

## Hikma 2024 April trading update – Q&A transcript

### Operator

Ladies and gentlemen, welcome to the Hikma April trading update. My name is Betsy and I am moderating your call today.

If you are streaming via a web browser, kindly press the Q&A button and type in your question. If you are on the phone, please press star one on your telephone keypad to ask a question.

I will now hand you over to your host, Riad Mishlawi from Hikma, to begin. Riad, please go ahead.

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### Riad Mishlawi – Hikma – CEO

Okay. Good morning, everyone. Thanks for coming here. It's good to see you all again.

As you all know, we had our press release this morning. We reiterated our guidance for this year. We also had stressed certain points. I'm just going to go through some of the messages that we had put across.

The first, to start with, is we're very happy that we started the year picking up the momentum of last year, so it's been strong across all three businesses.

As you know, last year, we talked about capacity for the Injectables for quite some time. We did say to everyone that we had installed two new lines, so we're seeing the benefit of those two lines now. They had relieved a lot of the problems that we had with capacity. Now we feel that the lines are giving us what we need.

The Branded businesses is off to a good start. We were also always talking about the currency, especially with the Egyptian currencies in that area. I think Khalid will talk about it a little more. But we see it easing off and better than expected, so we feel that this division is also off to a good start.

Generics is also performing well. You know all the story of the sodium oxybate and the momentum there. We feel that this is continuing, especially on the top line. We'll answer some of the questions that I'm sure you have. Last week, most importantly with this division, we had announced the change of leadership. I think we always felt that, this division in particular, we need to improve our R&D output, new product, BD and so forth. We announced last week - was it last week?

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### [Female 1] – Hikma

Yes.

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### Riad Mishlawi – Hikma – CEO

Yes, we announced last week for the change of leadership. Hafrun Fridriksdottir will be joining us. She has an incredible career in R&D and the technical aspects of this industry. We feel that she will fill in the gap that we desperately need in that division.

Overall, we're really excited. I think we're off to a good year and I hope this continues. We are confident that this will continue and this was why we reiterated our guidance. With that, I'll open it to all of you to ask your questions. Please go ahead.

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**Alistair Campbell – RBC**

Thank you. Yes, so thank you. It's Alistair Campbell from RBC. Maybe we'll just start with that change of leadership in Generics, more specifically increased emphasis on the pipeline R&D. Do you think you'll be able to deliver that and achieve that within the current broad margin construct you've set us for that business going forward?

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**Riad Mishlawi – Hikma – CEO**

Yes, I think so. The change of leadership will bring two different things. The first is strengthening our R&D. Our R&D output has been weak. We have a very soft submission rate, a very soft - our portfolio has been very soft for the future portfolio, so that's the first thing that we need to strengthen. I know this doesn't come overnight. That takes time to build. But the structure of this needs to be put together and the focus on getting this started and picking the right product for this division. I think the experience in doing this is very important and we're very positive. The other thing that it brings in is - as you all know, we want to invest in this business. We want to get products. The evaluation of which products should we go after, what companies can we codevelop products with, what companies can we acquire products with and what should we acquire, what - there are a lot of aspects to this that we need that deep technical knowledge to help us making that assessment. I think she will definitely bring a lot of that value in.

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**Emily Field – Barclays**

Maybe just a follow-up question on the back of that. Emily Field from Barclays. If you could just perhaps describe within Generics, R&D, are there any particular therapeutic areas or looking at more complex generics, more respiratory - if you could just maybe expand on opportunities for enhanced R&D investment just within Generics...

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**Riad Mishlawi – Hikma – CEO**

Yes, sure. Of course, we want to go to a good technology and something that we're good at, something that we can manufacture ourselves. That would be even better. As you know, we're good in nasals and respiratory products. We have lines for those. We have a good technology. We have also a good market share with some of those products. We'd need to build on that, so this is the focus is how to build the products that we have to develop or acquire or add to the portfolio that we currently have. I think that's the focus, also the focus on what technologies should we get into. We have a huge plant in Columbus. I'm not sure if any of you have seen it, but it's an absolutely beautiful, great area. It has a lot of technology. We can absorb more technologies. We can invest in those technologies. It's the same concept that we did with Injectables. Injectables, our success is we want to add not only [after] products but also [after] technologies. That will create differentiation.

Complex products is definitely something that we want to get into, but that takes time. We will start building that. We have some in the pipeline, but we need to build more. But also technology is something that will create great differentiation between ourselves, competitors.

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**Max Herrmann – Stifel**

Great. Thanks. It's Max Herrmann from Stifel. Just one going on to your R&D focus, can we have a bit of an update on it, the Ellipta collaboration that you had and what the progress is with regards to that in the Generics divisions? Also there was a big change in Advair. The generics opened at the beginning of the year and I'm trying to understand what was the driver to that. Glaxo seems to have given up on defending that franchise.

Then maybe with Injectables and the increasing capacity that you talked about with the two high-speed lines. Obviously, the rate of growth in the division means that that capacity will be used pretty quickly, so what are the plans in terms of expanding beyond those current two high-speed lines? Thanks, [Riad].

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**Riad Mishlawi – Hikma – CEO**

Yes, great questions. The first ones for Ellipta, I can give you more information. I can tell you that the collaboration is continuous. There's always an update in the evaluation. I'm happy that Hafrun will also help in the evaluations and where we are, what we need to do and how can we accelerate this. This is something that would very much be our desire to add to our franchise that we already have today, so I think her experience and her assessment of where we are will be very valuable in this case.

As far as Advair and what's happening in this year, at the beginning of the year, as you know, with the inflation act that they had, there were a lot of - GSK seems to have decided to let go some of the market that they had. Of course, as you can see - and you all probably can see - that we had increased our market share with Advair. We have about 25% of the market right now and I think Mylan has the 40%. I think there's an opportunity for us to pick up what GSK had left off. This is a complex manufacturing and we need to make sure that our production is up to that bar and we pick up the contracts that we can deliver, so we are very busy doing this. Our sales people, our commercial people are doing a great job with this thing, so it has been positive for us.

As far as the capacity in Injectables, we have a good problem in Injectables that whenever we add capacity it seems like it gets consumed very quickly, so it's good the demand is there. The only problem with that is adding capacity in this particular technology or particular segment is not easy. You need to have planning. But luckily our engineers are always ahead of the game.

We just started building our fifth plant in Portugal. Actually we started breaking around two weeks ago. Equipment has been ordered. We have huge [fliers] that have been ordered, lines that are already on order. This will take a couple of years before it actually materialises, but we're excited about this. As you know, the expansion of capacity in Injectables has been going on beyond Portugal. We have added a line in Cherry Hill last year. We added also a fast line in Portugal. We have completed two plants now in North Africa. That will be validated this year sometime. Probably we'll open the doors towards the end of this year. Italy is also - we doubled the capacity there. They're in the last phases of validation and installation and so forth. That should be coming in also at the end of this year.

But we also feel that this unit can also absorb a lot more demand, especially with contract manufacturing and the growth of our products. As you all know, last year, we added 17 new products to our pipeline. This year, we're also adding some good number of products, so we're always growing. We're growing our portfolio. Demand is growing. Contract manufacturing is growing, so

capacity definitely will always be needed. We are planning ahead of time to continue adding capacity as we go.

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**Paul Cuddon – Numis**

Yes, it's working. Okay, so Paul Cuddon from Numis. Just going back to Generics, I'm afraid, but you seem to be painting a picture of a weaker pipeline to come through in the years ahead. I'm just wondering to what extent your previous \$100 million to \$120 million base profitability is more uncertain or are your new plans intended to grow that baseline of Generic profitability? That would be the first question.

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**Riad Mishlawi – Hikma – CEO**

No. I'm very confident that the \$100 million, \$120 million that we had previously given the market is something that we can stick to. That would be a minimum number, but we want to improve on that. We want to make sure that the foundation of this division is strong. We want to build the future, so we don't want to depend on what we have today but what we will have and can get in the future. I think there are two things that the changes that we're doing in this division show. One is our commitment to this division. We believe that this division has the right foundation. We just need to make sure that we create the future to it. We have the right technology. We are in the right location in the United States. Fantastic quality record. We have output. One of the largest facilities in the US. We have all the elements to make this more successful than the way it is. I think what stands between us and doing this is creating a future, creating a portfolio of products that...

It seems like we've had products coming in every other year, maybe every two to three years. We shoot up and then that product comes down. We come down with it. We should be able to do that consistently. We should be able to have a momentum of products that when one comes and then comes down - because anything that goes up is going to come down eventually - we have one right behind it. It seems there's a void and a gap. This is why everybody is not trusting this division in a way and sometimes we call the cyclical nature of this division and so forth. But I think we can fix all that. The way to fix that is with a strong portfolio and a strong pipeline. That's what we're planning to do.

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**Paul Cuddon – Numis**

Okay. Thank you. No de-emphasis on the specialty portfolio? That will be something that you continue to increase the mix of within Generics?

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**Riad Mishlawi – Hikma – CEO**

Yes, the specialty is a fantastic idea, but it's a very difficult - it's something that we really need to do, but we also will need to make sure that we are realistic about what we're doing. Although a specialty business is something that we want to get into, it creates differentiation between us and other competitors. It gives us something on top of what we have today with a baseline of generic products. But we also have to know that we need to commit to it. We need to have more than one or two products in the basket, because it does require a lot of money to detail those specialty products. This is one of the things that we want to do. This is one of the things that we - I've talked about what Hafrun can help us to do and just assessing what other products can we add to that basket. No

matter how big the product is, the promotion of a specialty product on the market is extremely expensive. The more you have in that basket, the better you absorb that cost.

This is where our focus is. Our focus is how can we make the specialty more successful than it is today? We're on a good start. I think we have a couple of good products. They've been growing. I think they have a good future. But they will not have a fantastic future if we don't add to that basket more products or be creative in getting something else to absorb the costs that we have. We have a lot of ideas and we're working with a lot of different ways, but this is something that we recognise that we need to fix.

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**Paul Cuddon – Numis**

Okay. Thank you. Just from me, moving on to the US Injectables business, obviously Custopharm has been a fantastic acquisition. It's been a good contributor to growth. But focusing more on the organic growth drivers within Injectables, will that be lagging your 4% to 6% guidance for the division or could that be - sorry, 6% to 8% for the division or could that be up at that level on an organic basis?

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**Riad Mishlawi – Hikma – CEO**

Yes. As you have seen, the two main changes that we have made since I took over - and it's only been six, seven months - is that we appointed two presidents of two of the three divisions that we have - very strong in R&D, very strong technically. This is really to make sure that - because we believe that the future comes with good organic R&D, good technical knowledge that we need to get to within our Company.

Bill, who took over my role as President of the Injectables, is a PhD in chemistry and has been in R&D for quite some time, all his career, has great understanding. In the very few months of being in this role, he had really improved the R&D and organised R&D. I'm very hopeful. Obviously if you see what we had done last year and how many products that we had introduced to the market - and this year we have a great output coming in. But I think the output is coming from simple products. We are concentrated on the more complex ones. That's what Bill had brought in.

I think we need to do more of that. I think there are a lot of ideas of how to do it, not only organically 100%. It could be organically, but it could be with help with other people that are [in specialties]. Co-development is something that we're looking at. Partnership with API companies that we can make specialty API for a - all of those new concepts are things that we are very active doing in the background right now.

Of course, unfortunately, this is a business that - I did say that before - it's like a Christmas tree business. You plant the tree today so you can sell it in six, seven years. Nothing that you do today is going to show you tomorrow. But I think you need to see the activity that happened today that we can predict what happens tomorrow. I think that's what we're doing. We're trying to plant as many trees as possible. We're trying to make sure that we have the right processes in place and invest in the right place. It's not the lack of investment. The most important thing about R&D starts with - not investment, to be honest with you. It's about picking the right product. Picking the right product means you need to have a good understanding of the market, good understanding technically with the

products and so forth. I think this is where we see both the likes of Hafrun and Bill bringing in. That's why we had made those change and they've actively working towards that.

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**Victoria Lambert – Berenberg**

Victoria Lambert from Berenberg. I just wanted to get a better sense of your biosimilar strategy, so I know you do partnerships. It looks like you are well covered for some oncology products. But just wanted to get a sense of your exposure to immunology and ophthalmology biosimilars. Would you guys look to launching these products in MENA with a partner? Do you manufacture most of these products on behalf of your partner?

Then I just have a question on sterile drug compounding, how that's going, if you have all your licences. Then do you expect to break even?

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**Riad Mishlawi – Hikma – CEO**

Okay. For the first question, the biosimilars, it's a very tough industry as - you can hear about it from what everybody's doing. Some people are doubling up on it. Some people are just exiting right away. It's a crowded market. I think it becomes extremely lucrative when you are the first. First, second, third maybe in the market, that's when you really make a lot of your money. We are not - we came in with partners, because we can't make this ourselves. We had to partner with people. I think we partnered with the right partners, because we do have the right transfer costs with them. I don't think we are going to be number 1, 2 or 3 of those three products or two products that we have, so I think we have to wait and see. They might come to surprise us. But in either way, we feel that we can compete. If not because we are one of the first in the market, it's because we have a good cost base. I think we can compete based on that. This is in the US.

In MENA, it's a different story. In MENA, we're leaders. We are partnering with Celltrion and we have about seven products now. Is it seven? Six, seven.

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**[Female 1] – Hikma**  
[Seven].

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**Riad Mishlawi – Hikma – CEO**

Seven, right. We have seven products and it's growing. We have a commitment and a great partnership with Celltrion to take their entire portfolio to MENA. We've been growing the market even more than the brand themselves. We have captured not only market share from the brand, but we're growing that ourselves too. We have plans to fill the product ourselves in MENA. It's something that we are in discussion with our partner with. I think in MENA we are on a good footing where our future is very bright. I think we will be growing this business significantly in the next few years and adding more to the portfolio.

US and Europe where it's a different strategy, again we are not the pioneers and the leaders, but we think we will benefit from this as we get those products approved.

As far as the compounding, we are happy with where we are with the compounding. As I always said that compounding is a great business. You seem to know a lot about compounding, so you really know that it is a good business. You know that there's a lot of potential of that business, because a lot of the hospitals are keeping that business. Until they trust the partner, they really don't want to give up what they have. But they would like to give up what they have, because they're not in manufacturing. They are a hospital. But since they have that need and they need to satisfy it and they don't have many options, so many of them are choosing to keep it inside.

This is where we're coming in and we think we have a potential to grab this business. But we need to be careful also. We need to make sure that we start very slowly, we keep growing, we create a foundation and trust. Little by little, we add partners. That's exactly what we're doing. We have all the states right now, all the significant states, not all 50. I think there are a couple of that we chose not to go after. But the last one was California and we got approval for that. It is growing month on month. We had the change of leadership just - we announced it internally just a couple of weeks ago. We've recruited people from good reputable compounders, companies that do exactly that. We had built a good structure. We changed the structure to be a little bit more now that we have the infrastructure in place and the manufacturing in place. We concentrated on what to do with the commercial.

A lot of things going on, but we are very careful. The last thing that we want to do is disappoint somebody, make a mistake, not be able to deliver a product. We really need to build that, because we feel that this is a great potential. If we do it right from the ground up, we'll end up with a very good business in a few years.

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**Peter Verdult – Citi**

Hi. It's Pete here from Citi. Hope you're both well. Sorry for being late. Three topics, Branded, business development and compounding. I'll try and be quick on each.

But on Branded, despite what we're seeing across the region, despite FX, geopolitics, this business is performing extremely well. This is broad-based strength and execution on the strategy or is there anything you'd call out country-wise or product area-wise that's driving a better performance from Branded? That's question number 1.

On BD we had - I know you're not going to say what you're doing, but could you at least just characterise the environment for doing BD this year? Should we expect that something can get done? You don't have to repeat where your focus is. I know that. But I just want to get a sense check, the environment for BD. Good, bad or ugly?

Then last, it was coming back to the compounding business. This partnership you had with Civica all those years ago, once you get critical mass, the service levels, does that turbocharge this compounding business or is that a step too far? Because I know they're a very large hospital network. I'm just wondering whether your existing Civica collaboration would turbocharge your compounding business over time. Thank you.

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**Riad Mishlawi – Hikma – CEO**

I'll speak a little bit about the Branded and I'll give it to Khalid to talk about the currencies and what happened there. But as you know, in the last few years, we have been really investing in the Branded

business. We've been adding many facilities, especially in oncology. Our chemical facility, our API facility has been working very hard, trying to get unique molecules for oncology to service all these new plants that we have. We have a new plant in Algeria. We have a new plant in Morocco. We have one in Egypt. We are really covering the whole area, especially in oncology. This has been growing very impressively.

We are backward integrated. We've been really spending a lot of money expanding our API facility. As you know, our API facility was extremely small in the past, so we'd never really give it a lot of attention. But in the last, I would say, five to seven years, we have been looking - we have changed the strategy and we've started focusing on it. We've put some money into it. Right now we're seeing the fruits of all that. This is one big element of why the Branded is doing well.

Also, in the last few years, we've been investing a lot in BD, partnerships. We did very well in also going from - providing medicine more into the diagnostics now, more into a lot more transferring - maybe transforming the Company. I wouldn't say transforming, but adding to what we have from provider of medicines to also providing solutions to medical - so more of a health Company rather than just a pharmaceutical Company. That has been entirely throughout all of the region. Locally we've been expanding our facilities. As you all know, there are a lot of facilities being built in that region. The last one that we're planning to break ground very soon on is in Saudi Arabia. This is going to be happening very, very soon.

A lot of activity has been going on the Branded. Maybe we never really talked about it to everybody and this is why - but if you look at the last two years, the Branded, little by little, has been doing well. This year is not an exception. That was one element. There's an element also of the currencies and all this. You want to...

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**Khalid Nabils** – *Hikma – CFO*

Yes, just maybe heading to currency, so the performance has been driven across all markets. All markets have been doing very well, even in Egypt, although we have seen the currency and - but the business itself has been growing. One of the reasons why we've upgraded or slightly upgraded our operating profit guidance is the reason currency has been better than what we've expected. When it's going to stabilise, maybe there could be a further upside, but so far what we are seeing is we're seeing a very good momentum. This momentum has been driven across all markets.

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**Riad Mishlawi** – *Hikma – CEO*

Your question about BD and M&A, we have talked about the strategy that we have. One of the strategies is looking for the future. I think this is one of the things that we have to strengthen, because when we come to you and give you our results, you had already - you want to go and say, okay, what's next? Where's it going in the future? I think this is where we have to concentrate on. I think we're confident what we do today. I think we're confident what we can deliver at the year that we're talking about. But you all want to know and we want to assure you of what happens in the future now? Give us more on the future. This is why you're always asking about compounding. You're asking about all those potential breakthroughs.

I think this all happens with BD and M&A and, of course, with the portfolio R&D, building on R&D. This is where our focus is. This is why Bill is here. That's why Hafrun is here, because we feel that



that is where we - we need technical people to evaluate. We need technical people to be able to build our R&D. With those people added to our network, to our Company, we really can do better in R&D and BD. We could evaluate better. We can be assured, too, that this is the way to go. I think this is exactly what we're doing. We did that in the R&D in the presidents, in the management, but we also did the same thing in the structure that we have. In our BD in Bassam's department, as you know, in M&A and BD, we have restructured this department, added a lot of competent people to it.

We are focusing on this, because we feel that this is an opportunity today. As you know, we have a good balance sheet. A lot of companies don't. They're highly leveraged. We're seeing a lot of opportunities, so this is the time now that we have to evaluate to see what we can grab, what would be synergistic with what we have today. There are targets and currently we're evaluating many. I hope by near the end of this year we should have some, hopefully.

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**Khalid Nabils** – *Hikma – CFO*  
Compounding.

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**Riad Mishlawi** – *Hikma – CEO*

For compounding, we - I keep saying the same thing. It's a business that you - we all know - we started out thinking that this business is very much similar to the core business that we have. It is as far as the product, as far as the GMPs, as far as the control that you have in manufacturing plant. Where it differs a lot is in commercial. In our core business, we have four, five, six customers, our wholesalers basically that they sell the product. In this business, we have 5,000 hospitals that we have to - individual customers that you have to vet. You have to bring them in and you have to go through all the credit, through all the FDA licences and all this.

It takes time. It takes time. From us, we're happy to do it, but it's hard to get the attention of a pharmacist to say, hey, [unclear] you have to fill those four pages and we have to go through the process to get you in. That is going. We're putting more and more people into it to get more customers in. We feel that we can get few IDNs with [the] presentation of 100-plus hospitals. Maybe that would [unclear].

We've put a strategy together. How can expedite this process? How can we get more and more customers in? But before we do that, we want to make sure that we have the infrastructure. The worst thing you would do is you would get orders that you cannot satisfy. You have to make sure that both things are balanced. You want to encourage our commercial. Go and get orders. But you want to make sure that your infrastructure, your manufacturing is healthy enough that you can satisfy all these orders. We have been working on both. We have put all our systems right now [unclear] the water system has been validated. We've put all the equipment in. A lot of activities are happening on the ground, on the manufacturing floor. At the same time, we're doing a lot in the commercial. They're going hand in hand together. Progress is definitely very evident. We're very hopeful. Hopefully, we'll see it pick up pretty soon.

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**Peter Verdult** – *Citi*

You can't [unclear] think you can leverage the Civica collaboration.

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**Riad Mishlawi – Hikma – CEO**

Yes, well, we can. I think the first thing that we wanted to do is make sure that we have all the hospitals. We cannot go to Civica and say, okay, we'll give you, but you cannot sell in this state and that state and this state. That was one of the obstacles that we had. Now I think, with California being online, we should be able to say that. The second thing that we should be able to say that whatever order you give us we will guarantee we give you. The whole model of Civica is that guarantee. I think the team is working with Civica and multiple other wholesalers and GPOs. Yes, we want to make sure that whatever we promise, we deliver.

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**Christian Glennie – Stifel**

Hi. It's Christian Glennie with Stifel. Couple, please. The usual one on Generics and pricing in the US, what was it like in the first quarter and what's your outlook for the year on pricing? Then just coming back to the BD [unclear] partnership, talking a lot more about partnerships across your division, particularly Generics and specialties and others. Is that shift a response to something that you're seeing in terms of the strategic direction or is it more a reflection of your leadership, your philosophy and how you think you should be looking outside a bit more maybe than historically Hikma has?

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**Riad Mishlawi – Hikma – CEO**

I'll do the second one and I'll get Khalid to talk about the pricing. He's good at numbers.

For the second one, I would say it's not a shift. It's execution. We always knew that we really need to build our pipeline. We know that we can't make everything ourselves. We know we have to go out. If you look at some of the specialties that we have and some of the partnerships that we have, we've done well. We've done well in partnership, but I think we could have done better in execution. Some of those contracts that we have, we really did not go the entire way as we expected them to do. I think it is really not a change. We know that the future is going to depend on what products you have, on differentiation, on efficiency, on the size of your portfolio, all of that. It's just how you execute towards that. I think it's just a matter of execution.

You want to take the pricing?

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**Khalid Nabilsa – Hikma – CFO**

Yes. Pricing, we said at the end of last year that it's always been - and the pricing erosion in the Generics in terms of mid to high single digit. There's no change to - we are performing very well so far and this has been assumed in our guidance as well.

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**[Male 1] – Hikma**

Just going to pause and take questions from the line. [The Operator can now]...

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**Operator**

Ladies and gentlemen, if you would like to ask a question during the presentation, you may do so by pressing star one on your telephone keypad. When preparing to ask your question, please ensure your phone is on muted locally.

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**Male 1 – Hikma**

Take a question from the room while we're waiting?

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**Operator**

Yes.

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**Male 1 – Hikma**

[Unclear].

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**Max Hermann – Stifel**

Maybe I'll just - almost summarising what you've really been saying which is that BD is really focused on building product pipeline and helping to strengthen that. Your R&D emphasis is again the pipeline, so it's already focused on building for future growth. That's pretty standard for any pharmaceutical company, so why the change in emphasis? Is that not a change in the strategy there in terms of being much more focused on it?

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**Riad Mishlawi – Hikma – CEO**

I don't feel it's a change of emphasis. I feel that it's something that we had always talked about. I think we just need to execute better. [The answer to your question is I think] when you have a business that has a cyclical nature like what we have in the Generics today, you introduce a product and you go up. Then the product starts dying off and then you go down. Then you create this distrust with your investors, with the confidence in this business. We've seen it. We've seen a lot of people question why are you committing to a business that you don't have assurance and continuing to deliver every year the same way? I think we want to change that. I think we did say, look, we think this business has the right elements. I think it's missing few. We have to go after fitting those missing elements that it needs, those weaknesses. The weakness is in that portfolio. Everything else is not only good but it's fantastic.

The site is pretty incredible in terms of capacity, in terms of size, in terms of cost, capabilities, technology. It's got everything. We have great automation. I went for a tour with Hafrun, the new addition to the team, the new president of this. She's been there, done that. She's been in many companies and big companies, much bigger than ours. She said, this is the nicest site I've seen. She said, the automation is incredible that we have there. She said that some of the capabilities that we have is very impressive.

Why are we having difficulty in making this business bigger than it is today? I feel it is really related to, [as you know], keep introducing new products, keep being very active in development. I think we

kind of relaxed. The reason why, I think mainly we had a lot of changes in how we set up R&D and who led the R&D. We've taken R&D from BI when we acquired this facility. Then that had changed and somebody else had come in and stayed two, three years of that had gone. Then somebody else came in and then we changed the structure into global R&D. We have never really been a very sturdy, focused - we know where we're going. We know what we're going to spend. We know what we're going after. I think that's what we need to build.

It's not a shift. It's more of about we knew where we need to go. We just need to execute.

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**Khalid Nabils** – *Hikma – CFO*

Execution and efficiency as well. It's the output of the R&D rather than the spend, so it's more focused on bringing more efficiency, more output of the R&D and the investments that we are making.

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**Riad Mishlawi** – *Hikma – CEO*

We're willing to spend more. We always said that we would do 6% to 7% of our revenue. We're spending a little bit less, especially in that division right now. We have capacity to spend more. If it is justified, we'll even spend more than that. We just need to make sure that it's justified. We need to make sure that it makes sense and make sure that it would be worthwhile.

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**Seb Jantet** – *Liberum*

Hi. Seb Jantet with Liberum. Two questions if I may.

First of all, just - so hearing what you're saying about the pipeline in the Generics business. I'm wondering obviously, side acquisition, it's going to take a while to build that pipeline, so how should we be thinking about the CMO business during that phase? Should we be seeing growth in that part of the business [and float] capacity to utilise capacity in the short term?

Then the second question is just on sodium oxybate. I just want to pick up on something you said in terms of seeing volume growth there. I think the other main [AG] company is volume limited. I just want to check whether you've got any volume limitations on your AG agreement.

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**Riad Mishlawi** – *Hikma – CEO*

Hi. I'll take the first one and the second one - you guys want to take that one, the sodium oxybate? This is a very sensitive issue [unclear].

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**Female 1** – *Hikma*

We don't have any [unclear].

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**Riad Mishlawi** – *Hikma – CEO*

You just have to be careful what to say there. But your first one is in relation to - I'm sorry. The first question was...

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**Female 1 – Hikma**  
CMO.

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**Riad Mishlawi – Hikma – CEO**

...the CMO. As you all know, in Injectables, we had built a good CMO business. The philosophy of that CMO business was, when we build facilities, it takes a while before we [fold] that facility, so it's an opportunistic type of business where we can come and sell that capacity to somebody else who's ready to take it rather than having to sit and absorb the cost. It's been a successful model. We've done very well to a point where now we're saying, well, maybe it should be a separate business. We're still looking at that. I think we can do it and we're committed to do it, but we need to have the capacity before we commit to having an independent contract manufacturing unit in the Injectables.

Generics, we have the capacity. We have a very good plant as I mentioned before. Pristine quality record in the United States. I think it's got all the right elements to attract contract manufacturing. But contract manufacturing requires also contacts, requires you know who needs it, how you talk to them or how you bring it in. You transfer it [unclear] transfer methods. It goes through six, seven audits before they - it costs a lot of money to transfer products. You don't want to give your products to contract manufacture to somebody that can get you in trouble, so it does take time for you to get that trust going. It does take time for the auditing to take place. It does take time for transferring all the [methods], transferring [over].

We are in this process with a few clients, but also we feel that with the technical people that we had added, with the two new presidents that we had added - both Bill and Hafrun have done this. As you all know, Hafrun's experience is in companies that done a lot of that and also Bill. Bill was, as you know, CEO of a company that did only virtual, so they know particularly well how this thing goes. We're hopeful that with those leaders we can grow this business well. We're committed to this business. We know that we can do good at it. But we also know that we really need to reach the right person, the right company and offer them the right attractive contracts for them to be motivated to move their products to us. But definitely it's something that we're looking very closely at and we are optimistic that we can grow this.

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**Khalid Nabilsa – Hikma – CFO**

We have the good manufacturing base. We have a strong quality track record. We want to build on that, [whether on CMO] - at the same time, as Riad mentioned, bringing more into the specialty. Advair as well is growing very well. This business is delivering good growth, but we want, based on the output that we have, to have it much stronger. With Hafrun, we are sure that we can grow this business further.

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**Paul Cuddon – Numis**

Thank you. Paul Cuddon from Numis again. Just a few GLP-1 related questions. Are you distributing those for obesity applications in the MENA region? Could that be an opportunity? Could you actually manufacture them yourselves with any of your facilities? I know it's peptides versus sterile injectables, but could you rearrange the manufacturing? If you're not, are you seeing any dynamic

where sterile injectable manufacturers are switching capacity to GLP-1s to solve the shortages? Is that creating opportunities for you?

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**Riad Mishlawi – Hikma – CEO**

Yes, excellent question. It seems like GLP is like the new penicillins in the world. It's the new breakthrough. We saw the acquisition of Eli Lilly just a couple of days ago for this. Definitely it's something that we are looking at. We have partners for that, both in MENA and in the US. Did we say anything publicly about this? Okay, so we have partners. We're looking at different things and different options. We definitely are not ignoring this. But we know that we don't have it developed ourselves, so we have to go through partners.

As far as manufacturing, yes, we can manufacture it. It's not a problem with manufacturing peptides in our facilities. Most of those products are placed in a special delivery system like autoinjectors or prefilled syringes, both of which we can make, so I don't think it would be a problem. I think the first thing is get it out on the market. When we do talk to partners, we always have that option, especially in MENA because you do have the preference for localisation in MENA. We can consider that when we talk to people. For US, we are talking to partners that are able to give us the volume that we need.

It's something that we're watching very closely. We're talking to a lot of partners. Hopefully soon we could see something there. We'll see.

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**Emily Field – Barclays**

I know you mentioned track record in generics from a regulatory perspective. I think, in some of these recent meetings, you talked about the potential for greater FDA inspections [are] industry-wide in injectables. I was just wondering, how has that materialised? Then maybe dovetailing into that - the question in terms of how the shortage situation looks in the US for Injectables?

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**Riad Mishlawi – Hikma – CEO**

Yes, the regulatory inspection, as you all know, has picked up a lot since after COVID. During the two, two-and-a-half years of COVID time, there weren't much inspections, especially international inspection. Domestic and international FDA had frozen. They done a lot of virtual inspections where they ask you for the paperwork. They go through all the paperwork without having to visit the site. It has changed now. They've been very active. They've been visiting all the sites. We've seen people that had done well and people that had done terrible. We've seen a lot of warning letters. A lot of people had stopped manufacturing.

Yes, and the shortages continue. It's between 140 to 160 products now on the list. We do have a lot - big portfolios every now and then. We do have opportunities that come across those shortages. Our manufacturing plants are very good in turning on a dime and making sure that those opportunities are fulfilled and captured.

We have never seen orals in shortages, but now we're seeing them. It's not only limited to injectables anymore. We're seeing some of the orals coming up.

This is going to continue. I think this is part of the system. It's inherited in how the system is built in the US. As long as there's a lot of pressure on pricing and a lot of pressure on the manufacturers to reduce their costs, there will be options where you decide to pull out from manufacturing some molecules, because you get to a point where it's not profitable anymore and you go choose something else. That continues.

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**Victoria Lambert** – *Berenberg*

In orals, are you referencing the ADHD meds? I read a lot about that.

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**Riad Mishlawi** – *Hikma* – *CEO*

That's one of them. That's one of them definitely.

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**Victoria Lambert** – *Berenberg*

Okay, and antibiotics I think [unclear].

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**Riad Mishlawi** – *Hikma* – *CEO*

Yes, antibiotics, penicillins is one, but that's different. That's more related to API. But yes, there are a lot of different reasons why, some related to quota from DA and how they're distributed, some related to API. But it's new to see in orals and shortages.

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**Male 1** – *Hikma*

We can take one more [unclear] question from the room.

Okay, I think we'll wrap up. Riad, I don't know if you have any final words. Otherwise we can...

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**Riad Mishlawi** – *Hikma* – *CEO*

The final word is, look, we're - I've been a CEO for a few months now. It's been exciting. It's been travelling a lot, trying to understand what we have, what we need. How can we satisfy the needs? How can we fix some of the problems that we have? How can we accelerate the growth? That's been very exciting. It will be more exciting when we actually show something that is substantial. We're close. We feel that we are doing a lot now. I think if you do a lot, then results will show. Hopefully, you'll all see it soon.

But yes, we have a great Company, a good foundation, great people. We are a public Company. We work like a small group, although we're about 10,000 people. But we work like a small company. We're a public Company, but we work like a private company. We have a lot of advantages there in capturing everybody's attention and motivation and giving the right tools to grow. I'm excited. I'm happy where I am and I look forward to the future, so thank you very much.

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**Operator**

Ladies and gentlemen, this concludes today's call. Thank you for joining. You may now disconnect your line.