrade because of price, I think it's going to slowly migrate up. And if you start to think about how our performance, HADLIMA is doing versus the competition, we've already passed AMJEVITA, which had a six-month headstart on us in terms of share and our ex-share.

So I think, clearly, the team has been able to differentiate itself in terms of not only the product but also, the way that we execute and the strategy that we took. Many of the other biosimilars took a dual pricing strategy. We took a low pricing strategy because I always had the feeling that why are we in this if not to save money for the system and for patients? And if you're in a high WACC strategy, you're not saving money for the system or the patient. You're essentially potentially making more money for PBMs in the process.

So there are 60% of the lives right now are PBM driven and 40% of the lives are what I would call, more WACC sensitive type of payers, Medicare, Medicaid, Blue Cross Blue Shield, Prisms, [ph] VAs (20:43), Kaisers and so on and so forth. And so, I think we're much more of a very, very compelling value proposition for that. And you could see it in the uptake. Now, hats off to AbbVie. I think they've been able to do a number of, let's say, negotiation tactics, if I can call it that. That has been able to hold on to a majority of their share that they've had. But they went from $20 billion in their peak now, last – this year to $14 billion, next year they're staying to $7 billion and it'll just keep going down because $7 billion is still far too much value that's trapped there that needs to come back to patients and providers.

David Amsellem
Analyst, Piper Sandler & Co.

Yeah. So, I mean, to – if I'm thinking about it as the – as AbbVie backs off, there's I don't know, maybe this is a little harsh, but some of the crumbs, if you will, so you've come to the...

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

Listen, one man's garbage is another man's treasure. It's that the way they say it? Now, the way I look at it is the following. If that market ends up being not $7 billion, but more like $2.5 billion and we're 10%, 15% of that, we'll easily achieved the numbers I talked about in terms of the several hundreds of millions.

David Amsellem
Analyst, Piper Sandler & Co.

Okay. All right. That makes sense. So we got a couple of minutes left. I want to make sure we talk about China.

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

Sure.

David Amsellem
Analyst, Piper Sandler & Co.

So that was an interesting review in terms of some unique moving parts, and maybe talk to those moving parts briefly and then how you're thinking about the outlook in 2024 for China?
Kevin Ali  
Chief Executive Officer & Director, Organon & Co.

Sure. So across the board, we faced – Organon faced a number of macroeconomic challenges during the year and a number of challenges period. We had a recall at the beginning of the year. We finally gotten through that. In China, specifically, at the beginning of the year, the first quarter, we had overhang on COVID, which affected our ability to drive our – one of our fast-growing stars of our business over there, which is fertility. That has gone away. Then in the late second quarter, beginning the third quarter, we have this anticorruption campaign. Now that's fading away. Then, we – throughout the entire year, we had this, essentially, the economy's driving deflation as opposed to inflationary pressures over there. People weren't spending money, especially for fast moving consumer goods, patients going to the pharmacy, which is a big part of our business. The retail section, that was a bit challenged. Now that's starting to soften up.

So all the signals are pointing as we go forward. And as we move through the volume-based procurement, we still have some volume-based procurement processes to go through next year. But as we move through that, we'll be in a much healthier state.

Even with all of these headwinds, we're only like minus 1, minus 2 this year versus last year in terms of performance. So, the team is really good at executing and finding other opportunities. Next year you'll see on the positive side, we'll be growing. And in the following years, we're doing more BD – China for China BD. So we have opportunities to grow.

David Amsellem  
Analyst, Piper Sandler & Co.

How much VBP exposure do you have next year? Is most...

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

Not a huge amount. I think. Like I said, we got 25% of the business left. There's probably about 10% or less that is exposed to any volume-based procurement round next year. That's why essentially, instead of it being very high single-digit, low double-digit potential opportunity, it's more moderated because of the volume-based procurement [indiscernible] (24:05).

David Amsellem  
Analyst, Piper Sandler & Co.

And how much of your business overall in China is retail versus non-retail?

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

Oh, that's about two-thirds of our business now in the established brands business is retail.

David Amsellem  
Analyst, Piper Sandler & Co.

Is retail, okay.

Kevin Ali  
Chief Executive Officer & Director, Organon & Co.
And one-third is non-retail [indiscernible] (24:18).

David Amsellem
Analyst, Piper Sandler & Co.

Okay. And then, in the minute or so, 45 seconds we have left. Established brands, just maybe tie a ribbon around the discussion as we think about the stability of the business. How are you thinking about pricing dynamics for established brands globally and just the extent to which you expect a continued stability?

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

Not much pricing opportunities around the world. There's a few countries that gives us an opportunity to price – to take price, but there's always volume opportunities everywhere. And we've got more than 40 products in the established brands franchise, 60%, 65% of our overall business. Everybody expected those products to be declining, high-single-digit, low-double-digit. It's actually grown. It's grown since we've taken it over. We still expect growth over the next coming years, very small growth, but that's a heck of a lot better than what people gave us credit for.

David Amsellem
Analyst, Piper Sandler & Co.

And with the limited pricing erosion, I would imagine.

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

Limited – well, look, yeah. You're going to get more price. You definitely got a get price. We average, I would say, what mid-single-digit on price growth [indiscernible] (25:21).

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

Around the time of the spin, the CAGR on that would have been about a 3% to 5% decline. This year, it's going to be around 1% because the inflationary environment has enabled us to go back in and either limit price or even raise price in certain markets. So now you see more of the volume growth showing through.

David Amsellem
Analyst, Piper Sandler & Co.

Yeah. Got it. Okay. Well, we're out of time. Thanks, Kevin.

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

Thank you, David.

David Amsellem
Analyst, Piper Sandler & Co.

Thanks, Matt. And thanks everyone from the audience.
Kevin Ali  
**Chief Executive Officer & Director, Organon & Co.**

Good seeing you again. Yeah.

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

Thank you, David.