Hikma 2022 interim results transcript

Susan Ringdal:
Good morning, everyone. Thank you for joining our call today. Hopefully you'll have seen the prerecorded presentation that's posted up on our website. So, the format for today will just be Q&A. In the room with us today we have our executive chairman and CEO Said Darwazah, CFO Khalid Nabilsi, our Vice Chairman Mazen Darwazah, the President of Generics, Brian Hoffman and the President of Injectables, Riad Mishlawi. Said is going to kick off just saying a few words, and then we're going to open the floor for questions.

Said Darwazah:
Thank you. Thank you, Susan. Good morning, everybody. Let's get the bad news out first, so we can concentrate on the good news. Okay, this was a rather tough environmental to work with you know, supply chain disruptions, inflation, price erosion, and so on. It was tough, that, in spite of that, we still managed to deliver sales equal to last year. Of course, the generics did not do as well as we expected. We explained this before, that some products that we're expecting to get approval for this year was delayed until next year. And then with a price erosion -- with a significant price erosion in the market, the business underperformed.

But again, with that in mind, we still delivered sales equal to last year, profits down a little bit. And that's due to the high investment for this company in -- everybody will explain at the Group what kind of investments that we've been doing. We've bought companies, we started the compounding business, we are increasing R&D expenditure; we're increasing sales and marketing expenditure. So, a lot of, you know, in the MENA we're building new plants for the injectables. So, we're in a big investment mode situation right now.

The good news is that the divisions that are responsible for 80 percent of the profits, the Injectables, Branded, are doing very, very well, and will continue to do very well moving forward. We have invested so much in these two divisions, in products, in manufacturing, and new businesses that we're very comfortable that these businesses in the medium term will continue to do -- will do better than what they have been doing the last few years. And we think that over the next three years, we will have good growth CAGR of maybe around 9 percent annually over the next three years, which is better than what we've been doing before.

I also like to highlight that this is a very strong company, we have EBIT margins of 24 percent. We have net margins of 17 percent, which is extremely high in this industry, we have strong cash flow, we have a very good balance sheet. So, the company is in a very, very good situation. And we are very, very optimistic about the future, we are ready to face the challenges that are out there. We know that the Generics will be doing much better next year. And as I said before, the Injectable and the MENA business, the Brand businesses, are doing extremely well.

So, that's what I wanted to highlight: the Generics does not achieve what we plan to achieve, as the reasons I explained, however, 80 percent of the business is performing on a very high yield and doing extremely well, with a lot of investments that everybody will be talking about explaining what they've been doing. And we are very, very optimistic about the future of the company, about the possibility for growth next year, and second half of this year.

So, with that, we'll open to the Q&A session.

James Gordon:
Thanks very much, James Gordon for JPMorgan. Nice to see you all in person.

Said Darwazah:
Hello, James.

James Gordon:
Hello. I guess a question about like Generics. So, why things haven't gone quite so well recently, and why it gets better next year. I think the incremental thing maybe in the release, we already knew that there was some pricing pressure. And some new launches, we're not going as well as initially hoped. But the new thing is a bit more volume erosion, but for some more competition has come into sort of the business. So, why is that happened recently? And looking into next year, is the outlook effectively the same as this year plus you add on Xyrem and Ryaltris, whereas the other things you think will get better as well?

Brian Hoffman:
So, maybe I'll take that, James. Brian Hoffman, President of the Generics division. So, let me first start off with the environment in the U.S. for generics. So, it's a very competitive environment now. Many of our competitors are struggling. So, when we look at our business, we found ourselves having to defend some of our business and we've also had some difficulty growing some of our growth products. So, when you talk about defending many of our top products, we're the leading market share player so some of our top products, we've seen increased competition. And we've had to make decisions about whether we defend at a lower price or whether we let some of that business go. And that's why we've seen some of the volume erosion is we've made the conscious decision to let that business go because it's below our targets and profitability. And that strategy has been working. That's how we've been able to maintain strong high teens margins despite the volume loss.

Now, if I go to the other side of the coin, in terms of growing our business, we had expectations for growing several products throughout the course of this year and continuing into the second half. But given the level of hyper competitive intensity, we found a lot of the incumbents really defending their market share more so than they probably would in a different environment. So, we've had change, we've had challenges on our existing business and also challenging challenges on some of those growth products, which have resulted in the higher price erosion that we're seeing this year.

James Gordon:
Just one follow up. I think Generic guidance implies down about 20 percent this year. So, could we put 20 percent again next year and add Xyrem and Ryaltris, is it simplistic, or do you actually think some of this, some of these recent pressures might abate next year?

Brian Hoffman:
Yeah. So, looking at next year, you know, we're very confident about returning to growth next year, I think we have some, some very good launches that we're really excited about. So, the first one being an authorized generic Xyrem, that sodium oxybate product, we have a date certain launch of January 1, 2023. And we have a six-month period of exclusivity. So, we're planning for that launch, planning for success there and looking forward to it.

At the same time, we're also growing our specialty branded business, we launched our KLOXXADO naloxone nasal spray, in August of last year, we look forward to continuing to ramp that product the second half of this year and going into next year. We're also looking forward to launching our next branded product in Ryaltris. We're planning on launching that before the end of this year and then setting us up really well for the allergy season, in the first quarter of next year.

Now, in terms of price erosion for next year, I think we can all make our predictions. And it's very difficult to do, convoluting factor being the levels of inflation that we're seeing right now. And will that continue, or will it not? I think there's probably some other people at the table who can better predict better than I can. But if you do look at price erosion, let's say over the last 10 years, we do know that it's cyclical. So, if you go back to 2014 2015, those are some of the heights of the generis industry. And then you saw the declines in 2016, and 2017. And similar price erosion levels to what we're seeing today. We also saw the improvements from 18 to 20. So, certainly, my hope is that we're going to see price erosion improve. The level that it's at right now, in my opinion, isn't really sustainable for the industry. So, manufacturers will respond, companies will work to rationalize their portfolios, we could see consolidation.

Said Darwazah:
It's what we've seen in the past, you know, they try to keep on defending the last few, and then they start giving up and as they rationalize their portfolio, they exist apart or a big part of the market. So, that market stabilizes. And frankly. Sorry, Brian.

Brian Hoffman:
No, that was great. You know, the other -- I think the other factor that, you know, you know, could change the dynamics is also the FDA being much more active with inspections down post COVID, both domestically and internationally. So, it's important for us is that, that we're ready and able to capitalize on opportunities that we see if there's disruption for any of those reasons. We feel very comfortable in our supply chain, our flexible manufacturing. And we'll look for those opportunities.

Said Darwazah:
Brian, the issue of the FDA is very, very important. The FDA has been very much behind its schedule, especially on international inspection. The facility we have in Columbus, is, you know, has not only passed through every inspection with flying colors, the FDA actually uses this facility to train their inspectors there. So, it's a very high quality and we have seen activity now that they are starting to put out 483s and warning letters to many of the companies outside the U.S. Again, that's another reason why prices I think will improve in the next period because we think companies will be getting warning letters and will not be able to ship product.

Emily Field:
I just wanted to follow up on that point of cyclicality just because the prior CEO kind of brought that up a full year results and feels like just with the buying structure in the U.S. having changed in 2015, with or around that time with the emergence of those consortia, there's not a lot of data for us to kind of like, go back and check. So, is it a matter of competitors who are no longer profitable, like, fully come out of the market going bankrupt and kind of then we get to the other side of this? And then I know, you've talked about a normalized margin in the generics business in the past? Is that possible those to think about -- or sorry in Injectables. Is that possible to think about in Generics, kind of like should we think of this as an absolute trough margin and kind of normalized margin is in more that low 20s?

Brian Hoffman:
So, you're absolutely right, you know, customer consolidation, you know, took effect in 2014-2015, we really saw the impact of that in '16-17. So, you've got a relatively, you've got a

relatively small sample size to look at the cyclicality post then, but you do have the improving market conditions in '18-19 and '20, you know, following that really difficult period and '16-17. So, I think that that gives you something to point to, to hope that things improve.

You know, we think we can build on the margins where we're currently at now. And that's due to really our growth strategy. You know, we're looking to focus on more complex generics, and also specialty brands. And these are the areas that have higher barriers, barriers to entry and therefore, more attractive margins. And that's where we're making our investments for the future, so that we can continue to grow and to continue to expand our not only our top line, but our bottom line as well. Riad, I don't know, is there anything you'd like to talk about in terms of price erosion with injectables?

Riad Mishlawi:
I mean, it's the same thing, it's the same industry, it's close to the same model, except for the injectables is maybe a little bit different. It's less players on the market, more barriers to entry. But also, there's a lot of shortages there because of exactly what you're saying, you know, it gets to a point where people started, because of the limited capacity in injectables, it gets to a point where people start exiting nonprofitable products, and that creates gaps. So, some of the products that are really low margins at one point become all of a sudden the high margins because everybody exits the market. So, it is -- this is a cycle that we go through. And we see it in effect, the shortages and all that. So, it is not as much because of all the other elements as a Generic but you know, we see it as well.

Pete Verdult:
Thanks, Pete Verdult, Citi. Can we just wind it back a bit? We got straight to the nitty gritty, but we haven't addressed that sort of elephant the room has been a relatively abrupt CEO change. So, I just want to hear from you, Said. What is the message to the troops to the C suite? Is the strategy exactly the same as when Siggi left it? Or have you made any tweaks in terms of your message to the company and how you want to do business going forward? That's my first question.

Said Darwazah:
When Siggi joined the company from the beginning, Siggi said I'm committed to the period of about four years. So, it wasn't like a big surprise for us. He came in and he wanted to do a lot of changes when he first came and I said Siggi this is not a company in trouble, why don't you take your time, relax, get to know the company, get to know the structure, why we have this structure and get to know the team. So, six months later he came and said you're totally right. There's zero need for change. And it's the same team leaders that were leading the divisions before Siggi joined and are still leading the same teams. We have some more people join. We spent in the company -- we started the system and so on. But it's you know, the core of people, the core EC members are still there. And there hasn't been really a change of strategy during Siggi's time or after he left. We are obviously trying to enter -- you know we have very clear five-year plans for every business. I think it's clearer for the Injectable and the Branded, but the Generics also have a clear plan; they want to strengthen their specialty products and so on and Riad and Mazen will talk more about their business.

So, there isn't really a major change in the company. And I will remind everybody that I've been with this company for 40 years, and I was still the executive chairman when Siggi was running the business, so I was available all the time, available -- I attended all the meetings. I attendee all[the EC meetings, all the strategy meetings. So, we didn't, at least internally, we didn't feel like there was a big change with Siggi leaving [unintelligible]. And as you know we have committed that you will be looking for a new CEO, we are in the process of looking for a new CEO. Could be someone internal, could be someone external. So, the process will go on This year.

Pete Verdult:
My next few questions, one for Mazen and one for Riad. Just on Branded, we know the strategy, you've kept that -- you've kept the investment and you're trying to improve the portfolio, feel that with the H1 results, we're starting to see the benefits of that. But historically, Siggi and then Said as well as Susan have been absolute -- you know, it's not coming anytime soon, but just when, when do you see the fruits of your of your efforts in terms of improving the top line of MENA and, and also the margin? So, that's question number one.

Mazen Darwazah:
[inaudible] We are the only company [inaudible], we are seeing a shift in our product portfolio, now we have 80 percent of our sales in the MENA are coming from new products or long-lifestyle products rather than anti-infective. So, this is the shift that we have been building gradually. Now you remember the MENA is not one market, it's 18 different markets. And we have to have 18 different structures, and it's 18 different managements. And we have different currencies. So, with all of this, with all of the currency fluctuations, with all of the restrictions that governments are imposing on these markets, we are able to grow. We are one of the best run companies in the MENA, you can see clearly from the data, we are well positioned, and we are increasing our margins as we go forward. And this is why we say we will continue growth in the MENA and now it's about paying off the investments that we have done during the last couple of decades.

Pete Verdult:
Riad, did I hear Said say that the outlook for injectables is now 9 percent high single digit? Does that -- is that assuming or including the impact of your compounding efforts, Cutopharm, or would that be in addition? So I'd be interested to know your confidence and the level of stable rates.

Riad Mishlawi:
How we see the injectables, you know, there are lots of organic and inorganic, we're looking at -- we have done [unintelligible] expansion of our portfolio through R&D and through business development that we feel it's going to be coming to fruition very, very soon. We have expanded our manufacturing plants and still continue with expanding this capacity that we think we're going to put it in use. We're looking at expanding geographically, as you can see, we have gone to Canada, we went to France, we're on our way to Spain. And so adjacent businesses also -- you mentioned the compounding, the other things that we're thinking about. So, we put all that into perspective, which we're continuing with the same growth that we've been projecting and we've been doing for the past few years and we think we're going to continue strong but. you know, we're putting all that together we're trying to absorb all the other costs that also Said mentioned and the difficulties that we had with inflation and a lot of things with all of that continuing we're still going to deliver the same results.

Pete Verdult:
In the past you've always had a commitment or you committed to, on one hand recognizing that the margins are very strong right now but not sustainable but saying that low to mid 30s is a sensible target for this business on ongoing basis. Is there any change there in terms of profitability of injectables?

Khalid Nabilsi:
[inaudible] and all the plants that we have continuing growth in our business growth and expanding our market is going to deliver at such and such margin. Of course, if we have an opportunity, it's going to, as we are seeing now, there are certain opportunities, let's say for a contract manufacturing or certain products, then there's an upside to the normalized margin as we are seeing today.

Riad Mishlawi:
A normalized margin of 35 percent is a very -- not normal in the [unintelligible].

[laughter]

Pete Verdult:
You're comfortable with that, we don't want to be in a situation that we are with U.S. generics [unintelligible] slippery slope. [unintelligible] your comfort level with those sorts of --

Riad Mishlawi:
Yeah, we feel very comfortable. I mean, what we had done and continue to do I think we have competence in what we're doing and continue to do.

Said Darwazah:
[inaudible] Really almost every manufacturer -- you know, we bought Germany in the past to learn about oncology, and then we built a huge oncology plant in Portugal and we said we're going to close it. The reality is you have to upgrade the German plant three or four times already. So both plants are [unintelligible]. The same with Italy, we wanted to learn about lyophilization, then we built a huge lyophilization plant in Portugal. We had to upgrade the Italian one. So, whatever they can make there's huge demand. And they are in a very major growth mode, they're building new plants now, they're changing a lot of the equipment, constantly changing equipment to faster, you know, higher speed, faster speed. So, with the injectable is, you know, very comfortable that there is -- the demand will continue. And the last thing that Khalid said, we see big potential for CMO, you're talking about very, very profitable business. The compounding I think Riad understands the most, maybe he can explain a little bit about that. But obviously right now, we're in a big investment mode. And we'll be starting to see the benefits of that in the second half of next year, and then move on from there. But it is a big investment. It is a big facility. I visited last month, extremely impressive, big facility, it's a major investment. It's a major expense right now. So, even with absorbing all these expenses that we're investing, we're still delivering [unintelligible] at 17 at 24 percent margin. And he's delivering 38 percent margins. Want to talk a little bit more about the compounding?

Riad Mishlawi:
Compounding, we have to remember first we did not buy a business, we created that business. So, this is a startup, which means that you have to not only recruit the right people, and train them and get to know the business. If you don't know, it's a new business to us as well, we need to get the regulatory approval. And that takes time, especially with this environment. You know, FDA is very, very busy, they have a big schedule, we really waited a lot for them to come and visit us which they did finally a few weeks ago. We have to get every state approval: 50 states and each one has different requirements. We have to get hospitals signed up in our system because as you know, our core business, we don't sell straight to hospitals, [unintelligible] we do the wholesalers, so we have few now we have to put thousands of those hospitals in the system. All that takes time and all that needs to be built. So, we are in the mode of getting all that prepared. And we feel that, you know, a few months after everything is -

- all that foundation has been laid out, we should be getting very interesting. It's a business where there aren't too many people in the market. It's a growing business. And if you show the right -- the right attributes that everybody is looking at, and compounding I think we'll be in a great advantage.

Pete Verdult:
Thanks. I got a few more, but I think I'll pass off the phone [unintelligible].

Operator:
Moving on to questions from the phone lines. Our first question today comes from Keyur Parekh with Goldman Sachs. Please go ahead.

Keyur Parekh:
Hi, hopefully you can hear me okay. And thank you for taking my questions. Going back to the Generics business. Could I please understand better the bridging -- the building gap or the bridge kind of between where you leave off in 2022 and your growth in 20 -- confidence of growth in 2023? So, if we take the midpoint or the high end of your 2022 guidance, what do you expect to be the impact on your base business in 23? What do you expect to be the contribution from the two new launches? And is there anything else from a Delta perspective between those numbers? That's kind of question number one, and then I'll have follow up question as well please.

Brian Hoffman:
Thank you for the question. So, we're not ready to give guidance yet for 2023. But I think I can speak to those components at a at a higher level. So, if you take where our guidance for this year, we expect to build upon that next year, both top and bottom line. You know, you should put into your model some price erosion for next year. And then on top of that we have some very attractive product launches, which we're looking forward to. I mentioned the authorized generic version of Xyrem. We're launching our specialty branded product, Ryaltris and we're going to continue to grow our KLOXXADO and community health franchise. So, that will help us to grow into 2023 and that those are really the major components, but unfortunately, I can't give you direct contribution numbers.

Keyur Parekh:
So, as a follow up to that, your visibility on this business seems to be incredibly low, as envisaged by the guidance downgrade twice over the last three months. So, I'm just curious why you feel the need to provide growth guidance for '23 sitting here in August, and what drives your confidence that you have that visibility on the business?

Brian Hoffman:
Yeah, so, you know, when we first provided guidance for this year, we thought that there was a strong potential for us launching our generic version of Xyrem this year. But based on the trends of Xyrem, in the market, our market decline trigger was not triggered. So, now we're focused on our date certain launch of January 1, 2023. So, a disappointment, obviously, that we don't have that launch this year, but we get the benefit from it next year. So, it gives us more clarity on planning, which is very helpful, which gives us a lot of confidence. So, rather than looking at reports every month, now we have sort of the defined period of launch, which we think is really helpful from a planning perspective.

The base business, as, as always, your existing business does face competition. So, it's natural to look at next year, and that we will see some price erosion on the base business. You know, my hope is that price erosion improves next year from where it is this year. But our new launches, together with, you know, stabilization of our base business, and also some new contract manufacturing business that we brought on, we'll all help us to grow into next year.

Keyur Parekh:
And then, lastly, [unintelligible], you have spoken about the cyclical element of the pricing dynamic in this market. What is the risk that this is actually structural and not cyclical?

Brian Hoffman:
So, you know, we've been, you know, we've been dealing, you know, I would say the, you know, the structure, the structural environment that you're referring to is primarily due to customer consolidation, where the top three customers control about 90 percent of the volume, we've been now operating in that environment for over seven years. So, we're pretty used to how that works. And I think the entire industry has adapted to that. So, you know, I think it's more of cyclical trends that drive before because the structural changes have already occurred.

Said Darwazah:
I'd like to add, again, I've been in the generics business since 1990, it's almost 31 years now. And we continue to see that, and we -- the two things that we spoke about earlier. One is the regulatory environment, we know that the FDA is way behind on their inspections, especially on the foreign inspections, especially on the restrictions to Indian companies. And they have started moving up now and they will be under pressure to increase the number of inspections. And as they do that, we know we will see warning letters and we know we will see 483s. So, that, you know if you look at a big chunk of the cyclical business in the past, the shortages that happened in both the oral and injectable, were due to regulatory issues. So, we -- don't discount them, they are still there.

The other issue we talked about is when margins become so low, companies first try to defend it because they have raw material, because they're already committed, because they're already manufactures. But once they get rid of the supply, the inventory and so on, they stop manufacturing products that they lose. So, the number of people making the products go down. Now, will it be the same pattern of cyclical movement? We don't know. But there will be cyclical movement, there will be changes in the market. We've seen -- [unintelligible] seeing it happen for such a long time. And I think it will continue to happen, maybe in different ways than before, but it will continue to happen.

Keyur Parekh:
Thank you. I'll get back into queue.

Said Darwazah:
Thank you.

Operator:
Our next question comes from Harry Sephton with Credit Suisse. Please go ahead.

Harry Sephton:
Brilliant. Thanks very much for taking my questions. I have a few on the injectables business. So, in the first half, you saw about two launches in the U.S. but 29 launches in Europe. I think that the -- historically the message has been you'd look to prioritize new capacity really for the U.S., which is your most profitable markets. And that actually Europe was really the lowest priority market. So, I just wanted to understand the dynamics of such strong launch activity in

the European market and then potentially some weakness relative to your historical levels of launches, or could we see a much higher weighting of new launches in the U.S. in the second half of this year?

And then I had a question on your biosimilars strategy as well. As some of your competitors have mentioned the importance of cost advantage in the U.S. biosimilars market. And you signed a couple of in-licensing agreements. I just wanted to get your thoughts on why you think this is the right strategy for Hikma. And do you expect that you can still be competitive on price, despite your limited control on the manufacturing costs on these in-licensing agreements? Thank you.

Riad Mishlawi:
[inaudible] so much. Well, the first thing is that we are committed to still launch in the United States between 10 to 15 products this year, although we only launched two, but we are in the process in the next few months to launch five and then continue to get that number 10 to 15, we are committed to and we will deliver. The delay between the first half and the second half has to do a lot -- and it's not really the priorities. The launches that we do in Europe are different than the ones that we do in the U.S. The U.S. launches our brand-new molecules. In Europe, some of those launches are existing molecules that went from one country and we launch that same molecule in other countries, so you'll see us for example, launching the same product that we have in Germany, but they launched it in France now. So, we consider that a new launch. But in the U.S., it's new molecules. To make a new molecule requires you to do validation batches, three validation batches, your required to do the report, everything has to be done before you launch the product, you have to prepare for it, you have to make sure there's a lot of regulatory steps that you have to go through. And this is why typically, if you look back through maybe the last three, four years, we're always heavier on the second half in launches than the first half. So, I think this is a typical year; it's not atypical and we will be getting what we had submitted to between 10 to 15 in the U.S.

The attention still continues to the U.S.; it is our most profitable country, market. We continue to give it lot of attention, especially when it comes to new products. Your question about the biosimilars, we are in the process of building a portfolio. So, we know that going to the market with a biosimilar with one or two products is going to be cost challenging, because the detailing and the sales force if you're going to build is going to be very expensive. So, you really need to -- the more products they can carry with them to detail, then of course the better and the most efficient it will be. So, we are looking at a lot of partners, we're talking to a lot of partners to build that portfolio beyond the two products that we had signed. The cost structure is definitely something to consider. But I think the deals that we have made and continue to make we really look at that very closely. We'll look at the history. A lot of the people that had -- were the first in biosimilars face that advantage that we have now. We learned from them, and we learned that you know, where it starts and where it ends up with it with all the erosions that happened, good quick erosions have happened in the structure. And we're trying to build that in our agreement with the partners.

Said Darwazah:
If I can add to that, remember in the MENA we -- now how many years have been in biosimilars?

Mazen Darwazah:
We started 10 years ago, and we started launching that [inaudible] registration process. So, now we've been five years in the MENA.

Said Darwazah:
We have good experience. The products are very successful. Again, we are [unintelligible] I mean, we are not manufacturing them; we bring in from Celltrion. And they're very profitable, they were successful, and the partners that we are choosing, and you can take a look at them, they are very well-known partners that have very strong history, strong manufacturing history, and are in low-cost countries. So, we believe that we will be very, very competitive and the deals that we have made will ensure that.

Harry Sephton:
Brilliant. That's very helpful color. Thank you.

Operator:
Next question comes from Max Herrmann with Stifel. Please go ahead, Max.

Max Herrmann:
Great, thanks for taking my questions. Couple if I may. Firstly, just again on the Generics division, but a little bit on the move into the specialty pharma arena. Clearly, given the erosion, you've seen with the business now in 2017, 2018, and now again in the current year, does that not make you feel the move into specialty pharma should be accelerated, if anything? And what are your views on capital allocation into that?

And then secondly, just coming back on the question you talked about in biosimilars in the U.S., obviously, on Combogesic, that's a sort of your first potentially marketed injectable product. So, I wonder whether that sort of -- I know it's not a biosimilar but is that your first foray into building a sales force behind product in the Injectables? Just get some feel for that, thanks.

Brian Hoffman:
So I'll start off with the generics question. So, you know, when we look at our business, we're still supporting our generics business. But we also want to do more of complex generics such as our generic Advair products. We believe that that combined with our investments in specialty branded and also some very profitable CMO business that we have helps kind of insulate us from the more commoditized type generic. So, we're investing in all three areas. But you know what, what we like about our specialty brand and business is that, you know, we've got more clarity and more of a runway, we have IP protection. And there are higher barriers to entry for developing these products. If we are KLOXXADO nasal spray, for example, requires specialized manufacturing technology that not many players have. And then we're looking to leverage that for other products. So, we're excited about the potential for our specialty branded business, but we're still supporting our generics business with a focus on complex generics. And we're also growing our contract manufacturing business, which we believe as we continue to expand in those areas will help to give us more predictability and more insulation, to some of the cyclical price erosion.

Riad Mishlawi:
Around Combogesic. We are excited about this product. So, this was supposed to be approved the third quarter of this year. And as you know, the company got a CRL, not critical one, it's related to packaging, nothing about the data or the clinical. And this will be delayed for a few months, but we are preparing for it. So, there's a lot of studies that are being done, interviews with doctors, nurses trying to look at the data, we are really excited. The more we look at the data, the more we think that this product is very good products, especially with the environment of opioid now in the United States, I think it will -- it will give doctors alternative ways to control pain. Also, the good thing about it is that this product has been launched in

many markets. It's been launched in almost all the markets in Europe, in Australia and New Zealand, some parts of South America. And we're learning from those markets, we're looking at the data from those markets to see how doctors are reacting to it, how the pricing, the uptake, how it's behaving. And we're using all that data to make a very good launch in the United States. So, we're excited about and we feel next year, we are going to be busy trying to roll this out in the market.

Khalid Nabilsi:
So, in terms of capital allocation, if we find the right in opportunity and investment, I think we still have the firepower to do close to 1 billion in acquisitions or in opportunities that we see fit within our strategy. So, we don't have a limitation.

Max Herrmann:
So, just push back on the sort of the move to specialty because it's been pretty pedestrian if you take you know the launch of Mitigare your first foray into that and given you know repeated now you guys are talking about it being a cyclical market where you know, yes, you will expect recovery, but you'll then end up another period coming back into this erosion. Your move into specialty pharma has not been fast enough and shouldn't you be putting more resources behind that to accelerate that. That was I guess my question really?

Brian Hoffman:
Yeah. So, you know, colchicine, our Mitigare franchise were really a success story for us. That was really our first foray. We launched the product in 2014. And it's still making some meaningful contributions to our business today, despite the entry of multiple generics on a tablet dosage form. That has given us a platform to start to build from. So, our strategy and specialty right now is we got two verticals, one in PCP and EMC allergy, and the other in community health. So, we launched our first product into community health from a branded standpoint with KLOXXADO. But we also have our addiction therapy services, and also our Naloxone injection, which all are going into that channel. We'll launch our next product in the PCP ENT allergy channel later this year with Ryaltris. And then we have two additional products behind that.

So, we are growing from more of a steady measured perspective. You know, rather than we're growing -- we're trying to grow that business in a way which we always remain EBIT positive. As we know, when you launch new brands and requires an upfront investment, you need to invest in a sales force. Well we're trying to do that in a way where it's not a drag on the rest of the business. So, our specialties as well as our generis business are really working together. They're utilizing the same manufacturing, the same overhead. And we're trying to do it in a steady way which make a positive contribution to the overall division as well as the Hikma Group.

Said Darwazah:
And we are looking at several products that we can look to acquire to add to the specialty portfolio that we have. So, the company is committed to invest when there is -- when we do find something that makes sense to add to that portfolio. And we as I said, we are looking at a few as we speak.

Max Herrmann:
Great, thanks very much.

Emily Field:
Emily Field from Barclays again. Just a couple of clarification questions, and I'm sorry, I didn't --

I missed this in the premier remarks. Just was it and the 9 percent CAGR for injectables over the next few years on top line. Is that, is that right? And then, on this point about FDA inspections, so is that specific to generics and that there's, you know, probably a lot of underinvested plants out there that will face remediation actions. Has the FDA been on the sidelines prevented any new launches? Also, is that also kind of holding back growth? Thank you.

Said Darwazah:
I don't think the FDA prevents it because FDA has been very active approving products. But I think once they start moving faster in foreign inspections, we will be seeing 483s. And the first part of your questions, the 9 percent?

Emily Field:
Yeah, just clarification so that's 9 percent top line CAGR for the next few years in injectables?

Said Darwazah:
And MENA

Emily Field:
Okay. Thank you.

Said Darwazah:
You can see I’m putting them under pressure.

[laughter]

James Gordon:
Thanks, James again at JP Morgan. Just a question on Xyrem. I think when you updated the guidance to reflect Xyrem's delay before the magnitude of the downgrade was something like 160 million or something like that. And that's what the product would have done in terms of revenues in the second half of this year. So, then if the launch is on the first day of 23, you presumably have that and then something in the second half? Is that a safe assumption? Minus maybe a little bit of market shrinkage? Or do we need to completely rethink how we think about what the Xyrem opportunity is? How much should we be putting in our models? And can we take what you're going to have in '22? And a bit and stick it in '23?

Brian Hoffman:
Yeah. So, I can't answer it directly in terms of, you know, what you should model for next year, but what I'll say directionally is the revised guidance didn’t solely reflects generic desire and it also reflected changes to the overall portfolio. So, all that was incorporated in the revisions and guidance, but you know, it's a very meaningful opportunity for us. We do have a significant royalties to Jazz as -- during that six-month period while we're the AG, and it's an escalating royalties based on sales. But, you know, that's probably as much color as I can give right now.

James Gordon:
Thank you, and maybe just a follow up to that which would be to the first six months is just you but then without giving exact number, but in terms of how much lower than whatever that number would be, in the first half might have been in the second half. Do you think the second half is going to be a big erosion? Or how do you think about that?

Brian Hoffman:

Yeah. So, the -- it's the first six months, wherever will be exclusive, there are a number of other filers that would have the ability to launch show it on day 181. So, we do expect a significant decline in the second half of the year as it becomes a multi-source generic market.

Pete Verdult:
Just a quick one for Said or Riad. I'm sorry, Said or – sorry Khalid. Balance sheet. I mean, you've tried to buyback to signal that you felt the site was not reflecting the fundamental value given that didn't do much to the share price. Is your appetite to do more, or you'd like to keep that balance sheet strong to deploy for the business? So, any appetite to do something further as it relates to share buybacks?

Khalid Nabilsi:
Yeah, no update on the share buyback. At the moment we did the $300 million. I think we as a management, we prefer to keep some firepower to do further, I would say investments and isn't in our business. But if the opportunity comes and we think that we need to do further, the board will evaluate that then -- will consider it.

Pete Verdult:
And then one follow up for Brian, I know you're not going to talk in detail about generic Advair or Vascepa, but just conceptually, should we now be thinking of these two products as ex-growth and stable is the best or do you still believe they can be growth products?

Brian Hoffman:
So, I want -- let me take them both individually. So, you know, icosapent, last year we were the first generic to launch, we enjoyed a period of being, you know, a de facto exclusive generic for that product. Since then, more competitors have come in Apotex has come in Dr. Reddy's. And we expect more generics to come in as well. With icosapent, we've been working with our API supplier and alternative API suppliers so we can gain additional volume. So, we're -- our hope is with that product that we can continue to gain market share now that our API volumes are increasing, but pricing has become more competitive. So, I think we look at that as more of a volume opportunity at current or potentially lower pricing levels when new entrants come in. With generic Advair, you know, we still see growth opportunities with that. Unfortunately, the brand is still controlling about 50 percent of that market, and then the AG another approximately 16 percent. So, I think there's still an opportunity for generics to make more penetration into that market overall. We are working on developing the third strength of generic Advair, the 550 strength, that one only represents 20 percent of the market. But when we get that approved next year, that will put us in a better competitive position to take on more market share.

Pete Verdult:
Thank you.

Operator:
Our next question from the phone lines comes from Paul Cuddon with Numis. Please go ahead.

Paul Cuddon:
Hello there, team. Sorry I couldn't be there in person and thank you very much for squeezing my questions in. And I have three quick ones. I mean, focusing firstly, on Injectables, organic performance of 5 percent, which to what extent you've seen any impact from staffing shortages that have been cited, particularly in med tech, but also applicable to your injectable business as well? On the generic business, I mean, where do you see the potential for future efficiencies

given all of the increased investments that are going in on the branded side? And finally, I mean, how do you see the economic outlook in MENA versus the U.S. given and potential for kind of improving healthcare spend specifically in MENA and how does that benefit your presence there. Thank you.

Riad Mishlawi:
Well, from the Injectables point of view, shortages [unintelligible] the U.S. so they just come and go, but they don't go away completely. They just change ranking. So, if you look at our 10 top products in the last five years, maybe control substance will be in the top five this year and shortages will happen, Pfizer has been having problems with their manufacturing and they stop the product and they, you know, we become number one and they become number three and then the year after you will see it the other way around. So, it is not something that -- it is just part of the business, and you have to manage it. I think we have an advantage that more than 90 percent, I would say 95 percent of the products that we sell, our products are made in our facilities. So, if we can have the nimbleness and the fast reaction to those shortages, we can definitely, you know, capitalize on opportunities where the product that the market needs is nobody else is making it, and maybe we can get in and get a bigger market share. So, it is not something anymore that is strange to us, it is just something that we have to manage, keep a close eye on. Our growth is not -- wasn't really related to this, I would say particularly, I think we just managed our business well, we had significant contract manufacturing, as we had talked about, we had expanded our capacity, and we capitalized a lot in bringing more volume into the market. New expansion markets are contributing some to our business. So, we've had a lot of other elements I think that helped us in our growth, not only the shortages, but definitely shortages, managing your inventory, managing the market, knowing when to be out is just absolute parts of the business in the injectables.

Paul Cuddon:
Sorry the question was more on the nurse staffing shortages, and the ability to kind of actually deliver your injectable medicines, not specifically on the injectable products themselves.

Riad Mishlawi:
Yes, staff shortages, I think the whole world is struggling with and we are struggling as well. Especially in places like Portugal that tourism has picked up a lot this year and their grabbing a lot of our staff into the tourism industry. We were lucky. Well, I mean, we were definitely struggling with it. And we're feeling it very strongly. We're doing all kinds of job fairs and going to universities and trying to get staff as much as possible. So, we're struggling with it. And we have a lot of ways and doing a lot of different ways to go about it. You know, but I think what we had done well, in the last few years is we invested in our manufacturing facilities and made them a lot of -- we invested a lot in robotics. So, although we depend a lot on labor, but our lines can operate with minimal labor, as in comparison to other facilities that I've seen, we've done a lot of new equipment, as you know, if you're following us with the last five years that put a lot of new facilities on, new equipment on, and whenever we do that, we get the best of the best, mostly robotic and mostly not so dependent on labor. That gives us an advantage, not to really downplay the fact that labor shortages is a problem. It's been a problem with us and we're struggling with it like everybody else.

Said Darwazah:
I think part of the question is your customers, nurse shortages, physician shortages, that affecting your business. I mean the --

Riad Mishlawi:
We know that some hospitals and we know some clinics are struggling. We've seen it also from our competitors. Fresenius has said that publicly also. They're struggling with the with the dialysis, having that so it is not only us; it is industry wide. So, yes, I think hospitals and nurses and clinics are all struggling with it. Do we see it directly in our business? We don't see it as much; it might be bigger than we think. But I think everybody is suffering from it.

Brian Hoffman:
So, I'm happy to address a question on generic specialty and how do we make that more efficient. There's really two ways to do that. You know, one is by increasing your sales of your existing product over time. And the second is by adding additional products utilizing the same sales force and our strategies is to do both. So, we have two franchises I mentioned before: our Community Health franchise and our PCP allergy franchise. Our Community Health franchises, supports our KLOXXADO product. That's a fairly lean operation. It's a fairly small sales force. It's concentrated not only in the retail market, but also the state government market. As we continue to grow sales of KLOXXADO over time, we'll see that sales and marketing spend become more efficient and our margins expand. Within TCP allergy, we have currently our Mitigare, colchicine product, I mentioned we're launching Ryaltris soon. As those products ramp you'll see the efficiency there. But also, we plan on bringing two additional products in the market there with Bilastine and epinephrine. So we should have four products in the TCP allergy market which then makes that sales and marketing spend much more efficient.

Mazen Darwazah:
The economic prospects, as you know, we are in tier one markets in the MENA. And if we look at the breakdown of our sales, we see Saudi Arabia is the second market that we have sales as in terms of volume after the United States. And as you all know, the prices of oil are going up now, which will have more expenditure of the government for the healthcare prospects. And this position us been a very good position. Because we are now one of the top players in Saudi Arabia, we are number four or number five in terms of market share, we have a huge manufacturing platform. And we are investing, like Said said, been heavily investing in manufacturing sites, we've been investing in infrastructure for distribution, we have our own company in Saudi Arabia. And this positions us in a good position, taking into consideration all of the headwinds of the currency fluctuation in the Arab world, especially in Egypt, in North Africa, we have been able to mitigate that risk by also increasing our product mix and diversifying our manufacturing bases in these countries. So, this is why we will continue to see growth in that area. And we will see more expenditure from the governments in that area. And the expenditure will be directed more towards the tender business which we are well positioned to be in that category, because we're considered as a local company in all of these markets.

Susan Ringdal:
Great. So, I think we don't have time for any more questions. Do you want to say any last words, Said, before we --

Said Darwazah:
I mean, again, that for me, I [unintelligible] first starting doing business. A company that makes 15 percent or more net returns on sales is a comfortable company. Once you go below 15, you start like spinning your wheels, you know, you're tired, you're on a treadmill running but not going anywhere. At 15-plus, for me, that's the cutoff point, that's where you start being very comfortable. This is a company that's making, in a bad year, is making 17 percent. So, it's still a very comfortable company with a very strong position. Profits of $210 million in the first six months. So, it's a well-positioned company to continue to grow in the future. We've had a bad

year in Generics, but as Brian said, is very sure next year will be a good year. And the two other divisions that are responsible for 80 percent are in extremely good positions to continue growing and you saw me make the commitment of CAGR.

So, we're in a good position. I'm very excited about the future of Hikma, the continuous story of growth of Hikma.

So, thank you, everybody.

[end of transcript]