Hikma 2025 full year results - Q&A transcript (edited)

Guy Featherstone: Welcome to Hikma's 2025 Interim Results meeting with our CEO Riad Mishlawi and CFO Khalid Nabilsi. Before we start, I'd like to remind you that any forward-looking statements or projections made by Hikma during this call are made in good faith based on information currently available and are subject to risks and uncertainties that may cause actual results to differ materially from those projected. For further information, please see the principal risks and uncertainties section in Hikma's latest Annual Report. With that, I'll hand over to Riad for some opening remarks before we go to Q&A.

Riad Mishlawi: Thank you very much. Good morning, everyone. Let me start by maybe a few words summarising the first half. I believe we had a strong half. We have a strong revenue growth of about 6%. That's driven by volume growth across all segments. All the segments are doing well as expected. I think the big story and the most impressive part of it all is that we had revenue growth of 12% in the injectable division. Revenue growth means that we have good demand on our products. To be honest, it's a good indication for us that all the investment that we're doing in expanding our facilities and increasing our capacity will all bring in good results. That's happening as we speak today.

The growth did not happen in one region. We have 26% growth in Europe. That's something also very impressive. MENA, 16%, and MENA has been doing this year-on-year for the past few years and continues to do so. Of course, the US, we have a growth of 8%. That's all driven by new launches, driven by volume increases, and, of course, the Xellia portfolio that we had acquired middle of last year.

The branded revenue is up 4%. The branded division has been doing really well year-on-year with not only good growth, but also very stable margins, very stable profitability. That's a division that everybody questions, due to geopolitical problems, if we are going to be impacted at all. I think it's doing the opposite. I think the political instability is bringing us new business and then this business has been doing really, really well. Of course, we're doing a lot to feed it in new products. We're doing a lot of BD. As you know, we acquired a few products like the Takeda products last year.

Finally, the Rx division, the revenue is about flat, broadly flat, I would say. That's a division that everybody was worried about for a while. So, I think what we did this year, it's pretty obvious that it's very stable, poised for growth, good R&D team. We're doing a lot in R&D. Of course, you know that we had announced a big CMO contract. But I think it will be going into the full throttle in a couple of years, starting on next year. We're doing a lot of investment in that division, and I think the fruit of all this investment is going to be pretty obvious.

So, I think there's a lot of good news. There are some slight, I would say, unexpected headwinds, especially in the margins of the injectables. This is why we dialled down the injectables slightly. The good thing about it is that this is temporary, this is not something that will last. It's mainly driven by the FX, the strength of the euro. As you know, some of our cost in injectables is in euro, and we pay it in euro. That had slight effect. Of course, the uncertainty and the un-clarity created some inflationary costs, like shipping, some of the tariffs that we would have to pay, some of the inventory and so forth, that also added to that. It didn't really affect it that much, but we wanted to make sure that we're very transparent. We'll see how things are going, but we also want to be realistic that there are some headwinds, and we have to face them.

But as a whole, I think we are reiterating our Group guidance, and that's what's important. We continue to expect the Group revenue for the year will be between 4% and 6%, core operating profits in the range of \$730 million to \$770 million in 2025. The slight adjustment that we did with the injectables is exactly just to reflect what was happening, what has happened. That has been accounted for right now, and I think that will be behind us from now on.

You can see the branded. There's no FX headwinds in the branded. This is usually where the FX is, but in this case, it's not. It's in the euro, something unexpected. As you all know, in the beginning of the year, everybody thought that between the euro, there would be parity between the euro and the dollar. It's really the opposite has happened, and that's what skewed our numbers a little.

I just wanted to make one point is that if - I was looking at our share price this morning, and we had hit 52-week low this morning. Three months ago, four months ago, I believe we were at 52-week high. I believe that where we're sitting today, we have a much, much stronger business than we had three, four months ago.

Everybody was worried, for example, about the Rx business, our ex-Generics business as we called it. Everybody was worried, what are we going to do with it? A lot of suggestions. Should we sell it? Should we get rid of it, some of the parts? We heard all of that. What we have today is a very, very strong division, delivering. We have a great R&D setup there. We brought a leader that understands how it's run. We signed up a great contract manufacturing contract that will stabilise a lot of the income and give you a lot of profit, something that is predictable. It's going to come. Also, we are submitting very critical products such as the epinephrine.

So, we have transformed this division from the time when we used to sit there two years ago and say, it's going to bring between \$100 million and \$120 million. Well, it brought in \$190 million last year. Is that what...?

Susan Ringdal: Yes.

Riad Mishlawi: The \$190 million last year. We're anticipating to bring in \$170 million this year. It's doing well. It's got a great future. If all the products that we are submitting are going to get approved, that will be an incredible division. Despite all that, there is a lot of spending on R&D, focus on R&D, and still we're able to come up with numbers that exceeded what we had said before.

You look at the branded, year-on-year growth, year-on-year stable. Profitability is high. It has increased significantly from three, four years before. It continues to do so. We're signing a lot of contracts; we're signing a lot of BD contracts. As I said before, the political instability in that region is making a lot of the big branded companies that operate in that region come back to us and say, hey, you're local, you understand, why don't you just take our products? We have been very successful in signing a lot of those big products into our own and add them to our portfolio. You can see that from the numbers.

Injectables, I used to be, as you all know, Head of Injectables. I can tell you, I know all the injectables competitors that work with us and our peers in the same market, we are double or much higher in the margins than anybody there. Everybody wonders how we are able to get the margins. Let me remind you that we get these margins while we are operating in the US. About 60% of our products of the injectables are made in the US and the rest are made in Europe. So, we're not in low-cost areas. We're not in India, we're not in China, we're not in any of the low-

cost areas. We're still able to get margins that are higher than everybody else competing with us and without any sexy ones. We don't have big products. We have generic, simple products, but we're able to squeeze so much out of those.

We're investing in Bedford. That is going to be an incredible facility with technologies that are very unique in the US and in the injectables area. We're investing in Cherry Hill. We're adding more lines. There are a lot of investments that are happening across all injectables. We built new facilities in North Africa. We doubled the capacity in lyophilization in Italy. We are breaking ground for a very sophisticated state-of-the-art facility in Saudi Arabia. A lot of investment is happening in this division, because we really believe in it and we believe that we can do better than anybody else operating in the same field.

So, it's very confusing to all of us, how we see - going from 52-week low to 52-week high, is it the reaction of what happens on the day or are we evaluating the Company based on what they have in the future and how they're growing and what the prospect of the future is? So if it is about the future, I can assure you that the future of this Company is more positive than it's ever been. We are looking at how we are going to be organised to be more effective.

We are absorbing 11% more, or \$11 million more, in R&D than we have in previous years. We're still able to get numbers, we're still able to get an EBITDA number higher than any of our peers. We are operating, as I've said, in all - most of our products are coming from expensive territories like the US and Europe, and we're still able to manage for a profitability like that.

Khalid Nabilsi: Actually, increasing R&D by almost 20% as we highlighted year-on-year, and we still deliver.

Riad Mishlawi: We believe in R&D. We believe that this is our future, and we believe in growth. We are not going to cut R&D so we can get the numbers, and everybody is - we need to invest in the future and R&D is one of them. I think the reason why Rx had suffered for a while is because the R&D investment was limited. If we want to grow, we need to invest in R&D, but not only invest in R&D, invest in smart R&D. So, you all know the people that we had brought in, very R&D focused, very science focused. They know not only how to sell the product, but also how to develop it and how to make it.

So, we're counting on those people, we're counting on all of the organisation, and there's a lot more to do. I think the results show it. So, if the effects come in because the euro was unexpected and you have to dial down 1.5% on your margins, it's sad to see that the reaction is that severe, but that's how the market goes and that's what we need to do.

So, we're open for questions.

Operator: If you would like to ask a question, please press star followed by one on your telephone.

Shirley Chen (Barclays, Analyst): Hi, everybody. Shirley Chen from Barclays. So, maybe just on top of what you have said on Injectables high margin. So how do you find continuing this advantage? What would you do to be able to keep your high margin? We all know there's more and more [unclear] coming on, so how would you maintain your high margin at this scale?

Riad Mishlawi: I think the formula is simple and we mastered that formula. I think the high margins didn't come only last year. For the last 14 years, if you look at the injectables - maybe 15

years, I haven't looked exactly where or what - we had been delivering 34%-plus. We even had some years that we got to 40%. So, it's not a formula that's strange to us. It's a formula that we follow, and it's been working well with us.

But I think even now, we think that we can even do much better in terms of organise R&D better. This is something that we were not very strong at. We've recruited now people that understand this very well. We reorganised our R&D much better. We have a nice centre in Zagreb now that we had acquired with the Xellia acquisition that we are going to capitalise on. We're going to reorganise it. We're going to spend some money on it. So, we believe that the money that we are going to spend on R&D is going to come back much more than ever because of the location where we're spending it and because of how we are organising ourselves. We're putting synergies together. We're identifying the synergies across all divisions. We're doing a lot in that area, because we do believe in R&D.

So basically, when it comes to revenue, when it comes to margins, I don't see there's anything different. In fact, we used to get those margins without any, as I said, sexy product or big high margin or whatever product that [unclear]. We had simple generic products and were able to get that margin.

However, today, we do have that product. We do have Tyzavan that is very unique, protected for the next 10 years, only one in the market, a product that has huge potential. There's 30 to 40 tonnes of vancomycin being sold in the US, and we are the only one that has ready-to-use bags. We have a patent on that one that will stay with us for quite some time. So, we do have unique products right now. We have a lot of 505(b)(2) and then Tyzavan. So, if we were able to get that 35%-plus margins in the past, we should be able to even do better now.

Shirley Chen (Barclays, Analyst): Thank you.

Riad Mishlawi: Thank you.

Beatrice Fairbairn: (Berenberg, Analyst) Thank you. Hi. Beatrice Fairbairn at Berenberg. So, in the release day, you noted that the Group outlook takes into account the impact from tariffs in relation to inflationary pressures. Would you be able to kind of quantify this, which areas it's impacting most, and anything that you're doing to offset this?

Riad Mishlawi: Okay. Yes, thank you for your question. I really need to clarify the tariff thing. The impact of the tariff is not that big today, especially in our P&L. It might be in the balance sheet, because as you know, if you buy raw materials and it stays in your warehouse, it's in your balance sheet, not on your P&L. So, the impact on the P&L is not that much. However, an impact, nevertheless.

Tariffs are today - we are all anticipating what will happen. We're all trying to predict what will happen. Things are changing daily, as you all know. We know that there's some tariff on Europe, but we don't know if generic drugs are going to be included or not. But considering all of that, our US presence is bigger than anybody else. So, in the future, we are going to be - if tariffs are going to be severe, I think we are in a great position. If we're actually going to put that 50% on India, most of the companies in the US are getting their products from India. They're Indian companies, and many of them are sourcing their products from India and China. So, we are not, so we have also less risk in terms of the tariff.

But today the tariff is there. It's not affecting us big time. We have only 5% of our product totally in the whole Group that comes from China. In the US, it's even much less than that. So, it's not

going to be a big number, especially from China. From Europe, we don't know what's going to happen. If it does, it's going to be a slight small number, but we still don't know. But if you compare us to the industry, I think we're sitting on top of everybody else because of the way that we're structured.

Khalid Nabilsi: This indirect impact, like increasing shipping cost, because of the tariffs, it's like shipping cost increase. You see, as Riad mentioned, very minimal impact for this year in tariffs, but combined maybe it's around \$6 million, \$7 million impact between shipping, inventory. Tariffs, it's not a significant amount that affects us. That significant - like why we've come down on our margin, it's mainly the FX. When we gave the guidance, the euro was to the dollar 1.04. Today it's 1.16. If our cost base in euro is higher than our euro income, this will have an impact, a translational impact. Translate today €100 million to dollar, it was \$104 million. Today the same €100 million, it's US\$116 million. So, this is the impact. This is why we brought our [unclear].

Riad Mishlawi: I think what's important to investors is when they look at some downgrade, to see if this is structural or not. This is not a structural downgrade. This is not a structural impact on the Company. This is something that we're reacting to the environment around us, something that we cannot control. Shipping had gone up. At one point, when there was this tariff war that's happening between China and the US, there were no containers. Everybody wants to ship now before the tariffs go in effect. So, you'd pay two, three times more if you want to ship your product out from overseas coming in here. That eventually will have a small effect. You add those little small things together, it becomes a number. It brings you number 1%, 1.5%.

But the important part, again, is this a structural problem or is this a temporary problem? It is definitely not a structural problem, even that there is something that we - we did say also in the announcement about product mix, and I want to make that point. As you saw, the increase and the growth that we're having, a lot of it is coming from Europe, 26% Europe. So, 26% at a lower margin than the US, so the growth is great. But also if you want to maintain your margin, you should not be growing that much, because it's going to - but you are growing in areas where there's less margin than you do in the US. Adding to that the fact of Xellia, Xellia is - as you know, it's bringing in - is this a public number?

Khalid Nabilsi: Yes.

Riad Mishlawi: Can we say what the number is?

Susan Ringdal: Just roughly.

Riad Mishlawi: Yes, roughly.

Riad Mishlawi: Yes, roughly around \$50 million, a little bit less than that. But these products are coming from third parties while we are getting our facility ready. As we all told you, we have the facility that is ready to take all this product in and more and have room to also grow in these technologies like aseptic bag filling and lyo.

It does take time, but right now we're depending on third-party. You depend on third-party; you are not going to make the very big 35%-plus margin. You are going to make less. You have to pay for the third party. You have to pay for shipping. All that is going to disappear once you have your facility up and going in Bedford and which we are anticipating to do that in 2027. So, all of the pressures that we have in our margins today to be more than double our peers, it will even do better in the very near future because of what we're doing.

Kane Slutzkin (Deutsche Numis, Analyst): Thank you. It's Kane Slutzkin from Deutsche. Just on the injectables piece in April, you'd spoken about new entrants coming in, two of your larger products. Just wondering how it's looking there or how have you reacted, whether that's from the pricing or just volume? Then just on the CMO deal, I think you mentioned something around 26. I was under the impression it's 27. Just want to confirm that. Where in clinical development is that asset, if I may ask?

Riad Mishlawi: You're talking about CMO?

Kane Slutzkin (Deutsche Numis, Analyst): Yes, the deal is CMO.

Riad Mishlawi: Okay, the deal, CMO. What was the first part? I'm sorry [unclear].

Khalid Nabilsi: About the product mix, injectables?

Riad Mishlawi: Yes, about the product mix. This is our business, right? This is the business that we have. So, you have to anticipate. You have to look ahead. You know that a competition is going to come. You know that some products are going to be - you're going to lose some margins, and you are going to have to make them up some other way. This is going to happen. So yes, unfortunately, this happened at the same time. Two of our big products got competition and then we had to dial in on the market share and some of the profits. It did impact us. But we made them up in other ways.

So, the impact of this is, yes, it does go up and down, but not so significantly, because our portfolio is one of the largest in the US. We have 175-plus molecules in the US in injectables. Some will go down, some will go up. You just have to be able to be paying attention to the market, being there before everything happens. We did anticipate those coming in. We did anticipate that we're going to lose market share. We'll see how these competitors are going how reliable they are, and then we act. So, we've been in this business for quite some time. We know how to deal with competition. But yes, this is one, but the other one that actually affected us is the growth in other areas with the lower margin. So, this is what the product mix is going to happen.

As far as the contract manufacturing, we all told you, I think this is not new to all of you, that there's going to be a big sizable investment in our facility by our clients to facilitate the ability to produce for them the high technology product that we are going to be making for them. This is going on today. We are building, we're adding equipment. It's significant. It's significant value that we're putting in that facility, that they are putting in our facility.

That shows a lot to the trust that a big branded company would do - coming in and putting hundreds of millions in your facility to make it ready. They trust your quality program. They trust your ability to technically be able to produce and giving you a very huge critical product for you to make for them. So, it tells you about what they have found. These guys, they're very picky. They're branded companies. They get the best of the best; they hire the best of the best. They come to you and see you and they were able to give you a big critical product, that I think says volumes about your ability and about your capabilities as well.

This is what's happening right now. I think we are building right now. We start next year with slight volumes. Towards the end of the year, we expect that will increase significantly. It all depends on the approval time. We are anticipating sometime next year, but it's not our product, we really don't know. We know that that's the forecast that we're getting. But we're very excited

about starting as soon as this product gets approved, and then we're praying that it gets approved. Their success is our success, so we're looking forward for this to go to full throttle.

Operator: First [online] question comes from James Gordon with JP Morgan. You may ask the question.

James Gordon (JP Morgan, Analyst): Hello. James Gordon, JP Morgan, thanks for taking the questions. One question was just about injectables margins, so you've trimmed the margin this year. So, I think you may have partly answered it, but is it fair to say the majority of the trim is because of FX or how much of it is FX versus the other factors that you talked about? Then sort of connected to that, should we extrapolate the margin comments or guides for this year to next year, or do you think things will be different next year? That would be the first question, please.

Second question would be GLP-1. So, it sounds like your liraglutide launch is going reasonably well, but updated thoughts on whether you will or won't do summer? It sounds like you're not doing summer in Canada next year, but are you going to do it in Europe and US?

Then maybe a third one would be, we heard about Hikma Rx or the generics pipeline quite a bit at the event a few months ago. How quickly do you think that's going to start coming in? Do you think we're going to see a significant boost from generics pipeline coming through next year, or do we need to be a bit more patient?

Riad Mishlawi: Okay, thank you very much. You want to take the margin part?

Khalid Nabilsi: Yes. So, if you look into the margin, when we gave the guidance at mid-35%, as Riad mentioned, we've anticipated in that, when we gave the guidance, that there will be some price erosion on some of these products, but maybe it's slightly higher than what initially was. So, you bring it to the low end of our margin, but the main impact is coming from the FX. So you could assume around \$13 million, \$14 million, \$15 million coming from FX of euro, and the \$6 million coming from the other costs related to indirect impact of tariffs, shipping, inventories. So, this is where we got into the 32%, 33% margin you see today.

As far as GLP-1, as you know, liraglutide is - we started this when we were the only one in the market after Teva that introduced the authorised generic. So, we introduced ours 25 December, I believe, on Christmas Day last year. Done well. Today we just have one competitor that has been added to this group. The product is doing well. We're still selling it, although I think at a lower price. But we had managed to also renegotiate the transfer price to us, so our margins are still healthy.

As you know, there was a lot of compounding happening in the GLP-1 last year. So, a lot of people that wanted to get the semaglutide didn't have to buy it straight from the manufacturer or from the - they compounded that product. The reason why is because they were allowed to, because the product was on shortage.

Well, since then the product is not on shortage and compounders are not allowed to do that anymore. So, the semaglutide went back to the high price that it has always been, which gave the opportunity for liraglutide, the difference as - if you don't know, the liraglutide, very similar in indication to the semaglutide, except it's daily while semaglutide is weekly. So of course, for convenience, everybody would prefer to go to the semaglutide, but because of the cost now, especially that you can't get it compounded, then we are seeing demand increasing on the liraglutide.

Whether we are going to the semaglutide, I think it's still patented. There is a couple of countries in Europe that the patent will be expired next year, and I think Canada will be one also, and a few countries like Brazil and this. But by and large, I think most of the countries will still be restricted by patent.

The thing about patent that maybe people don't understand, it's not about selling the product in a patented country. It's about not being allowed to even make the product if it's patented. So, I can't make the product in Portugal and sell it in Canada because it's not patented in Canada. You can't even make it in Europe, because it's patented in Europe. So, it's not about only where you sell, it's also where you make.

So, this is not something that we're entertaining and doing. We have some deals for the MENA market to bring in this product, but I don't have an exact date for you. But of course, in MENA we are the largest, the strongest local Company, and we always are looking out for interesting products like this. We do have a deal that we are trying to finalise. We should be introducing this product. I don't want to say when but depending on - we are actively looking for it.

I think the last question was - I think that's it, right. Oh, I think the last question was about the Rx.

James Gordon (JP Morgan, Analyst): That's right, so as in do we get a boost - you've been investing more in generics or Rx R&D, but when does the boost start coming in? Is that a '26 story or do we need to be a bit more patient?

Riad Mishlawi: Yes. As you know, I always say our business is like Christmas trees. You plant a tree today so you can sell it in seven years. You have to anticipate, you have to be patient. Nothing that you do today is going to get you a result tomorrow. You have to wait. In our case, in Rx, that's exactly what we're doing.

But the good news is we can tell you what we're submitting. So, we did tell you that we are submitting a very interesting product like epinephrine nasal, very unique product, extremely valuable one, very easy to administer and a huge demand and potential on it. We had done all the studies, successfully. We had a lot of conversations with the FDA. We're anticipating of submitting this product towards the end of this year, which means that this - if you give it 18 months of the regular review time, if it all goes well, I think we should have it within that range of time. That will give a big boost to the Rx. It's not the only product that we're submitting, but this is the product that I can talk to you about, because we made that public.

But I can tell you that bringing Hafrun in, that was her focus. She revamped the entire R&D department. She brought in new people. It's a lot focused. We're working on interesting products. We're submitting a lot of products. I think the result of all that is going to be apparent soon. But while we're doing this and spending more on R&D, we're still getting great results for the Rx. I mean, it's not like it's suffering because we're taking away the money and put it in R&D. We're putting more in R&D, significantly more in R&D. Still we're coming with really high teens of profitability margins, operating profits. So, it's doing a lot better than we ever thought. The contract manufacturing effect that is going to bring to it is definitely going to make this division extremely interesting.

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

Riad Mishlawi: You're welcome.

Operator: Thank you. The next question has come from Victor Floch with BNP Paribas. You may proceed.

Victor Floch (BNP Paribas, Analyst): Hi. Thanks so much for taking my question.

So maybe first one on Paris. So, it's fair to say that concerns for the EU pharma has meaningfully eased since Liberation Day. But on the flip side, it's fair to say that it's now broadly assumed that the EU pharma manufacturing capabilities will have to be rebalanced overseas. So, in this context, I'm just wondering if you've seen any significant uptick in terms of interest for your CMO offering. So, this was my first question.

Then on US compounding, I think you frame it as the key driver for the long-term and your \$5 billion 2030 guidance objective. Should we expect at some point that you will be able to refine the exact contribution from this business to top line and potentially form a guidance that would help us to better capture this opportunity?

Finally, on liraglutide, so I think last quarter, you've added it to the fact that the expected end of semaglutide compounding would be a tailwind for your liraglutide generic, as it would represent a low-cost option compared to the EFT list price of the Covid step down. So, in the meantime, we have absolutely seen that the compounding is still very much alive, capturing something like 30% of the semaglutide markets, and also, we've seen Lilly and Novo going for direct-to-consumer cash channels. So just wondering if you still believe that it could materialise as a tailwind for liraglutide? With semaglutide generics, do you still think that you could drive growth with liraglutide, even though compounding is still very much alive? So yes, that's all for me. Thanks so much.

Riad Mishlawi: I'll try to answer some of them and Khalid will help me with some. Let me start with the tariffs. Again, it's not clear for us how tariffs is going to come about. I mean, we heard that there was some agreement with Europe. We heard the 15% there, but we really don't know if that includes the generic drugs, if that includes something else or excludes. This is still unclear for us. We're trying to clarify it. We're trying to talk to the government to see if - but unfortunately the confusion is not only limited to us. A lot of people are confused. So, we hope that this will be cleared soon, and then we'll see if this is going to be any effect on us or not.

Khalid Nabilsi: But even if it has an impact on the industry, we are well positioned, as Riad mentioned. So, we are well positioned in terms of our manufacturing plants or in the US, the Bedford expansion that we have, even for the injectable business, will be ready in the coming, let's say, 18 months. So, we'll be able to benefit from that.

Riad Mishlawi: Yes, so we built the business to make sure that the local companies, they operate in the local market. So, a lot of the US revenue that we get is generated and born in the US, so there would be - if there is tariff, and if it's a severe tariff, as I said before, it will affect us. It will affect all the industry. It will affect a lot of the peers that we're competing with, a lot of them. I think the effect on us will be there, but it will be at minimal if you compare it to our peers. It's something we're looking for.

I think the government is - they are looking at the tariffs and they are careful about how they are going to implement it, because as you know, shortages in the US are still there, especially in the injectables. If you are going to put the tariffs, you have to be very careful not to increase that problem or create a bigger problem than that. So, this is why there's a lot of back and forth on this one. Sometimes we hear it's included, sometimes we hear it's excluded. Sometimes we

hear if the API is Chinese. Sometimes we hear that if you transform the API, it's not. So there isn't really a great and clear definition on how the tariff is going to be implemented. Again, I think the government has their challenges as well, and that's why there's a lot of back and forth.

As far as the US compounding, our compounding business is doing great. I think we are in the right direction. A few things are happening in compounding. I don't know if you guys are following the compounding business, but the compounding business has been very much challenged by the FDA in the last few years, last few years in particular. FDA just don't want compounding to be a different business or have linear rules than the core business. So if you are doing injectables, these rules apply. They don't care if you're doing it by compounding or you're doing it aseptic to aseptic or doing it from aseptic to non-aseptic. The rules apply.

In the past, when the compounding started, there were some rules that were a little bit lenient, I would say. They were a little bit more you can get away with. Right now, the FDA is coming back and withdraw those rules. They're putting their foot down and they're saying, you have to act that way or else. That created a lot of warning letters. It created a lot of people going out of business, and a lot of pressure. So, if you look and read about compounding, you'll see a lot of our peers, even the largest, have gotten warning letters in the last two years.

Fortunately for us, we are creating - compounding in the way that we learned how to do aseptic business, which is our core business. We just copied what we do, but on a smaller scale. So when it comes to compliance, we have probably one of the cleanest records in compliance. So that's from the compliance point of view, which is very critical and a big risk in compounding. So that has been put to bed. We've done a lot of investment to make sure that this is done.

Of course, it's not easy when you have a batch - our average batch in Cherry Hill, for example, is one million units. Our average batch in the compounding centre is 300, 400 units. So to scale that down is incredible. You have to use everything differently. You have to use a lot of manual steps. But that has been now done. We've gotten all the approvals of all the states. We've gotten the blessing of the FDA. We know what we need to do. From last year to this year, we had tripled the revenue of this centre, but it's way short where we need to be. Our aspiration, we think that we can be the leader of the compounding business in the United States. We need to do it slowly. This is a very critical one. You don't want to make a mistake.

In this industry, trust is very, very important. Your client needs to trust you. They depend on your product. You're not going to stop an operation because the bag of fentanyl did not come in. You cannot do a heart surgery that you're going to make \$600,000 from it and now because of \$20, you're going to be cancelling that. That they don't want. That you do it once and they will cut you out. So, you need to build your trust. That's exactly what we're doing. It's very much proven by the fact that we have tripled the revenue there. We're short from our goal. We think our goal would be big. We think that we should be - in the next two or three years, we should be really hitting the hundreds of millions, hopefully \$100 million soon and build on that one.

So, there's a lot of automation that has to happen. We have equipment that are on order for the centre. I think there's a lot that we learned in the last two years what we need to do. We thought it would be very typical and similar to the business that we have. It's not. It's the relationship, the way that you sell, the way that you make, the way that you inspect it. All of that is different. But we all know that now and it's only going up from now on.

So, compounding I'm happy about. The future is bright. We are really implementing our strategy exactly as we designed it.

Finally, the liraglutide and the semaglutide question. I'm not sure if you know the semaglutide will not be off patent until 2031, in some cases 2030, but it's not in the near future. So, it's not going to be at a time when you are going to have liraglutide and semaglutide both generic and both competing. Of course, semaglutide when it comes to generic, liraglutide will have a very weak case for. Nobody is going to take a daily product when they can do it weekly. Who knows? By then you could take one maybe every year. This industry is advancing so much. They say that the oral is going to come out now, very effective. So, this industry is moving.

Today we know that semaglutide is doing well. Semaglutide is patented and with a very high price. We're managing to get some revenue out of liraglutide. That's all we hope for. We're managing this as the industry evolves and as the competitors coming into the market.

Operator: Thank you. Our next question has come from the line of Seb Jantet with Liberum. You may ask your question.

Seb Jantet (Liberum, Analyst): Morning, everyone. Just checking you can hear me all right? **Riad Mishlawi:** Trying to.

Seb Jantet (Liberum, Analyst): Okay, so just three questions if I may. First of all, just on the branded margins, obviously you had quite strong margins in the first half. You're guiding to margins for the year sitting at around 25% or so. You've obviously got stronger growth coming through in the second half. So, I'm just trying to understand, what are some of the drivers that are going to impact the margins in the second half in the branded division?

Second question is just around the injectables business. You've called out, in the past, calcitonin, testosterone as products where you've seen some competition. I know you said you've reacted to that. I'm wondering if you could just let us - or give us a sense of whether that pressure is ongoing or whether you're seeing that pressure beginning to stabilise.

Then the last question was just on vancomycin. I'm just wondering if you could give us an update on the black box and whether you've had any progress on that front. Thank you.

Khalid Nabilsi: You want to take the first one?

Riad Mishlawi: Yes.

Khalid Nabilsi: I'll take the first one. So, the branded business, it's a similar case to last year. Last year we had a strong weighted H1 and we delivered margin in line with what we had this year. This is mainly was due to the timing of the tenders, so this year is going to be similar to last year but maybe to a lesser extent. I would say the branded business is delivering an excellent performance. I think maybe it's slightly now - given that there's no currency impact, maybe this will improve a little bit on where we guided initially. But it's going to be around the 25%, so it's on the top end of our guidance, I would say.

Riad Mishlawi: For the injectables, the two products that we have difficulties in, or let's say we face competition in, and I think we did say that in April, is testosterone and calcitonin. We did anticipate people are coming in. We've been in a leading position with testosterone for years, so it's just a matter of time before somebody comes. There are seven, right now, people that are in the market. So for us to be able to continue the lead on the testosterone for the past years was magical, so it was only a matter of time before this is not going to hold any. It doesn't mean that we lost the entire thing. We still have it, but of course, with the competition, prices are going to suffer.

This is a very tough product to make and expensive to make. So it's not an easy product, but the margins are very, very healthy, of course. If you are going to lose some of that margin, you have to replace it maybe with more volume or less margin. That's exactly what we had been done. This is why it's such a great indication when you see our revenue has gone up. It shows that, by volume, we can replace the high margins with medium margins but more volume just to replace what we had lost. Calcitonin, I would say the same exact thing.

But I think the product mix that we refer to is not the loss of those, the margins of those products. It's the fact that we have other geographies with lower margins growing faster than the ones with higher margins. We saw that MENA and Europe had grown at a much higher pace than the US, at a lower margin than the US, and what is anticipated. So [unclear] and Xellia, of course, Xellia adding significant revenue with healthy margins, but with less margins than our organic products. So, with that, the combination of that, that really had a little bit of pressure. Not much, but we offset a lot of it. But still, we're discounting a very small number related to that.

Finally, for the vancomycin, we did get approval for the vancomycin for removing the box. The new product without the box is called Tyzavan now. It's going to be a branded product, patented, unique to the market. That will be replacing our product that we used to call Vanco Ready, which used to have the black box. So, we are in the transition in doing so. We are expected to launch Tyzavan towards the end of the year. As you know, this is a branded product, so it needs to be detailed. But we are very optimistic that this product, as soon as we get the momentum going, it will be a very, very big and interesting product for us. But yes, there's no black box on Tyzavan. It's safe to use with everyone, including pregnant women.

Seb Jantet (Liberum, Analyst): Thanks.

Operator: Thank you. Our last question is from Sidhartha Modi with Barclays. You may ask your question.

Sidhartha Modi (Barclays, Analyst): Hi. Thanks for taking my question. Continuing with the last question, Tyzavan was approved, but then what I got from my call with IR is there is still some inventory left for Vanco Ready and you would like to exhaust that inventory before you can launch Tyzavan in a meaningful way. So I just wanted to know how much of that inventory is left and would this spill over in the next year?

My second question is on the contribution of 503B and your CMO business into your \$5 billion peak sales ambition in - yes, I mean in the future, yes. How much of that would come from these two businesses and what would be the impact on margins?

Third, if I may ask you one last question, a lot of manufacturers, branded manufacturers have been talking about DTC sales. Do you want to give any colour, if such thing is implemented, what would be the impact on Hikma's general business? Would it be a headwind or a tailwind for you?

Guy Featherstone: Sorry, Sid, please could you just repeat the third part of the question? Thank you.

Sidhartha Modi (Barclays, Analyst): Yes, so the first question that I asked was about Tyzavan. Basically, what we were told is there is still some inventory left for Vanco Ready and you would like to exhaust that inventory.

Guy Featherstone: We got that.

Sidhartha Modi (Barclays, Analyst): How much of that is left? The third one, okay, so the last question...

Guy Featherstone: Thank you. We had the first two. Just the third part, thanks.

Sidhartha Modi (Barclays, Analyst): Yes, yes. The third question was about DTC sales. A lot of branded manufacturers have been talking about DTC sales in the US. What would be its impact on the general business of Hikma? Do you see this as a headwind or a tailwind for yourself?

Sidhartha Modi (Barclays, Analyst): Direct to patient sales is what I mean.

Guy Featherstone: Yes, okay.

Riad Mishlawi: I'll talk to the Tyzavan. Tyzavan today is being manufactured by third parties, so the flexibility of dealing with manufacturing with the forecast and inventory and all that is not as flexible as if we make it ourselves. As you know, if you have a third party making it for you, you have to give them the forecast ahead of time, and you have to give them a committed forecast. This is number 1.

The second thing is Tyzavan and those bagged products. The label and the expiration and all that is printed straight on the bag. So, you have to not only be able to anticipate, but you have to commit to it with the label on it. So, there's a lot of parts that you have to pay attention when you put orders in, how much risk you're going to have, and how much dating are you willing to sacrifice, because you're not going to make the product ahead of approval and wait until the approval happens, which we do in some cases. But in this case, the expiration date is printed on the bag. So, if you do it before the approval and wait, you might only get a few months left by the time you have approval, so the risk is big. Of course, this is not made by you, so the flexibility is not there.

That's why the strategy is to get all the inventory done with Vanco Ready while we are making the change to Tyzavan. This is going on as we speak. Tyzavan is being manufactured today, and we are depleting all of our Vanco Ready before we have the Tyzavan out. We don't want the customer to have two types of product. We want the product to go away and replaced by a better formulated product without a black box.

As far as our goal of the \$5 billion in five years, I think we're very much compliant with that. We reiterate that and we think we can get that. It's not an impossible goal at all. As you see, our revenue is growing. All our divisions are striving to get there, so we have no worry about that.

Now, how much CMO will the \$5 billion include? It would be a significant part of our business. I cannot tell you exactly how much, but I would say it would be a lot more than what we're doing today. I don't know if that is going to tell you much, but I really can't tell you an exact number, because it depends on many things. Contract manufacturing is going to be coming. We have today contract manufacturing in our businesses, as you know today. We are adding a significant contract manufacturing in Columbus that will be making a critical product for a branded company as we had announced before. That will add significantly to the revenue of contract manufacturing.

From the injectables point of view, as Bedford gets completed, we believe that a lot of contract manufacturers that we deal with today would want more volume that we're limited to give to today because of our limited capacity, and our capacity is more working for us than the contract

manufacturers. But we will be happy to add more volume to them once the Bedford facility is complete. So, with the Bedford facility and with the CMO in Columbus, we believe that a significant amount of contract manufacturing will be added to the business that we have today.

How much of the compounding business is going to be in the \$5 billion? I hope - I don't know. I hope a lot. Let's see. We are working very, very hard on this business because we see there's an opportunity there.

This business is not going to go away. This is a need that hospitals actually really, really need. They've been very hesitant to trust somebody. Whenever they trust someone, they get big warning letters and big compliance problems with the FDA. The biggest leader of compounding today has gotten two warning letters in two years in a row and a lot of other ones that had closed some facilities and hit with warning letters on others. We have been spared. We have been compliant. We have been doing that very slowly, because we don't want to get into that position. So, I think we are now - we've built a great foundation to build a great business on, and I hope by 2030 this business will be significant and doing really well.

The last thing is direct business. We love direct business. I think it's great if we can do it, and we are doing it. We're trying to increase it. But there are a lot of difficulties. Today, our dependency on GPO in the business is about 50% in the injectables. The branded is a lot more when we go through the PBMs. Direct business is difficult because of the contracts that hospitals have with the GPOs and how the business really runs. So, there is some compliance that hospitals need to have.

So, if you are, I don't know, a hospital that works with a GPO, you have some commitment to be in compliance to continue taking volumes from them and they give you some credit to the volume that you take from them. So, with that, it makes it very difficult for them to buy directly from you. They have to go through the wholesaler; they have to go through the GPO contract.

So, we like it, we'd like to increase it, but there are some difficulties in logistics of how to go about it. We do have a significant one today, though, more than our peers in direct selling to our clients.

Yes, lastly, I think I would say that the compounding business is direct, and it has to be direct. By law, you cannot go to a wholesaler. It has to be straight from your manufacturer to the customer. So as we grow this business also, direct sales is also going to increase.

Sidhartha Modi (Barclays, Analyst): Thank you so much.

Operator: There are no questions on the line. I'll pass the conference back over to Riad Mishlawi for any further remarks.

Riad Mishlawi: Well, thank you very much and thanks for your questions. I think I just want to reiterate what I said in the beginning. We have a better business today than we've had three months ago or than we had last year or the year before. We have grown the business significantly. We have put the foundation to grow the business, but we know that this business is not a business that the reaction or the result happens immediately. It does take time.

Today we are investing in this business, and you can see how we are investing in this business. We're increasing our R&D spend. We have changed the organisation and the people in the organisation. We identified our need, we identified that R&D is something that needs to be

improved, and we did exactly that. We brought leaders that understand R&D, and we gave them money to spend on R&D.

We created a portfolio selection committee that knows exactly what products to go after. We enhanced our BD team, and now BD team is going beyond what we know. We're going to China, we're going to India, we're going to Europe, we're going to all where the opportunities are to see if we can bring in technology and expedite the approvals or the portfolio that we have.

We have been increasing our infrastructure. We've been spending around \$200 million in capital expenditure every year, and that's for a good reason. You can see Bedford facilities now. We'll have state-of-the-art facility in Ohio. We have Cherry Hill that we are adding more and more lines. It's extremely modern now with a lot of robotics there, making a lot of products. Same thing with Portugal. We're adding another plant in Portugal. Our capacity is not only being built, but it's being utilised. In the injectables, our capacity is being utilised at a very, very high level. Rx, our capacity is being utilised by us and it will be also utilised, a lot of it, by the contract manufacturers.

So the money that we're spending on capital expenditure in both IT, in automation, in capacity, in equipment, all that is going to benefit the future. It's benefiting us now, but we can see the future is definitely going to be benefited, especially with the indicators that we see today. Our volumes today or our capacity today is at a very high level, especially in the injectables.

Our demand is there. You can see 12% increase in top line, which shows you that the demand is there, so there's no worry about where that is going to be utilised. Our contract manufacturing demand is very, very strong. We have a lot of contract manufacturers coming to us, especially of how we are positioned. We are offering clients redundancy in the US and in Europe. We have plants that are capable to do the same thing, so if you want to have a safe product, you make it in the US and you make it in Europe. You reduce your risk significantly with this redundancy.

So, we have all what it takes for us to grow, and we are growing, and we are showing the growth. But again, you have to spend before you see results. We are spending and we are continuing to show good results. So, it's not that we are spending and sacrificing the margins. On the contrary, we are spending and we're still bringing in higher revenue, higher margins, and the top of the industry. I looked at a lot of our peers. We heard a lot of our peers' results for the quarter. We looked at our results. Still with the downgrade, the slight downgrade that we did in injectables, we're still on the top of the chart when it comes to margins and growth in revenues.

So, we think we have a good business. We think the future of the business is fantastic. Whatever we're doing today, we'll be doing it better tomorrow. Thank you very much.

Khalid Nabilsi: Thank you.

[END OF TRANSCRIPT]