“Shilpa Medicare Limited

Business Update Call”

July 08, 2024

MANAGEMENT: **MR. VISHNUKANT BHUTADA – MANAGING DIRECTOR – SHILPA MEDICARE LIMITED**
MR. ALPESH DALAL – CHIEF FINANCIAL OFFICER – SHILPA MEDICARE LIMITED

MODERATOR: **MR. DIWAKAR PINGLE – ERNST & YOUNG GLOBAL LIMITED**

Moderator: Ladies and gentlemen, good day and welcome to Shilpa Medicare Limited Business Update Call. As a reminder, all participant lines will be in the listen-only mode and there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal an operator by pressing star then zero on your touchtone phone. Please note that this conference is being recorded.

I now hand the conference over to Mr. Diwakar Pingle from EY IR. Thank you, and over to you, Mr. Pingle.

Diwakar Pingle: Thank you, Rico. Good morning, everyone. Welcome to the conference call hosted by the management of Shilpa Medicare Limited to discuss the recent milestone achievement in the CDMO business of the company.

Representing the company on the call today, we have Mr. Vishnukant Bhutada, Managing Director, and Mr. Alpesh Dalal, the Chief Financial Officer. Detailed information regarding the update has been mailed available in the Stock Exchange as of July 4, 2024. In case anyone requires any extra information, you can reach out to us and we'll be happy to provide the same.

The management will initiate the call with further details on the dynamics involved in the milestone achievement in the CDMO business, followed by a Q&A session with the participants in the call. I would like to state that some of the statements made on today's call could be forward-looking in nature. A detailed disclaimer in this regard has been mentioned in the conference call invitation available in the Stock Exchange.

With that said, I would now like to invite Mr. Vishnukant Bhutada, the Managing Director of the Shilpa Medicare Limited to take this discussion forward. Thank you and over to you, sir.

Vishnukant Bhutada: Yes, very good morning to all. Welcome to this conference call. Today's call is specific only for the development of our CDMO business partner, Unicycive Therapeutics. I'll just brief on the OLC, which is the Oxylanthanum Carbonate, which is NCE, and this has been bought by the Unicycive. And with this, they have approach us in late 2020 for the development of the end-to-end this particular product, means from API, manufacturing validation, DMF and thereafter develop the formulation which can be used to reduce the hyperphosphatemia and help the kidney patients on this. It was not a simple task.

We have taken this challenge and with the expertise in our API, which has always expertise in the development of complex API and a formulations team, we have completed the drug master files of the API and made the formulation and given to them, which they have done the human clinical study and it has been passed recently, which they have announced recently also. They will file the NDA now in this particular quarter.

With this, we have requested them to made a binding agreement for the supply of the finished formulation, including API manufactured at our site. They agreed to this and along with this, they have agreed for the US $10 million milestone payment. Now, they are placing the binding agreement order for the 5 million tablets to be delivered before the June '25 and 15 million tablets before the December '25.

We need to supply them the product in next and with this binding agreements totally, the agreement is there for next four years. Along with this, they are also funding us creating the dedicated block for them, which shows how important this product for them. We are also equally committed them for the timely delivery of the API and formulation as early as possible. So, we have given the brief on what is the molecule, how it is used.

This is into the hyperphosphatemia and which is normally happens when the phosphate levels increases, which damage the kidney because of the increase in the phosphate level in the blood. This particular drug is used to bind the phosphate and help making the kidney patients healthier in this. This is what the most important functions of this particular product. This is all from my side.

Now, I am open for the Q&A.

Moderator: Thank you sir, we will now began question and answer session anyone who wishes to ask question press * and one on the touchtone telephone, if you wish to remove yourself from the question que you may press *, participants are requested to use handsets while asking questions, ladies and gentlemen, we will wait for a movement for the question que assembles

The first question is from the line of Rahil Dasani from MAPL. Please go ahead.

Rahil Dasani: Hi, am I audible?

Moderator: Yes sir, go ahead,

Rahil Dasani: First of all, good morning and thank you for this opportunity and thank you for arranging the call on this update. So my first question has two parts. Primarily, among the six phosphate binders, although OLC seems the most efficient across perimeters of adverse events and binding capability and volumes required, the nearest competitor in terms of these factors is Fosrenol and that is a very widespread generic.

So, first of all, what would be the pricing difference between the two and what's the incentive to upsell OLC against Fosrenol? This may be more of a question for Unicycive, but this would be impacting our volumes. And since you have worked so closely on this product, maybe you can share some ideas.

Vishnukant Bhutada: Definitely, once they are doing on this, the most important what I – whatever the information we had, it is like a rest all phosphate binder. They have to take eight tablets a day. Here, they have to take only two tablets a day. This is the most important – and this is not, they have to take it every day and it is very painful when it is going to be for the kidney patient to swallow eight tablets a day against which OLC has the advantage of taking only two tablets a day. So the pricing and all probably will be done by them only. It is not under our purview, but definitely when they are doing all these things, they must have taken this into consideration.

Rahil Dasani: Yes, sir. So for the other binders, you are right, it is 8 to 12 tablets, but for Fosrenol, it is three tablets and same is for OLC. So that is what I was trying to understand from the Fosrenol point of view.

Vishnukant Bhutada: Main product is Sevelamer Carbonate you are talking or what now?

Rahil Dasani: Not Sevelamer. This is also Lanthanum Carbonate.

Vishnukant Bhutada: No, Lanthanum Carbonate is not three tablets a day. It is eight tablets a day.

Rahil Dasani: This announcement has been made by Unicycive itself in one of their preclinical trials where they have made comparisons with Fosrenol. The tablets are three for both of these.

Vishnukant Bhutada: No, it is eight tablets a day.

Rahil Dasani: Okay, that's fine. Sir, the second question is, first of all, where are they filing this product initially and where do they plan to file it for the coming two to three years?

Vishnukant Bhutada: Which one?

Rahil Dasani: Where are they filing OLC for now initially and where will they be filing OLC in the next two to three years?

Vishnukant Bhutada: It is only OLC they are filing it somewhere. They are filing for US only currently.

Rahil Dasani: And is that the only plan or will they also target other geographies?

Vishnukant Bhutada: Of course that is for the Japan and China, for other all countries also they are equally seen because these patients are available all over the world. So they will be definitely taking this for the global but the currently main target is for US.

Rahil Dasani: Okay and what will be the total phosphate binder sales being currently done in the US?

Vishnukant Bhutada: I think it is more than a billion.

Rahil Dasani: More than a billion dollars, that is extremely nice. Sir the last question is, Unicycive is to place the binding orders from June and like you said, you will get 5 million tablets pre-June and 15 million post-June. So if you could exactly separate the visibility and you said you will get a binding contract for 4 years. So what would be the volume for each of those years?

Vishnukant Bhutada: For each of those years, it will be a multi-million. Initially, they are giving us by seeing this by June 25, they are giving this 5 million and December 25 is a 15 million. And every year definitely once the patient takes more and more probably with this, without getting this filing and without putting the approval, they are placing this order. That shows that how confident they are on their product.

Rahil Dasani: Got it. That is all for me. I will get back in the queue. Thank you very much.

Moderator: Thank you. The next question is from the line of Krishna Kansara from Molecule Ventures PMS. Please go ahead.

Krishna Kansara: Sir first of all congratulations on winning this very important contract. You are getting selected by a US pharma company and that too for such a critical drug is a very good news for the shareholders. So congratulations on that.

Sir my first question is regarding the broad timeline of this contract with Unicycive. So if you could just walk us through the entire timeline of let us say each milestone or the approval timeline or the commercial sales period. So just a brief idea of when will we achieve each of these milestones and when will the actual revenue from commercial sales will start coming in.

So for example let us say the USFDA approval is expected to come by mid-2025. So, before that also, can we expect some portion of the milestone fees to be received? If you could just give us a brief idea of the breakup of the milestone fee as well as the commercial sales, that would be helpful.

Vishnukant Bhutada: Yes like from this quarter we got the getting the signing milestone. Then on the filing and acceptance we have one milestone. Then probably on approval we have a bigger milestone. And then on a launch.

Krishna Kansara: So this $10 million is the cumulative milestone fees that we will receive over a period of time or is this the upfront fee that we will receive?

Vishnukant Bhutada: No, it is not upfront fee. It is a cumulative fee.

Krishna Kansara: Okay. And sir when will the actual commercial sales, when will they start exactly? So when will they contribute to the revenue?

Vishnukant Bhutada: Their actual sales will start mostly by if they file it in this quarter. Normally it is NDA filing. So their approval will get in 10 months. So even if you take 12 months approval timeline, because this already they have done enough discussions with the FDA. So probably they will be more confident of getting the products max in a one year approval.

Once that is done then before that we have to start the commercial supplies because after getting the approval they will not wait for the supply. So before getting the approval probably we need to manufacture, give them enough supply in the market. So the supply will start from next year for sure.

Krishna Kansara: Next year okay.

Vishnukant Bhutada: Next year first quarter onward it will start.

Krishna Kansara: Okay understood. And sir you mentioned that -- sorry?

Vishnukant Bhutada: Our financial year I was mentioning, not their financial year.

Krishna Kansara: Correct correct. And sir you mentioned that the current agreement is of four years. So is this agreement extendable to, let us say, next few years once the initial agreement tenure is over or is this only for four years as of now?

Vishnukant Bhutada: No, it is four years plus automatically renewal for four years provided with some riders that depends on what we need to perform, what they have to do. I think with that, but totally it is four years plus another four years.

Krishna Kansara: Okay. And sir what would be the tenure of the new drug application that Unicycive will file? So is it five years or is it more? I am just trying to understand the runway that is available for us?

Vishnukant Bhutada: So it is for definitely it is more than that five years.

Krishna Kansara: Okay.

Vishnukant Bhutada: Because now they have 20 years. I think it will be not less than 10 years or 12 years for sure, but I am not knowing exactly frankly, but I think once it is a NCE molecule so you can understand they have enough runway.

Krishna Kansara: Correct. Okay sir. Thank you sir. That is all from my side.

Moderator: Thank you bye. The next question is from the line of Deepak Sharma who is an investor. Please go ahead.

Deepak Sharma: hello,ya, Sir thanks for the opportunity and congrats for the achievement. Can you please put some color on the EBITDA margin in this molecule?

Vishnukant Bhutada: It is a NCE molecule. So I think we are the exclusive supplier for them. So we have enough like CDMO margin like we have the margins in this that much we can tell you above 50.

Deepak Sharma: Above 50? 5 0?

Vishnukant Bhutada: Yes.

Deepak Sharma: Okay. And please you are talking about the four year contract. So the number you have given there 15 million tablets.

Vishnukant Bhutada: No no**,** 15 million is only for the tail supply, we have to supply before December. It will go to multimillion later on every year. It is just initial signing they have given it.

Deepak Sharma: Okay so the total revenue which we are expecting this is $10 million for the four years?

Vishnukant Bhutada: No no no, 10 million is only licensing and the sales volume and that figures are different than this. The 10 million is only licensing fees.

Deepak Sharma: Okay licensing.

Vishnukant Bhutada: Which will be completed before the launch. So after that there is a sales revenue.

Deepak Sharma: Okay sir. Thank you sir.

Moderator: Thank you. The next question is from the line of Neha Kharodia from Abakkus AMC. Please go ahead.

Neha Kharodia: Am I audible,

Moderator : yes madam pleas go head,

Neha Kharodia: Yes. Good morning and thanks for the opportunity. Sir I just wanted to understand how big the revenue generator can this project be for Shilpa?

Vishnukant Bhutada: It is a multimillion, but I think today projecting for the next year we have some indications from them, but currently telling will be difficult but it is a substantial revenue for Shilpa. That much we can tell you.

Neha Kharodia: Okay. Can we quantify it in some way?

Vishnukant Bhutada: No, currently I cannot do that, but it is a substantial revenue. That much I can tell you.

Neha Kharodia: Okay. And sir, when you mentioned that the capex will be funded by the innovators, so is it like totally -- the capex amount is that we are expecting for the project?

Vishnukant Bhutada: Totally, almost they are giving around $6.5 million.

Neha Kharodia: And that will be the total capex done or like we also will have to do some of the capex?

Vishnukant Bhutada: No no. We are not doing. This is for one dedicated block. We are putting it only for that.

Neha Kharodia: Okay. And sir, in terms of asset turnover for this project?

Management: asset turnover is the following around, So Neha, I think you are asking the same question in a roundabout manner. When you talk about the revenue potential and all, I think Mr. Bhutada has already indicated that we may not be able to provide or quantify the amount exactly. I think we will have to, you just need to wait and see how it progresses.

Neha Kharodia: Okay. Sure. Thank you.

Moderator: Thank you. The next question is from the line of Sanjay Kumar from ithought PMS. Please go ahead.

Sanjay Kumar: Hi. Thanks for the opportunity. So, in the previous question, you said that they are providing 6.5 million for the capex. Over and above that, we will be receiving 10 million in license payments. This, I believe, will be spread over 5 years according to Unicycive Annual Report. Is that right?

Vishnukant Bhutada: No. Once it is before the approval of NDA, almost 95%, 90% of this will come. Once it is launched, it may be 1 million. That's all. So, once it is approved, then before that, 9 million will come to us.

Sanjay Kumar: Okay. So, and once this milestone is, licensing is done, do we have any milestone based on sales or will it only be sales-related revenue that we will be getting?

Vishnukant Bhutada: No. Only sales-related. Then, the milestone doesn't come into the picture because in actual, it starts.

Sanjay Kumar: Okay. So, on that sales, we are saying we will be doing 50% EBITDA margin.

Vishnukant Bhutada: It's tentative.

Sanjay Kumar: Okay sir. So, and second, in our PPT, we have mentioned that we have three NDA filings of which two is already approved. The third one was mentioned as pending. Is this the pending NDA that we were talking about?

Vishnukant Bhutada: No.

Sanjay Kumar: Or is it something else?

Vishnukant Bhutada: It's a different one.

Sanjay Kumar: Okay. That's still in pipeline.

Vishnukant Bhutada: Yes, that's different.

Sanjay Kumar: Okay. So, that's it from my side. Thank you.

Moderator: Thank you. The next question is from the line of Girish Bakhru from OrbiMed. Please go ahead.

Girish Bakhru: Yes, just a clarification. Actually, you say this is a new product. Is it NCE? I mean, I'm just trying to clarify. Once approved, will it have NCE exclusivity?

Vishnukant Bhutada: Yes.

Girish Bakhru: So, for 5 years, like any other product, because Fosrenol being Lanthanum also, I mean, is there a certainty the FDA will approve another Oxylanthanum as an NCE or it will be just approved as a new product?

Vishnukant Bhutada: It's NCE.

Girish Bakhru: Okay. And just on the 4 year contract, can you give color on how pricing generally typically moves in such kind of a contract?

Vishnukant Bhutada: Pricing will be telling difficult for me. But as I mentioned, NCE molecule has a good, very advantageous product they are launching into the market. Their pricing is also very good and they are also a very good company. They are also giving us enough money.

Girish Bakhru: But in case their acceptance in the market is low, they are allowed to, of course, negotiate with you for lower pricing, right?

Alpesh Dalal: Girish, I think some of these things are commercially very sensitive matters. We wouldn't be in a position to talk about it in advance. So, kindly pardon us.

Girish Bakhru: Sure. If you could give indication, are there any committed volumes under the contract?

Vishnukant Bhutada: As would be 20 million. Currently, they are doing the binding purchase but that's not that we have it currently.

Girish Bakhru: Okay.

Vishnukant Bhutada: And of course, once they launch it, they will give. Once they are getting it near to approval, the more and more binding orders will come.

Girish Bakhru: Sure. Thank you so much.

Moderator: Thank you. The next question is from the line of Harsh Bhatia from Bandhan AMC. Please go ahead.

Harsh Bhatia: Yes sir. Thank you. Good morning. Just two quick questions. One, sir on this four plus four-year timeline of the manufacturing agreement, should we assume that for the first four years, we will be the exclusive suppliers because the binding agreement is for the first year? So, should we assume that exclusivity is for the entire four-year period? I'm just trying to clarify. It may be repetitive.

Vishnukant Bhutada: Yes, it's for four years exclusive.

Harsh Bhatia: Okay. And last clarification, this manufacturing agreement is a global manufacturing agreement rather than only U.S. manufacturing agreement, right? This will be a global manufacturing agreement?

Vishnukant Bhutada: Yes.

Harsh Bhatia: Okay, sir. Thank you. Congratulations.

Moderator: Thank you. A reminder to all participants, ladies and gentlemen you may press * and one to ask question, The next question is from the line of C Srihari from PCS Securities. Please go ahead.

C Srihari: Yes, thanks for the opportunity am I audible, hello,

Moderator: yes please go ahead,.

C Srihari: So, my question is, the innovator has another molecule, LDC, which is comparable and that is also in Phase 3 currently. I think it's a pending FDA approval. So, can you please throw some light on that?

Vishnukant Bhutada: This is LDC, same lanthanum oxycarbonate.

C Srihari: That's right. Yes.

Vishnukant Bhutada: Oxylanthanum carbonate and lanthanum deoxycarbonate. Both are the same.

C Srihari: Both are similar?

Vishnukant Bhutada: Yes. So similarly that is the same. We call it LDC, you call it lanthanum deoxy carbonate.

Moderator: sorry sir, I request you to use your handset, you are not audible, you have lot of noise in your background

C Srihari: , is it better now,

Moderator: yes sir, please go head,

C Srihari: Yes so basically based on what I've read, I mean, they've already done the filing for LDC and USFDA has some queries.

Vishnukant Bhutada: Lanthanum deoxy carbonate, is that talking or which one you're talking?

C Srihari: I'm talking about LDC.

Vishnukant Bhutada: Lanthanum deoxy carbonate. No from FDA, they must have taken the clarification not the filing.

C Srihari: So you mean to say LDC and [LPC] are the same molecule?

Vishnukant Bhutada: Yes.

C Srihari: Okay, thank you.

Moderator: Thank you. The next question is from the line of Rahil Dasani from MAPL. Please go ahead.

Rahil Dasani: Yes. Hi, sir. So, just to confirm about the client funding the new plant you said the total spend would be 6.5 million and that's what we are spending wholly on the plant, right? Nothing from our side?

Vishnukant Bhutada: Yes.

Rahil Dasani: And what would be the capacity of this in terms of tablets?

Vishnukant Bhutada: It's not tablet, it's an API plant. It's not for tablet.

Rahil Dasani: Okay. And if you can just share maybe in some terms of utilization as to how much would this plant suffice in terms of the supply? It would suffice for the next two years, for the next one year?

Vishnukant Bhutada: It will definitely suffice for the next two, three years.

Rahil Dasani: Okay. And when is this unit commercializing?

Vishnukant Bhutada: Once we complete this, it is not that the existing suppliers of API will do from our existing blocks. It is not that we are not stopping to wait for this getting the block ready. This block will get ready in the next one year.

And then when they feel that there will be an increase in the volume, so they have given us saying that, you please put us the dedicated block for us which will not hamper their deliveries. That is the reason why they are funding us for this dedicated block. So currently we are supplying from our and this will take care of their supplies.

Rahil Dasani: And the next question is, which other search projects are being done, which are closer to commercialization stage or even have a significant potential in terms of the molecule?

Vishnukant Bhutada: I have not understood your question.

Rahil Dasani: Which other search projects like OLC are in the pipeline, which are closer to commercialization stage or even have a significant potential in terms of the molecule?

Vishnukant Bhutada: Currently, we are talking only on OLC today.

Rahil Dasani: Got it. The last thing is, I was again going to the clinical trial reports of Unicycive. The Fosrenol, I am sorry to repeat but the tablets required are again three. Yes, the weightage and the surface area is higher but the tablets required are three. So maybe if not for this call but for next call, if you can confirm this so that we can get a lot better idea on this.

Vishnukant Bhutada: I said it is eight.

Rahil Dasani: Okay, sure.

Vishnukant Bhutada: Thank you,

Moderator: Thank you. Reminder to all participents you may press * and one to ask question. As there are no further questions, I would now like to hand the conference over to the management for closing comments.

Vishnukant Bhutada: No, thanks for attending this conference with the short notice. We are committed to deliver such complex molecules in the near future also. Shilpa being the specially working on such type of projects since last four or five years and we continue to do that. That much we can say on this. Thanks for attending all.

Moderator: Thank you. On behalf of Shilpa Medicare Limited that concludes this conference. Thank you for joining us and you may now disconnect your lines.

Vishnukant Bhutada: Thank you.