



Shilpa Medicare Limited

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17 August 2023

To
Corporate Relationship Department
BSE Limited,
1st Floor, Rotunda Building,
P.J. Towers, Dalal Street,
Mumbai – 400 001.

To
National Stock Exchange of India Limited
Exchange Plaza, 5th Floor,
Plot No.C/1, G Block
Bandra Kurla Complex, Bandra (E)
Mumbai – 400 051.

Dear Sir/Ma'am,

Scrip Code: BSE- 530549/ Stock Symbol: NSE – SHILPAMED

Sub: Transcript of the Q1 Conference call

In furtherance to our intimation dated 7 August, 2023 and 11 August, 2023 with regard to the Q1 FY24 Conference call held on Friday, 11 August 2023 at 03.00 PM IST, please find the enclosed transcript of the call.

Thanking you,

Yours faithfully

For **SHILPA MEDICARE LIMITED**

Ritu Tiwary
Company Secretary and Compliance Officer



Shilpa Medicare Limited

Q1 FY24 Earnings Conference Call

August 11, 2023

Moderator: Ladies and gentlemen, good day and welcome to the Shilpa Medicare Q1 FY24 Earnings Conference 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. And now hand the conference over to Mr. Siddharth from CDR India. Thank you and over to you, sir.

Siddharth Rangnekar: Thank you. Good afternoon, everyone, and welcome to the conference call hosted by the management of Shilpa Medicare Limited to discuss the first quarter performance for the period ended June 30, 2023 and the discussion on the strategic initiatives that are underway. The management is being represented by Mr. Om Prakash Innani, Chairman of the company, Mr. Vishnukant Bhutada, Managing Director, Mr. Alpesh Dalal, Chief Financial Officer. We shall have Mr. Vishnukant Bhutada lead the discussion with his perspectives on the business performance and the strategic progress. He will be followed by Mr. Alpesh Dalal, who will give his views on the financial and operational highlights.

After the management comments, there will be an opportunity for getting your queries answered. Before we commence, I would like to state that some of the statements made on today's call could be forward looking in nature and a detailed disclaimer in this regard has been captured in the conference call invitation which is available on the Stock Exchange website. I would now like to invite Mr. Vishnukant to take this discussion forward. Thank you and over to you Mr. Vishnukant ji.

Vishnukant Bhutada: Thank you for joining us today on the call. I will be sharing prospective of Shilpa Medicare first quarter results 23-24. I will commence with the operating progress and combine it with the highlights on the strategy. I will be followed by our CFO Alpesh who shall take forward the discussion on the financial aspect. Subsequent to our speech, we will be glad to address queries and concerns from the participants. I will commence with the key updates of the quarters.

I will go by the segment wise first. Within the API, we have completed the augmentation of our facilities to offer the peptide, polymer, CDMO services. These new subcategories within API represent a step up in a value creation for us, but conversely are associated with the certain gestation period. We are taking exhibit batches of the initial products of our clients in the peptide and in response are likely to translate into the firm commitment. This segment also makes the polymers, again which are also high end product within API, which we are making for the

innovators.

Our CDMO business is ramping up well to a sizable order position. We are also venturing as per the strategy into the non-oncology API. Wherever we can make an impact, timelines have been followed for the delivery of the project which has boosted the CDMO business and clients are providing new contracts. During FY24, two new DMFs has been filed and to add around 231 DMFs, we have filed across the geographics. Some of these APIs are oncology products that will see the expires throughout around up to 2028.

Our focus is also on developing the API that can replace imports where these are presently coming from the outside of the country. By enhancing utilization and capabilities of our existing products, we are seeking to enhance the engagement with the existing clients for our core API and this will show the results. And all these things considered, I am confident that our API business once again will be the crown jewel of the performance. The again the highlights on the formulation, I will just start it.

We have on oncology the new drug application from the Pemetrexed injection 1000 mg, 100 mg, 500 mg and the 100 mg formulation approved by the US FDA. This was the first NDA approved in our Shilpa. The unique formulation supply as a ready-to-use product solution and this product approval from the third party manufacturing sites. Commercialization arrangement is in place for the Amneal pharmaceutical LLC for the US market.

Planned to launch under J-Code program by Q4 FY 23-24. US market size approximately is around USD 735 million. We filed the, again, one Nilotinib capsule, which is also filed into Germany. And this is a centralized BCP procedure we are filing. The product filed in the Europe and expected launch of this complex product will be Q2 FY24, partnered already with the two customers in the European market. And European market is approximately USD 418 million. And for US, the pivotal studies also ongoing. We have one more product that is called as SML NUD07. This has also entered into the phase 3 study. We already received the CDSTO approval for this to start the phase 3 clinical study. The most important is the indication of this is NAFLD that means non-alcoholic fatty liver disease. This we will be able to complete this study Q2 or Q3, FY24. This is the most common liver disease which is affecting almost all part of the world and the huge population pool is there for this. And this is the unmet need where you know they need these particular drugs on this NAFLD and we are happy to say that the phase 3 studies already started on that.

Then the first partnership deal in to the transdermal patch. So as you know that the transdermal patch also is a very complex development which is for the future it is required and we have invested for the 2-3 years in this.

We are happy to say that the first partnership we have done already with the European company on this and the pivotal study we will plan in Q2-Q3. While Ema Science device already we have taken it on that and the size of this molecule is around USD 240 million. Then we have launched the film formulation also into the US market. We are partnering with the other companies, vitamin D3, melatonin, methylcobalamin, simethicone and green tea. These are all dietary supplements has been you know marketed now into the US. Then we have received on a biosimilar update, we have received the high concentration Adalimumab the into the India market. Hopefully, we should be able to launch in this quarter.

We already partnered with, we are going to launch with us as a Shilpa and one more with the big Indian company.

Then we have done this recombinant albumin already phase 1 study already initiated. As you know that NBE, ie new biological entity status we already received it from the authority and this phase 1 study will be completed by December 23. Then one more molecule Aflibercept, Phase 3 study already we have received the approval from the CDSCO for the starting the study. As everybody knows that Aflibercept is a very complex ophthalmic molecule and we already completed phase 1. Now, Phase 3 we are starting it, Phase 3 we will start by next quarter we will start the Phase 3. And this is what on the complex formulations we are doing it.

We are on a crucial task to facilitate the launch of new products under the API and Formulation as these will bring us the predictable cash flows. The new segments are closer to giving visible contribution from the commercialization of the product and will help us to enhance our margin profile overall. As touched upon by me earlier, we are looking at rationalizing R&D expenses and monetizing our work as swiftly as possible.

You will see the operating cash flows from the year, which Alpesh will explain you separately. We are doing several cost-cutting measures into the R&D including the formulation R&D without compromising on the niche segment. With that, and on the US FDA front, the update is same as we have completed our all remediation measures and we are waiting for the FDA to come and do the inspection. Other than US, almost all the regulatory authorities in the world have approved our facility and were continue to export to the other part of the world including US some of this the shortages product.

And the unit 7, the interim unit 7 analytical lab has cleared USFDA inspection recently with VAI classification in March, April 23. This is the second USFDA inspection within one year. The Dabaspet Unit 6 which is MHRA approved has started commercialization of the some of the ODF products in the nutraceutical and dietary supplements category in the US market. And soon we are going to launch into the RoW as well as in the European market. One product Dossier ODF has been completed satisfactorily viewed by the UK MHRA and expected to get the approval in the recent future. Commercialization of some of the products into India is ongoing either from the unit 4 site or the CMO site.

Commercialization is U.S for one more OSD product will start from the CMO site. With that I draw to the close to my opening remarks and hand over to the CFO Alpesh to continue. Alpesh, over to you.

Alpesh Dalal:

Thank you sir and good afternoon, everybody. I will provide the financial highlights for the quarter, for the first quarter of the current financial year. So, from revenue perspective we reported a flattish quarter with revenues of INR262 crores on a consolidated basis. However, we witnessed strong improvement in our profitability backed by our focused efforts on bringing in operational efficiency and improve monetization of our investment in R&D to higher licensing fees.

Consequently, our EBITDA stood at INR50 crores higher by 74% year-on-year and 23% sequentially. The improvement in EBITDA has helped us turning in black at PAT level as well on a consolidated basis.

On the debt front, our net debt as at the end of the quarter stood at INR745 crores compared to INR764 crores at the end of the previous quarter, resulting in a lower net debt at about INR19 crores. And a quick update on our capex that we have incurred. During the quarter we have incurred capex of roughly around INR30 crores, and of which majorly it has been in our albumin facility where we have invested roughly about INR24 crores for the

albumin.

And I also wanted to update all of you about another major development which we have completed just yesterday where we have successfully completed issuance of NCD of INR450 crores to select marquee investors on private placement basis. Now this NCD issuance will help us reorganize our debt portfolio in a manner that helps us spread our repayment obligation in line with our expected future cash inflows with an initial moratorium period of 27 months.

So, this should ease out the overall pressure that we had on our cash flow. So, with that intent, this arrangement has been carried out. And on operation front, as Vishnukantji was mentioning earlier, that we are prioritizing the launch of products that are ready in various segments that he spoke about. And we are also ensuring that our overall cash flow gets restored, right?

So, obviously, these are all being done on the back of efforts that we are doing to curtail our spend on R&D without really impacting any of our developmental efforts which are required for our business purpose and we are also optimizing our working capital requirements to generate sufficient operating cash flows. So, as I had indicated last time also that we had positive operating cash flows.

During this quarter also we have had decent operating cash flow being generated of roughly about INR70 crores that we have done. So, overall I think the business is coming back on track and with those closing remarks, I would like to open this forum for Q&A.

Moderator: Thank you very much, sir. We will now begin with the question-and-answer session. Thank you. We take the first question from the line of Shivan Sarvaiya an Individual Investor. Please go ahead, sir.

Shivan Sarvaiya: Hello, thank you for the opportunity. So a few questions from my end. So just a clarification, you said the NCDs that were raised were for a moratorium of 27 months. Did I hear that correctly?

Alpesh Dalal: Can you repeat your question, please? I didn't hear it clearly.

Shivan Sarvaiya: Hello, can you hear me?

Alpesh Dalal: Yeah, we can hear you. Can you please repeat your question?

Shivan Sarvaiya: Yes, sir. This is just a clarification on your opening remarks. You said the NCDs that you issued yesterday INR150 crores. The moratorium is 27 months. Is that right?

Alpesh Dalal: Moratorium is 27 months. That's correct.

Shivan Sarvaiya: Okay, sir. And the rate of interest here that we would be paying?

Alpesh Dalal: The rate of interest is slightly higher than the normal rate, but it helps covering up on the operational size where we are able to get better terms on our supply prices. So, overall we'll be able to more or less take care of the impact of increased cost that we may have.

Shivan Sarvaiya: Correct, and sir if you could quantify that rate?

Alpesh Dalal: I think some of these things we may not be able to immediately quantify, but we'll be able to provide you in due course.

Shivan Sarvaiya: Sure. And so my next question is on the API business and this pertains to slide number 20. So historically, we've been bifurcating the API business between Onco, Non-Onco, CDMO, CRAMS, and others. So, at this time, the CRAMS piece does not show here. Is there a change in the way we look at the API business?

Alpesh Dalal: See, basically, CRAMS business is something that, if you recall, in the previous calls also we indicated that by design we are bringing it down and we have now stopped doing that particular CRAMS business because that was a planned move that we had. Since, there is no CRAMS business that we are doing anymore, that particular block has been taken out.

Shivan Sarvaiya: Okay, okay. And in terms of the CDMO service, could you just explain a little bit more, a bit nuanced way, what is exactly that we do here in the API piece when we say CDMO/ Service?

Vishnukant Bhutada: CDMO we are doing the -- especially for the new drug development, so some of this like either it is into the any special molecules if we have to work for them, some of these we have to make the pilot batches, we have to make and give them for the phase 1 study or phase 2, phase 3 study. These are the things particularly covered in the CDMO-API business.

Shivan Sarvaiya: Okay. And sir, what would be the client profile in the different number of clients, the phase at which the molecules are currently some colour there?

Alpesh Dalal: Client profile, what kind of clients do we have?

Vishnukant Bhutada: These clients are, some of the clients are the U.S; region wise I can tell you more is from the US, not from the any other part, some other part, but 75%, 80% is coming from the U.S, where such development takes place more. And typically what happens in the US, the smaller company takes up to phase 1 or the phase 2 and then the bigger company acquires that particular brand and they take to the phase 3. This is what is happening. We have the mix of all.

Shivan Sarvaiya: Okay, fine. And sir in terms of others, what is there in facing others and why is it so volatile in the sense, quarter-on-quarter , we see a lot of volatility in these numbers?

Alpesh Dalal: So I think on the other side, actually there isn't much volatility. What has happened was that in Q1 of last year, obviously this other also includes whatever CRAMS business that we had, which is not there in this quarter. So, that is one portion that results into this difference which is coming up. And the other portion in last year Q1 that we had was that we had done this slump sale of our business from Shilpa Medicare to Shilpa Pharma. So, goods which were on Highseas basis, we had to do a facilitation transaction to ensure that we were able to import the goods correctly. So there was a Highseas sales done, which was a one-time small Highseas sales done of about INR16 crores, which is sitting and getting reflected here in others.

Vishnukant Bhutada: And to add this, currently we have almost 7 active IC projects ongoing currently into the CDMO. We have different projects, as I mentioned, US, Europe, some of these from Europe, this is what I can tell you.

Shivan Sarvaiya: Okay, okay. Okay, sir. And one more question on the formulation part. So the license fees part of the business, could you just help understand how the license fees are on, what is the -- is this like a stable cash flow or these are based on certain milestones and how much of the INR53 crores would be license fees and how much would be PDC

Alpesh Dalal: Your voice is not clear. Voice is not coming very clearly.

Shivan Sarvaiya: Can you hear me now?

Moderator: Sorry to interrupt Mr. Shivan, are you on your headset sir?

Moderator: If you are on a headset, I would request you to switch to your handset.

Shivan Sarvaiya: Yes,

Shivan Sarvaiya: Hello, am I audible?

Alpesh Dalal: Yes, Shivan yes, slightly better now.

Shivan Sarvaiya: Okay, so my question was on the license fee, PDC in the formulation business. Could you explain the flow of the license fees, the way it occurs, on what basis are these license fields earned, and what is PDC, and if you can bifurcate between license fees and PDC?

Vishnukant Bhutada: As you are probably aware any licensing fees once it is given or agreed that means, that they have due-diligence already has been done of that particular product and we get the initial milestone or the second milestone once we file in that country. There are several initiatives and signing after verifying and they are ascertaining that they are confident that what we have enough material to license this particular product in their region. This is the one initial requirement. for doing, I am accounting or agreeing for any milestone deed. So, this is what it has been done and if the milestone payment or the licensing fees is not a new for us. Licensing fees every quarter we are getting it. Sometimes it is little more or sometimes that particular milestone or that particular quarter, there is why, we take into that quarter more.

But this shows that the, strength of our R&D and strength of our regulatory and strength of our plant and the people. So, once they are confident on all aspects, it is not only on the product, it is not only on the regulatory, it is not only on the pivotal and the pilot data, which you have generated. So, these are all has been taken into the consideration including the plant audit sometimes. So, these are all safety, technical, all once that is done, then they will agree for the licensing fees.

This is what the major, I can say about the licensing fees and this is a regular in nature. The PDC is a product development charge we call it, I think Alpesh can explain more on that. But the, each of the licensing fees, whatever we are getting it, it is a differentiated product, which we are doing it for that like a specially as I mentioned the

transdermal patch, what we got it in this particular spot licensing has been done.

The second the NDA approval, what we got it. That licensing milestone also has been in this particular quarter. One NCE molecule, which we are doing it from the API to the formulation development, that also has been captured in this particular quarter. And this is the beginning, this is not the end. Here from here, again it starts more. Not only the licensing revenue, as well as the commercial sales also is, that is a part of this platform.

Shivan Sarvaiya: Okay.

Alpesh Dalal: So, Vishnuji mentioned that there are different milestones, there, which are captured, and based on, as and when we keep achieving those milestones, we keep receiving our licensing fees. So the licensing fees that we have received this time also is a combination where we had signed up certain agreements in the past, where we have achieved a new milestone and we have received those fees. In certain cases, we have entered into a new arrangement, which has given us new licensing fees and all. So it's a combination of the two. And it's a very regular feature in any formulation business in the pharma industry.

Shivan Sarvaiya: Okay. So do we expect this to sustain, the INR53 crores, and growth from here? Like is this the end of a phase and which we keep growing on?

Alpesh Dalal: On a rate, this is, based on the R&D pipeline and it's a churn that happens. So, there are, as and when newer products keep getting developed, that ends up providing new opportunities. So, it is a continuous process that you have.

Shivan Sarvaiya: Thank you. I will come back in the queue. Thank you.

Alpesh Dalal: Thank you.

Moderator: Thank you, sir. We take the next question from the line of Kaustav Bubna from BMSPL. Capital. Please go ahead, sir.

Kaustav Bubna: Yes, hi. So, last time we spoke, Alpesh, the message was that, the company strictly does not want to add more debt to its balance sheet. And then we come out with another INR500 crores, INR400 crores, INR500 crores of debt. So I wanted to understand, why the shift of strategy and also what is our total debt now after this debt NCD issuance. And also, is it fair to assume that, you have chosen to go the debt route instead of the rights issue route? Because you all had come out with a rights issue notice and then didn't get back on that. But then instead raised NCDs. So then does the rights issue stand canceled?

Alpesh Dalal: Okay. So let me answer the first part first. Whilst we have taken this NCDs of INR450 crores, this has been predominantly utilized to retire our existing term loans. So, it is not adding on to the debt burden. Right, this was just as I mentioned in my opening remarks as well, that this was more of a reorganization of our debt, right. So, obviously, there is slight increase that would happen because of the quantum that we have got, but it is still within, our overall acceptable limits.

Second question on the rights issue, we basically are not really, rights issue is still very much part of our strategy.

Rights issue typically requires certain regulatory timelines to be completed and all. And in the meantime, we wanted to, as I mentioned earlier, reorganize our debt. So this is only towards reorganization. This is not towards increasing our debt. And, rights issue again is planned with a predominant intent of deleveraging our balance sheet. And, we will do so once we have that rights issue in place.

Kaustav Bubna: Okay, great. Thank you so much.

Alpeh Dalal: Thanks, Kaustav.

Moderator: Thank you. We take the next question from the line of Shaikh Mohammed Ayaz, an individual investor. Please go ahead, sir.

Shaikh Ayaz: Good evening, sir. Congratulations for the excellent set of results. I just want to ask that, what kind of performance we expect from the further process, whether this performance will continue or we can expect some bullishness in that?

Vishnukant Bhutada: That is the reason why I said that to make the predictable cash flow, I have given in opening remarks itself, mentioning that the predictable cash flow is very important for our company. We were losing for, last one or two years because of this unpredictability, not because of us, but on a regulatory front from the US FDA. But now we are coming back on track and we fairly feel that, this will definitely continue, not only continue, it will improve.

Shaikh Ayaz: Okay, sir, thank you.

Alpeh Dalal: Thank you.

Moderator: Thank you. We take the next question from the line of Shivan Sarvaiya, an individual investor. Please go ahead, sir.

Shivan Sarvaiya: Thank you for the opportunity again. So, question on the Albumin part. So, what would be the total investments we would have done in the Albumin project till date?

Vishnukant Bhutada: Total investment where, you are asking? No, but where?

Shivan Sarvaiya: In the Albumin business?

Vishnukant Bhutada: No, this is the different, we are doing some in the capex, some in the development, what is the argument?

Shivan Sarvaiya: Yes, suppose, what would be in the capex and what would be in the development part, the total investment?

Vishnukant Bhutada: I think, we will come back to this.

Shivan Sarvaiya: Okay, sir. And so we were supposed to start selling the recombinant human albumin as an excipient this year. So is that on the card?

Vishnukant Bhutada: Yes, definitely it is there on the card. This year probably what will happen, we will give them the excipient grade

because now we are preparing the drug master file also on this. And once we try to give the, submit the samples, getting it there in the formulation approvals and all, we will start definitely this year.

Shivan Sarvaiya: Okay, so far, by when? And so what is the top line that you expect to be done with the excipient sales?

Vishnukant Bhutada: Now it is a very small quantity. We have currently 1,000 liters of, for months. So I do not think we will have any substantial sales from this excipient grade. But yes, anyhow whether you have a longer or smaller, you need to get established yourself and get it approved vendor. That major work will be completed before our commercial facility put into that operation. Otherwise that will take more time. Here, what we are trying to do is, with the existing facility, completing the DMF, submitting the sample to the customers, getting it approved in that formulation and start commercial supplies, whenever you get.

Shivan Sarvaiya: Okay, sir. And sir, in terms of CDMO for the biological piece, where are we currently, are we expecting the revenue to flow, if they are flowing, what could that be?

Management: Yes, definitely the CDMO is the biggest opportunity into the biologics. We are continuing to explore this. We have some good leads are also coming into that.

Shivan Sarvaiya: Okay, sir. I will get back to you offline for the capex on the albumin part of the business. Thank you.

Vishnukant Bhutada: Sure.

Moderator: Thank you, sir. Thank you. As there are no further questions, I would now like to hand the conference over to the management for closing comments.

Alpesh Dalal: Thanks, Seema. Basically, thanks a lot everybody for coming and joining the call. And we hope to continue with the good performance that we have had this quarter. And we will keep in touch with you and keep updating you about the progress of the business that we have. Thanks a lot. Thank you.

Moderator: Thank you. Ladies and gentlemen, that concludes this conference. Thank you for joining us and you may now disconnect your lines.