Xellia asset acquisition – Q&A edited transcript, 17 June 2024

Riad Mishlawi – Hikma – Chief Executive Officer:

Good morning, good afternoon, everyone. Thank you very much for joining this call. So, just a few words for introduction. You probably have read all of the announcement that we have put out for this latest acquisition. It's a modest acquisition in terms of the size relative to the Group and relative to the injectables business. But I'm very excited about it. I think it really adds a lot of strategic value and potential to the existing business that we have in injectables.

I think it's really exactly what we need as fuel to ensure our – to maintain our high margins and ensure our growth in the coming years. It's bringing to us several different values in the products. As you know, the deal will be – will add a selection of commercialised products, including the Vanco Ready premix, ready to use vancomycin. In addition, we have a pipeline of 10 products, primarily the RTU premixed bags, and they will be launched throughout the next five years or so.

From the manufacturing point of view, we'll have a huge facility with big manufacturing technologies that we have there, including lyophilisation, six lyos there, very equal and similar to the ones that we have here in Portugal. In fact, they're exactly the same type, same manufacturer, same size. So, transfers would be easy. It will add the capacity that we have been building in Portugal. This takes really usually a lot of time to build this type of capacity. This is something that we can get on, hopefully, in two years. We should be operational, but it may be over two years, we'll see – depending on the delivery of some of the equipment that we're going to need.

Importantly, also an R&D centre. This Company will – this deal will give us an R&D centre in Croatia, in Zagreb, Croatia, with a team, a very competent team that we believe that not only from their competencies is proven. They had developed very interesting products, and their pipeline is really very, very interesting. So, we're very excited to add this to our injectable strength – injectable division strength.

You all know we've been talking about those three things actually in the injectables. We've been talking about increasing our capacity. So, this is going to definitely do that. We've been talking about R&D that we want to really focus on R&D, try to get more value for less cost. This is exactly what this is going to bring us. On top of it, I think specialty products in the pipeline and the commercialised products, we're getting very interesting, unique products there that we can grow, and we can enhance through the coming years. So, excited about it.

I think strategically, it has an exact fit to what we need. I think we can really do a lot with that. This will also be something that will take away or decrease our capital investment that we already have for the injectables. It will take some of the spending that we were anticipating to spend in the next five years and we'll invest them all – invest most of them in this site. Bill, do you want to add anything to this?

Dr Bill Larkins – Hikma – President Injectables:

No, I think that's a good start, Riad. Thanks.

Riad Mishlawi – Hikma – Chief Executive Officer:

Maybe we can open it to questions now?

Operator

Thank you. As a reminder, if you would like to ask a question today, please do so now by pressing star, followed by the number one on your telephone keypad. Our first question today comes from the line of James Gordon with J.P. Morgan. Please go ahead. Your line is now open.

James Gordon – J.P. Morgan:

Hello. Can you hear me?

Riad Mishlawi – Hikma – Chief Executive Officer:

Yes.

James Gordon – J.P. Morgan:

Great. This is James with J.P. Morgan. A couple of questions, please. The first question was just, so you're adding on a pro forma basis $75 million of revenues. But I assume in terms of growth, we don't just grow those revenues. We do some effectively revenue synergies as you're going to have a faster growth in the injectable-base business. So, can you quantify that at all? How quickly does that come through? How quickly are the top line synergies from the deal?

Second question would be margins and EPS. So, can you talk about how accretive this could be at the bottom line, medium term? So, how much benefit there could be? Then finally, in terms of CapEx, so you're doing this two-to-three-year enhancements project. So, what would the incremental CapEx be from doing the deal? How much is that reducing CapEx for the base of the Company if we think about it that way?

Riad Mishlawi – Hikma – Chief Executive Officer:

Okay. Let me start with the first question. So, we did talk about this will bring in about $75 million in revenue. We did also say in the first 12 months, although we think this is with good margins, it's not as large of the margin that we already are operating the injectable division at. So, it's slightly less, but we believe that it's a matter of time before we realise all the synergies that we have and we start increasing the margins there, especially I think when we get to manufacture it ourselves. Right now, we will be manufacturing it through a contact manufacturer until we do the works that we're expecting to do at the site.

So, today it is accretive. It's got good margins, but it's not as good as the current margins that we're carrying with the division. I don’t think – we did say it's neutral. It's a very small $75 million in comparison to the $1.2 billion, $1.3 billion that are the injectables overall. It's

very small and the effect will not be huge. But I think as we grow it, as we add products from the portfolio and as we start moving it into our own facilities, I think this will increase the margins and also the top line, I believe.

As far as the CapEx, I would just say that today we have intentions in two things. We keep talking about it. I think there are two things that we've been focusing on with injectables. One is to grow our capacity, especially unique capacity with the unique technology. Lyos have been really – we've been utilising the huge capacity that we have, and we've not – we have a bigger demand than what we can use. So, I think from the lyo capacity, this will be coming in really handy there.

Also, we'll be adding technologies, of course, like the premix filled in sterile environment, which is also very unique. There are not too many companies that are able to do this very complicated process. This is something that Xellia had invested in, and I think we can use this one also, not only for Vanco Ready and for the pipeline that we will be – will have acquired, but also internally, we have a few projects that we've been working on that require that technology.

I think the other part of it that we are also looking into that now with this adding capacity and some of the capacity that we're adding this year, we added last year, and we continue to add to the injectables, we'll have plenty of capacity to do what we always wanted to do is do a contract manufacturing part or division or subdivision of the injectables. We've been very good at it. We have the right quality, we have the right plants, the technology. We've been doing well, as you know, we've done remdesivir in a very short time and we do a lot of other ones, including biosimilars.

But we can't really take on a lot of potential customers or expand our contract manufacturing because of the capacity limitation that we have. So, our own portfolio and core business is growing while also the contract manufacturing has potential to grow. So, we have to choose between which one do we focus on and definitely, we want to focus on our core business. So, we're limiting how much new business of contract manufacturing we can take. I think with that added on, in addition to the ones that we're working on and expanding the capacities, we will have an interesting contract manufacturing division, which is something that I think will be very good, very lucrative. It would be a great expansion to the growth that we will have.

Bill, anything else you want to add to this?

Dr Bill Larkins – Hikma – President Injectables:

No, I think you've said it well, Riad. So, I think maybe just the one thing, just briefly on that too, is you mentioned on the margins overall. I think as we bring this – as we endeavour to bring these products, both the R&D pipeline and the existing commercial products in-house over the medium term, I think we'll see increased margins on those, as you mentioned.

Riad Mishlawi – Hikma – Chief Executive Officer:

Anybody else?

Operator:

The next question comes from Paul Cuddon with Deutsche Numis. Please go ahead, Paul, your line is open.

Paul Cuddon – Deutsche Numis:

Thank you very much. I've got two questions, please. Obviously, you have some kind of history with this site. So, I'd just be interested in a bit of backstory as to why now? Did you have some sort of option agreement on this site if it came available again? Then secondly from me, just with an eye on the potential FTC, do you think you may have to sell some assets within the Xellia portfolio, thinking specifically the vancomycin HCl? Thank you.

Riad Mishlawi – Hikma – Chief Executive Officer:

All right. I'll take on the history and maybe, Bill, you can take the FTC point.

Dr Bill Larkins – Hikma – President Injectables:

Okay.

Riad Mishlawi – Hikma – Chief Executive Officer:

Actually, the history of the site is very interesting. As you know, in 2014, we had acquired the BI assets in Bedford, and that included the entire site, which had four sites at the time and an R&D centre. Within that acquisition also, we had 114 products. In fact, this is when I met Bill. Bill used to be the General Manager of that at the time. So, with negotiations, what was between us and BI through myself and Bill, we sat opposite each other, negotiating for many, many days.

But when we did acquire it, we realised two things. The first thing is that the site itself was – although two of the sites – there were four factories, four manufacturing plants within that site, two of them were older and two of them were new, brand new, in fact. One of them didn't even touch any products. It was only water. They were just installing the equipment at the time and some of the equipment were still in boxes. So, at that time, the facility was under consent decree. So, it needed a lot of time to be – especially with the FDA from the regulatory side, it has to be – there has to be some corrective actions to be done. There was some equipment that had to be installed, validation had to be done.

So, there was a lot of complications to manufacture anything in that site. There were still validations to be done and the consent decree didn't make things easier. So, what we elected to do is if we wanted to transfer the products that we acquired, we needed equipment because the products – there was huge, 114 products. We elected to transfer about 80 of them and we did not have the capacity, especially the lyo capacity to transfer all of them.

So, what we elected to do is to tear one facility down that was the newest facility, take all the equipment, including six lyos – seven lyos, I believe, two lines, a lot of packaging equipment and a lot of things. We just took everything out and sent them to Portugal at the time. It was

180 containers that went – came to Portugal. In Portugal, we built two facilities using this equipment. It was built within record time. I think within two years, we had the facilities up and running. The products were transferred at the time. So, we utilised this capacity immediately.

Then we had Xellia, they were looking for contract manufacturing at the time and we told them – I know I had a meeting with them, and I suggested that they could buy the remainder of the facility. I just wanted the R&D centre to make sure that the transfers of these products continue, and the history and the expertise were all within this R&D centre. So, we decided that we will sell the rest of the facility the way it is, without the equipment of the last site and keep only the R&D centre, and that's what we did.

Since then, Xellia had repaired the last site that we demolished to take all the equipment out. They put new technologies there, which is the aseptic bag filling technology, a very complicated technology. They also repaired their lyo. They spent a lot of money, a lot of money on it. I don't want to tell you the number, but it's in the hundreds of millions. Also, they were successful of getting out of the consent decree.

So, the site today is very different than how it was before from both regulatory side and capabilities. This is why we were very enthusiastic actually, if we can get that site, we can get it going. It's right next to our R&D centre. So, transfers will be easy. It's got the technologies that we need. The lyos are exactly the same type and the same model that we have here today and size. So, transferring between sites become easier and the aseptic bag filling is a great technology that we've been wanting, we've been looking at, and we have a lot of products that we're developing that needed this technology.

So, all in all, we felt that it really fits, and we went after it. I think we were successful in having an agreement with Xellia to acquire the assets. You want to do the FTC, Bill?

Dr Bill Larkins – Hikma – President Injectables:

Yes, so on the FTC side, so we're not anticipating the need to divest anything of any meaning. So, we're not expecting the FTC process will result in any meaningful divestiture of products from our side.

Operator:

Our next question comes from Peter Verdult with Citi. Please go ahead, Peter, your line is now open.

Peter Verdult – Citi:

Thanks. Peter Verdult, Citi. I've got a few, but Riad and Bill, I'll ask them one at a time not to give you overload and some of them will only require very short answers. Just with the current portfolio today that you talk about, $75 million, is that sticky business, declining, growing business? When the pipeline comes through, should we assume that you think this can match the high-synergistic growth outlook you're giving for injectables? Just the current state of play of the business you're acquiring today and what the pipeline might do in terms of transforming the growth outlook.

Dr Bill Larkins – Hikma – President Injectables:

So, Riad, I'll take that one. So, the business today is – we do see it as sticky. So, the bulk of the product deal is around Vanco Ready-to-Use. So, it is a patented product in the US. So, we have patent life out quite a ways on that product. So, we're expecting that to be – that revenue stream to be quite sticky. We are looking at some opportunities and the potential to even grow that further than it was under Xellia when it gets into our commercial organisation. Then as far as the pipeline as well…

Peter Verdult – Citi:

Bill when you say…

Dr Bill Larkins – Hikma – President Injectables:

Sorry, go ahead.

Peter Verdult – Citi:

Sorry, go ahead. Apologies.

Dr Bill Larkins – Hikma – President Injectables:

So, on the R&D side, I'd say it's probably similar. So, it's similar types of products for the most part that are in R&D there. Those will be originally planned. Most of them will be originally planned to be outside at a CMO just based on the timing it's going to take to get the Bedford site back up and running the way we want it to run. Then we see those products with even more increased margin as we bring them back in-house once that facility is ready to accept them.

Peter Verdult – Citi:

Thank you. Bill, just a follow up, on the IP on Vanco Ready, can I push you roughly when does that currently expire?

Dr Bill Larkins – Hikma – President Injectables:

I knew you were going to ask me that question. I don't remember the exact patent expiry. I think it's – don't quote me on it – but I think it's in the – sometime in the early 2030s.

Peter Verdult – Citi:

Okay, I won't hold you to that. Okay, then speeding up, just on the – are you willing to discuss what the contingent is raised to? Is that a specific product in the pipeline or is that a sales milestone? Anything you're willing to say on that contingent.

Dr Bill Larkins – Hikma – President Injectables:

So, Riad, do you want to handle that one? You want me to handle it?

Riad Mishlawi – Hikma – Chief Executive Officer:

Yes, go ahead.

Dr Bill Larkins – Hikma – President Injectables:

So, on that, there's some milestone triggers around sales on a specific product. I don't think we can probably say too much more about that unless Riad feels like it.

Riad Mishlawi – Hikma – Chief Executive Officer:

But I think it's definitely beneficial. I think it's definitely something that we'd be excited to – if it happens, would be excited to pay, would be willing to pay happily. So, there are good milestones, I think, for both of us. I think if we can get that, I think it will be great for both of our companies.

I just want to tell you – I wanted to say a couple of things about why we are shutting down the site for two years, two and a half years, something like that. I just want everybody to understand what the rationale behind it. I think we believe that the site today is very well equipped. It's got the right equipment, but we don't think that it's – it would be as flexible as what we would like it to be.

We've been in this lyo business now for 20 years since the last time we got into the lyos. We know how best to run this type of process and we think that we need to redesign certain things with the lines, the way that we load those lyos and unload those lyos. We believe that automation in this process is very important for many reasons, for the quality reasons, but also for efficiency. If you want to fill, those lyos need to be always running. It's like when they're not running, you basically are losing money.

So, in order for you to make sure that they're continuously running, you need to load them and unload them at the fastest rate. What we do here in Portugal, after many years of experimentation, we have automatic loading and unloading that does this extremely efficiently without having any operators needed. So, this is the type of installation that we need to have in this plant.

We elected to stop production. They were producing, but we elected to stop completely and work on it because you really can't run half a site and you can't run a site and fix it at the same time. It's just – this is asking for trouble. It's like changing a flat tyre as the car is running. You really need to stop, do it right, validate it correctly, bring the right people in, train them and then come in strongly with the capacity that you need, with the products validated as you go. So, that's why we elected to stop run it, redesign it, put the equipment that we need, automate it as much as possible.

This is the US. So, you really need it to be automation for many reasons, efficiently, quality, but most importantly, also cost. Then as we are ready, we'll bring in the products and transfer all the products in.

Peter Verdult – Citi:

Got it. Last two from me, Riad, I know I've hogged the call, but hopefully you don't mind. You've be very clear since you assumed the CEO role that you're not interested in buybacks and dividends. You want to invest in the business. This is obviously a bolt-on strategic, it still gives you lots of firepower. I think you've talked about a billion in the past. So, just could you high level, give us a sense of the environment to do further business development? Is it improving, just remain the same? I realise you're not going to tell us what you're looking at, but just – I just want to kick the tyres in terms of whether the environment to do more BD is improving or not.

Then just because we've got you on the line, when we look at the IQVIA data for both injectables and US generics, the trends look very favourable. So, just we'd love to get your sense of how you think the business is doing. It feels that they're firing on all cylinders, just wanted to kick the tyres with you and checking them out.

Riad Mishlawi – Hikma – Chief Executive Officer:

Yes, as far as the environment and the BD environment, we've been looking at a lot of opportunities. We're trying to find opportunities that fit with the needs that we have. We need to – we've been talking to all, but as you know, would be the – you have to study 20 to get one, if you're lucky. So, we've been very, very active. I think there are a lot of assets that are available today. We're looking to see. We've been very active. We had to increase our BD department with a lot of resources. We're looking all over the world in all divisions and then not only in injectables, but also in MENA and in the generics and we're busy.

So, I think this is a good, great asset that we found, and we jumped on it. We've been really negotiating this for quite some time, maybe a few months. Similarly with other also opportunities, we're doing the same. So, we're excited. We're happy that we have a strong balance sheet that we can use. We just need to use it wisely and we need to make sure that we'll put the priorities of what we need to invest in first. So, that's exactly what we're doing.

As far as how we're doing, we're in line. I think things are good. We're aggressive. We're doing some changes, small changes to the organisation that is giving us big benefits in the way that we're organised and the way we collaborate. Some of the organisational changes also give a lot more efficiency to the processes that we have. We're seeing a lot of results for – as a result of those changes. So, I'm excited. I think things are going in the right direction. Hopefully we'll be coming in with good news, routinely, to the market. The market can have a huge trust in the growth and sustainability of this business.

Peter Verdult – Citi:

Thank you.

Operator:

Our next question comes from Max Herrmann with Stifel. Please go ahead. Your line is now open.

Max Herrmann – Stifel:

Great. Hopefully you can hear me. Just three questions, if I may. In terms of the Croatian R&D facility, can you give us a little bit more colour on how many people, and what the – I assume this is all anti-infectives, but is that the core business that was doing the R&D for Xellia? That's the first question.

The second one was just on in terms of other products beyond the Vanco Ready. I see there's a daptomycin product. Is that, again, branded? Is there any promotion going behind these as they find themselves as a specialty pharma business? Then just in terms of your thoughts, in terms of the increased complexity of the business, this will add – it obviously adds quite a few new locations.

Riad Mishlawi – Hikma – Chief Executive Officer:

Bill, you want to take the R&D part?

Dr Bill Larkins – Hikma – President Injectables:

Yes, I'll take a run at both and then you can add on. So, the Croatia R&D site, we're taking substantially all of the team in the R&D centre in Croatia, minus a few that I won't get into on the call. That site is primarily focused into ready to dilute, ready to deliver, ready to use types of products. So, that's mostly what the pipeline is there. It's consistent with the commercial products that they've developed. It has been the R&D centre for the Xellia pharmaceutical business. So, that will be coming to us. Those are primarily the skill sets that they have there.

As far as the products go, so the Vanco Ready-to-use does have some level of promotion. The daptomycin product that you referenced really generally does not.

Riad Mishlawi – Hikma – Chief Executive Officer:

Do you want to talk about daptomycin?

Max Herrmann – Stifel:

Could you elaborate in terms of how many people are promoting it and how many people are at the R&D facility?

Dr Bill Larkins – Hikma – President Injectables:

So, I don't know that we're prepared to talk about the exact number of people at the R&D centre today. I think we'll have to share that at a later point. On the commercial side for Vanco Ready-to-use and the daptomycin product, we are taking substantially all of the commercial organisation from Xellia as well in the US. So, we'll make sure we have a seamless transition of the Vanco Ready-to-use and Dapto products into our portfolio and make sure we don't have any hiccups with respect to sales.

Riad Mishlawi – Hikma – Chief Executive Officer:

So, if I may add a couple of things to what Bill has said. From the R&D point of view, from the centre, I think Zagreb is going to add a significant capacity of R&D, but not only for the US. Being in Europe also, they can also help us in some of the growth that we're experiencing in Europe and some of the support in both R&D and regulatory. I think those are things that Bill was thinking about, and they will come. We need to, of course, reorganise and look at how we're going to run this, but that's what we're thinking. It is in the EU, and it can support both territories.

Daptomycin is a product that is – it's not the usual daptomycin that they have. It is a specialty daptomycin. I think it's room temperature, correct me if I'm wrong, Bill, but I think it's a room temperature daptomycin while the regular one is a controlled temperature, and which gives us a little bit of an edge over the competition. It's a very crowded market, but we think that we can get some edge there. Bill, you want to correct me, if I'm wrong?

Dr Bill Larkins – Hikma – President Injectables:

No, you're right. So, yes, there is some benefit. It just doesn't require any significant detailing.

Riad Mishlawi – Hikma – Chief Executive Officer:

The complexity of the injectables, yes, this is – as you grow, it becomes more complex, but I think it's something that we are expecting. I think the US is our largest market and we're happy that this one will be servicing this market, will be in that market. Especially of bags, we have, as you know, we have premix bags here in Portugal, but as shipping becomes expensive, the bags – the cost of shipping a bag becomes very, very expensive as well. These are big, bulky and heavy bags that you ship across the ocean. At the end, we pay a lot of money. Now it's a little bit better, but during COVID times and sometime after COVID, it was really costing us a lot to ship those across.

So, being in the US, in the market that we can sell with those bags, I think gives us an advantage. I think we can service the market not only faster, but also, it's relatively inexpensive in comparison to shipping all the way from Europe. So, this is why we're excited about making a centre of excellence for bag manufacturing in that facility.

Max Herrmann – Stifel:

Thank you.

Operator:

Our next question comes from the line of James Vane-Tempest with Jefferies. Please go ahead. Your line is now open.

James Vane-Tempest – Jefferies:

Hi, thanks for taking my questions. Just a couple if I may, please. Firstly, just thinking about the capacity. We've talked about numbers of lines. I appreciate that volumes and units are probably product specific, but can you give a sense in terms of how much this site could expand your overall unit production capacity, please? Second question is just on the pipeline of 11 projects. I'm just wondering what kind of markets these are addressing and to give us a feel as to when these could come through and the materiality of those, please. Thank you.

Riad Mishlawi – Hikma – Chief Executive Officer:

Okay, I'll take the first one and Bill can talk to you about the pipeline. So, from the capacity point of view, I can tell you units, but you see, when it comes to lyo, it's very hard to do it in units because every product has a different drying time. A product can dry in the lyo in 24 hours and some products take seven, eight days. So, it's not fair to say the units, but I can tell you today, for example, in Portugal, we have 10 lyos. It's pretty big capacity and the lyo – we'll be adding six to those 10 that we have. So, we'll be adding about 60% more to the existing network that we have for the US market.

So, it's significant. They are 300 square foot each. So, if you look at it from a square footage point of view, it's also a significant number of square footage – lyo square footage that you're adding. Also, that we are – the way that you run the lyos is important for you to maximise your output. So, this is why we're really investing in creating a very efficient process in loading and unloading those lyos. So, drying time, you can't change much. This is inherited in the properties of the product, but you can load lyo and unload the lyo. The process can save you a lot of time and therefore you can just turn the lyos around and go for other batches.

So, just to give you an example, a lyo like this would probably fit around 100,000 – and in one load, 100,000 [two millilitre] vials, a little bit more than that. So, 100,000 needs to be loaded in 12 shelves, I believe, or something like this. Then they would have to be loaded and they would have to be unloaded. So, the process is very complicated, and it has to be done in such a delicate, very important way because you'd be loading several products as you all know. Stopper is not all the way seated. So, it requires – you have to be extremely careful about how to do it.

We experimented in a lot of different ways here in Portugal, but in the last few years, in the last, I would say, seven, eight years, when we started now adding the new capacity, we now do automatic loading, no humans, no room for contamination. We thought this is the best, most efficient and very much big assurance to the quality. So, this is what we're planning to do there. So, it does add significant and if we automate it, I think it will be a very, very significant amount of products coming out of that facility.

Bill, you want to take the pipeline?

Dr Bill Larkins – Hikma – President Injectables:

Yes. So, on the pipeline, there's, as Riad mentioned in his introduction, there are 10 products in the pipeline for the Xellia R&D Centre. One of those was recently filed. There's a wave of timelines for the existing remainder of those products. We're expecting those to start

launching in the 2025 timeframe and launch throughout the rest of the decade. So, we're expecting that there'll be some meaningful growth opportunities out of those products.

Then also as Riad mentioned, we're intending to really leverage that Croatian R&D Centre as well. We're going to be adding additional product opportunities into that centre as well from our list of interesting pipeline products.

Operator:

We have no further questions. So, I'll now hand back to Riad for some closing remarks.

Riad Mishlawi – Hikma – Chief Executive Officer:

Well, thank you, everybody. I hope that we answered all your questions. Again, I just wanted to reiterate that we think that this is a very exciting opportunity, especially for the strategic potential of this acquisition. I hope that we can demonstrate that in the near future. So, thank you very much and see you soon.