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<<James Vane-Tempest, Analyst, Jefferies Group LLC>>

Good afternoon, everybody. My name is James Vane-Tempest. I'm Jefferies European Specialty Pharma analyst. I'm delighted to have Hikma here this afternoon for a fireside chat. I'm joined here on stage by Riad Mishlawi, the CEO; Khalid Nabilsi, the CFO; and Susan Ringdal, Head of Investor Relations. And thanks all very much for joining us this afternoon.

Perhaps Riad, to start if we could have a very brief summary of Q3 with your latest kind of IMS, perhaps even some points from your recent site visit, which you held for the market last week in Morocco for those unable to attend. And then we'll jump straight into Q&A.

<<Riad Mishlawi, Chief Executive Officer>>

Okay. Well, thank you for having me, James. Q3 looks good. So we reiterated all our numbers. We're very well into our plan of to meet good results and growth for the company in all divisions. We had hosted a bunch of analysts and investors to our plant in Morocco actually to demonstrate two things. The first one is what we're investing in this division a lot. And we would like people to come and see where the money is going and where the investment is being concentrated on. But most importantly is to meet the team that we have there.

Traditionally, this has been a very stable division. But in the last few years, growth has been accelerated there in both the top line and the bottom line. And we wanted people to come and see. We keep having questions whether this is sustainable or not. So we thought it would be best for the people to come and see in their own eyes what we have been investing in and meet the team and have more confidence in what we do.

<<James Vane-Tempest, Analyst, Jefferies Group LLC>>

Thank you. Before jumping into the segments, I'd quite like to start off perhaps thinking of the Group perspective, what you're doing from a contract manufacturing perspective? I guess, the CMO business, we've seen it really kind of pick up over the past few years. You've talked about selective contracts kind of historically you've announced kind of like a new contract. Obviously, it's a very different business in terms of thinking about longer-term duration and attractiveness. So how should we think about the materiality of that going forward and what type of business you're kind of looking to build there?

<<Riad Mishlawi, Chief Executive Officer>>

Yeah. The CMO business traditionally was more opportunistic business and mainly it was in the sterile manufacturing and the injectable division. Because once you, if you expand in the injectables, it actually takes a lot of time to move your products into the new equipment or the new addition. And for us to accelerate the utilization of the facility, we use contract manufacturing to do so.

Later on, I think in the last few years, we found out that we can do better at that. We can partner together with bigger companies, big branded companies, do contract manufacturing at a consistent level. It's not an easy business, but it's very much complementary to what we do. It provides stability to your business. What you're going to be making, what the bottom line is going to be at the end. So when we did in the last year, when we revisited our strategy for the generics, we thought a good stability element for the generics division is to create a CMO division – subdivision there. It's – we have the capacity, we have also the quality record.

It is in the United States. So we went after to see if we have any potential clients that would take this on. And we're lucky we found very, very good clients. So we're looking at it now as a good, stable business that we can stabilize the entire division. In the future, we don't know we think that this is going to be a good stream of growth, but you have to be ready for it. You have to have the capacity for it. You can't have your core business and your CMO business compete with each other. So you have to have capacity that is allocated for the CMO. Only then, you can decide to really think big about the CMO and see if you can take more contracts. We know today a lot of those CMO are being grabbed and bought, so it is an opportunity for us. So we're trying to see how can we capitalize on this without really harming our core business. So we're doing exactly that.

<<James Vane-Tempest, Analyst, Jefferies Group LLC>>

And it is a competitive business. So I guess the types of products or indications you feel you can best compete. Is there anything you can share in terms of where you feel you can best compete in that area?

<<Riad Mishlawi, Chief Executive Officer>>

Yeah. You don't want to add complexity to your already complex operations. So you would want to have one or two or three or a handful of big clients. You don't want to do 25, 30 clients there that you have to add more complexity and demands and audits into your facilities. And it becomes extremely difficult. As you could imagine, that anybody would bring a product, they would bring procedures; they want it to be made in a different way. So you would have a plant with different procedures, different way of doing things, and it just makes it too complex.

The best way for contract manufacturing in our eyes to do is to identify big three few clients, three to five, maybe 10 maximum clients that you can deal with, they give you one or two or three products. So you don't really add complexity. I think this is the – what products, it really depends. We would like to be big branded products. We don't want to contract manufacturer products that compete with our core business. So – and I don't think any clients would want to have that. Nobody would want to bring contract – products to a contract manufacturer that eventually will be their competitors. So the type of products would be mainly a branded type of products.

<<James Vane-Tempest, Analyst, Jefferies Group LLC>>

Understood. And we recently had obviously the U.S. election. Just kind of curious how you think that's going to impact your industry in the U.S.? And I guess perhaps also your business I guess you actually have a big U.S. manufacturing presence with what you've got in Cherry Hill and Columbus, Ohio. So curious from an industry perspective and from your perspective how you see things shaping out at the moment?

<<Riad Mishlawi, Chief Executive Officer>>

It's very hard to guess. I think everybody agrees with that. So – but if we think of what had Trump been talking about and what he had done when he was the President of the United States, he talked a lot about Made in America, he talked a lot about nationalizing a lot of the manufacturing of medicine in the United States, talked about prioritizing that, giving advantage to those manufacturers. And he talked about tariffs and make it difficult for imports coming into the U.S. If that actually materializes, we will be sitting on a big advantage. We make products in the United States for the United States market. So I think in this – if this materializes, I think will be a great advantage to us.

<<James Vane-Tempest, Analyst, Jefferies Group LLC>>

Thinking about the Xellia acquisition you made, I guess that concluded in September, can you just perhaps give us some expectations of how that business can contribute to what you've got already, both in terms of synergies, potential financial performance. A lot of people are kind of wondering what the scope of that asset could look like and how it ramps up. So any flavor there would be helpful.

<<Riad Mishlawi, Chief Executive Officer>>

Sure. That's a very important asset for us, very strategic. It really fits exactly what we're looking for. Just to remind everybody that wasn't a process. We actually went to the company, we kind of agreed that would be a win-win situation for both of us and made it happen. What it brought to us is really three important things. The first one is an expansion of capacity. We will be part of that acquisition includes a big facility in Cleveland. We actually have an R&D center there just across the street. The facility is pretty big. It has six huge layouts at 300 square foot each, automated lines.

But it also has another facility that is concentrated on making sterile IV bags, aseptic IV bags, which is a very rare manufacturing process. Usually bags, when they're filled, are autoclaved. You heat them up to sterilize them. If you – if the product can't take heating – can't take heat, and many products can't take heat, you can't put them in a bag unless you put them in a sterile way, which is a very complicated way.

So the Xellia has few products and pipelines and an R&D center actually working on creating a lot of products that exactly that taking them from the 50 mL, the 100 mL into the IV bag in a sterile way. So it does have that capability. So this is one that brings in. The second it would bring in is a team in Zagreb, R&D team of about 75 people that are extremely competent. They know their business well; they have developed a very nice pipeline. And we would be very happy to complete those pipelines and they develop products that we – that are on the market, like VANCO READY, a vancomycin in the form of liquid, which is very rare to find. This is something that would be commercializing.

And the last are a handful of products that are being commercialized. All of them are differentiated and specialized. So we need to definitely, we think we can extract a lot of value. I think integration is going to be key. And in the next two years, we'll be working very hard on integrating it very well.

<<James Vane-Tempest, Analyst, Jefferies Group LLC>>

And just thinking about integration, it does add quite a lot of capacity. So I guess how long do you think that could take to kind of ramp up? Is that margin dilutive? Sort of, help us sort of understand the timing for those synergies to come through?

<<Riad Mishlawi, Chief Executive Officer>>

The facility is ready to go now, but we elected to – so there are two facilities. One as I said, IV bags, aseptic one has lyophilization. But the lyophilization is not up to the standards that we want it to be. We use a lot of automation in our lyophilization, automatic loading, automatic unloading, very much – very as less of intervention by humans as possible. This is a very critical process and easily can be contaminated. So we use a lot of robots for that. So we decided that we are going to pause.

We are going to basically reconfigure the whole facility and bring in all the robots. That's going to take us around two years to do this, an investment of 40 plus million. But we think it's better to do it now rather than operate the facility and fix the facility at the same time. It's like driving a car and fixing a flat tire, it just doesn't work like that. So this is an industry where you can't make mistakes and we can't afford doing something like this. So we elected to move everything into a third party to manufacture while we are fixing – what we're fixing today and as soon as the facility is tight and everything has been installed, we'll come back and move our products into it. For the margins, I'll hand over to you.

<<Khalid Nabilsi, Chief Financial Officer>>

Yeah. As we – when we announced, we said that this transaction will bring around 75 million in sales. These are going to be neutral to the Group earnings, which means it will have slight dilution to the injectable because the margins for the Group is less than the injectable. So – but it's a very good performance so far, what we have seen since September. And once we bring these products to our manufacturing plant, as Riad mentioned, we'll see much better profitability.

<<James Vane-Tempest, Analyst, Jefferies Group LLC>>

Thank you. And thinking about R&D in general, I guess, I know we're chatting about injectables, but we can think about the oral business as well. I guess you've had a certain number of launches you kind of plan to do every year. But I also kind of sense there's maybe a drive to focus on smaller, kind of perhaps more material products, so perhaps generating more cash flow. But investors also do seem to kind of very much focus on the absolute number of kind of new launches. So how should we think about your R&D philosophy going forward in terms of how the teams are structured and what's essentially kind of going to be a more important data point for us to focus on?

<<Riad Mishlawi, Chief Executive Officer>>

Well, R&D is definitely going to be a major focus in all of our divisions. So starting with injectables, as you said, it's been healthy to a certain extent. We have been introducing 10 to 15, the most in the industry 10 to 15 injectable products a year into the market, smaller products. What we want to do is we want to continue with this, but we would rather have the number to be small and the products to be bigger. So we have now – we're launching this year. We're about – we're going to finish the year with about 11, 12 products. Last year we had about

14. The year before we had 20. So we continue launching a lot of products, but those are relatively small.

I would rather see eight and big products rather than having 15 and smaller products. It takes a lot from the facility to make batches to launch validation batches, you have to do stability batches; you have to put on stability. There's a lot that you need to do. So the smaller the number that would be better but of course the value of those products should be bigger than that. So today, we're in the process of changing that. I think we have an addition of about 70 some people that will be added to the R&D in injectables.

We think we are going to increase some of the spending on R&D. We're going to focus on R&D in all divisions. I'm talking now about the injectables. Similarly, what we will do and the generics as you probably know, we had changed management in the Generics and we have brought in a very experienced R&D person that has been in the industry for quite some time, worked on massive products and knows the chemistry well.

She will be heading this division and she has already done fantastic in terms of putting the right technical people in the right place, identifying the products that we want to go after. So there's a lot to do there and we're starting to do. But I think most importantly we want to say that R&D is going to be focused in all divisions. We will be spending more money on R&D, but we will probably get a lot more than we traditionally get for that amount of money.

We have Zagreb that is a new R&D center that we will utilize. Today we have about 80 people in Zagreb and we are planning to even add more. I think that will give us a lot of value for the money that we're spending on R&D. But really, the focus is to build a very healthy pipeline.

<<James Vane-Tempest, Analyst, Jefferies Group LLC>>

And how do you think about the competitive environment within that? Certainly speaking to some global healthcare investors, they look what's happening on some of the Indian generic companies, for example, and there's several hundred and it's pending. So do you see the competitive shift in the U.S. happening there or how do you see that playing out?

<<Riad Mishlawi, Chief Executive Officer>>

Playing out in terms of bringing in new...

<<James Vane-Tempest, Analyst, Jefferies Group LLC>>

In terms of the Indian companies actually being able to kind of launch more products in the U.S. and maybe they've done before, if there's those pending ANDAs?

<<Riad Mishlawi, Chief Executive Officer>>

I mean, it hasn't changed. I think there were a lot of number of pending ANDAs for approval in United States from many different companies. Especially as you said in India, especially during the GDUFA time when and FDA announced that they will be charging for all those applications. It used to be for free and all, sudden you have to pay now $200,000. I think it's even $280,000 now. So at that time a lot of the companies just concentrated on just submitting anything that they can submit so they can avoid the fees.

So there are a lot that are stuck there. Whether they come to fruition or not, I really don't know. But what we see around us and the people that we compete with, we're probably one of the most approvals and submissions that we have. So we're very active. We just want it to be a lot more valuable, a lot more material.

<<James Vane-Tempest, Analyst, Jefferies Group LLC>>

When we speak with investors, they generally seem comfortable with the top line outlook in injectables, but we often get more pushback on the margin. So I guess what gives you confidence in terms of maintaining, so I guess you've talked – given some kind of midterm framework, but they are best-in-class, they kind of have at the moment. And so the sustainability, kind of what you have at the moment amidst the topic?

<<Riad Mishlawi, Chief Executive Officer>>

We kind of struggled with this because a lot of people just thought that this is lucky. We are getting margins that are almost double to the closest competitor that we have. And people thought that this is lucky. It's going to go away, it's going to normalize. And it's been 12 years right now and we've been ranging between 42% to 35%, so it's been very, very healthy and people are asking us why and it's very simple, so we have three reasons why.

The first one is the fact that we make most of the products that we sell. So a lot of the companies our size, they start looking for third-party collaboration, which is likely so we do too. And once you collaborate with somebody, you know that the margin is going to have to be shared between you and the partner so that automatically will lower your margins. The second thing is the fact that we make a lot of the products and some of them injectables especially in Portugal, which is considerably lower cost in the United States.

And I think we have a huge portfolio and with the portfolio that we have operating in the U.S., we have a huge plant in the U.S. in Cherry Hill, New Jersey. We are able to be monitoring the market very closely. So whenever there's a shortage, we are first to jump. We're flexible enough and efficient enough that we can turn on a dime take advantage of the shortage that we have, introduce the market that are needed.

And if you're doing – if you can do this day on – day-in, day-out very efficiently, you can use your WAC prices rather than, you know, you can – you can kind of capitalize on the, you have a contract price, you can capitalize on how you can best benefit, I would say from this situation. So we are there to make sure that the patient gets the drug and we are sure that our business continues. So being in the market, manufacturing in the market where you distribute your product makes it very easy.

<<James Vane-Tempest, Analyst, Jefferies Group LLC>>

Your biosimilars entry into the U.S. I guess will be behind some of your peers. So how do you expect to enter the market and capture share from the established competition and how do you plan to sort of allocate your investments?

<<Riad Mishlawi, Chief Executive Officer>>

We are – our investment is very small in biosimilars. We did get into the business because it is a big business and as a pharmaceutical company, we should be in a big business like this. But when you were coming in late, we knew we can't compete with the giants it's going to be number one, two and three. And we knew if you become six, seven and eight ranking coming into the market, you're not going to be – it's not going to be a big blockbuster product. It's going to be something that you will compete maybe based on value, based on relationships, based on bundling with your product if you can and these type of.

So I think we are where we're supposed to be, we are where we expect it to be. I think we can easily have a good and positive return on investment. But we never expected for it to be huge. I think we expected it to be decent products and I think there will be decent products.

<<James Vane-Tempest, Analyst, Jefferies Group LLC>>

I know it's part of your others business now but I guess for compounding what do you see regarding the timeline for this to be a meaningful contributor? You've been very clear that this is a gradual business to kind of take time. But certainly, when you look at the overall market opportunity, whether that's a $1 billion or whatever, kind of, industry data point you look at, we get questions from investors thinking when could this be, say $50 million to $100 million? Is this talking three years, five years, seven years just to give a sense in terms of the scale of the ramp when the infrastructure is in place?

<<Riad Mishlawi, Chief Executive Officer>>

Yeah. What you said James, is exactly true. This is a very nice business and that's why we got into it. But again, this business is delicate, it's labor-intensive business. You have to be very careful. This business is not there to make mistakes. And mind you also that we have a core business of a $1 billion there that we don't want that small business to affect our core business, so we had to go very, very slow. We had to automate. We had to invest in a lot of ways that we can eliminate possibilities of contamination or mistakes.

And as you all know, if you know compounding, a lot of our competitors have gone into big deep troubles with the FDA because of mistakes. So we took it very easy. We were not really wanting to jump into this one and make the profits right away. We took it easy and we built it as we went – as we went on. It's been two years right now. I think the last few months have been great. We've been progressing.

We had a dedicated team now. All the team is complete; all the licenses now have been approved. So it's just a matter of how to grow the business. As I said, every month is better than the month before. When will we be $50 million to $100 million? I would assume three years should be easily – that should be attainable easily. The more the FDA is looking at this and the more they are regulated, the more the hospitals are encouraged to go out. But they just need somebody they can trust. We think that we can fill that gap. We just need to be very careful and do it slowly.

<<James Vane-Tempest, Analyst, Jefferies Group LLC>>

Yeah. A number of companies such as [indiscernible] (0:21:39) or Generics, a number of companies talked about a continued benign pricing environment. So should we consider that to be upside to your guidance for this year just given, I guess at least we've understood the commentary on guidance on pricing to be a little bit more, kind of balance?

<<Riad Mishlawi, Chief Executive Officer>>

It's a pricing environment is different from one company to another. But we've seen it different than what we have saw in the past, nothing like two years ago where we saw a double-digit price erosion. Today it's more of a mid to high single digit. So it's kind of stabilized. It's in line with our expectation and we just reiterated our guidance. So no change. We upgraded the guidance that we in August compared to what we expected earlier in the year. And this reflects the strong performance that we have seen in the generic and the performance of our portfolio.

<<Khalid Nabilsi, Chief Financial Officer>>

It's inherited in the business. I mean we expect the price erosions in all of our divisions. We just have to be very focused on what to do to make sure that we fill in that gap and more. So that's where we're not going to ever assume that enterprise erosion is going to stop. We are going to assume that it's going to continue. What we need to do is find ways to fill that gap when it happens.

<<James Vane-Tempest, Analyst, Jefferies Group LLC>>

Understood. I guess as this business kind of comes through, I guess the – you have the sort of the period of generating good profits from sodium oxybate and I guess we know the royalty rate is kind of much higher. But I think a lot of people can understand that this is still a very good kind of top line opportunity. But we really need to kind of focus this across kind of the profitability level. So it is a way for you to kind of help us sort of disaggregate what is kind of the core business versus what you're sort of gaining at that, as that sort of normalizes. That does give an element of uncertainty to investors?

<<Riad Mishlawi, Chief Executive Officer>>

Yeah, I mean, I just have to explain that sodium oxybate is not a typical – typical thing that we do. So it's, it's – we started when we bought this business that was part of that acquisition. They had started on it years and years ago before we started and we benefited from it. So it's an authorized generic that we got. Typical authorized generic agreement. You make a lot more in the first six months and later on you will have to pay higher royalties.

Your top line stays high, your royalties increase significantly. So your ratios also are impacted, that's exactly what happens. So I know that there's a ratio thing now. Is it going to be less or more? I think definitely the top line is high because of the effect of the sodium oxybate. The ratios are lower because we are paying significant royalties to the brand. It is still bringing an absolute number of profits, so we are benefiting from it.

But typically, if you look at this business, you have to look at it outside of the sodium oxybate. You'll find out that it's stable, it's growing, the profitability are healthy and we're doing a lot to make it even healthier. We're putting a lot of investment in R&D now and we're putting a lot in terms of investment in technology and expanding our line and expanding our capacity. And last that we just added contact manufacturing now to help this business go forward.

<<Khalid Nabilsi, Chief Financial Officer>>

And the business today is much better than where it was two years ago.

<<James Vane-Tempest, Analyst, Jefferies Group LLC>>

Yes, understood. Mindful of time, perhaps time for one or two more. Earlier this year you got the [indiscernible] (0:25:16) approval in the U.S. I guess. How do you see Hikma participating in the broader GLP-1 opportunity given competition?

<<Riad Mishlawi, Chief Executive Officer>>

Well, everybody is looking at GLP-1, right? I mean this is the biosimilars. 10 years ago, everybody was talking about biosimilars; 30 years ago, everybody was talking about oncology. This is the buzzword right now. It's a great product, great series of product. It's been changing, new innovation is happening. We're happy that we will have liraglutide. We will be introducing it at the end of this year. We haven't had any approvals yet. We only have Teva in the market. That's only authorized generic. So hopefully this will continue and hopefully for at least a few – first few months of the year we will benefit greatly from.

<<James Vane-Tempest, Analyst, Jefferies Group LLC>>

Thank you. With that, we're out of time, unfortunately, so thank you very much, Riad, Khalid and Susan. Thank you.

<<Riad Mishlawi, Chief Executive Officer>>

Thanks James.