Hikma 2024 full year results – Q&A transcript (edited)

This is a notice that the statements or comments that will be made during this presentation may include forward-looking statements. These forward-looking statements and comments may include risks and uncertainties and our actual results or performance may differ due to variety of factors. Thank you.

Operator: Ladies and Gentlemen, welcome to the Hikma FY24 Results. My name is [Ada] and I will be the operator for today's call. If you would like to ask a question during a presentation you may do so by pressing star followed by 1 on your telephone keypad. I will now hand you over to CEO, Riad Mishlawi. Please go ahead.

Riad Mishlawi: Good morning, everyone. Thank you very much for coming. Thank you very much for being online to listen to this. I should introduce my colleagues. I'm usually here with Khalid but this time we're all together so you'll have a chance to ask directly to the Presidents and the responsibles of each of our divisions.

Starting with Susan, Head of the Investor Relations. Bill Larkins, he's the Head of the Injectables division. Khalid Nabilsi, as you all know, he's the CFO. Mazen Darwazah, he's President and Vice Chair of MENA. We have also Hafrun, she is the President of the Generics division.

I have to start to say that we had a fantastic year this year. It's been a year since I've taken over the CEO position and not only that but also three of the people that we have in front of you here, this is their first year, the positions that they are in. Hafrun had joined us in April and Bill took this position replacing me when I took the CEO.

So, despite new management, we also had added new management in to the EC. We manage to work very well together. We manage to really do a lot of things as part of the execution of the strategy that we had. I believe we had really a stellar year, a lot of things we had done in preparing for the medium term and the long term for the Company.

Let me start with the year. I think we have a great momentum here. We had excellent results. We were well ahead of our original guidance in February last year. We are about $140 million ahead of revenue and $40 million ahead of the EBIT.

Injectables, growth of 10% in revenue, $1.3 billion for the first time with $468 million, up from $444 million last year, of core operating profits. The margins were 35.3% and really the most impressive part about it is in all three geographies - as you know the injectables is the only global division that we have that services MENA, Europe and the United States, and in this case, in last year, all three of those geographies has seen significant growth, especially in both MENA and Europe.

Branded division were up by 9% in constant currency to $769 million, with a core operating profit of exactly 24.6%, $182 million of core EBIT. Very good performance and, really, a lot of things that has happened in that division also to prepare for the medium term and the future. A lot of construction, expansion of capacity, and putting and installing new technologies there.

In Generics, very impressive 11%. As you know, with sodium oxybate coming in the year before, coming into this year, with a very low margin since our royalties had increased significantly. Still, we managed to do 11%, over $1 billion in revenue with a core operating profit of $170 million. Two years ago, we came in to all of you and were talking about this

division saying, $100 million to $120 million, and since then we're really doing much, much better than this.

Even in tough years when we had headwinds, we still have managed to do very well. 16.4% of the margins, that's for a year that we had some headwinds, is very, very impressive. I think we will talk a little bit about the future of this division and tell you a lot that is happening there.

We had some really excellent strategic progress. As I said, we really put a lot of irons in the fire in the last year, not only externally and not only with the investors, trying to communicate our strategy correctly, but also within the Company. We've done a lot in the management, in our structure. We've done a lot in looking at expansion of markets, Europe has expanded. We did a lot in R&D and we'll talk about this in the next section when we talk about next year.

But what we did last year, of course, Xellia was a big thing for us. I think it was a great acquisition. It's really giving us exactly what we needed. R&D was our focus. We really needed to increase R&D. We needed to increase capacity. We needed to get some infusion to our pipeline. Really, Xellia has given us all of this. So, with some very good products and with good future, with good pipelines that we are finishing right now.

I think also coming in, in the United States with a huge facility and very unique technology is [unclear] for things and [unclear]. At this time with the geopolitical situation, I think it's made it even sweeter. So, we have a lot of things going on with Xellia and we are progressing very well against it.

We launched liraglutide. We're still the only ones in the market. We were the first in the market after Teva had gotten the authorised generic; we're still the only one approved besides them. It just shows that our BD had chosen the right partner, we're very active in doing more business with them and I think this is really a testament of how we're going about expanding our pipeline, not only through our organic R&D but also through partnerships.

We signed a significant CMO for Generics. This is also something that we have talked about when we talk about the Generics and what do we need to do in the Generics. We talked about we have capacity that we can use some contract [unclear] for that capacity, and we did.

We went after big branded companies and we have a very impressive facility, very impressive quality record in the US, so that will give us a huge advantage and we've found a lot of people that were very, very interested. We finally chose one that has a great potential and we signed a significant contract there. So that is very much how our progress, I guess, the strategy that we have put forward.

We partnered with Emergent on Kloxxado. We can talk a little bit more - I'll leave it to Hafrun if you have any questions about that but I think this is very good. I think we can do better that way. Much more effective marketing and much more cost management there. So, I think it's a great deal and I think Hafrun can expand on that one.

The Branded business. For a long, long time it was very much stagnant at 20%. In the last three years, you see the growth. This year is not an exception and the future will not be an exception. We feel that the momentum is there. We feel our sites have been growing. We are still growing and investing significantly in MENA and you can see the results. So, this is something that will not stop and the momentum will continue.

Injectables, we're keeping the margins in the mid-30s. We're looking at absolute increase in profits. So, we need to invest in the business and we are investing in the business. We are investing in R&D. We are investing in capacity. All that costs money so to be able to maintain the margins at the very high level, highest in the industry, and still – from absolute value, increase the profitability, I think, it's a great achievement.

We're really prioritising this absolute profit growth. I know a lot of people are stuck up on the margins whether it's half a per cent more, half a per cent less, but we had some impressive ratios but as you grow, we need to also look at other geographies that we can expand in, not as high but still give us an absolute growth in our profits. So, we have to really give the balance to how much are we growing versus how much is our ratios being affected.

For 2025, strong guidance also, good EBIT growth. Even when you include – and this is something that is very important. We had committed that we want to spend money on R&D and this is why we recruited the people that you see in front of you, the R&D experts. They've all been in R&D, they have PhDs, done this, done that, and you can't recruit those people and tell them, no, we cannot expand the budget. That's the reason why we recruited them and that's the reason why we're expecting them to do.

R&D is our future. We really need to now – a very significant Company and we can't get away with just simple R&D. We have to go to the complex one and we have to go to very sophisticated R&D and that requires substance. So, we are increasing our spend by 20% and still coming in with a good forecast for next year and good guidance for 2025.

So, I'll leave it at that and if you have any questions the team is here and we can just go as deep in details as you want.

James Gordon: (JP Morgan, Analyst) Thank you. It's James Gordon from JP Morgan. Maybe two questions on Injectables, because that's where I've had some questions from people this morning. The first one was on the top line. I think in H2 you did something like 8% organic local currency but then the guidance implies for this year, for '25, more like 3% to 5% organic local currency.

So, the first question is why would there be that slowdown and does your previous guide that you gave in 2023 that Injectables should be something like high single digit business, does that still apply? Is '25 a little bit exceptional or have things actually slowed both for '25 and for the medium term?

Riad Mishlawi: No, I don't think so. I'll take part of this one. I'll give it to Khalid to talk a little bit more about the numbers. Our growth in the Injectables is still very, very healthy however you do have two markets that is affecting your ratios when you talk about ratios, in particular. We're growing significantly in Europe with lower margins. If you compare this year to next year, Europe had done over 20% growth this year. They took a lot of opportunities and they grew significantly.

For next year, we're not expecting the same amount of growth because of two things. One, we really grew very much this year and the second thing is the fact that the Euro and the FX headwind is not really helping you much there. At the same time, you have MENA also that is growing and also impressive that it was not the same expected ratio that we have in the US. Still though, the US is growing.

We do have also a few – if you look at some of the things that we're doing like liraglutide, we have – growing some products that are partnered products and that you would have to share

some of the profitability with the partners so it's not as high in terms of ratios, in terms of the profitability. But, again, from absolute value, it is more so.

Maybe this is why compiled together and taking [Xellia] out, you would get to the 5% growth rather than – but I don't think – I think it's very hard for you to take a chunk of something that we are all working on, the whole unit is working on Xellia.

We are putting a lot of effort into R&D to complete some of the pipeline. We've put a lot of effort into regulatory. A lot of our engineers and operations are doing so much to complete the plans. Although this is all behind the line and it's not really – has to do anything with revenue but still there's a lot of effort being there to make it to start producing.

Khalid Nabilsi: As in Xellia, for example, focusing on certain products, you take some of the products that you've been working on, so all in all the strategy is to grow the business. So, as Riad mentioned, you have a very tough comp for Europe, growing at 20%, you have the FX in Europe.

At the same time, you have the normal price erosion for the Injectable business that you have to compensate and we always said part of our strategy is either BD, organic or new acquisitions. With Xellia this would have helped to achieve a very strong growth of 7% to 9%.

Riad Mishlawi: I just want to add something. When you put guidelines and put ratios and all this, you have to put yourself in our place too. There are a lot that you're doing – a lot of it, you will achieve but you have to also give some room to yourself because you do have products that will get approved but it's not up to you to when you get that approval. So, you have to estimate, would I get it in July or would I get it in December? That makes the whole guidelines shift.

So, you have to be somewhere in the middle. But I'm very optimistic how healthy are the Injectables. With the addition of Xellia and the pipeline that we have in Xellia and some of the products – we did put in the guidelines some of the interesting products that we are going to have in the medium term. This is something that is unusual.

Usually, we don't talk much about the medium term. But we would like to talk about those things and if you can ask questions and I think Bill will explain to you some of the key products that are coming in with – and Hafrun, with both of those divisions. So, you can see that there is a lot that is happening, not only just [the hope].

James Gordon: (JP Morgan, Analyst) Just a follow up, so that was the second part. So, would that imply then that, say, in '26 or '27 or the medium term, you think Injectables could still be faster than 3% to 5% medium term because actually there's going to be benefits from Xellia in a couple of years, you're investing in R&D?

So you haven't changed the medium term aspiration, it will still be a high single digit and is the medium term aspiration still that you keep to the mid-30s Injectables margin, even with faster growth from some of the lower margin areas?

Riad Mishlawi: I think the growth is going to be very, very healthy in the medium term for the Injectables and there are reasons for it. So, we expect in the medium term, for example, for Xellia to be completely – what you say?

Bill Larkins: Integrated.

Riad Mishlawi: Integrated, sorry, integrated into the division today. We think that the facility will be completed and even now while we are building this facility, we're getting a lot of

people knocking on our doors for contract manufacturing. We will be making our own products right now.

We depend on some of the products for contract manufacturing to fill some of the work that we have. We will be able to fill our own. We will have some of the biosimilars at that time approved that we are waiting for approvals for.

Then we have one of the interesting products that we working on right now which is the Vancomycin ready to use. I think Bill can talk a little bit about it. This is a very, very big and key product. Vancomycin is a huge product used in a lot of hospitals for many infections. It comes in a powder form. We will be the only company that will offer it in a ready to use liquid form which we think that we can have the opportunity to take a lot of that market.

On top of that, we have a lot of pipeline products that are being worked on. Some on our own and some of the ones that we also got after we bought Xellia. So, all of that is coming from the medium term. A couple of the ones we have originally and what we do originally, I think that gives a very healthy outlook for the future. Markets as well, like in Europe, seeing growth in MENA. We are investing in many sections in capacity so we see more growth.

So, across all divisions, across all regions, in the Injectables business, we will see continuous growth. So, no change to our outlook on the medium term.

James Gordon: (JP Morgan, Analyst) And that comes back to topline [unclear] margin for Injectables?

Riad Mishlawi: Yes. We always said that the margin is going to be in the mid-30s. We see no reason why it should go – we're investing a lot in R&D but still we are managing to continue the stable mid-30s.

James Gordon: (JP Morgan, Analyst) Thank you.

Alistair Campbell: (RBC, Analyst) Alistair Campbell from RBC. Just a couple of questions on Generics, if I can. I still get a few questions on Generics profitability. So, basically, you talked about the $100 million, $120 million base which clearly, you've exceeded significantly in 2024, the outlook for 2025, around $160 million-ish, that kind of level. The question I still get asked though is, is there still a meaningful contribution at the profit level from oxybate in that 2025 number?

Is there a risk that some of that erodes in 2026? Can you, to the degree you can, quantify that? Then maybe, in terms of the investment you're making in R&D in the [unclear] unit, what sort of timeframe do you think before that starts to fit into an inflection upwards in terms of topline for the unit? Thank you.

Hafrun Fridriksdottir: Do you want me to talk about sodium oxybate? I can go through that.

Riad Mishlawi: Go for it.

Hafrun Fridriksdottir: Yes. We expect similar numbers both on the topline and the bottom line this year as we had last year for sodium oxybate. So, I think beginning of next year we expect there will be a number of – Generics will be able to launch that product so that's something with this, quite visible and quite well-known. So, we still assume a significant contribution from that product into our pipeline next year as well.

For short term or for new product, when I came into the business, of course, I looked into what product was ongoing and which one were progressing well and probably one of the most exciting one was epinephrine nasal spray which we are hoping that we will be able to

submit sometime this year. We have had a lot discussion back and forth with FDA and we are starting some discussion with all the regulatory bodies as well.

So, the plan now is to submit that sometime before the end of this year. I'm not going to talk about any specific month but that will be a 505(b)(2) application so it should not take more than – yes, of course, you never know how long time – the regulatory procedure takes but under normal circumstances it should take maybe 12 months. So, hopefully that will benefit us latest in early '27 or so.

Then over the last nine months, we have started nine new products internally and then we have also been utilising the capability in the other functions. Now, we are co-developing. We've started five new co-developments with MENA which will clearly benefit us as well. So, I am quite optimistic about the future and the new pipeline but we will, of course, continue to add new product in.

We are very focused on nasal sprays. We are very focused on inhalation products, without naming any. Of course, as Riad mentioned, that's why we need to spend more money on R&D and of course, that will not necessarily help with the profitability in the short term but, of course, in the long term it should.

Susan Ringdal: The CMO partnership that we signed will definitely support the profitability of the Generics business from 2027.

Riad Mishlawi: So, sodium oxybate in, correct me if I'm wrong, in 2026, January 2026…

Hafrun Fridriksdottir: Yes.

Riad Mishlawi: …will be open. So, we will have also the choice whether we want to stick to be the authorised generic or go on our own. So, that's a decision that we have to make. A lot of the Generics can come in at that time. The only complexity with this one is if we go out and go on our own, the patients will have to re-sign with our [own] program so it's not – you'll lose everybody and everybody will have to be coming back.

So, if you do have Generics coming in then that's going to be now a challenge with what you need to do to make sure that the patients continue coming to you for [unclear] program. So, there's a lot of decision making that we'll have to do by the end of the year to see what is the best way we should go. But either way, I think we have done a fantastic job with the way that we are today as an authorised generic.

We may have a chance to see if we can continue with what we are. Maybe just change some of the royalties there or go on our own. So, we'll have to choose to find out what the best way for us. As Khalid is saying, CMO is a big thing. We're spending a lot of money, capital, our client is spending a lot of capital in our plan to get the plant ready. It's a big product that we will be servicing for this company and I think for the medium term it will be very healthy, profitable and healthy for this division.

You put on top of it some of the products that are coming in, including epinephrine and some of the products that we have coming in today, I think we have a very healthy medium term also for the Generics, as well.

Pete Verdult (BNP Paribas): Just two topics, please. Hafrun, maybe for you, I'd love – rather than peppering you with questions about exact products and when you're going to launch them, I'd love to hear what you liked when you turned up at Hikma in terms of the R&D, what you didn't like, and what you've done in terms of changing the strategy? Just high level rather than product specific. That's question number 1.

Then to Riad or Khalid, just on compounding, I know it's a lot, it's a slow burn and it's – you're investing for the long term but it feels a little bit – just reading between the lines, it feels a little bit that momentum is gone there. Just give us an update on how you're thinking about that business and what [unclear] - I think last year we were talking about maybe even getting breakeven this year. That doesn't seem on the table. But just give us an update on the compounding business. Thank you.

Hafrun Fridriksdottir: Okay. So maybe I can start with what I liked when I came into Hikma from an R&D point of view. Of course, it was quite an impressive team which is located in Columbus, Ohio but we've still been trying to figure out – I mean, did we necessarily have all the right people there or did we need to replace people or add some new people in.

I hired the new Head of R&D in middle of last year and he started in end of last year. His expertise is mainly on inhalation products so that is something which we want to be focusing on, moving forward. We also have the capability, of course, in Columbus to produce those products so that's something which is important.

I've been looking into all kinds of processes and procedures and there is always an improvement opportunity and we are just working on those and making good progress. But also, as I mentioned earlier, there are more opportunities to collaborate, cross functionality, between the functions and do more together. That's something which we have already started on and I strongly believe in.

Khalid Nabilsi: We have Zagreb as well now…

Hafrun Fridriksdottir: Sorry?

Khalid Nabilsi: We have Zagreb as well and – that we've capitalised on and having the team there as well for both Generics and Injectables.

Riad Mishlawi: Yes, to talk about the compounding, we are very happy where we are with compounding. So, we had to actually start from a blank sheet of paper and start again. As I told you before, when we got into the compounding we thought, okay, we do exactly the same thing, just on a smaller scale.

When we go into the compounding, when we found out that, no, it's a different business altogether. It's a different client that you have to service. It's a different way that you have to manufacture. It's a different way that the FDA is looking at you. It's a whole different – we really do benefit from the fact that we know this business well. That we manufacture the products well.

But as a business it's a whole different ballgame. You have to ship your products straight to your clients. So, in the United States, we are the third or the fourth largest – second or the third largest in volume but we have about a handful of customers because we sell to the wholesalers. That's what we have in our system. Now, we have 4,000 different customers that you would have to get the [DA] licence for, that we would have to vet, that you would have to get the financial credits for, and all of those things. So, it took us a while to get going.

Coupled with the fact of how do we manage this facility without – managing this facility would be very easy, we know this inside out. We started finding out, look, our people that are selling these products, selling our core business, are not the same people that should be selling the compounding. The people that manufacture in our core business are not particularly – would be very good in managing the compounding. So, we did a whole reshuffle.

We got new Head of Quality, new Head of the Plant, new Head of the Laboratory. We changed the way that we manufacture things. We got the Head of Commercial who had 20 years' experience with [SEA] in the past, another compounding. Once we did this change, since then every month has been a record month from the mother before. Every month including this month. Including January which is the toughest month to do it. So, we are very happy where we are. We still want to take it easy.

As you know, Fagron just the other day got a warning letter, [unclear] got a warning letter, SEA got a warning letter. So, the FDA is looking at this business and saying, I'm going to straighten out this business. I'm going to make it a lot more compliant than what it was before. We are doing well. We're communicating with the FDA. We have fixed many of the issues that they want us to fix. So, we believe we're on good foundation and the future, I think, is very positive for this.

Pete Verdult: Is breakeven on the table this year or is that [unclear]?

Riad Mishlawi: No, it is there. If it is not there, it's just slightly less but it's there. I think that's…

Paul Cuddon: (Deutsche Bank, Analyst) Thank you. Paul Cuddon from Deutsche Bank. Bill, in one year you've increased the submissions for Injectables products by about 50%. I'm just wondering if you could elaborate on where those submissions have gone, particularly therapeutic categories, geographies, and what that might mean for the midterm growth aspirations.

Bill Larkins: Yes. So, overall, it was a focus when I came in to make sure we drove the products through the pipeline. So, we had a lot of things that were either in development, that had technical challenges or were sitting at FDA so we spent a lot of time in R&D kind of – well, we call it cleaning out the pipes. So, it's really around driving those things to completion. It was mostly in the US was the focus on that so the bulk of those products came through there.

It then freed us up to be able to do more which is then to add in more complexity into the pipeline which has been one of our focuses going forward. So, it freed up the capacity to do that. Then along with that, I think, with the Xellia acquisition as Riad talked about a little bit as well, we got this interesting development centre in Zagreb as well. They have some unique expertise in what we're calling in our strategy these ease-of-use products that are ready to use bags, ready to dilute products, ready to deliver products.

They had a basket of those products in the pipe. We have a basket of those and from a Bedford side as well. So, we've kind of combined all that together, strategically. So, I think, in the coming hears we're going to continue to see that kind of growth coming out of those types of products, as well.

Paul Cuddon: (Deutsche Bank, Analyst) Thank you. Secondly, on the Generics CMO which I think you must have signed before the talk of Paris entered the pharma narrative. To what extent would others like you to be manufacturing products for them in the US with the potential of Paris coming on, Canada, Mexico, others, or is that something that you're don't really see as…

Hafrun Fridriksdottir: Maybe I start with that. We get a lot of requests of new CMO potential contracts. We have visitors almost – I would say every other week, companies which are interested. So, it's not the lack of interest, it's maybe more capacity. So, we can, of course, only do so much and, which Riad mentioned earlier, it will save quite a lot effort, both

preparing for it and when we start the manufacturing it will be significant volume. So, we had to decide what can we do, what capacity will we have? We don't have endless capacity. So, we could clearly take on more if – yes, it all depends on what kind of capacity [unclear].

Riad Mishlawi: I think, there are two things we have come to the CMO. I think if you want to grade yourself that you are a good CMO, you have to see if those companies that come to you continue coming to you and continue adding products to your pipeline. We have [unclear]. So, we have a limited capacity in the Injectables but still we see a lot of people coming to us. As you know, we did a great deal with Gilead for remdesivir.

We introduced our product in record time to the US during the COVID time. We see Gilead still coming to us with a lot more interest in doing more business with us. I think that's a testament of our quality, our collaboration. Also, we do biosimilars. We are lacking capacity but capacity is coming. We are building – probably doubling our capacity, especially in [unclear] in the next two years. We're adding a huge facility in the US with six lyos over 300 square foot. Those are considered very huge lyos.

We're adding six of them. We're also adding lines for filling. We're adding lines also for [heptic bag filling]. So, capacity is coming. Also, in Portugal, as you know, we have the big facility that we broke ground and that will house four huge 400 square foot lyos. So, I think from the capacity point of view, we're in progress. We're ahead of the game. We should be – a lot of that should be coming in, in the next year or two.

So, when we talk about medium term, we're considering all of that too because that will be coming. We are still healthy today and I think that, in addition, to what we have today will be – we're just sitting in a very good position.

Christian Glennie: (Stifel, Analyst) Good morning. Christian Glennie from Stifel. Maybe one on Branded and the margins there and, yes, you did come in at your – roundabout a 25% level for the year but the split between the first half and second half was particularly dramatic, and if there was maybe some expectation there may be a bit of upside, it would have been maybe on a Branded margin, for example, maybe a bit above the 25% so to come in sort of sub 20% implied by the full year number.

Is there any particular to call out there that maybe didn't quite come through in the second half or was that – I know it wasn't on track but nevertheless – and then as you think about '25, what might be the rough split again in terms – or the weightings in terms of that margin for '25?

Khalid Nabilsi: First of all, I think in the MENA, our team did a great job and you have to remember the MENA is 17 different markets. It's not one market like the US. So, every market has what we call the private sector and the public sector. The public sector usually is a tender. So, our sales are split between private and public sectors. The margins really are differentiated whether it's a tender business or it's a private business. So, it's a matter of timing when you sell this product and when you ship them, this is what differentiates the margins.

So, as a whole this is why we say we're near the 25 margin as a Group. Remember, five or six years ago our margins used to be between 19 and 20. So, during the last couple of years, we have really switched our business model from acute medications to chronic diseases. Chronic diseases, basically, is a long-term project where we are adding on our pipeline, cardiovascular, diabetes and hypertension. So, this is where our growth momentum will be in the future.

So, we are shifting gradually from an acute business to chronic business. We are shifting from tender business to more private sector business. So, this is where we'll be able to maintain our margins. Plus, in the MENA, as you are aware, that many countries have what they call protective legislation. So, once you are in a country like Iraq, for example – I'll give you Iraq. Iraq today has something like 92 manufacturing facilities. So, if you don't manufacture in Iraq anymore you will be stopped from exporting to Iraq.

So, the same thing goes in Saudia Arabia. Now, we are seeing that shift. We're seeing it in Egypt. We're seeing it in Morrocco. So, this is why we have extensive footprint and this is why we're trying to maintain our margins in difficult situations. So, we are confident medium term that we will continue to be in the range of 25 going forward. Hopefully, we'll have CAGR of 6% to 7% as we grow during the next five years for the margins.

Riad Mishlawi: But in terms of the split between H1 and H2, it's in line with our expectation. So, it's timing of tenders that took place in the first half related to certain high value products. In the second half, we continued to sell, of course, but not the same, let's say, amount of tenders but we have as well increase in sales or marketing activities.

Usually, in the MENA most of the marketing activities takes place in the second half, more than the first half. We increase our R&D standard in the second half. So, this is why – nothing I would say abnormal for us other than the split between H1 and H2 but for the full year it's in line with our guidance.

Khalid Nabilsi: I have to add just a little bit for this. I think if you look at the UK market, for example, there are many tenders going on. If you look at some of those – so they're not all at the same time. In MENA, huge tenders happen at one time. Algeria, one huge tender. Saudia Arabia, one huge tender. It used to be many tenders. They combine them all in to one tender. Because you win that tender at one time, you deliver at one time, and that's why the bulk happens at one time.

Christian Glennie: (Stifel, Analyst) That probably is similar [unclear]…

Riad Mishlawi: Maybe to a lesser extent than 2024.

Christian Glennie: (Stifel, Analyst) Thank you. Maybe on the usual questions around pricing but maybe specifically just to clarify on the Injectables price – in terms of to what extent there's any [unclear] – what is the ongoing pricing erosion within both Injectables, in the US particularly, and in Generics?

Bill Larkins: Price erosion, is that what you're talking about? So, mid to low single digits, kind of typical trend.

Christian Glennie: (Stifel, Analyst) That's on change? I'm just trying to get [unclear]…

Bill Larkins: Yes. We're not expecting any significant change in that going forward.

Christian Glennie: (Stifel, Analyst) Yes. Similar in Generics?

Hafrun Fridriksdottir: It was around 6% last year but it's all based on the product mix. It's difficult to guess. Many of our product which we are selling in the US are quite old, they've on the market for a long time so maybe you see less price erosion in this kind of product. You see normally the highest price erosion for those which are [unclear] and then more company comes in. So, it's difficult. But it's a similar average that has been over the last 10 years. Some years have been more. Some years has been down to 15 but last year was around 6% for us.

Christian Glennie: (Stifel, Analyst) Thank you. Maybe quickly on liraglutide, at the moment you're still the only straight [unclear] generic, as it were. The longer that goes on – just give a bit of context around the potential benefit you might have from staying the only player in that market as you go through the year or in another way [unclear], how much is that expectation put in the current guidance for injectables?

Riad Mishlawi: Bill, do you want to take that?

Bill Larkins: So, yes, a couple of points on this one. (1) I always like to toot our Hikma horn on this one. So, we are the first and only approval on this product. So, Teva actually is the authorised generic so they actually don't have an approval in the US, we're the only ones so I think that's important about our performance.

So, we're expecting near-term competition. We're hearing that competitors are launching in the near term. If they don't for various reasons, then there'll be potentially upside to what we're forecasting for the year. But we're forecasting in more competitors coming in this year.

Christian Glennie: (Stifel, Analyst) None approved as yet?

Bill Larkins: They're not approved as of yet.

Operator: Ladies and gentlemen, if you would like to ask a question, please press star followed by 1 on your telephone keypad now. Our first question from online is from Beatrice Fairbairn from Berenberg. Please go ahead.

Beatrice Fairbairn: (Berenberg, Analyst) Hi. I just had a question on the US biosimilars, I was wondering whether you could provide an update on the status of your partner's denosumab biosimilar following it's FDA filing in December, when should we expect an approval for biosimilar and what sort of ramp up should we anticipate? Thanks so much.

Susan Ringdal: Did you catch that?

Bill Larkins: US…

Susan Ringdal: US biosimilar progress.

Bill Larkins: Okay. As you know we have two biosimilars in the US, ustekinumab and denosumab. Both of those products are under active review with FDA as we speak.

Beatrice Fairbairn: (Berenberg, Analyst) Great. Thank you.

Bill Larkins: So, expectations on timing, we're forecasting that we'll launch both of these products in 2026.

[Over speaking]

Emily Field (Barclays): I know there was a lot of attention to the [unclear] announcement last week that the pricing discounts are developing in a much more aggressive way than they'd initially expected and I think some investors had been [unclear] with the cross-US biosimilars. Have you noticed any changes in the pricing outlook or discounts to random products just at a high level?

Bill Larkins: So, we did see the same thing on Ustekinumab so the drop already is over 85% so just with the few launches, already. I think what maybe puts us in more unique position than a lot of others is the partner that we have on Ustekinumab specifically and the cost structure we have on it, we think we'll be able to be in a really competitive place overall. So,

we've kind of forecast it in, our view of our launch in '26 with kind of this level of erosion maybe even a little bit more so it's not shocking to us.

Pete Verdult: Just a few from me. Pete Verdult, BNP Paribas. Just to the whole team, just the ambition, if any, that you have as it relates to semaglutide. I mean, you've done liraglutide, and I apologise already looking beyond that but just what level of ambition, if any, do you have in terms of semaglutide?

Two, could you help me here qualitatively, how much of the US business can you supply through Cherry Hill and Ohio versus the network you have in MENA? I realise you can't give exact numbers but it's a tariff related question.

Then Riad, I ask you this every year, which is you're not going to say what you're looking at and what size but just the environment to do business development in terms of what you're seeing, how excited are you about being able to do further – utilising the balance sheet further this year? Are there opportunities out there – just characterise the environment for BD at the moment.

Bill Larkins: If I may, I'll jump on few and then you can add the rest around it. So, I'll start with peptides and then move in to GLP-1s. So, I think peptide, specifically, we have a unique skillset within Hikma. As I mentioned with liraglutide, we also had the first launch of calcitonin, as well. So, we do have a skillset both in R&D and regulatory in peptides and we're going to leverage that going forward.

We're certainly going to be in the GLP-1 space going forward both either through internal development or partnerships and many products and combinations of those. So, we'll be – certainly going to be participating in the GLP-1 space going forward. As far as then the plant in Cherry Hill and what part of the business for the US, Riad probably has a better view than I do so it's – that plant can do over 200 million units out of that facility. We do have the ability between Portugal and Cherry Hill where there are overlaps in the production.

So, if we see opportunities for the US specifically around tariffs there is an opportunity that we can shift production of some products from Portugal to Cherry Hill, and vice versa. We have those types of opportunities as well. You probably know better on the overall markets furnished out of Cherry Hill.

Riad Mishlawi: Yes. Sure. So, overall, we have Generics completely US made, manufactured, sold in the US, over $1 billion. Then we have the US Injectables that are around – a little bit more than $800 million, actually, is coming from the US manufacturing between three plants, Cherry Hill, Portugal and a little bit in Germany. Cherry Hill actually makes probably around 60% of this and the rest between Germany and Portugal. As Bill said, we have the ability to change that ratio if we chose to move some of those products to the US.

So, all in all, I would say not more than 20%, maybe a little bit more that is made outside of the US. None in India, none in China, all of Europe. I think compared to many of our competitors, when it comes to this, we are a lot more US based than a lot of our competitors, even US companies that we compete with. With [unclear] coming in, that ratio would be incredibly big as US manufacturers.

Pete Verdult: BD?

Riad Mishlawi: For BD I think we have a great opportunity right now especially with the world begin so nervous. A lot of the foreign companies that had invested a lot in going to the US, making facilities that are FDA approvable, now they're very nervous, what would happen.

We would like – some of them are our partners that we have products from. We would like to expand that relationship and see if maybe we can help in this where we can move some of [their IPs] to our own facilities in the US.

I think we will be discussing a lot with our partners. I think also because of our manufacturing, the majority of our manufacturing happens in the US, I think that would be a good proposition to most of them.

Paul Cuddon: (Deutsche Bank, Analyst) Thank you. Paul back on. Just a clarification on the Vanco Ready product you acquired and was on the market and you now need to gain approval for a reformulated version so I'm just wondering what was wrong with the original product and what the implications are for when you might get approval and the market [unclear] thereafter.

Bill Larkins: So, the product on the market today is a product that has a black box warning on it as people are probably aware. We have a reformulated product, NDA product that's under review, actively with FDA now. We're expecting some news on that later this year. That box is a reformulation with NOB – sorry, it's a product that has a reformulation where the box will be removed. Sorry, just one other thing I'd add too, it is a patent protected NDA to 2035.

Riad Mishlawi: Yes, I think just wanted to say a couple of words about this product. This is – would be or will be a very important product. Vancomycin is used for a lot of infections. It's used in all hospitals. It's a huge market in the world especially in the US because they use this one more than anything else. In Europe they use another antibiotic that doesn't exist in the US. But it's a big, big product. It is usually offered by body weight so you have different brackets of it.

This is offered as a powder. So, in order for you to infuse it to a patient you need to dilute it into the right ratios of liquid which is complicated. So, what happens most of the vancomycin administered in the US is compounded. So, the compounding pharmacies, the compounding companies and pharmacies, they get the product, they dilute it, they put it in different brackets of bags and sold to the hospital. In this case, once we get approval that there's no need, there's something that exists already, six different brackets that we have depending on the body weight that you have, ready to use, liquid form, doesn't need to be compounded.

The most important thing, the one that comes from the pharmacies that are already compounded is good for few weeks, months, couple of months, maximum, while our product definitely has a much, much, much longer expiration date.

Bill Larkins: I'm going to actually add one thing on top of that. So, this product is used for sepsis and so getting this product to the patient quickly is important. If you don't people can lose limbs and/or die so you have to get this administered quickly. So, all of these things that Riad's talking about of taking it from a freeze dry product to dilution, the time really matters. So, this product really has an enormous upside if you can just grab it, administer it to a patient so that time is really, really important.

Paul Cuddon: (Deutsche Bank, Analyst) One more maybe on Generics and thinking about the CMO contract and then the potential impact to that in 2027. In broad terms I think you talked about utilisation and Generics being 50% to 60% or so, if that's the right number, and therefore, once that product's fully online, '27 and beyond, does that shift – is that sort of a contract that would shift significantly, that utilisation rate, if it's possible to say.

Riad Mishlawi: I'll say a couple of words and Hafrun answer this.

Hafrun Fridriksdottir: Yes.

Riad Mishlawi: The capacity utilisation that we keep talking about is with the existing equipment that we have today. This contract will put a lot more equipment and capacity in addition to what we have.

Hafrun Fridriksdottir: Yes, and also, how you calculate capacity. I mean, do you calculate it based on the number of people you have or do you calculate it based on equipment you have? I would say that – maybe Riad doesn't fully agree with me, I say, we are 100% utilised based on the number of people which we have.

But with this contract we will need also, of course, to add a lot of equipment but also people to support that business and that's something which we are already in progress of doing. So, I'm not willing to give you utilisation numbers because I think that's – you can calculate that in so many different ways.

Riad Mishlawi: But the fact that you are able to increase capacity today by adding more people, working more shifts, working on weekends, you can do that. We're not doing all of that today. So, yes, maybe we're utilising more than that 50% to 60% but usually, again, what Hafrun is saying, depending how you calculate capacity, is it the maximum capacity that you can get to or what's your capacity that you're working at today? I think we're working at the capacity that matches our demand but if the demand increases, we can also increase the capacity.

I just wanted to repeat what I started with and what we tried to put across which is the medium term. We talked about it in many of the questions that you have asked. But if we look at the next two to three years, so let's take division by division, if you look at the Generics, we're just talking about it today, and the medium term, we will have the project of contract manufacturing will be at full throttle delivering a lot of financially health numbers to this division.

We will have interesting product coming and then getting approved. Nasal products like epinephrine and other technologies that we're working on. I think a lot of what we have – the R&D that we're spending money will be coming in to fruition. So, I think that Generics will be in a very, very good position in the medium term.

If you look at the Injectables, we talked about – last question was talking about biosimilars coming in also soon. Talked about the Vanco Ready, the Vanco Ready to use coming in, also very soon. We talked about Xellia, the plant that will – in the United States with huge capacity and technology, something that is very good to have especially today. That will also increase our capacity, give us breathing room to also get more contract manufacturing opportunities.

We also talked about the pipeline that we got from Xellia and the R&D centre that we will be looking at completing many interesting projects there and we think that we can complete it. I think a lot of them were halted by Xellia because of financial – with their financial means, not because of any obstacles in developing those products. So, we feel that we can complete those products.

Compounding business should be healthy. It's going on the right track. We think that we also can be doing a lot with this business. I think this business is going to be a big contributor to our growth.

MENA, also momentum is very, very healthy. Continues to show the capabilities we have invested significantly in the last two years or three years in MENA and we are still investing.

We have new facilities in Morrocco. We have new facilities in Algeria. We're breaking ground into new facilities. Saudia Arabia, we're doing another facility of oncology in Saudi Arabia. We just finished a facility in Tunisia. So, we have been investing in the capital expenditure there and increasing a lot of time in R&D.

All the Group is increasing in R&D, about 20%. Significant increase in R&D. Still being able to get you numbers that are good, healthy, with healthy growth and spending. We need to spend on this business to grow. So, doing that while we're still maintaining growth and healthy numbers, I think, it's a great formula and I think we are [unclear] this today and we will be at the medium term.

Multiple Speakers: Thank you.

Operator: This concludes today's call. Thank you for joining. You may now disconnect your lines.

[END OF TRANSCRIPT]