Innovating for affordable healthcare

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Date:17th November 2022

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National Stock Exchange of India Limited
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Dear Sir / Madam,

Sub: : Intimation U/R 30 of the SEBI(LODR) Regulations - Transcript of Q2 H1 FY23 Conference Call
Ref: Stock Code: NSE: SHILPAMED/BSE-530549

In furtherance to our intimation dated 12th November 2022 & 14th November 2022 with regard to the Q2 H1 FY23 Conference Call held on Monday , 14th November 2022 at 11.30 AM IST, please find the enclosed transcript of the call.

Thanking you,

Yours faithfully

For **SHILPA MEDICARE LIMITED**

RITU TIWARY
Digitally signed by RITU TIWARY
Date: 2022.11.17 14:40:41 +05'30'

Ritu Tiwary
Company Secretary & Compliance Officer

Shilpa Medicare Limited

Q2 FY 2023 Earnings Conference Call Transcript

November 14, 2022

Siddharth R: Good morning, everyone and welcome to the con call hosted by the management of Shilpa Medicare to discuss the quarterly performance and strategic initiatives underway. The management is being represented by Mr. Omprakash Innani, Chairman of Shilpa Medicare; Mr. Vishnukant Bhutada, Managing Director; and Mr. Alpesh Dalal, Chief Financial Officer.

Mr. Vishnukant Bhutada will lead the discussion with thoughts on the business model and strategy. He will be followed by Mr. Alpesh Dalal, who will elaborate on the financial performance. There will be an opportunity to get your queries addressed at the end of the opening remarks from the management.

I would like to share, at this point that certain statements made on today's call could be forward-looking in nature and a detailed disclaimer in this regard, has been mentioned in the earnings presentation, which is available on the stock exchange website.

I would now like to invite Mr. Vishnukant to take the discussion forward. Thank you. And over to you, sir.

Vishnukant B: Thanks, to all. And thank you for taking the time and joining us on the call today to discuss the second quarter performance of Shilpa Medicare Limited and strategic development on the business. I will share the updates with you segment by segment, and at the end of the discussions we'll have the Q and A session.

For the ease of the reference, I will follow the same format as the previous call and share the incremental updates business segment wise. Shilpa Medicare as you know that it is present in a multiple segment, API, Formulation, ODF, Transdermal, and Biologics.

As usual, I will commence with the API. Within the API, we offer Oncology, Non-Oncology, Peptide, Polymer, CDMO and Intermediates. In this, the business approach, we have focused initially on a complex Oncology products and high end on the Non-Oncology offerings. As on 30th September 2022, we had about 40 plus Onco APIs and 18 plus non-Onco APIs in the market, along with around 219 DMFs file across the geographies. In the US, EU, these are all segments and including the ROW markets, we have filed our DDMS, including Canada, Japan, Russia, LATAM, and China.

In our Oncology business, where we enjoy the leadership positions in number of the products. We work on optimizing our operations by continuously improving our processes and enhancing the best size of the Q molecule to retain the competitive

edge. On the non-Onco front, we have now commercialized few key molecules, which we started working on the last few years. Now we have started the commercialization of products like Acetylcholine, Phenylephrine, UDCA, Ursodeoxycholic acid, et cetera. And we are now taking at least another three products maybe before December to see that these are all three products at least we will take the exhibit batches and which will help us to grow our revenue in non-oncology for the next years. So, every year at least four to six products will be added in the non-Oncology segments.

Our efforts on the Peptides have started showing the promising results with our first peptide product, having complete plant validation, during this quarter. We have five more products in a various stages in this segment. Peptide being a very niche area in a complex area. Of course, it took little time, but we're happy to say that the technology which we adopt in the Peptide, very few companies are adopting this and our commercial plant is also for making this peptide is ready, from there only we are taking this exhibit batches.

On the CDMO side, we are working on developing complex processes for MNCs of higher APIs, I'm happy to say that we have secured three new projects during this quarter. This revalidates Shilpa's capabilities in handling the complex sciences. I wish to reiterate here, that we're pursuing an initiative to enhance the competitiveness with the API, which includes strengthening backward integration into the internships, build improvements in existing APIs, and build upon the scale of the manufacturing.

Moving on to Formulations. We produce Liquid and Lyophilized injectable sterile dry powder injectable and oral solid in Oncology and adjunct therapies. In additions, we have developed a portfolio of complex products for the international market. I am happy to share that this quarter, we have launched two new products in the European market Pemetrexed RTU injection, which is a first of its kind in the world. No one has the ready to use Pemetrexed injection. Other people's, one or two people have ready to dilute, but we have RTU injections. And in Europe, we have received the approval already and we have launched also commercially in the last quarter. In the US we have filed this particular product and we are hoping to get this, the clearance, maybe this quarter or the next quarter. And the Prucalopride also we have launched in the European market.

Also, as an update to what I have mentioned in the last call, we have now received CDSA approval for the Tranexamic acid tropical hemostatic spray, which is a first of its kind in the world. This Tranexamic acid is known for the hemostatic properties, but normally people take orally and in injection. The first time the development of the hemostatic spray will pave away to the, including into the army, dental surgeries, injuries, trauma, there are various applications can be used this Tranexamic acid spray. And this will give a very good opportunity to launch into the India, ROW, EU and US markets.

Additionally, we have not received and now we have received the tentative approval for Tenofovir Alafenamide tablet, as of first to file submission of the NCE-1 of course, the launch date is much later.

So, on the regulatory front, our Jadcherla facility was recently inspected by the Canadian and Australian Authority and the Analytical Services Division at Nacharam, Hyderabad received already the EIR from the US FDA. As far as the import alert, at of our Jadcherla facility is concerned, we are still awaiting the response from the US FDA and we'll update as soon as we hear anything from them. To elaborate more on the US FDA, we have completed our all-remediation measures. And as per the procedures and the commitment given to the FDA, we're submitting all our reports, including the third-party reports to the FDA. Now, we have completed all remediation measures suggested by the third party, including in-house, whatever the findings,

whatever we have done, we have submitted to the FDA already. And we are waiting for now to hear from them on the inspection. I'm happy to share that none of the consultants, or none of the any auditor, or none of the third parties have suggested us to withdraw any ANDA, which has been filed recently. After verifying (inaudible 0:08:22) data, no strategy, no micro relations has been found by any of the inspectors in our, the inspection.

The inspections of the Canadian and Australian Authority was triggered only on basis of FDA and we requested them to come and inspect our facility, which they came and inspected the facility. None of them have shown any critical observation. Of course, a minor observation, which can be addressable, and we are soon to submit all this replies by this month or next month, early.

As on 30th September, we have 188 products with the approved status in the selected market. These dossiers were to have filed. To the addition to this, we have 242 products pending approval across various market in the world.

Moving forward over R&D expenses continuously working towards the developing of ISO ((b)2)s, and complex generics. As it has been a trend for us we look forward to monetize our researched effort through out-licensing this products to the strategic partner. And this has shown that except last quarter, some of the licensing has been made. But some quarters you are seeing the licensing revenues is coming into some quarters, will be more, some quarters will be little lesser.

In ODF and transdermal segments, we have combo like, which is a first of its kind line in the country. We have 22 products in ODF and 6 in the transdermal segment of which 4 products we are commercializing for the US market in this quarter. This would be a aim at both the India and the global market and represents a healthy but niche opportunity where there is a large untapped need among the patient for such offering. And transdermal patch and the oral dissolving films have shown a great interest in the value additions of the existing products and recently we have mentioned that our ODF facility has already been inspected by the UK MHRA and was approved by them. And the recent we have registered our products, the nutraceutical products in the US and this quarter we are launching these products in the US also.

Moving along, we are pursuing Biologic segments as well, where there is objective to produce the difficult to make the products at our world class facility in Dharwad. We have completed Phase 3 human clinical trials of the high concentration Adalimumab, which is first of its kind in India. We expect to launch in this market in the Q4 post receipt of the Requisite Regulatory Approval.

In Biologics, this is a segment, which has a long gestation period. Now we have came almost to the end where we got the Phase 3 approval of the Adalimumab. We are completing another one or two molecules, one more, another one molecule will go for the Phase 3, now, in the next quarter, once we submit to the RCGM already approval has been received for the application and we'll soon start the Phase 3 study in the next quarter, which is also none of the Indian companies has got the approval on (inaudible 0:11:49)

Of course, this trials and all will take another one year, but I'm happy to share such a difficult molecule has been cracked by our R&D division at Biologics. And to continue to look the CDMO segments also at our Dharwad facility just to monetize the early book so, whatever the other products will take, it's time to launch into the India as well as the other markets. Meanwhile, we are trying to see that the CDMO opportunity, whatever we can get it from this various India as well as from the other customers we continue to look at the CDMO agreements, at our Dharwad facility and check to growth this business through strategic tie ups.

Shilpa Medicare is following a differentiated model within Pharmaceuticals. The key competitiveness in the complex products across the value chain in several segments, we are offerings in the final stage of the market introduction and moving toward this superior business mix. The complex business it takes time and that complex business, majority of the developments has been completed or at the Phase 1, or at the Phase 3 table in the various segments.

So, this we'll be trying to complete, these are all regular updates will be given at the respective area. We will soon update that also. With this, I come to the conclusion -- again, before that I wanted to emphasize on the third-party transfers of our products in the oral and injectable for the US market, where soon this quarter will be early before before March 2023, almost 6 products will be completed for the transfer and next year onwards, we will see that even with this FDA, if it is delayed or with any reason, at least we'll see that the 6 products will be launched in the next financial year.

With this, I come to the conclusion of my opening remarks and would request our CFO Alpesh to share the financial perspectives with you. Thanks for you all for joining this call. Thank you.

Alpesh Dalal: Thank you very much, sir. I welcome all of you to our earnings call for the quarter and a half year ended, September 30th. I'll briefly take you through the financial performance during the period under review.

Now in quarter 2 of the current year on a consolidated basis, our revenues were at INR 267 crore as compared to INR 297 crore in Q2 of FY22. And our gross margins, were at 56% as compared to 66% in Q2 of last year.

Now, this lower gross margins are primarily on account of the pricing pressures that we have witnessed in some of our key products in both API as well as Formulation segments. Also coupled with some cost increase in certain major products that we have got. So, to counter these pressures, the company has taken several cost rationalization initiatives on a proactive business and reduce the overall volatility in the business that we have.

Now, we have also worked towards reducing our overall remedial costs for the Jadcherla site. And that has helped us in reducing the pressure on the margin as well. All these have resulted in EBITDA for the quarter at about, INR 17 crore on a consolidated basis, with margins of 6% and PAT for the quarter at (INR 19 crore), mainly impacted by higher finance costs and depreciation costs.

Moving to the half yearly numbers. This revenues were at INR 537 crore as compared to INR 536 crore. So broadly it has been a flat period, on the comparative basis and the gross profit was at INR 316 crore with a 59% margin. EBITDA was at 8% and INR 45 crore was the number and PAT was at (INR 16 crore), for 6 months of this year.

From a borrowing perspective, our gross borrowing as on 30th, September, 2022 was at INR 802 crore compared to INR 835 crore at the end of September 2021. And the net debt was at INR 755 crore as compared to INR 814 crore at last year. With this brief update on our performance, other numbers are available in our investor presentation.

So, with this brief update, I would like to open the forum for Q-and-A.

Moderator: The first question is from the line of Niharika Jain from Aequitas Investment.

Niharika Jain: Sir, regarding this Tranexamic acid, which we are talking about so is it like a patented product for us? And what kind of margins and price are we looking for this particular product?

Vishnukant B: To answer on this, it's patented all over the world. We have some granted patent in some part of the world, some part of still it is going on, but we'll get this patent of the in the majority market. So, it's first off, its kind in the world. So, we have applied the patent for all over the world. The margins and all of course, you can understand that until and unless we launch this in all the market, we will not be able to comment. But as build the new and the niche products, definitely there will be handsome margins.

Niharika Jain: Okay. And India, when are we planning to launch this particular product, or are we targeting more of like catering to US or global markets for this?

Vishnukant B: No, no, it is for all market. It's a global market. India will, of course be here we will launch first, but specially ROW market will be opening, will be very early and we are in discussions also with some of the companies. So, I think India and ROW will be the first. Europe and US will be the second.

Niharika Jain: Okay. And for the CDMO projects, three projects I think we have been awarded during this quarter. So what stage products are these? Like these are under development stage or preclinical or commercialization? The three products which you mentioned.

Vishnukant B: I will not be able to comment because we have CDA with them, but I can tell you that some of the products, normally the CDMO works like a Phase 1 or Phase 3, Phase 2. So, these are the molecules come to us and these are the totally new, either the totally NCE molecules will be there. Some are in the intermediate form; some are at the API level also. So that much I can tell you. But these are the NCE molecules, and it is at the various stage of this development from those who are developed these projects.

Niharika Jain: Okay. And also, I think in last call you had mentioned that we are the first company to be qualified by for DRDO for some high energy polymer. So, have you already started supplying this? And again, what kind of margins and size are we looking for this?

Vishnukant B: No, no, we are already started supplying to the DRDO on this, but their order, you can understand that getting at DRDO and accruing our products in their inner systems is challenging, but happy to share that they are used our material, they are happy, but they're placing the one by one the orders. We already delivered the one, now we're going to deliver the second order to them. And answering those specific questions, we're working with them.

Niharika Jain: So currently it is not very much, even the size of it, which we have supplied or?

Vishnukant B: No, I don't think I'll be able to specify that. But it is the slow process, that much I can tell you. And it'll maybe next one or two years down the line, this can have a substantial business for Shilpa.

Moderator: The next question is from the line of Ankit Gupta from Bamboo Capital.

Ankit Gupta: In the API business at our Raichur plant, last four or five years, we haven't seen much growth in the Oncology as well as non-Oncology segment. So, we had put up so much investment in the plant, but the ramp up hasn't been that great. So, what are the challenges we faced on the API side that is hindering our growth in this segment? Till now we can still understand the formulation because of US FDA, the impact is there. We haven't been able to ramp up that under API side also it seems the ramp up hasn't been that good.

Vishnukant B: No, I don't think you are correct, ramp up is there. If you see the last two years growth, there is substantial growth in the API segment. What has happened, the CDMO business, which we're doing with the ISBCA, that INR 350 crore has been moved totally in last two years. So that we have replaced and still there is a growth. So, you can understand that there is a growth in the Onco, there is a growth in the non-Onco molecules. Of course, the INR 350 crore is the revenue which was there from the ISBCA that has gone away, but we have replaced that also, with this also. So that is why you are probably seeing it, that there is a growth, but not the substantial as for your definition.

Ankit Gupta: Sure. And sir, on the ICE, do you think, we can again, get back some orders from them or that relationship is now over and there won't be any revenues from ICE?

Vishnukant B: I think this year probably, maybe INR 25 crore, INR 30 crore, next INR 40 crore will be there. So, we are totally now, because we are starting our own Ursodeoxycholic acid also. So of course, that business will come, but slowly it'll be ran.

Ankit Gupta: Sure. And sir, on the API side, we are seeing lot of players have entered the oncology segment and it has become a bit competitive. Any views on the competitive intensity on the Oncology side, especially on the API side?

Vishnukant B: Onco API, I don't see more people are coming. Those who are there, they're only there. So, I don't see that any -- maybe one or two someone, even if someone comes also, but I have not seen any, at least in this -- when we give the quote or when we discuss with our customers, I have not found out that someone serious player has came. Someone must have came in the local or other market, but for the US and other, all regulatory approved apple to apple comparison people are not there.

The second on the competitiveness and the competitions, of course the competition is not coming from the API segment. The competition is coming from the Formulation. So, your API is consumed into the Formulation. So, what happens ultimately when there is a price pressure in the Formulation, the API need to be re aligned with them. And we have very good customer base on the Onco. Normally they do not ask us to reduce the price until there is a price pressure. Our genuine reason for that. So, we always support to our customers and all the customers, those who are there, they're working for not only the existing molecules, for the new molecules also they are working.

Ankit Gupta: And sir on the Biologics side, when do you expect revenues to start flowing in for us?

Vishnukant B: I think definitely between the next 9 months to 12 months, we can see the CDMO business and this Adalimumab also will be launched, which we're going to take this because this is a first off in India. So slowly it'll be moving and we're working with the various customers on this, plus ROW market also, we're trying to register. I think between 9 to 12 months hopefully we can see the revenue coming from Biologics.

Ankit Gupta: Okay. And Adalimumab in India and ROW, what will be the market size of this product?

Vishnukant B: Market size is much bigger because it's the world largest product Humira and the high concentration product is not available neither in the ROW market, except the originative I'm talking, nor in the India market. So hopefully I think a good market how much we'll be able to convert that into that, maybe after one or two quarters, once we launch, then after one or two quarters we'll be able to comment on that more. But we're trying to, wherever such opportunities are there, we are approaching each and every region customers to get that market side.

Ankit Gupta: So, and this last question on the API, we appointed investment bankers for looking to offer opportunities on API side. So, what are our broader plans for this segment? Are we planning to do some IPO on this or like what are our plans for this, for the API segment that we have?

Vishnukant B: I think, Alpesh will be better to answer, but I can say you that all options are open. I think, API being a very mature and the sustainable business and there is enough opportunity, still we're not grown in the Polymer, non-Onco, Peptide, intermediates. There are huge opportunities are in line with that, in the API itself. So, this, were seeking all, options open. Alpesh, am I correct?

Alpesh Dalal: Correct, sir. So basically, Ankit, what we are doing is as, Vishnu ji was mentioning that API basically, a couple of segments in our API business are mature businesses, they are growing wel,l and I can quickly tell you that in FY22, our API business growth was at 30%. So, we haven't had that kind of a slowdown in the business over there. That was despite the CRAMS business going down, roughly by about INR 30 crore. So, despite that, we had a growth of 30% in that particular business. So certain segments are at mature stage. And certain other businesses are at nascent stages So, we are just working with some investment banker in company. We have already mentioned that we have taken services of O3 Capital for that. And we are trying to determine the best possible course of action. The idea is to monitor this particular asset. The manner in which we monetize this asset or the way we take it up either through the IPO market or through strategic investors or through private investors is something that we are working closely with the investment banker to determine.

Ankit Gupta: And also, if you remove whatever costs that there on the API side as well as on the Formulation side. So, what will be the steady state margins in the API business that we have seen over the past few years and even in H1 of this year?

Alpesh Dalal: From margin perspective, when we look at our API business, historically the margins have been better, but as I mentioned in my commentary as well, that there are pressures on selling prices as well as on the cost. So, when you look at the API business per se, we typically have EBITDA margins in the region of about, 23%, 25% kind of range we have got. In the past, we have had better margins, but due to the pricing pressure now, it has been slightly under pressure right now.

Moderator: The next question is from the line of Vineet Narang from White Oak.

Vineet Narang: I had just one question on the Albumin side. If you can update us, what is the status there? Are the facilities ready? Has the product been stabilized? And who are the other players in the industry working on this Albumin product?

Vishnukant B: Our Albumin is not a regular Albumin, first of all. Ours is recombinant Albumin. So, which doesn't need the blood as a source for to manufacture this. And it's pure than 99 point plus pure material, what we're getting with our process. So currently in India, I don't think anyone has this recombinant Albumin, anybody is doing it. We are doing

the company now at this stage. The current status of the constructions of the new fermentation facility, which is now at the mid of the construction and the erections. Hopefully by September or December we should be able to complete next year, by September and December, we should be able to complete before December '23, we should be able to commission this facility.

Answering on your questions on the Adalimumab, we have got this Phase 3, -- Phase 1 from the set meeting and we're manufacturing now the batches, clinical batches to take this for the clinical trial. So that we're doing it from the Hubli facility, the current facility there already, we can do that. So, by the time our facility is ready, at least we'll be ready with the Phase 1 and partly Phase 3 data also.

Moderator: The next question is from the line of Tushar Bohra from MK Ventures.

Tushar Bohra: First quick clarification. So, we mentioned Albumin Phase 1, right? So, we should be able to start phasement trial soon for Albumin, right, to the previous participant? Cause you mentioned Adalimumab instead of Albumin.

Vishnukant B: I mentioned Albumin, he was asking the questions of the Albumin.

Tushar Bohra: No, for the clinical trial. So, we should start by when, sir? By when do you expect the batches in place?

Vishnukant B: Once we complete our the clinical trial batches immediately can be start because the permission is already there. Only we're waiting to complete the clinical trial batch manufacturing at the bigger scale at our Hubli facility.

Tushar Bohra: So, we should be able to launch it in this quarter or by next quarter? By when do you think we'll be able to launch?

Vishnukant B: What is the meaning of launch?

Tushar Bohra: Meaning the clinical trials, by when do you think we can launch clinical trials, yes.

Vishnukant B: Clinical trials? Okay. We should start that clinical trial. I will not be able to tell you today on this, once we are having the data of this clinical batches. Hopefully the batches is started already, but until and unless the batches comes out, then I will not be able to tell you on this, whether it is starting in this quarter or the next quarter, but we're hopeful that at least before, the next quarter, it must start.

Tushar Bohra: Sure. Second, sir, you mentioned three key products and non-Onco APIs have been launched commercialized this quarter. If you can give more data points around those and, any other important products that we should monitor over the next couple of quarters, which can be relevant for the company?

Vishnukant B: Yes. Of course, these all three products we have, whatever the capacity we created for the last year and this exhibit batches was also completed, the drug master files were ready, now we're filing in various market. So, the commercial launch in India is already there. Enough capacity also has been created for these all three molecules. And the next molecules, which now exhibit batches are going on, I will not be able to disclose the names today, but I think next quarter we should be able to give you precise names also, which are also equally very good product.

And as I mentioned earlier also, product selections in the non Onco is not just to create the competition among the existing players, how we're going to differentiate ourselves because the strategy in our API was very clear. Let's have a differentiated product. Second one is, can we have enough capacity to create and to sell this

particular product? Third, are we able to, withstand on this competitive scenario from the existing player? And if yes, then how we're differentiating them in terms of the yield, in terms of the quality, in terms of the regulatory, in terms of our existing goodwill. And can we manufacture the -- is there any Chinese raw materials used in this? Can we replace the Chinese to India? So, these are the five, six factors we take into the consideration before taking any non-Onco molecule.

It is not just because we wanted to increase the top line and later on when the competition comes, then we are out of it. Very selectively verifying all these things. And we have another six, seven molecules in the pipeline, which will differentiate it. And these all parameter at least if you verify seven parameters, we withstand on a five, six parameters and then only we're taking this particular product. Hopefully before this December and before March, we should be able to complete at least another three products for our next year commercial month. The capacity creation for this particular product is ongoing. We may not be able to complete the capacity in this particular year, but I think the one or two products at least the capacity creation also will be completed.

Tushar Bohra: Sure, sir. Quickly on the gross margin. The sharp compression and margins that we've seen, is it something that we should expect for next couple of quarters as well, or do you think that we should be able to recover and stabilize at a higher gross margin in Q3, Q4? And what led to this fall as well, which product specifically?

Vishnukant B: The gross margin on the some of the products, which is purely depend on which products are moving in which quarters. Sometimes it happens at the higher ones. First, we are adding more non-Onco products, which doesn't have the high margin like Onco and the other molecules. Of course, we should understand that reality that we are launching the non-Onco molecules, non-Onco molecules from the existing player we are taking this market share.

People are accepting our entry, we are going cautiously in this particular, not just by reducing the prices, but of course we have to be a competitive or little lower than what the existing peoples are there, to take us into their Dossier and in the ROW market also. So, this is what current strategies follow. Of course, we're also monitoring the high value products, the Onco will be there. And as, and when we're adding the more products in non-Onco, with the backward integration and the scale of the capacity, the margins can come to the normal level. It maybe one or two quarters slight pressures will be there

Alpesh Dalal: Tushar, on the Formulation side, we currently are majorly dependent on one product till now. So, as we are able to launch more products there, I think that because this one product that we have in the market has had certain pricing challenges and all. So going forward when we have more products coming into our formulation basket, I think we should be able to stabilize the margins, with a larger basket of product available.

Vishnukant B: The more important in this, I will add something for Alpesh that the Formulation business is a different business. And we are learning probably this, other than because we launched first into the US and rest all markets, fortunately we were started registering two, three years before. In this, especially in the Europe and ROW market, probably we are seeing that almost 350 Dossiers were filing in the ROW market, which is not a small number in Onco and adjuvant therapy. And what we're trying to do it in this Onco, other products also, none of the products are going to take with the third-party facility, where we feel that there is enough opportunity, like a Prucalopride. Prucalopride launch was done in the Europe and filing in the US. Now we are already doing it in the US.

So Prucalopride is a niche product. So, that product we have taken, because it was a non-Onco, so we have to take it in the other facility, which we completed successfully Dossier also got approved and last quarter we were able to launch in the European market. So, such strategy, Onco, non-Onco, minus US, Canada, Australia, then the other all markets, also Europe, of course, we are focusing more and we have got very good partners in the Europe because we are not doing directly on our own. And they have great interest in our existing products. I think formulation business after two, three quarters, definitely we can see this ramp up, minus US, if the US gets also cleared, then you have substantial revenue from there.

Moderator: The next question is from the line of Manish Bandari from Vallum Capital.

Manish Bandari: I have a few questions. You have spoken about the launch of Adalimumab and also Albumin some time in India. So, I wanted to know about the marketing spend, what we have today and how much of more expense we need to take on the marketing side or we'll go through the partners? And you've given the timeline, so just wanted to know about the marketing tie ups?

Vishnukant B: So, on Adalimumab we are doing on our own launch also with our India team as well as we are working two companies, we have signed on that, and we will launch through them also. So, India market, it is not that only we are launching ourselves and the other peoples also because they also don't have this particular product. So, we are trying to work with them within more number of people and trying to get as much as market shares as possible. So, on Adalimumab I have said on the marketing.

For Albumin, I can tell you that Albumin is such a product, where no marketing is required. It's all over world, including India, 365 days. This is a shortage product. So, this product, if we are able to complete this and launch it into the India market alone has such a huge demand, which cannot be catered by anyone. So, marketing on the Adalimumab, I don't think is required because now, also people are asking us that, can you give it immediately, including the ROW market. So, I don't think that the Albumin needs more marketing effort today and, but yes, Adalimumab is required on that because Adalimumab's originator is there in some of the markets in ROW and India. We're trying to tap whatever the best possibilities are there; we're trying to do that.

Manish Bandari: Vishnu ji, my second question was related to the cash flow, which can you have to sacrifice potentially by scale or maybe a strategic partner in API business? So how we would run the show because the cash flow from the other business opportunities will take some more time to come through? So, I just wanted to know the strategy in detail in the process since we have express interest of getting a partner at the API?

Vishnukant B: Our cash flow, the major debt, whatever we are seeing has been used for the biologics and the BioCare, the Albumin plant. These are the two area, wherever the 100% of this, whatever the borrowing has been done, has been utilized are most there. So, if we get the CDMO business and if we complete this Albumin plant next year, I don't see there is any issue on getting the revenue from that plus other than API, I'm not talking on anything on the API, other than API, we have in our Formulation, Onco, non-Onco, Transdermal Patch & Film. So, these are the division which is now almost getting matured, so it is transdermal patch and film, whatever we were there last three years, we are just spending on that.

We completed the UK mature approval. We are launching in the US this film, it is not that something we're launching into the any other market and US launching is not possible until, unless the verification is done. Customer has done stuff around it. Use this for the their research and all, and this is commercially launching, it is not just trial launching. So, even the Transdermal Patch, Film Formulation, the Onco business of

our formulation, European launch, ROW market launch or the any other market, Canada, Australia, so many are going to get, so in a one year, I personally feel formulation division also has a huge potential, which we have spent for several years of our R&D. And you can understand this Tranexamic acid product, which is a first time in the world. The films which we are producing in the first time, the Onco complex injection like are ready to use Pemetrexed, which is not easy product. These are the unmet need in the market, but nobody was able to do that.

And with our expertise and the R&D expenditures, of course I agree that the fruits have to come somewhere we should see the revenues on this. I feel that now we're consolidating our research also and trying to see that which are immediately hanging fruit that we should try to take it immediately, do the licensing activity also with the various customers, launch with them in the US and the other market. Europe market also, we're trying to see the partner, ROW market also we are trying to see. Now we are in a mode where we're consolidating our all R&Ds at all over, whatever the strengths are there and trying to see that each area has enough opportunity to grow. So, the cash flow, I personally feel on Biologics will of course, once we start, even if we trade now, Formulation business itself has enough potential in next two, three quarters for growing only.

Manish Bandari: Sir, the problem I see in the company as a long-term observer is, we would have a cash flow, which will again, get turned into the employee expenses and the R&D expenses. Finally, the fruit of the labor is the free cash flow. And unless until you know the business well enough that this further research activity from the Biologics is kept at a hold. Otherwise (inaudible 0:46:14) prophecy of the cash flow going back into the research will come into place. So, is there any strategic change, which you are doing now today at this juncture, looking at mismatch of the cash flow where all the incremental expenses significantly related to the R&D or to the capital side will put on the hold and only the monetization of the existing asset will happen for next three or four years? Monetization from the generation of the sales or revenue as well as from a strategic partner. So, just one hazy thing, which I have in my mind is on the line of thinking you have?

Vishnukant B: No, thanks, Manish ji, I respect this and that is the reason I use the word consolidation of all the R&D and the marketing activities. It means that wherever the possibilities are there, which we are working for the next five years, seven years down the line, we are holding for some time, which are the low end input where we can do it immediately in six months to one year, let's complete that all activities. The market, which were untapped or which were not doing the licensing because we feel that this is a very good opportunity, we will complete and then we'll do it. We're trying to see that the marketing partner is roping in this. So various factors we're trying to use into this, where consolidation on the R&D and the marketing activities, appointing the -- specially on marketing, the various people to see that including India market, the ROW market, specific people to look on this particular products and getting the licensing in that respective market. But all efforts are parallelly going on. I fully understand that the company was earlier cash free. The debt free company was there.

Now we are came into the situation where the debt is there. Hence, we are trying to see that how we can be as soon as possible debt free, and then, we can grow with that. And we are learning from the mistakes also. Some of the mistakes was there that we have done always, midsized company like us has invested into the Biologics and other, and the long-term project. Of course, but we are happy to say that some of the very tricky products has been getting approved from not only from India, but from the European and the US market. And I fully respect your suggestion. We're consolidating all our efforts and trying to see that what is the maximum utilization we can do with the current assets, not the future assets.

Manish Bandari: So, when should be the most optimistic launch of India Albumin commercial launch in India?

Vishnukant B: 2024.

Manish Bandari: So, you mean the calendar year or financial year?

Vishnukant B: Calendar year means you never know because the Phase 1 and Phase 3 we need to complete. Phase 1 will start for that, will be there for six months and Phase 3 will be there for the nine months.

Manish Bandari: This is India?

Vishnukant B: I think India. But this Albumin, once you do it, because we're doing with the European R&D all this study. So, I think it can be useful for all ROW market also, because as an ancient all over the world there is a shortage products. The day when you complete this clinical trial and submit it to the authority, they will give on a very fast track approval of this. So, India, ROW, all markets will be open in 2024

Moderator: The next question is from the line of Anuj Sharma from M3 Investment.

Anuj Sharma: Vishnu ji, few questions on Albumin. Now this recombinant Albumin, which you are producing is theoretically, completely able to replicate the existing Albumin, or there are only few applications wherein this can be useful?

Vishnukant B: Rather, this is not exactly replicating. It is a much superior than the existing one. The current, what we are developing recombinant Albumin can be used as excipient, which is a, very high margin product and high value also, because excipient is used in a vaccine, excipient used in a drug product, like, Abraxane and all, Arborol, there is a liposomal product. So, all liposomal products the Albumin with the high purity is used.

You must be knowing it, that the current the Albumin has a huge disadvantage because the consistency from these market is not there in the Albumin because human blood varies from one region to other region, and it varies, so impurity levels are also different. So, using it as a excipient grade and getting the consistent quality of that particular product is a very tough for the people, those who are using this Albumin and doing the formulation. So, there are some restrictions also to develop the liposome formulation. This can be totally avoided because you are going to get the consistent quality of 99.99% purity of the recombinant Albumin.

The second one is the, of course we can use as a drug, so anybody will be happy to take particular products because it doesn't have the impurity, and it is a much safer and pure form available against this market. Plus, another two, three applications are also there, which I'm not able to share today, but some of the peoples are developing some other technology where they can use this Albumin. But I personally feel the drug is there, you have a wide excipient is again a great potential to be used next two, three years. But the excipient grade has to be used and put it into the formulation, submit it into the authority. Some ROW market and India market can be available. But in the US and Europe market, probably it's a two, three years' time. But for that we did not have to do this clinical trial. Once we complete this, the exhibit batches, once we complete the clinical trials and we file this, the drug master file people will start using in 2023 our excipient grade the Albumin for sure.

Anuj Sharma: Okay. My second question is pricing is still far away. I understand that, but based on the pricing of existing Albumin, were we to price it somewhere lower, I mean, how are we thinking about pricing of this product versus the existing? Will it be economically beneficial to the patient or the consumers?

Vishnukant B: The price in Albumin is the secondary. Availability of this particular product is most important. The second one is, of course, you are to see that what is current pricing. Are you able to sustain in this particular, or even if the price get lowered down, are we able to do that? We have done all that exercise. And I'm sure that we'll be competitive in this, even the drug product, forget about the excipient, excipient is much higher where you always have a value addition. But here, even at the drug product level, we are sure that we are cost competitive against the existing product.

Anuj Sharma: And my last question is, again, this is because of lack of information or data. Given the competition, is competition also close by on products like Albumin or we are by far the closest to the finish line as far as this product is concerned. I mean, I'm sure you would've analyzed the competitors or people who are working on this, just some light into this direction.

Vishnukant B: Sorry, I not exactly understood your question.

Anuj Sharma: So, I'm saying are competitors also or other players also developing a similar product and or close to developing a similar product. So, we might get the product right, also the timing right. But are others also following us some data into the competitive environment or the other players who are making this product or trying for this Albumin product?

Vishnukant B: Of course, they will be there. I'm not saying we are the only company, but currently we have granted patent from the US and Europe. So, we our process is patented for, somebody else can also do this particular product. But I can tell you that even if another five facility comes, the scale at which we are doing it, then still there is enough scope to take everyone into the system because there is always gap of this Albumin in all market.

Moderator: The next question is from the line of Sahil Chopra from KIFS Trade Capital.

Sahil Chopra: So, sir, what kind of CapEx companies looking for FY23 and '24?

Vishnukant B: We are not doing any more CapEx currently except the Albumin what we are doing it. And of course, the maintenance CapEx for the API division. Rest all we are now currently holding it. The Albumin, the project needs CapEx. We already invested around INR 175 crore, if Alpesh I am correct? The balance, I think around INR 175 crore need to be invested.

Sahil Chopra: In next one year?

Vishnukant B: Yes, of course.

Sahil Chopra: Okay. And in past three years our company has incurred around RINR. 1,000 crore of CapEx. So, when will be, the benefits from the scene will be fully flown to the company? Any timeline, 2, 3, 4 years, something?

Vishnukant B: I mentioned that the biological facility is already ready where we almost invested INR 700 crore on that. So that facility is ready. Product is also getting approved. There is an interest also is coming for the CDMO. And the other end, we're trying to get the approval also in the US by filing some of the products. So, this is what our future plan of Biologics is. The next one, two years, probably, maybe next two quarters or three

quarters, you'll see that the revenue started coming into the biologics, which is a major asset block is there, from where currently the revenue is practically negligible.

On the Albumin, of course, once we complete this and then we'll be able to do that. So currently that 24 as I mentioned that we should be able to, and immediately the production whenever we are doing this, how we be able to sell it from that particular facility because we're completing all registrations and other documents from our existing facility. Then there will be a site change and the necessary procedures will be there. On API and the formulation, whatever, the investment, whatever we are telling, all this started doing the revenue.

Of course, the revenue started, I personally feel from the asset as well as the products, which we have it at our portfolio or in R&D is not completely commercialized. That is why consolidating on the various products and trying to see that as how we can launch in this market, either transferring these, some of the products at the other side, or partnering these, or launching in the various market. So, these are the areas which we are currently more focusing on, and of course, on the FDA clearance as early as possible.

Sahil Chopra: And my last question is related to this margin. So, if we see last 15 years history of the company, our margins are around 20%. So, when our company can reach these kinds of margins, again, is it possible or any timeline regarding that?

Vishnukant B: Alpesh?

Alpesh Dalal: So, Sahil, as we have explained earlier that the existing businesses have seen some pressure on the margins. The next takeoff of business mainly on formulation side when that happens, like, ideally if there was no US FDA related challenges, we probably would've had few more products in the market. But that has taken some time. But we are, as Vishnu ji mentioned a while back, that we have registered products from alternate site. So, those should start coming in. We are looking at additional products coming in our, API business both on Onco, non-Onco side, more on the non-Onco side coming in. So those are obviously slightly lower margin product, but, they expand our reach and all. So, it takes some time to build up this portfolio.

So, we are hopeful that in the foreseeable future, we should start seeing improvement in the margin, also typically, our first half of the year is softer than the second half of the year. So, we hope that we probably are able to see some improvement straight away in the second half itself. But from there on, we should be able to build up as soon as we are able to get some more product approvals and also get some traction on our Biological business as Vishnu ji was mentioning that we will have first of our product probably coming to the market.

We are looking at some CDMO opportunities there. So as in when we start cracking into those businesses, we should be able to start ramping up our margin. Our margins were basically impacted by some of these investments that we have made, which have not yet started yielding results for us. So that our base business is still steady and we are generating sufficient margins over there. But these additional investments that we have made, once they start kicking in, then we should see improvement happening in the margins as well.

Sahil Chopra: We can expect it to happen in next two years?

Alpesh Dalal: See, it is difficult to specify the timeline because a lot of these things when we are trying to get a business generated out of some of these investments that we have made, it would be dependent on the opportunities that come across our way. As you

are aware that we were expecting some significant business opportunity through contact manufacturing of vaccines related to covid and all, which unfortunately will not happen. If that were to happen, we probably could have started seeing much better margins right away. So, it is dependent on the kind of opportunity that comes across our way. So, it'll be difficult to specify a timeline at this stage. It could be even earlier than that, and it probably might be around the timeline that you are mentioning.

Sahil Chopra: And my last question is related to debt. So, what kind of debt to equity or what kind of debt level company is comfortable with?

Alpesh Dalal: So, see currently, as I mentioned on the call that we are at a net debt of which is in excess of INR 750 crore, and hence we are also looking at certain asset monetization opportunities to bring it down. Typically, our idea would be to make it a zero-debt company back to where we used to be. But if we were to do it in a gradual manner, and not at one short monetization, then probably, we will try to get it down by at least currently, if you see broadly we are at when I look at my debt equity, I'm at 0.5 times, thereabouts, but I would want to bring it down to say, 0.25 at least.

Moderator: The next question is from the line of Tushar Bohra from MK Ventures.

Tushar Bohra: Sir, just to understand, what would be the drag on the business from segments which are currently not yielding optimum utilization or optimum return, meaning the biologic segment and probably Transdermal ODF as well? What would be the operational loss from the segments that is dragging the overall performance?

Alpesh Dalal: I think Tushar, we can come back to you on that a little later. You can get in touch with us and we'll get back to you on that.

Tushar Bohra: And sir, the total gross block today on the books, and working capital, how much would be being contributed by the API business? A ballpark number?

Alpesh Dalal: Of the gross block you're saying?

Tushar Bohra: And working capital also?

Alpesh Dalal: Yes. We've got about INR 380 crore of gross block and working capital of about INR 320 crore plus in my API business.

Tushar Bohra: It includes gross block and INR 320 crore working in API business?

Alpesh Dalal: In API business I've got a gross block including my capital, working progress of INR 380 crore. And INR 320 crore of net working capital. So broadly, put together, I'm at about INR 700 crore.

Tushar Bohra: So basically, sir, the part of business that the investments in biologics, formulations, all the other parts, we are seeing that more than INR 2000 crore gross block is invested across these, as on day today?

Alpesh Dalal: So, all the businesses put together, I would have about a network of about INR 1300 crore plus and almost INR 1400 crore. And the gross block would be.

Tushar Bohra: So, your accumulated depreciation would be about INR 400 crore? So, you're saying that close to INR 7800 crore gross block is deployed in your other segments, right?

Alpesh Dalal: Yes.

Tushar Bohra: Okay. So, sir by when do we start expecting, -- we've heard on biologics, but overall if you can just give, sort of the strategy for monetization of this utilization of this gross block systematically for each of the other segments? Like by when do we start to see material progress and utilization and contribution, net contribution to the -- other than formulations for the other segments, when do we started seeing net contribution to the profit loss for the other segments, including transdermal as well?

Vishnukant B: I mentioned know already, that almost all the facilities, which was there transdermal and the film being, importance was getting this approval, which we got the UK. Launching in the market, that also we started in the US market. And of course, we'll start with European market. Because now we got the approval of UK, we find some dossiers also. So next one year onward, maybe next year, '23, '24 we can see the revenue started coming from that asset, which has been blocked at the transdermal and the film.

On the biologics, already 22 times that the Adalimumab now being ready for the launch. Next quarter onward, we will be able to launch this is the local and next year we should be able to launch in the ROW market also. And some licensing revenue, some of the things which we wanted to do it not only for the licensing, CDMO work what we're trying to do, there is a great interest on the CDMO also. So hopefully the biologics also will start coming from the next year onwards. These are the two. Rest all is the formulation is of course it is there. The formulation we're working, once we get the -- at least we got now the Australia and the Canadian clearance, hopefully we should be able to get it except the US but the US also, we have completed all work and I given every detail review what has been done by this third party, and we're waiting for the FDA to come work, plus transferring the products to the various site. Hopefully as to answer the very broadly to your question, that we should be able to see some revenues traction from the next year and a half quarter onwards. So, I think hopefully we should see the revenue jump from that.

Tushar Bohra: Sure, sir. My last question quickly on, Pemetrexed RTU, that we've launched in Europe. What is the early traction around that? And if you can give for some kind of guidance around how in terms market share or in terms of volumes, profitability on that product for Europe?

Vishnukant B: Profitably and all I'll not be able to share, but we were able to launch in the European market and we were the first to launch RTU into the Europe market. And we have good partner, so there is no reason that we will not get the market share of this particular product. But I think definitely there will be a good traction in this particular product in the next quarter onwards.

Tushar Bohra: So Q3 onwards we should see?

Vishnukant B: Probably, because we are launched this one. So, I think once they're coming in the market, they will go to the getting the tenders in these areas. So, these are the things will ramp up slowly. It'll not ramp up immediately because we are not the only company because there is a lio formulation is available, but we are going against Lio RTU. So that is the differentiated formulation is coming and there is a great advantage also. People likes it. Only thing is once you launch into the market, then you slowly ramp.

Moderator: The next question is from the line of Manish Bhandari from Vallum Capital.

Manish Bhandari: So, my question is related to the Albumin, we have lot at the stake related to the albumin. So, I wanted to understand that whether we need to do the investment of incremental INR 170 crore before we get the approvals, all approvals in place, otherwise, if there is [Technical issues] formulizations, what happens to such kind of situations.

Vishnukant B: I think, it's the situation where should we do now or should we do later on or should we get an approval and then you take a two years to complete this and then do it. So, by the time you get approval, and all, and if you don't have a facility for the Albumin like a product, then you have issue, but I agree that there is a debt currently, should we do currently or not? Of course, we're doing little slowly and the various opportunities and this one we are seeing that how to mitigate such risk also, maybe in one or two quarters we will have more clarity on. But I take your suggestion, sir, that at this current stage, investing that much should we do some other risk hedging strategy in Albumin also.

Manish Bhandari: Sir, my last question is related to the international marketing. Would you use the partner?

Vishnukant B: Yes, we're doing partnering only. We cannot not do on our own. So, I think yes, yes. All will be partners, in US also we launched through the partner only.

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

Vishnukant B: So, we thank you all of you for participating in our functions for earnings call and showing interest in Shilpa. We will continue with this effort of updating you regularly at the -- after every quarter result, and we look forward to your continued interest in Shilpa. Thanks a lot.

Alpesh Dalal: Thank you.

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