

Hikma 2023 interim results transcript**CORPORATE PARTICIPANTS**

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**Q & A**

**Susan Ringdal** – *Hikma Pharmaceuticals – EVP, Strategic Planning and Global Affairs*

So, I can welcome everyone to Hikma's interim results Q&A. We have Said Darwazah, our CEO, Khalid Nabils, our chief financial officer, and Riad Mishlawi, president of injectables, and our incoming CEO. So, welcome everyone. We hope that you have all had a chance to review the presentation. And we will use this session for Q&A. For people in the room, if you have questions, please take the mic off the table, and answer your question using the mic.

With that, we'll hand it to Said.

**Said Darwazah** – *Hikma Pharmaceuticals – Executive Chairman and Chief Executive Officer*

Again, good morning, everybody. And welcome to Hikma's results for the first half. As you can see, the -- we think that every division has performed extremely well. The injectables have shown good growth. And Riad will explain later that there were some extra costs on that division. I will explain in detail what they were but the growth in sales was good, and the launch of products was good. We're able to launch a lot of what we call 505(b)(2) products. And these are products typically that are new to the market. So, they are like in between a generic and a branded, for instance, cefazolin is usually used in one gram and that's the originator and that doesn't come in a stronger strength. But we got approved two and three grams, two and three grams. So, it's something new for the hospital. And there are many, many products that we got approved for. So, they're really good products, but they need a little bit of promotion. So, they're somewhere between, as I said, the branded and the generic, but we think that they will do extremely well, because they really address what patients need and what the hospitals need. Europe did extremely well, MENA did extremely well, the U.S. is doing fine. It's picking up and Riad will explain a little bit more later on. MENA, again, although we had some very, very difficult headwinds with the currency situation in Egypt and Sudan, the unfortunate happenings in Sudan, we still manage to give a very good result with growth of...

**Khalid Nabils** – *Hikma Pharmaceuticals – Chief Financial Officer*

It's almost 17 percent. Yeah.

**Said Darwazah** – *Hikma Pharmaceuticals – Executive Chairman and Chief Executive Officer*

So, that was very, very good. We were able to deliver a lot of the oncology tenders in the first half. So, that gave a big, big boost. And those are very high profitable type very highly priced profitable products. And the Generics. Two things, obviously, first, was that the portfolio, the original portfolio, we have done much better. The question everybody's asking is what is going on in that market, as are the prices improving, are -- and the reality it's a mixed bag, at least from our perspective, we've seen some products prices still go down. And we've seen some product prices go back or stop being reduced. For instance, amoxicillin, because of the shortage is priced better, and many others, but we've also seen an uptick in volume. So, even the ones that had price reductions had a lot of the other major increases, because of the volume increases. So, obviously, demand is picking up again. We believe that there is softening now. I don't think there'll be a lot more pressures. You're seeing the FDA still doing the foreign inspections, still issuing out the warning letters to

many of our competitors, which obviously can create more opportunities and shortages moving forward. Cash flow was fantastic --

**Khalid Nabilsi** – *Hikma Pharmaceuticals – Chief Financial Officer*

Yeah, growth of 31 percent in cash flow.

**Said Darwazah** – *Hikma Pharmaceuticals – Executive Chairman and Chief Executive Officer*

-- everything is good. We're ready. I'm ready to hand over to Riad, Riad is ready to take -- Riad is actually -

[laughter]

-- come on. And I'm ready to hand it over to Riad. It's been a very smooth transition. Obviously, everybody knows him in the company extremely well. So, there have been no glitches at all. And with that, I will hand it over to my colleagues and they can give you some more details.

**Khalid Nabilsi** – *Hikma Pharmaceuticals – Chief Financial Officer*

Questions hold on too, because Said gave a good I'd say brief about all of the segments. So, I think maybe we'll open it up for Q&A. And the growth in the branded businesses.

Victoria Lambert:

I don't know. Hi, it's Victoria Lambert from Berenberg. And so, I'll start with the first most obvious question, which is just about how Hikma may benefit from some of the supply issues that there may be from the tornado impact on Pfizer, from the North Carolina facility. Yeah, that would be helpful.

**Riad Mishlawi** – *Hikma Pharmaceuticals – President of Injectables*

Well, I mean, we have to start by saying that this is a really unfortunate event. You know, and I hope that will not cause shortages to patients, we did communicate a lot of our customers, you know, if they face any shortages that will be willing to step in. But as you all know, you know, our capacity has been utilized well, so this is very temporary, if it happens, we still haven't seen the impact yet. But if it does happen, that will be temporary. And we will have to kind of take it one by one and see if we can step in, and how can we step in and what would be the, you know, the, at the end of the day the consequences of this event. But we haven't really seen a substantial uptake right now, or demand, increase in demand, I think Pfizer has multiple facilities. And as they did communicate to the market that some of those products are made in several facilities, and they might be able to produce them in other facilities. FDA doesn't seem that is panicking, customers are not panicking. So, you know, the pictures seem very horrific, you know, and, as we know, a perennial plant, a septic tank like this, you know, without a warehouse, even if you have the production facility intact, you still need to do some fixing, before you go back to production, it will take some time, whether this is going to yield to significant shortages that will, you know, will spill out to us and, you know, or opportunities for us or not, we still don't know.

Pete Verdult:

Riad, can I press you on that? When you say you've only got limited capacity that we will have some of us want to see plant et cetera, et cetera and other plants around the globe. Sorry, Pete Verdult, Citi. Just to push, Riad, on that prior question on, you probably don't want to give us your exact capacity utilization right now. But ballpark, can you give us a sense of how tight it is or flexibility to maybe step in? Thank you.

**Riad Mishlawi** – *Hikma Pharmaceuticals – President of Injectables*

Well, the good thing about it is that we always seem to be ahead of the curve in some way. So, we did install two fast lines in our both facilities in Portugal and in Cherry Hill, the Cherry Hill line went online a month ago, a month and a half ago, it will take some time to ramp it up. But it's a very fast speed line, it will give us a significant increase in capacity, liquid capacity. And an identical line is being installed today in Portugal. And that will be online in a matter of I think by the end of September. So, we are adding to the -- we are adding

capacity to the system. We operate by making sure that all capacity is utilized on -- in any circumstances. But as you know that when you have a temporary opportunity, you're not going to drop your own product to take on this. And then we'll have to come back, and it takes a while to come back. So, we really manage those things very delicately. And I think we're just watching; we know that we're adding capacity to our facilities. And if it happens that we can pick up some more capacity, some more opportunities from this, we're ready.

Pete Verdult:

Just the last one before I hand the mic over just on those opportunities, I think can you talk a bit more about what you did with Akorn that you've picked up some lines or equipment, I don't know whether you've picked up products, but just Said was talking about it two or three months ago about the environment for you, giving you a balance sheet to sort of pick off some interesting opportunities. Just give us a sense, talking about Akorn and then more broadly, the opportunity to do more there more activity there. Thanks.

**Riad Mishlawi** – *Hikma Pharmaceuticals – President of Injectables*

So, I'll say a few things and I think Said might have to add things. I think from our point of view, the opportunity that Acorn has given us is we have we put our hands on equipment right away. You know, as you know, in this industry, if you want to order lines, it takes two years before they're delivered and installed. And in this case, we got lines that we really need, as you heard Said many times saying about our intention to increase the CMO to increase the CMO means you need more equipment, you need more capacity, you need lines, and that was something that we can utilize immediately and that's exactly what we did. So, the lines are already had been transferred and our facility been installed now in the phase of qualifying. And I think we already have a -- we have a purpose for them. So, I think from that point of view, I think it really served a purpose. We did also pick up some ANDAs. And as you all know, it takes some time for us to transfer them to the facility and turn them into additional revenue. But that's the intention. So, that's -- Said, do you want to add anything?

**Said Darwazah** – *Hikma Pharmaceuticals – Executive Chairman and Chief Executive Officer*

Yes, basically the equipment that we got, a lot of it will be going to Columbus. As Riad said, the engineering team has already installed them, which is amazing, because which takes a much longer time, they need to be qualified, but shouldn't be very difficult. And it will be very helpful. It will add significant CMO business for the Columbus facility, in addition to the 70 ANDAs, of course, as Riad said, it takes time, we've identified the first batch that we are working on to move both the injectables and the orders. And it will give us some new technologies that we didn't have like --

**Riad Mishlawi** – *Hikma Pharmaceuticals – President of Injectables*

It's all the ANDAs that we get we are prioritizing them --

**Said Darwazah** – *Hikma Pharmaceuticals – Executive Chairman and Chief Executive Officer*

-- the equipment, there is liquid equipment, there is illiquid single doors, there is a small -- some ointment equipment. So, it's a very nice pickup. It's a very nice pickup and obviously by them going out to the market, they created shortages that we benefited from.

Alistair Campbell:

Sorry, Alistair Campbell from RBC if I could just in. Can really touch on generics Xyrem, obviously an increase in guidance in generics. And it sounds like some of that's from increased confidence about generics IRM's sustainability going into H2. But then you also got a better underlying generics business anyway. So, I know it's early for 2024 guidance, but what should we be thinking about as we roll forward? Have you got a bigger headwind because RM's doing so well? Or actually is the underlying business strengthening enough that we should be quite comfortable about progression in the 2024?

**Khalid Nabilsi** – *Hikma Pharmaceuticals – Chief Financial Officer*

Yeah. Generic Xyrem has been, like we said from the beginning, that generic Xyrem is included in our

guidance for this year. And it's an opportunity and it's more weighted towards the first half and affects the profitability and the second half royalties to jazz is going to increase. So, the profitability will go down. But we always said that this business is a business that will deliver between 100 to 120 million in profitability, we are confident of our ability to maintain this going forward, we could see some opportunities. Now this year, we have seen some contract wins, we've seen some favorable pricing environment. So, across whole all of our base business, some products, we've seen competition, some products, we've seen that we are able to do better than expected. And this is why -- this is one of the reasons we are upgrading our guidance. Now we will assume that you assume that in the second half will continue to sell generic Xyrem. But again, I'm just reiterating that it's going to be at a much lower, I would say profitability.

Emily Field:

Hi, I'm Emily Field from Barclays. Riad, you mentioned, you know, relative to Rocky Mount that the FDA is not panicking, and customers are not panicking. But you know, before the tornado, it seemed like there was a little bit of panic, at least in the medical press about the shortages of platinum chemotherapies. And I think that the FDA was allowing for some importation from China. So, maybe just kind of -- Rocky Mount will do what it's going to do and come back online when it's online, but maybe just kind of a higher-level question on the status of injectable judge -- drug shortages overall. Because I think that, you know, over the years, we've talked about that as just being something that hasn't gone away. And in your mind, is that getting worse? Is it getting better? And then my second question is just on branded. It sounded like some of the oncology tender wins were in -- realized in the first half and perhaps there's been a had been expected in the second half. So, just a question on sort of cadence of the branded segment from a top line basis from first half to second half.

**Riad Mishlawi – Hikma Pharmaceuticals – President of Injectables**

I'll take the first part of the question in terms of shortages. Nowadays I think it's just part of the business. It's just not going away. It's just a matter of how we need to manage them. And I think the government is looking at a lot of different solutions. I don't think they really hit the right, you know, solution yet. I don't think they found it. I think they're trying. I think there was a bill three weeks ago to -- for, I think, to fund \$500 million for manufacturers to stock more APIs and more products for critical products just to alleviate some of those shortages, but it is part of the business. And there are reasons for it. The main reason, especially when it comes to injectables, is that capacity cost money and you're not going to leave capacity this idle. So, if you get a product that goes below a threshold below your cost, you're just going to drop it and move on. So -- and I think this is the problem. The problem is, with the competition coming in, and the pressure on the costs all the time, pressure on the prices all the time, it gets to a point where manufacturers need to choose. And unfortunately, shortages happen, this is one for it. And it's particularly when it comes to cytotoxins and the cancer drugs, it happens to a point where one company had picked up most of that part of products, you know that one company got in trouble. And they just got a warning letter, I guess, yesterday. And basically, they had an input alert by the FDA. And of course, they could not make any more products, they had to fix their problems. And that created shortages, not only in the U.S., but worldwide, I think Europe is also struggling with this. But this is the problem. The problem is systematically of how this business goes, the reliance on one supplier for a critical product like this, I don't think it's something that I think the government had learned from it, I'm not sure what they will do. But definitely, it's a lesson learned. We are in our plant in Germany, which is dedicated for these products we can't make enough. We try to increase. But as you also know, it is very difficult. This is not -- this is a very slow business, rigid business, regulated business, you can't just decide to pick up and make products, it takes time for you to get the raw materials, it takes time for you to increase. So, as much as we are making, we are benefiting from that, but still there are shortages in the market, unfortunately.

**Said Darwazah – Hikma Pharmaceuticals – Executive Chairman and Chief Executive Officer**

And it will continue to be. For the Branded, as we said the first half in spite of very, very strong headwinds in major currency devaluations in Egypt and then maybe Riad will give more detailed numbers. And Sudan, obviously a big, big mess in Sudan. We were able to have an extremely good first half, as you saw from the results, a lot of that attributed to delivery of oncology tenders, but also markets like Algeria, Egypt are doing extremely -- actually Egypt, in units is doing astronomically well, but in dollars is not. Algeria and Saudi

Arabia are doing very, very well. What we were saying we're reiterating guidance for the full year, which means that we expect the second half to see more headwinds. The actual currency, and I mean, we said we're not going to --

**Khalid Nabils** – *Hikma Pharmaceuticals – Chief Financial Officer*

In a way, just adding to what Said just mentioned, if you look into the Branded business delivered the growth of 11 percent, in the first half 41 percent in profitability. But across all of our markets, we had significantly good growth across all of our markets, including Egypt and local currency. Now, the way to look into this, that you have some pull forward of some of the tenders, let's assume 50 million, take it from the second half to the first half. If you look into the profitability of this, it will be almost evenly distributed. So, it's nothing I would say that would continue affecting the second half. Second, we were able, we maintained our guidance, despite significant reduction in sales coming from Egypt, probably impact of 50 million and Sudan, another 50 million, so total 100 million, and we are able to maintain our guidance for the branded business. This is - there will be some as well investments in the second half in R&D, there will be some investments in sales and marketing. And maybe if you look into H1, H2, what the implied guidance for H2, you will see like a drop in margin. But no, it's shifting some of the sales, investing more in R&D, investing more in sales and marketing. But all of our markets are doing very well. At the same time, the launch of the products, the focus on chronic diseases, that it's the growth in chronic diseases is delivering good results.

Edward Thomason:

And can I? Sorry, Edward Thomason from Liberum. Can I just have a follow up on what's going on in Egypt? So, if you look through the statements, you obviously record some bad debt in Sudan, that's understandable with the conflicts you've yet to actually account for any in Egypt. And there's also been an increase in net trade receivables. Are you having any problem extracting cash from customers? Are they paying on time? Have you noticed Egypt's that's --

**Khalid Nabils** – *Hikma Pharmaceuticals – Chief Financial Officer*

If you look historically, if you look -- in Egypt, it's not the issue of collecting on receivable. The issue more is finding dollars to pay for your raw materials. So, this is the issue. It's not our use to our third party rather than collection, collection is perfect in Egypt, even better than any other market. It's the availability of dollar. Now we managed to find ways to working with third party to get like banks from outside Egypt to get us dollars. So, we are paying our dues and things are getting into better in terms of paying to our suppliers. It was an issue at the beginning of the year, and now it has been resolved. So, we continue to supply and at the same time, we are increasing our export from Egypt to get foreign currency used to pay for our raw material. In MENA in general, we don't have an issue with receivables in terms of bad debt, maybe 1-2 million discrepancies in tenders, but all in all, we never had a major issues, but the issue is the length of the payment term. This is where we have in tender, so we have to invest more in working capital. So, some governments they pay after two years, three years. So, we take this in our calculation even in when we submit for a tender that it's going to be paid in, let's say two to three years. So, I would say we have no issues related to I would say receivables, some of it is very minor, I would say, bits and pieces here and there.

Edward Thomason:

And then just two other questions just more strategic. Firstly, are you still infused by the opportunity for biosimilars in the U.S.? There's clearly a lot of competition. That's accelerating. How would you look to grow this going forward and potentially adding capacity, manufacturing capacity yourself? Is that still on the table? And then secondly, just is there any update on the launch of sterile compounding and how's that going?

**Riad Mishlawi** – *Hikma Pharmaceuticals – President of Injectables*

Okay, so three pieces, one related to the biosimilars and then one related to the compounding and the one related to the capacity is that what it is?

Edward Thomason:

Yeah, biosimilars, the sterile compounding, and just generally how you'd like to expand the capacity for going

forward?

**Riad Mishlawi** – *Hikma Pharmaceuticals – President of Injectables*

Well, for the biosimilar, as -- you know, as we were just discussing it actually the other day, how the polarity between companies, you know, some companies are putting everything into the biosimilars, and other companies are just exiting the biosimilar. So, it really depends on some of the people that had entered early on some people that had to enter in the midway. I think from our point of view, we really haven't changed, we have good partners. I don't think we want to do it on our own. I don't think we want to go into the development of biosimilars, but we also we don't want to lose the opportunity to be part of the biosimilars. So, we are in investing and partnering with partners, we have two today, we are understanding more about you know, this year, it would be very interesting to see what's going to happen to Humira and how the bio -- the biosimilars is going to come out when you have seven, eight, you know, competitors in the market, although it's a huge product, but still. So, there's a lot of learning that is happening, a lot of explanation that's happening, why people are exiting and why people are doubling on it. I think our -- so far, our strategy is the same, we want to partner with good partners, and we want to, you know, benefit from our distribution strength. And sometimes from our manufacturing, we could be manufacturing the finished dosage in our facilities. At the same time, you know, we will be also, you know, looking to expand what we have today we have two products, and we would like to see if we can expand, you know, a few more. And we're looking for partners to do so.

In terms of the compounding, I just need to remind you that the compounding is a greenfield project, it is not something that we had bought. Greenfield means that you have to build the facility to make sure that they are all equipped with the right equipment. Until today, I think next month we will start installing a water system. So, we're still in the process of furnishing this facility in the -- with the right equipment. And then the most an out of hand type of out of control biggest is getting the regulatory part took us a long time to get the FDA to come and visit us and they did visit us and came up very, very well. Which is great considering what's happening with the market today. You know, the last victim is now CAPS, CAPS is struggling with their compounding I think they temporarily closed their facility in Pennsylvania, you know what happened with Nephron. So, all indications show that we are on the right track, we want to build this, this is a very interesting business, very complementary to what we have, but it is different. It is something that we have to grow. It is something that we have to get clients to although we service all the hospitals, you have to remember that the hospitals in the U.S. had been burned several times with compounding. You know, I mean, the last one was Nephron not too long ago. So, they're very hesitant in going just because you're Hikma you have a good reputation and getting finished goods. They're just going to change their compounding strategy and suppliers, too. It takes a while to get them to come in. They want to come in, most of them they want to come in and see, especially the IDNs, they want to come in and inspect you themselves, even if you had an FDA inspection and pharmacy inspection and all that. So, it does take time to grow the clientele, it does take time to grow the system. And -- but the confidence is still the same. We think that this business is a good business very complementary. We know it very well, we know how to do it very well, we just need to also get the confidence of the customers there. So, I think the interest is not any less than it used to be.

**Said Darwazah** – *Hikma Pharmaceuticals – Executive Chairman and Chief Executive Officer*

Yeah, the compounding will do very well. We're very, very comfortable with that. And, you know, it's just a question of time. Unfortunately, two of the big states, California and -- which --

**Riad Mishlawi** – *Hikma Pharmaceuticals – President of Injectables*

New York.

**Said Darwazah** – *Hikma Pharmaceuticals – Executive Chairman and Chief Executive Officer*

-- New York still have not gotten there. They're the biggest. So, to be successful, you need to have all the states giving in, so we'll come through that. Biosimilars, it's, you know, Riad said, it's three, the market is split, there's consolidating, many are getting out selling, and others are buying. So, we've actually been following very, very closely. We've been working with partners like McKinsey and others to, you know, gather

as much intel about companies because about that, because there will be opportunities, there will be companies up for sale, there will be portfolios up for sale. So, there might be opportunities in the future. As I said, we're really monitoring very, very closely, trying to gather as much information, seeing what's going to happen and so on. And the mean, obviously we're doing very well with the biosimilars. As we said before, the nice thing about what we've done is we haven't really sort of taken market share from the originator, we've expanded the market by doing better promotion, expanding promotion, and having much bigger access, patients have a lot more access now to biosimilars, and they're being used much more actively. So, it's doing very, very well, very profitably, and we have a great partner there.

Pete Verdult:

Can I ask? [unintelligible] forgive the question, but it's not often we have you here all round together. So, I mean, there's a clear strategy for a group and divisional level, and you're executing on it. But at the same time, Riad, you're taking the helm in a matter of a month, and every CEO wants to put his or her mark on the next chapter. So, just any early thoughts as to, you know, how you're thinking, where your focus is going to be, what you might do, I'm not saying anything needs to be done differently, but you wonder how you're going to make your mark and where you think your areas of focus will be? Thank you.

**Riad Mishlawi** – *Hikma Pharmaceuticals – President of Injectables*

Well, I mean, the good thing about it is I've been at the company for quite some time and the strategy of the company, I was part of the strategy of the company for all this time. So --

**Said Darwazah** – *Hikma Pharmaceuticals – Executive Chairman and Chief Executive Officer*

Ask him this when I'm not around.

[laughter]

Embarrassing the guy.

**Riad Mishlawi** – *Hikma Pharmaceuticals – President of Injectables*

No, seriously, I do think that we have a great strategy, I think we can do better maybe on execution, I think there's always room to improve. There's always room to get to the nitty gritty things. And I think this is what we want to concentrate on maybe more tactically, how we can improve to implement the strategy faster. But as far as the direction and what the strategy is, I'm not sure if there's a big difference there.

Victoria Lambert:

Sorry, it's Victoria Lambert, again, from Berenberg. On a similar note, last year, you guys were talking about maybe selling off the generics part of the business. Now, you know, things are improving there. So, what is your like, feeling or view on what you're going to do with the generics business? Is it -- yeah?

**Said Darwazah** – *Hikma Pharmaceuticals – Executive Chairman and Chief Executive Officer*

Yeah, as you know, as we explained many times before, we feel that we have some really strong advantages over other manufacturers, for instance, we feel the CMO is going to be a big part of the business. We already -- we're already over 100 or something.

**Khalid Nabils** – *Hikma Pharmaceuticals – Chief Financial Officer*

15 percent, yeah, almost.

**Said Darwazah** – *Hikma Pharmaceuticals – Executive Chairman and Chief Executive Officer*

Yeah, and we are already -- I mean, it's already a big part of the business. We are securing new contracts; we are being visited by a lot of potential clients. But it's you know, when you want to move a product from one competitor to another, as you know, it's -- it takes a year and a half to do that. So, there are contracts in place, and we are trying to implement them by getting them done. It is a business that will grow, and it will

create less cyclical, it will help balance. The other thing we said that we're working very hard to grow the specialty business, which is also will create less cyclical, the generics themselves. We always have to remind ourselves that 80 percent or more of what's prescribed and used in the U.S. is generic so they're not going to go away. It's just not going to disappear. It's who's going to be last standing and who's not, you've seen a lot of the American competition exit the market, they've taken decisions to exit the generic market, a lot of the Indian competition decided to concentrate on India, they -- they're finding that India's more profitable for them. So, I think that we have done a great job of navigating even at the most difficulty, which was last year, we still ended up doing, you know, mid-teen EBIT, a good thing among the best margins in the industry. And we've shown that this year will be able to come back. So, it is -- so far it is a business that will stay strategically part of the group.

**Riad Mishlawi** – *Hikma Pharmaceuticals – President of Injectables*

I think to add to that, this is a business that serves the U.S. And it is made in the U.S. it has had an incredible quality record all these years. It makes critical products. And as you all read the news, and I think the local manufacturing in the U.S. is something that the U.S. wants to grow and wants to focus on and wants to help. So, I think we are sitting in a very good spot to take also advantage of that.

Thibault Bouterin:

Thank you very much. Thibault Bouterin Morgan Stanley, just in relation to what you just said on the U.S. generics. Just trying to understand, you know, you're thinking about how pricing is going to evolve in the midterm, because so far, we've seen with the cycles of the pricing, some pricing pressure, and then you know, improvements. So, just wondering if there's something structural this time as we see companies go bankrupt, and you just mentioned some changes in the industry. Or if you think ultimately still, we're seeing a good phase of the price cycle today and ultimately down the road, maybe two, three years. You think this big pricing pressure could come back?

And my second question is on the U.S. injectables business, something you know, we've been talking about for some time, do you think we're getting through a phase where we are going to see less losses of exclusivities from injectable products and so maybe a bit less opportunities for your obviously something you're not seeing on the midterm.

**Said Darwazah** – *Hikma Pharmaceuticals – Executive Chairman and Chief Executive Officer*

So, go quickly, the generics and then Riad can pick up injectables. As Riad said, it's funny, the government and Congress, the government was trying to address these, the FDA, everybody's trying to address these shortages and trying to understand why and again, as Riad said, they're taking decisions. Now fortunately, they still haven't. A lot of these are due to you know, pricing pressures, the FDA, when you know, we did the JUFAs [spelled phonetically] is instead of approving new products, they approved more and more of the same products and then suddenly at 10 competitors and the price just get. But what's happened is many have exited said, you know, this is we're not going to do that. And I think that the buyers themselves have also realized that by squeezing and creating being a big part of the creation of the shortages, the buyers themselves, they know that they're losing out also. So, there we see more tendency to work more long term, to try to make some longer-term contracts and so on. So, I think we will continue to see some prices go down, some prices go up. But overall, like the real cuts that we saw last year, I think -- I don't think we'll see again, so prices will stabilize. And you just have to realize if I can do this, at this price comfortably and successfully, we can go on, I think as we increase our output as we do more manufacturing, whether you know, contract manufacturing or for our own, but as we increase our portfolio and so on, we will bring our prices down and become more competitive. So, we've really learned how to thrive in a really cutthroat market, which we learn to thrive in it. And I think we do it very, very well. In addition, I think there will be benefits to it being made in America, we're probably one of the very, very few that are still doing it in America doing it profitably because the others went bankrupt. We're still doing profits and we're still doing it well. And we've talked a lot about our track record. When it comes to the FDA, the FDA uses our facilities as training grounds for their own inspectors. So, we've high quality, excellent track record, still doing it very profitably. And I think we will be one of you know, the companies that will continue to be as we say last man standing or less company standing will be there.



You want to take over?

**Riad Mishlawi** – *Hikma Pharmaceuticals – President of Injectables*

In terms of the injectables you know, this is not recent, exclusivity has been definitely reduced to very minimal now it's not a big benefit anymore as it used to be. You know, I remember at the time when 20 years ago when you know the bid event venue [spelled phonetically] and the likes, they would have 10, 15 products on exclusivity basis and they make a lot of money out of that, this time has gone for many reasons. The biggest reason is the branded company are defending those very, very well. They -- you know, by the time you get the exclusivity is pretty much the channels are all filled, there's sometimes also there's a generic also in the market.

I think we never depend on this route. Although we have few. This year, we have one. It's never really a big boost for us. I think what we depend on is the number of launches that we have, and the quality of the products that we are developing. This year we already have 11-12 approvals so far. And they are quality products, although they always start slow. As Siad is mentioning, those are a little bit different than the conventional meat two [spelled phonetically] type of product. There are prefilled syringes, a lot of them are bags, a lot of them are 505(b)(2), so it takes some time for that to pick up. But this is what we're focusing on. We're focusing on quality development, something that we call NTEs a little bit more new to the market. And I think this is what we feel that our growth is going to be in developing those specialty products rather than just waiting for an exclusivity that we can get for six months and the product goes away.

Christian Glennie:

Hi, Christian Glennie from Stifel. Following up on generic Xyrem. Can you give us a bit more of insight or flavor in terms of market shares that you had in the first half and how do you see that evolving in the second half? You seem to be saying that you've seen one entrance -- other generic entrance so far, but I think we previously mentioned about four were lined up, but any particular reasons why, you know, that there's some technical reasons why they -- why there's other entrance might not come in the second half.

**Khalid Nabils** – *Hikma Pharmaceuticals – Chief Financial Officer*

In terms of generic Xyrem, I think the consensus had like 100 million in sales for generic Xyrem for the full year, probably 70 million coming in the first half. I would say probably we are guiding towards higher than this. We are not giving any specific, usually specific related guidance on certain products. But all what I can say that it's the first six month were in line with what we have guided, or the consensus has, with a high margin, the second half is going to be probably in terms of sales, similar to or higher than what we -- what the market of consensus has, with a royalty, I would say. Anything else in terms of --

Christian Glennie:

In terms of the other potential launches the competition.

**Susan Ringdal** – *Hikma Pharmaceuticals – EVP, Strategic Planning and Global Affairs*

We are the only AG that -- we were the only AG that didn't have any market share constraints. So, the other potential AGs to come in had some market share constraints, only one of them so far has launched. And so, with -- yeah, they have the opportunity to -- only to take limited volumes. So, we've been very happy with the market share that we've taken, it took us a couple of months to ramp that up. But now we're very happy with, you know, with how the sales are going. We haven't disclosed a lot in terms of, you know, what our market share is or you know, we're not going to disclose the revenue by product. But we are comfortable that we can continue to sell and, you know, at around the same levels that we are at the moment. So, we feel that we should have a good contribution from this product in the second half, albeit at a lower margin due to the higher royalties.

Christian Glennie:

Okay, thank you. And then in terms of the talk about exclusivity periods are on the generic side, is there anything in the pipeline that could be a significant product in the say next couple of years with an exclusivity

period?

**Khalid Nabils** – *Hikma Pharmaceuticals – Chief Financial Officer*

Say that our team has been actively looking into how to bring specialty or complex products to the market. So, there are certain plans but nothing I would say we can now explicitly talk about but yes, there are some that we are working on, and we know that it's -- there are few products that will come in the future.

**Susan Ringdal** – *Hikma Pharmaceuticals – EVP, Strategic Planning and Global Affairs*

We also took the opportunity this year having such a good year, it's such a great opportunity with generic Xyrem We wanted to take the opportunity to leverage some of the benefits of that to invest back into the pipeline. And that's why the margins in the second half of the year will be lower, because we're going to meaningfully increase our investment in R&D in the second half of the year. And that's, you know, it's a great opportunity having the results that we're achieving this year to be able to enhance the pipeline.

**Conference Call Operator**

Ladies and gentlemen, if you join us via phone line, and would like to ask a question, please press star-one on your telephone keypad. That's star-one on your telephone keypad. Our first question comes from James Vane-Tempest from Jefferies. James, please go ahead.

**James Vane-Tempest** – *Jefferies*

Hi, good morning. Thanks for taking my questions. Just a couple on the branded please. So, Sudan has taken an impact this business despite small scale into the have an impact every period of so given the written down community and as it's going to be no feature impact? The second question is just on the gross profits in branded, I mean, margin of north 53 percent. I think the last time it was at this level is 2009 or so. I know you mentioned some high margin tenders those that kind of really one off? Or should we think about those potential new era of profitability in this business? And then related to that, obviously done very well in constant currency in that business. So, what would it be given to exceed the upper end of your guidance and cost of currency in the branded business? Thank you.

**Khalid Nabils** – *Hikma Pharmaceuticals – Chief Financial Officer*

What's the first question I did not --

**Susan Ringdal** – *Hikma Pharmaceuticals – EVP, Strategic Planning and Global Affairs*

Sudan. Should we assume no future impact from Sudan?

**Khalid Nabils** – *Hikma Pharmaceuticals – Chief Financial Officer*

Yes, Sudan, I would say Thank you, James, Sudan. It had more sales, especially in the second half of last year. And now we don't expect to have sales and this year, we assume no sales for Sudan. Now, is it a market that we are not going to continue to sell? We don't know at the moment you usually in certain situations in the past, you would continue to sell medicine, but maybe the business model would shift more towards selling either directly to governments or selling directly to certain distributors. I don't think that will be operational, even if we the worst stops today, it's going to take on one or two years to come back to operation. So, this is why we are saying we are holding our decision to operate till we have a better views on what would be next. It could be a need for our medicine, of course, but it's not assumed in our guidance.

In terms of the gross margin, as I mentioned earlier, we had -- you have to assume that you take out approximately 50 million from the first half, put them in the second half margin will be almost similar gross margin. So, there's a I would say benefit as a result of the scale or -- that we have seen in the first half. And we've guided to say that our I would say our sales profitable could be in line with last year in on the reported basis because of the impact of Sudan, Egypt. So, we've done, and we will -- we are doing very well in concert currency, and I would just want to highlight and repeat. It's like the impact of Egypt alone is around 50 million in sales and the impact of Sudan is over 50 million so total we are able to compensate over 100 million and

we are maintaining our guidance.

So, anything that I did not?

**Susan Ringdal** – *Hikma Pharmaceuticals – EVP, Strategic Planning and Global Affairs*  
I didn't understand the [inaudible]

**Khalid Nabils** – *Hikma Pharmaceuticals – Chief Financial Officer*  
And anything else James?

**James Vane-Tempest** – *Jeffries*  
I didn't quite catch the answer on profitability.

**Riad Mishlawi** – *Hikma Pharmaceuticals – President of Injectables*  
Can you repeat the question on profitability? Because it was not clear?

**James Vane-Tempest** – *Jeffries*  
Yeah, sure. The gross margins were north of 53 percent I think so just to help us kind of understand the push and take factors there. And is this an era of profitability for that segment? Sorry if you answered it and I missed it.

**Khalid Nabils** – *Hikma Pharmaceuticals – Chief Financial Officer*  
I will say there's no change to the historical profitability levels that we've seen. It's just phasing out some of the sales from one half to the other half.

**James Vane-Tempest** – *Jeffries*  
Okay, thank you.

**Conference Call Operator**  
Our next question comes from Harry Sephton from Credit Suisse. Harry, your line is now open. Please proceed.

**Harry Sephton** – *Credit Suisse*  
Brilliant. Thanks very much for taking my questions. My first one on the U.S. injectable first half performance. So, you talked about the increasing competition. But if you look at the organic growth within the first half, and you take out the cost to form annualized benefit, it looks like you had an organic decline there. Can you maybe just touch on where you're seeing the competition coming from? I think we're anticipating there probably be a few tailwinds from some of the invitation bands we had from Indian generic suppliers last year.

My second question is on the strong meaner injectable performance. So, last year, we saw it as a very strong waiting to the second half of the year, with the performance being so strong in the first half of this year, is there a similar dynamic to what we've seen in branded where there's a tightening of tender contribution. And so, actually, this year, you might expect a more even weighting from what the first half to the second half for 2023?

And then just my third question is an update on the contribution from your specialty portfolio. So, Kloxxado and Ryaltris. I haven't seen any further detail provided in the results. So, it'd be interesting to get an update on the performance of these products. Thank you.

**Riad Mishlawi – Hikma Pharmaceuticals – President of Injectables**

If I start with the injectables, I think, yes, in the U.S. sales, yes, U.S. injectables, you can see that year on year maybe it's a little bit softer, although there is a growth of about 5 percent. But we've had -- yes, we have some competition. Pfizer was one of them that was competing with us on the controlled substances. You know, our price differences is dramatic there. So, you know, the competition is it's hard to manage in a way. But you know, there are other products, also, the product mix is very important here. And we've seen it but also, I think, from the volume point of view, which is also important, we've haven't seen that we've seen the pickup in demand, we actually are trying to build facilities -- tried to build capacity as much as possible to respond to that demand. There's also demand in contract manufacturing, which we can do more of because of capacity will not be able to so now that we have increased the capacity significantly in the liquid, we hope that we can pick up some of that one.

But you know, the -- I don't think this dramatic; I think it's just depending on the periods is depending on the product mix. I think the profitability in a way considering that the injectables is financing the compounding business without getting any benefit from it yet, considering there is some -- this benefit. Sudan is one. This benefit of the euro, which was also significantly there. So, we have we had a lot of also headwinds that we had to manage and coming up with a mid-30s results and growth of 5 percent I think it's --

**Said Darwazah – Hikma Pharmaceuticals – Executive Chairman and Chief Executive Officer**

You think competition from India I think what it was part of, or is it more Pfizer?

**Riad Mishlawi – Hikma Pharmaceuticals – President of Injectables**

It's hard to say when you say from India is a product made in India or is this an Indian company. So, it's very mixed now. So, they come from all over. I think India you can see some competition and you can also see some opportunities, you know, some has given us some opportunity because of the problems that they are in, on the other hand, also we have Chinese now that they have finished goods that are coming in companies like Shiro, for example. They've been coming into the U.S. now and some of them have taken over some of the products that we had. So, competition comes and goes. I think our size is big, our portfolio is growing, we are at 150 now and more. We introduced already nine this year and we're planning to introduce more so it's I don't think it's any specific where it's coming from, its coming from all angles and we just have to be ready.

**Khalid Nabilsa – Hikma Pharmaceuticals – Chief Financial Officer**

I just want to reiterate what Riad just mentioned that our guidance assumes that there will be some softening in the first half for some of the U.S. business, so we knew, and this is why we've guided towards 36, 37 percent in margin. We know that there are certain m factors that will impact the margin as Riad mentioned, we are paying for investing in Dayton which is costing some money which affects the margin by almost one percentage point. At the same time Sudan has effect sales close to 20 million which no longer there. So, it has some profitability for the injectable business.

**Riad Mishlawi – Hikma Pharmaceuticals – President of Injectables**

The euro.

**Khalid Nabilsa – Hikma Pharmaceuticals – Chief Financial Officer**

The Euro for the full year will have an impact on currency, it's -- but we've never mentioned when we had gains. So, last year, we had gains, this year we are having an impact on margin, but it's -- it affects as well, one percentage point. So, the fundamentals for this business are still intact, it's one of the highest margins in the industry compared to our peers. And we always said that it's in the mid-30s. And if we have some opportunities, some capitalizing on certain shortages, it will go up to the -- higher than the 35 percent. So, nothing has changed. Our expectation is everything is delivering in line with our expectations so far for the injectable business. At the same time, the more growth we have in Europe, and in MENA, which has a lower margin than the U.S., it affects the margin in total for the injectable business. So, it dilutes a little bit the margin. What is the other question sorry of -- is there any?

**Harry Sephton – Credit Suisse**

Okay, yeah. So, the second question was on the MENA injectable performance. So, last year, you saw it's very much waiting for the second part of this year, sorry, the second half of last year, but this year, are you expecting more even performance given the strong performance in the first half?

**Khalid Nabilsa – Hikma Pharmaceuticals – Chief Financial Officer**

Yeah, yeah, I think we will see some phasing as well. Similar to the branded business, we had a very solid growth in the first half, but MENA continues to growth. And it's in line with the guidance that we give overall for the injectable business.

**Harry Sephton – Credit Suisse**

That's great. And I'm sorry, the third question was on the specialty portfolio, and whether you have an update on the rollout of Kloxxado and the launch of Ryaltris, and what that contributed to the performance in the generics business in the first half.

**Khalid Nabilsa – Hikma Pharmaceuticals – Chief Financial Officer**

Yeah. So, both products are delivering in line they are growing nicely, I would say Ryaltris, we are growing, we are seeing good growth in prescription. But we have, like, to convert this into dispensing is something that we are working on. There's increased insurance coverage on it. So, it's performing, I would say in line with our expectation, we're seeing some good growth is takes -- it's both they are I would say now marketed as brand products. So, it takes a gradual increase in sales. Kloxxado is delivering and we are seeing nicely and we're seeing the month-on-month growth. And it's delivering according to our expectation.

**Harry Sephton – Credit Suisse**

Brilliant, thank you.

**Conference Call Operator**

We currently have no further questions. I would like to hand over back to the room.

Emily Field:

Okay, maybe your kind of just following up from some of the comments, Susan, that you made on generic Xyrem, you talked about kind of taking a couple of months to scale up volume. And at the first quarter trading update, the commentary was that everything with generic Xyrem was going according to expectations, obviously, you know, quarter way ahead of the guide, guidance raised for generics. So, what's the bigger driver the continued revenue expectations for generic Xyrem or more of the base business performing better? Both?

**Susan Ringdal – Hikma Pharmaceuticals – EVP, Strategic Planning and Global Affairs**

Yeah, I think definitely the better than expected -- the better-than-expected growth that we saw in the first half we would attribute to the base business and not to generic Xyrem, generic Xyrem came in pretty much bang in line with what we expected. But we were cautious as to the outlook for generic Xyrem for the second half of the year, because of the potential for other AGs to come onto the market. But we now feel a bit more comfortable with the potential to continue to deliver some good -- to achieve some good revenues from that product in the second half. So, I would say primarily the upgrade at this stage is because we expect to have a better contribution from generic Xyrem in the second half of the year. And then there's a little bit from the continued benefit from the base business.

Pete Verdult:

So, are we going to see you again Said, now? Or not? Do you get to --

**Said Darwazah** – *Hikma Pharmaceuticals – Executive Chairman and Chief Executive Officer*  
Of course --

[laughter]

Thank you, everybody.

Multiple Speakers:  
Thank you.

[end of transcript]