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Hikma preliminary results 2022 transcript | February 23, 2023

Susan Ringdal:

Good morning everyone, and thank you for joining Hikma's results Q&A today. Hopefully you have all been able to download our pre-recorded presentation from hikma.com.

I'm very pleased to have our Hikma management team here with us today. We're joined by our CEO, Said Darwazah, our CFO, Khalid Nabilsi, the Vice Chairman of Hikma and Head of the Branded Business, Mazen Darwazah, the President of Injectables, Riad Mishlawi, and the President of Generics, Brian Hoffman. With no further ado, I will pass the call over to Said.

Said Darwazah:

Thank you, Susan. And good morning, everybody. I'm sure you've already, or I hope you've already read the releases. I'm extremely happy with the results this year. In a very relatively tough year, we have delivered resilient results. Our top line is almost the same as last year, and the core operating profit is down about 6%. And when you consider the extra interest rates that we paid, the shipping, the fuel, the inflation and so on, it really shows that the company delivered very good and very resilient results.

The injectables and branded businesses of course have done extremely well. They were able to cover the downfall in the generic sales with very good growth and still hopefully much more growth to come.

We have a very strong balance sheet obviously. Net debt is around $1 billion, so we still have a lot of firepower. We have successfully integrated two companies, Custopharm and Teligent. We are entering into new markets, especially in Europe. In the MENA we are the third-largest company there now. We saw that in Saudi Arabia, which is the largest market there, we are number one.

And finally, generics delivered, in my opinion, reasonable results where we had margins of about 15% and delivered about $100 million in EBIT. So I'm very happy with all our results and look forward to having a great year ahead of us. So with that, can we please start taking the questions?

Moderator:

If you would like to submit a written question and are watching via Spark Live, please use the ask a question button. Alternatively, if you are participating in verbal questions, please use the raise hand feature at the bottom of your screen to ask a question. And if you have dialed in, please press star nine to enter the queue. Once you've been invited to ask your question, please turn your camera on, unmute and ask your question.

Our first question is from Peter Verdult at Citi. Peter, please unmute yourself and ask your question. Thank you.

Peter Verdult:

Yeah, thanks, Operator. Morning, everyone. Thanks for doing the call. Hi, Said and team. Peter Verdult, Citi. Three questions please.

Said, the obvious one for you, CEO search. If you were to frame the sort of innings we're in, are we in the late stage of naming your successor? And are internal and external candidates still in the running or is it an external hire we should be thinking about, given the time it's taken?

Secondly, for Brian, could you talk a little bit about the CMO business within US generics, the current scale and dynamics and how you expect to grow that? Just a little bit more flavor and insight there.

And then Riad, just on the compounding business. I think we are expecting first sales this year, but can you remind us where we are in terms of generating meaningful sales, timelines to profitability? And if I could push you on what you think a peak sales opportunity or when you speak to Said what you think the long-term opportunity here is. Thank you.

Said Darwazah:

Thank you, Peter, and thank you for getting that out of the way from the beginning. We are really at a very advanced stage, I have to say. We've had a very thorough search and we are at a very advanced stage right now. We have very few candidates still in the running, and we are still looking at both internal and external.

I think that we would be able to announce relatively soon. Maybe, I don't want to give an exact time, but I think within the next six weeks we should be able to announce our candidate and hopefully, I'm sure I will be very happy with the candidate and I hope the market will be happy with them. So anything more on that? Peter?

Peter Verdult:

Sorry, Said. Can you hear me?

Said Darwazah:

Yeah, I can hear you now.

Peter Verdult:

Yeah, you'd think after three years I'd have worked this out, how to unmute myself, but I didn't. No, I mean, look, I'm not going to push any further. I think that would be all I can, so I'll-

Said Darwazah:

We're at a very advanced stage and we should be able to announce quite soon. And we're still looking at internal and external. So we haven't [inaudible]. Okay.

Peter Verdult:

I suppose my only follow-up question would be, when Siggi arrived, I mean, obviously the Hikma business was under pressure, he needed to make some changes to US generics. I mean, it's not as if the strategy or the company's having problems at the moment. So what are you hoping for in terms of what do you want the new CEO to focus on or to sharpen up? Because you have a clear, coherent strategy across the divisions, so I'm just wondering what you're hoping the new CEO brings to the table.

Said Darwazah:

I think if you look at the businesses, it's very clear that all three businesses, but specifically the injectables has an extremely bright future ahead of it. And I think that one of the biggest issues of some... We could probably sell twice what we were selling if we had capacity and so on.

So I think we need somebody that can deliver on making sure that we will be able to deliver, to have all these three divisions delivering on time and what's required from them. So to push the existing strategy forward and then give us the luxury to start again looking at is there anything else we'd like to enter and how do we enter that what we're always calling the fourth part of the business. But right now I think executing on our strategy is very high so that they can deliver and execute the strategies that we have.

Brian Hoffman:

Said, would you like me to take the CMO question?

Said Darwazah:

Yes, please.

Brian Hoffman:

Hi, Peter. Great to see you. Thanks for the question. So CMO is an important part of our business, an important part of our strategy for the future.

So when we acquired Roxane Labs and the facility in Columbus, Ohio in 2016, we inherited a fairly sizable contract manufacturing business. And since we took over ownership of that business, we've tried to grow it. We're really grateful to have a fantastic state-of-the-art high-quality facility in the United States. It's one that has over a million square feet of manufacturing space, over 80 acres with a really diversified set of technologies.

Within our existing footprint and within our existing infrastructure, we have the ability to increase our capacity. So we're very interested in bringing in more volumes to that facility, we certainly have the ability to do so. And not only are we bringing in business that's accretive from a margin perspective, but as we bring in that additional volume, it lowers the cost overall across our entire portfolio.

So it really works well with the rest of our business. It's synergistic with it. And as we've now put a really a focused initiative to advertise it, to engage with primarily branded partners, we've been able to generate a lot of interest due to the vast technologies we have, the high-quality track record we have and the US-based manufacturing.

So we've been engaged with multiple potential CMO partners at various stages of development, from the early stages to partners who already commercial and are looking for a commercial partner. So it's an area that we want to continue to grow, and improves the rest of the business and also improves our margins.

Said Darwazah:

Okay. And the third part of the question was?

Riad Mishlawi:

About compounding, I believe.

Said Darwazah:

Okay. Okay, [inaudible].

Riad Mishlawi:

So, hi, Peter. And regarding compounding, I think we still believe that this is a fantastic business to get into, very complimentary to what we do, but also this is a business that we started as more of a startup. So the disadvantage of starting a business that you have to really building and build it block by block, get state by state approvals, make sure that all your products are in line with the stability and all the data that you have.

However, the advantage of building that, you do it right, you do it carefully, you do it in a very strong foundation. And this is exactly what we're trying to do.

So as you would know, you need to get 50 states. Right now we're at 39. We still have 11 states to go. We are trying to make sure that we don't overpromise, because in this business, continuity and reliability of supply as much as the quality is very, very important, so we really don't want to go in very aggressively and very prematurely and end up introducing products that we cannot continue or take on more than we can supply.

So we're doing this very carefully. We're doing this step by step. We're still looking to get another 11 states there before we cover the whole United States. But we're really progressing very nicely. We're putting a nice crew in together. We are adding to our portfolio more and more products.

We're going to the hospitals, having interviews with the pharmacists in the hospitals to make sure what are their needs. So we want to go in with the niche products, not like any other compounding company that we have out there.

We learned a lot from Nephron and their experience there and the void that they had left in the market when they are mostly right now they're not delivering a lot of the compounded products there.

We believe that this is still a great opportunity. I don't know what meaningful means. I think we'll do this year of course much better than last year, which we haven't done much, but I don't think we really see the meaningfulness of this business until maybe a year or two after, maybe in '24, '25. We're still building. I think we'll get to the 50 states by the middle of this year I hope, and then we'll be able to start aggressively growing the business.

Peter Verdult:

Thank you.

Said Darwazah:

Thank you, Peter. [inaudible]-

Moderator:

Our next question comes from...

Said Darwazah:

Yes?

Moderator:

Sorry, our next question comes from Thibault Boutherin at Morgan Stanley. If you'd like to unmute yourself and ask your question. Thank you.

Thibault Boutherin:

Yep. Thank you very much for doing the call. If I can just push a little bit on the assumptions behind the guidance for generics, and Xyrem within that.

So I know you're not going to give us exactly what you expect from Xyrem, but just maybe the assumptions that you are using in particular for the second half of the year of this product. Because what we know is in theory, you have three more generic makers who have signed agreement with Jazz to launch authorized generic.

But as far as we can see from the FDA website, it looks like only one of them actually had an approval. So when you think about the evolution of Xyrem opportunity in the second half, can you tell us kind of what expectation and what assumptions you have behind the evolution of the market?

So the first question, and maybe just related to Xyrem again, and thinking ahead of 2023, when you think about the generic business, obviously the Xyrem piece is probably going to start eroding next year. And if you could just tell us conceptually if you think it's realistic to have this business kind of being flat-ish or even potentially growing out of Xyrem, or if we should reasonably assume that we have a step-down of generics in 2024. Thank you.

Brian Hoffman:

Okay, great question. So first off, our generics guidance of low double-digit revenue growth does include sodium oxybate, so that's including in that number. I can't give you specific guidance on sodium oxybate, but we're excited to have launched the product in January.

We view the product as making a contribution across the entire year. We expect the other filers to launch on day 181 in the second half of the year, so we expect that to have an impact in the second half of the year.

Brian Hoffman:

... And then we also, as we've disclosed, the second half of the year, our royalty payments for the authorized generic to jazz do increase. So we expect sodium oxybate to be a significant contributor in 2023. And then as you mentioned in 2024, we do expect, following the exclusivity period, that that'll be a smaller contributor in 2024. But what we're really focused on strategically is to continue to grow the business. We're working very hard on growing our base business, our complex generics business. We're continuing to grow our contract manufacturing business as well as our specialty business. So our aim is to continue to grow this business beyond 2024, but of course, sodium oxybate will be a lower contributor then.

Moderator:

Our next question comes from, Paul Cuddon at Numis. If you could please unmute yourself and ask your question. Thank you.

Paul Cuddon:

Hello. Thank you very much. I've got a few questions, please. I mean, firstly on the success of Custopharm and particularly calcitonin far beyond the six month exclusivity. If you could elaborate on the expectations for that particular product and maybe how you think about the broader injectables pipeline. Secondly, we've been discussing antibiotic shortages around the world and to what extent that might be benefiting Hikma. And thirdly, just on the strong recent prescription trends for things like VASCEPA and ADVAIR and what your expectations are for the rest of the year, please.

Said Darwazah:

Thank you. Riad, can you take the first two parts and then Brian the last?

Riad Mishlawi:

Sure. As far as Custopharm and calcitonin, with Custopharm we will have the benefit of a full year this year. We had integrated the company very well. I think we benefited a lot. The good thing about it is when we acquired this business, we dialed in our assumptions that a new competitor will be in the market. And there was, as you know, Endo had entered into the market. So that has been assumed when we did the acquisitions. It had contributed a very well to the overall growth of the injectables and with very high gross margins. So we're happy where we are today. We're benefiting both from the pipeline, from the commercialized product, as well as from the team that we have in the R&D in the development.

As you know, Bill Larkins, one of the CEOs of this business, has joined us now and he is heading the injectables R&D, and we're benefiting a lot from his experience and from his knowledge in this business. So we're happy so far. Things have been going exactly as expected and in line of what our expectations were when we acquired it.

As far as the shortages, we're learning more and more that the shortages are not only in the US but it is worldwide. So now that we're expanding in Europe, we're learning that countries do have shortages as much as the US does, and we were able to work with those countries to take it from one country and feed it to another country. So we're working with the agencies. Canada is a great example. For example, they had contacted us for some products that we have already approved in the US but not in Canada, and we've had some shipments go there because of that. Same thing with France, same thing in Spain.

So we think that this is something with that we can really capitalize on with a large portfolio that we have and being so global and having products all over the countries. We can definitely be watching this very, very closely and try to capitalize on it whenever it's possible. One is to make sure that the patients are benefiting from having a product on the market where they really need it, and from us creating a really good relationship with the regulatory agencies. So this has been happening and we're doing good at it.

Brian, want to take the last one?

Brian Hoffman:

Yeah, happy to do so. I think I'll address the antibiotic shortage first. So in taking a step back in 2021 and 2020, we really saw much more limited antibiotic use in the United States. Due to covid and social distancing and people not traveling as much, we saw much lower demands. So the shortage situation that we experienced as an industry in the fourth quarter of last year really caught a lot of us by surprise. I think it caught our customers by surprise, caught us by surprise, and certainly put significant stress on our operation.

I'm really pleased with the way that our teams responded. So we quickly ramped up our production. We went through a 24/7 scheduling of production. We went above and beyond that and even air shipped products to get the product into our customer's hands as quickly as possible to do everything that we could to resolve that shortage. So it was a revenue growth opportunity from 22 over 2021, but it is a lower margin product for us. So not as material to the bottom line, but of course, very important to our customers and very important to our patients. So I'm really pleased with the way that our operations and supply chain teams responded.

Since then we've seen that demand taper off a little bit, but we're expecting a little bit more of a spike now going into the spring season. So we're preparing for that and working very closely with our customers. My hope is that given this situation that we can begin to think longer term with our customers and how can we prevent these shortages in the future. And I think it requires a really good partnership from both the manufacturers and our customers about let's plan for demand better and maybe excess demand so we can avoid this situation in the future. So that's my hope for antibiotics. I think if we partner well, we can do a better job moving forward.

Regarding VASCEPA and generic ADVAIR, I kind of put them in a similar bucket. Our expectations for this year is that we will see on both those products some more competition, which could result in price erosion. So our guidance anticipates that. The opportunity I think both for VASCEPA and generic ADVAIR is that we see greater brand to generic conversion. So in the case of VASCEPA, the brand still controls over 60% of the market share. And with generic ADVAIR, the brand still controls just over 50% market share. So where I think the opportunity is for generics, even if we do see more competition, if that equation starts to shift more toward generics, I think that'll create more volume opportunities and give us a chance to grow those products. So that's our hope, but our guidance does anticipate some price erosion on both.

Moderator:

Our next question is from Emily Field at Barclays. Emily, if you'd like to unmute your line and ask your question. Thank you.

Emily Field:

Hi, thanks for taking my questions. Just a couple on generics. One, I think that you'd been talking about expectation in the guidance for 2023 of double digit price erosion, if I'm correct. Given the improve ... I know IQVIA data can be helpful or not directionally, but it does look like that's been trending much better lately. So in your view, is that a conservative assumption or just any thoughts on base business generic pricing?

And then maybe also if you could give just a little bit more color or figures around this rationalization of the R&D pipeline that resulted in the impairment charge and just more details on how you realigned the portfolio there. And then a question on branded. The guidance now with a range between mid single and high single, not that that's a significantly wide range, but just if you could give any details on the drivers that will result in the lower end versus the higher end. And as that is constant currency, if you are expecting significant currency, a currency impact at this time for the year. Thanks.

Said Darwazah:

Thank you, Brian, then Mazen.

Brian Hoffman:

Great, thanks Said. So I'll start off with the generics questions for the first round price erosion. So in 2022, we certainly saw a low digit price erosion, a low double-digit price erosion, I'm sorry. And that was pretty consistent throughout the year. And so given that we saw that in the fourth quarter, our expectation and certainly in our guidance, we're expecting to continue to see that trend.

I think there are some signs that it could be improved next year, and that's always our hope that things get better rather than worse. I think we're seeing the FDA be significantly more active in inspections. Could that create disruptions? Could competitors have supply chain disruptions, et cetera? All those things could help improve the overall environment. But our guidance does contemplate that that low double-digit price erosion will continue into 2023.

In terms of the rationalization of the pipeline, what we do as part of the ordinary course is we're always constantly reassessing our pipeline. And in any given year, we're also constantly looking at what can our P&L support in terms of an investment, and we'll make prioritization decisions along the way. So that's really part of the ordinary course. We managed that very closely as a division and as a group overall.

And then in terms of your specific question around the impairment, we did take an impairment, as you saw, that was due to really two things. The first, due to the intangible assets around generic ADVAIR for our reduced expectations. We reassess that every year. So this was a, we've taken impairment before. This was another one that we took on the intangible assets and that we also took an impairment around the property plant and equipment due to some excess capacity for generic ADVAIR as well as some of our other respiratory assets in the pipeline.

Mazen Darwazah:

Good evening. For the MENA. Actually, this is the first time that we guide mid to a high range single digit in the MENA. The reason is that we're growing in the MENA with new therapeutic classes and we're getting more in licensed products in the MENA in the pipeline. Now, what really depends is the Egyptian market. Egypt today is our third largest market in terms of volume, and the currency in Egypt has been quite, I would say, during last year and the beginning of this year, it has been very volatile. So a lot depends on how the market will end up in Egypt, what the currency will be like, but we will update the market hopefully within a year half.

But we still do see a growth in the MENA region and other markets. We're doing quite well in Saudi Arabia and North Africa, like Algeria and in other markets where we have presence for a very, we've been here 45 years, so we've witnessed this before and we can maneuver through the different cycles that we have in this market. So we're confident that we'll be able to achieve the guidance that we've had on a constant currency basis.

Emily Field:

Thank you.

Mazen Darwazah:

Thank you.

Moderator:

Just a reminder, if you would like to submit a written question and are watching via Spark Live, please use the ask a question button. Alternatively, if you are participating in verbal questions, please use the raise hand feature at the bottom of your screen to ask a question. And if you've dialed in, please press star nine to enter the queue. Once you've been invited to ask your question, please turn your camera on, unmute, and ask your question. Our next question is from James Gordon at JP Morgan. James, if you could unmute yourself and ask your question. Thank you.

James Gordon:

Thanks a lot. I think I'm unmuted. Thanks. James Gordon, JP Morgan. A couple of questions. One was also about the generics and the respiratory impairment or the right down there. Are you generally investing a bit less in generics now and redirecting that investment into injectables and branded, and then more of a focus? Or are there other areas of generics where you're going to invest a bit more? How should we think about that? Is this an investment division or more like a runoff for cash division? Second question would be branded. So the faster growth you've guided for this year, mid to high single digit local currency, is at the growth rate which we could now sustainably plug into our model, as in this used to be a mid-single digit business. This is now mid to high and it could even be high single digit over the next few years. How should we think about that? And then the last question was, I think Said mentioned the fourth arm of the business or what could be a future fourth arm. So what areas are you considering in as the fourth arm and where would you not invest? Which bits could be up for going for there?

Said Darwazah:

Thank you. The company is growing and our capacity to invest, obviously, is growing, and I would say we are not cutting down on investment in generics, but with the extra capacity that we have, we're dedicating that more to the branded and to the injectables. We have been talking about expanding capacity significantly, both in MENA and in US and in Europe. In the injectables, we are building new facilities for the injectables in the MENA, expanding Italy, Germany, Portugal, and in the USA. So a lot of emphasis been going on there. But we are still going to be investing in generics. As I said, we're not reducing but maybe not increasing. Brian, would you like to put a little color on that?

Brian Hoffman:

Yeah, happy to do so. I think as Said mentioned, we continue to invest as a group. I think overall we're contributing about six percent of our revenues to R&D, and generics is also in line with that. I think in any given year, we need to make adjustments to reflect the performance of the business, what the P&L can support. And I also think at any given year, you could have particular products that are in your pipeline that may be more expensive than others. So we could go up from that six percent in a given year as the P&L supports, as well as which specific projects that we're working on. But we continue to reinvest for the growth of the business.

Said Darwazah:

Thank you, Brian. So the idea of the new business is, we started some time ago a VC fund with $30 million to invest in digital health. This was like six, seven years ago. Recently, we've really expanded that fund. We've increased the value of the money that they can invest. We've asked more of our new board members to become involved and they are more savvy about the business in the States and so on. So we'll be looking at getting not just into digital and so on, but maybe start investing in Stage Three, things like that, products that initially we can bring to the MENA. Because the MENA has the infrastructure to support originator products, because we have a lot of end licensing, and then see where that trip takes us.

I think, again, we have been adding expertise in biosimilars. We have been adding expertise in biologicals. We'll probably keep adding that kind of expertise, looking at different opportunities. Before I hand that to Mazen and Riad, do you have anything else to add to what I just said? You're on mute, Riad.

Riad Mishlawi:

Sorry. No, I just wanted to emphasize what you had said. We're putting a lot of money in expanding our capacities and getting into new technologies. So as Said has said, we are expanding Portugal, today as we speak. Same thing with the US and Cherry Hill. We're doubling the capacity in Italy, expanding in Germany, and we're building new facilities in both Algeria, Morocco, and we have big plans for Saudi Arabia. So we're putting a lot of money in investing in the new technologies, in capacities, also in BDs and increasing our R&D to increase our portfolio.

Said Darwazah:

Okay, thank you. Obviously in the portfolios that we have, we're looking more and more at complex generics, both for the injectables and the orals. And as Mazen said, for the MENA, more and more end licensed products, oncology products, biosimilars and things like that. Mazen, you want to take the branded question?

Mazen Darwazah:

Yeah, sure. For the branded, when we got to the branded, one of our major issues in the MENA is not selling. The MENA is a very volatile market, so it's very important for us to collect our money. So we are very prudent on how much we want to expand in the markets and keep our healthy cash cycle. And this is why we are witnessing many companies now leaving the MENA, for the factor of the currency fluctuations. But because we are very entrenched in the MENA for the last 45 years, we know how the system grows.

Now, we will continue growing on a single to mid to high as we go forward. But what's more important than that, which we stated five years ago, that we want to sustain our profitability and increase it by quarter basis point as we go forward. So it's not how much we sell in the MENA, it's how much profitable the MENA business will stay as we go forward. So in a nutshell, a lot will depend on the fluctuation of the currency. A lot will depend on the political situation in these markets. A lot will depend on how we have and manage our cash cycle as we go forward and continue improving our margins going forward.

Said Darwazah:

Okay, next question please.

Moderator:

Our next question comes from Harry Sephton at Credit Suisse. Harry, if you could please press star six to unmute your line and ask your question. Thank you.

Harry Sephton:

Brilliant. That should be unmuted now. Thanks for taking my question. So we've seen some 483s and invitation bands at some of the Indian generic companies. I'd like to get your sense on whether you're seeing any significant benefits to yourselves from any of those, and how do you view your ability to gain market share in injectables in the current environment?

My second question is, you partnered on a peptide formulation partner a couple of years ago, and I wanted to get your take on the peptide injectable market more broadly. Clearly, it's one of the largest spaces in branded medicines currently. And is this partnership a sign that you're looking to be a meaningful player in this market longer term, including in the GLP-1?

Maybe a third question just on financial fees. How are you seeing the impact of inflation refreshers on margins in 2022? Can you quantify how much that has been a drag in 2022? We've tended to see an inventory lag effect from inflation impacts to cost of goods sold. Is this something that you're expecting in your guidance for 2023 as well? Thank you.

Said Darwazah:

Thank you. I've always been saying that during Covid, the FDA was not really doing major foreign inspections. Most of the inspections were being done online, although in the US they were still being very active for the US companies. And I've always thought that once they go out there and start doing the foreign inspections, they will be issuing a lot of 483s and warning letters and so on, which we have seen. We have seen a major ramp-up. We've seen this before. I don't know if you remember six, seven years ago. That was really what caused the major growth in those years and then caused the shortages and caused all these things to happen. Obviously, there are benefits for a quality company that can deliver, that is ready to pick up the slack. Maybe Riad, would you like to talk a little bit more about that and then answer the other question? And then we can ask Khalid to answer the financial question.

Riad Mishlawi:

Sure. Yes, of course. Between, I think the major ones that were lately hit by the FDA, Sun and Intas, in both, we have some overlap products. We're watching the market to see how we benefit, capitalize on this. Sun in particular, we have few important products that we overlap with. Intas more in Europe.

But yes, I think as this happens, how ready and how flexible we are to capitalize and benefit from that is important to us. And we are agile, we are flexible, and we think that we'll be able to capitalize. How much, it's still not clear. We don't know. We know that there's an import alert on Sun, but we don't know what they can send to the US and what they can't. This wasn't clear for us. But I think the market can tell and shortages can tell, and we're watching the market very closely and we'll be ready to capitalize whenever the opportunity arises. And as Said said, this is the course of business. This happens all the time. It hasn't happened in the last two, three years because of the pandemic. I think the FDA did not make it to a lot of inspections, but we will see it more and more right now. I think they're getting more active.

As far as in our R&D, yes, peptides is a very important area where we're developing. We're looking at it and we're hiring a lot of expertise in our development centers. We're also looking at partnering with a lot of other companies through some kind of a BD licensing or co-development. We understand that this is very complex, but also it's very key to our differentiated product ambition that we have. And we are trying to find few partners that we can co-develop with and create together some kind of a partnership in getting to the market with those important products. But this is amongst our strategy of bringing in differentiated products to the US.

Said Darwazah:

Thank you, Riad. Brian, is the generic business going to benefit from all these 483s and warning letters?

Brian Hoffman:

We are starting to see some disruption on the market, similar to injectables. There are a number of companies who've gotten significant 483s and/or warning letters. So we're always monitoring to see if there's opportunities, and we're hopeful there will be some.

Said Darwazah:

Okay, thank you. Khalid, do you want to take the financials?

Khalid Nabilsi:

Yeah, thank you, Said. So in terms of cost of inflation, as you know, this is a global issue now and we're seeing it more in utilities, consumables, freight labor. But we continuously look into our cost, supply chain, procurement, using our scaled relationship to drive efficiencies. In 2022, we've seen around $20 million plus in cost of inflation and we will see some as well more in 2023, but all anticipated into our guidance.

In terms of inventory, I would say, as you've noticed in our financials, there's this big jump in inventory of around $100 million, the cost more of stocking the inventory, and for the reason to make sure that we have continuity of supply. So we don't anticipate significant, I would say, increase in API but mostly in the consumable side. But it's all reflected in our margin and guidance for the group.

Said Darwazah:

Thank you, Khalid. I'd like to add-

Harry Sephton:

Brilliant. That's helpful. Oh-

Said Darwazah:

I'd like to add, there are two things that are different now than they were, let's say six, seven years ago, regarding the 483s and the warning letters. In the past, when a company got a warning letter or a major 483, we used to see the FDA not approve new products for them. Right now, that's not happening. They get the warning letters and they still get some products being approved. So we're trying to figure out where the FDA still stands on that.

The other thing was, prices used to rise significantly when there were shortages. Right now, it's more difficult. Obviously, somebody that's not on a contract, you will have to pay more than those that are on a contract. But relatively to where we were seven, eight years ago, where the industry stood its prices significantly, that has moderated. So the price increases, there will be benefits, but not as big as they used to be.

Harry Sephton:

Yeah, that's helpful. If I could just quickly ask another one on the US generics. I understand that your US pricing assumption for 2023 is for the erosion of price to continue to be low double-digit. It seems that commentary from some of the Indian generic companies is that it's more stabilized pricing. So I'd like to understand a bit more whether the pricing you're seeing is being largely driven by specific products and your product mix. So is it generic Advair and Icosapent, the larger products, which are seeing a more meaningful price erosion? Or are you seeing the low double-digit price erosion more broadly across your portfolio?

Brian Hoffman:

Yeah, great question. I mentioned in the fourth quarter last year and pretty consistently throughout the course of the year we saw double-digit price erosion. We're expecting that trend to continue, but as you highlighted, price erosion is always a function of your portfolio. In some of our larger products like Icosapent and generic Advair we do anticipate that some new entrants could come into those markets, which would result in price erosion. Given the size of those products, would be more significant for us. We are seeing... We're still seeing competitive intensity in some of our other products. Overall, for the business that's why our guidance reflects low double-digit price erosion.

Harry Sephton:

Okay, thank you.

Moderator:

Our next question is from Christian Glennie at Stifel. Christian, if you could please unmute your line and ask your question. Thank you.

Christian Glennie:

Hi. Good afternoon guys. Just following up on the generics and the guidance for this year, 2023, on the margin side, the 16% to 18%, to understand what some of the swinging factors might be there to go to lower or higher end of that range. Is it really your success with generic Xyrem or is there anything else to be aware of there in terms of the fluctuation there? Then, which may be a related point, any comments to make at this point in terms of expectations around some of the specialty products? Ryaltris, obviously, launched last year, but this will be the first proper sort of allergy season this year. Then Kloxxado any impact you're seeing or expectations around the change in Narcan to OTC and the like? Any comments on that one? Thank you.

Brian Hoffman:

Okay. Think a couple questions there. First, on the guidance range. There's a number of factors that could push us to the higher end of that range generic Xyrem being one of them. Others we're just talking about price erosion. If that's lower than what we are anticipating that could improve some of our other products. If we don't see new entrance on and or if we see them later then we're projecting that could push us to the higher end of that range. We have some new product launches and we have some products that we launched late last year, which were ramping this year. If they do better than expected that could push us to the higher end of that range. We're also seeing volume growth this year, whereas we saw volume erosion last year. To the extent that volume growth is greater than we've anticipated for this year that will also push us to the higher end of the range. It's a number of factors that we've reviewed as part of our guidance.

I'm sorry. Your next question on generics was?

Christian Glennie:

Yeah. Any comments on the specialty products, Kloxxado, Ryaltris in terms of expectations this year?

Brian Hoffman:

Right.

Christian Glennie:

Versus last year.

Brian Hoffman:

We're continuing to focus on our Kloxxado product and both the RX pharmacy market, as well as the state government market. We're looking to continue to grow that product over the course of the year. We also got approval and launched our Ryaltris allergy nasal spray product. We're now going into the peak allergy season right now, so we're seeing some good prescription growth on that. We're working closely with our retailer partners to get that stocked and get the pull through at the pharmacy level. Both those products we expect to be contributors to our growth this year.

Moderator:

Our next question comes from Victoria Lambert at Berenberg. Victoria, if you'd like to unmute your line and ask your question. Thank you.

Said Darwazah:

We can't hear you.

Victoria Lambert:

Can you?

Said Darwazah:

No.

Victoria Lambert:

Hello? Hi, can you hear me?

Said Darwazah:

Yeah, we can hear you now.

Victoria Lambert:

Oh, there we go. I've got a couple of questions, please. The first one is on the branded business. You guys mentioned at the JP Morgan Healthcare conference that you guys are now number three in MENA. Who did you overtake? What are the things you learned? What is the goal in that region? Then on your biosimilar strategy, is the strategy there still to go into partnerships? Is there an update from Bio-Thera and Richter with timelines for those products? Then I noticed for your generics business your target, I think, it was to reach 30% of sales from specialty that's been moved to 2026 from 2025, just wondering what informed that change. Thank you.

Said Darwazah:

Thank you. For the biosimilars right now our main strategy is to work with partners and we have been adding quite significant amount of products, both for the MENA and for the US. Mazen and Riad explain a little bit more regarding those. Mazen also you have a question of who did you overtake to become number three.

Mazen Darwazah:

In the MENA the market has always been dominant by multinational. We have Sanofi, we have GSK, we have Pfizer, and these companies. Now, we took over the market share of becoming number three. Now, we are one of the top five players in the MENA in terms of multinationals. We took another multinational and the succeeded them. That was GSK if I remember properly. The reason is that we increased our market share in Saudi Arabia, and in Egypt, and in Morocco, so we have advanced in these markets and, therefore, we were able to upbeat those companies. Now, like we said, we are number three in terms of volume. Also, you have to look at another thing in the MENA that there is a called tender business. Many times the tender business is not being calculated in the IMS or the IQVIA data, so now we're talking about the pure private market in terms of statistics. Riad.

Riad Mishlawi:

Yes. Sorry. As far as the biosimilars, as Said has said our biosimilars continue to be a very important part of our business. We would like to grow it and would like to keep it continuously filled with the pipelines and products. In MENA today we have three products that are commercialized. We have six products that we had agreed with Celltrion and three to be launched soon. We think that this business has been a good business for us. A good partnership with Celltrion. I think, we're trying to expand that one to see if we can do fill and finish as well with the new facilities that we're building in North Africa. We can get the advantage of being local manufacturers of those. There's a lot of focus in MENA on biosimilars. It's a big driver for the growth that we have.

As far as the US with Bio-Thera and Gedeon Richter we're happy with the partnership so far. We feel that we are on time. We're anticipating launching those two products in 2025. We are looking and talking to a lot of different partners also to expand our portfolio in biosimilars. I think, very soon we'll start building the commercial arm for that. We have already started hiring expertise in this field. We think that this is something that we'll be focusing on as we grow the business into the biosimilars. It is an important part and I hope this will grow and will have better news or more news about partnering with other companies, with bringing in more products.

Victoria Lambert:

Thanks. On the generics business the specialty target being pushed off by you any comment on that.

Brian Hoffman:

Every year, as we do as a group, we refresh our five-year business plan and we reassess how all components of the business are growing. We're still very optimistic about our specialty business. We have three branded products on the market today, we have two more in the pipeline, and we're still looking at other opportunities for that business. Our expectation is that business is going to continue to grow, but we're also making some very good progress on some of our other strategic growth areas, our contract manufacturing business, our complex generics business, and growing our base business, and looking at where we can selectively look at international market opportunities. I think, as a function of putting that all together the percentages and timing may have changed, but we're still optimistic on all those strategic growth areas for the business unit.

Victoria Lambert:

Cool. Thank you.

Said Darwazah:

Thank you.

Moderator:

I'll now hand over to Guy Featherstone for written questions. Thank you.

Guy Featherstone:

Thank you. Yeah. One in for Brian. Brian, how do you see Amazon's new generics prescription business affecting you and could you be a supplier?

Brian Hoffman:

Today we haven't really seen much of an impact on our business with Amazon. We are speaking with Amazon and we are finding opportunities to collaborate with them. We do supply them some products today, so we do see that there's a potential opportunity for us to do more business with them. Their focus so far has been more on cash paying customers, so it's been a smaller portion of the market, but we'll stay close to that new channel and see how that evolves over time.

Guy Featherstone:

Thanks Brian. One more question, a two-parter. Firstly, for Khalid on the balance sheet could you explain the shareholder equity fall from 2.4 to 2.1 billion end of 2022? Did the acquisition of Custopharm affect this? Then, secondly, to Brian on chargebacks in the US is there anything to update here about chargebacks and changes in policies for 2022 or 2023?

Khalid Nabilsi:

Sorry, Guy. What's the first question?

Guy Featherstone:

On the balance sheet, the reduction in shareholder equity. I think probably related to the [inaudible].

Khalid Nabilsi:

Yeah, it's mainly related to impairment and dividends. It's nothing I would say impacting the business itself.

Guy Featherstone:

Thank you. Brian, did you get that question?

Brian Hoffman:

There's a question about chargebacks. Chargebacks are part of the ordinary course of the business. As a company we're a continuous improvement company, so our internal operations we're always looking at ways whether it's chargebacks, whether it's other support areas, we're always looking to see how we can do things more efficiently. Chargebacks being one of those areas, but I don't see anything noteworthy for me to highlight there.

Guy Featherstone:

Thanks Brian. I think with that, assuming there are no other questions on the line, which I can see there are not, I will hand over to Said for some closing remarks and to wrap up the call.

Said Darwazah:

Okay. Thank you. Thank you Guy. Thank you to all of us that participated. Thank you team. We'll see you soon. Take care. Bye.