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## *Shilpa Medicare Limited*

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Exchange Plaza, 5<sup>th</sup> Floor,  
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Dear Sir/Madam,

**Sub:** Transcript of the Q4 Conference call

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

In furtherance to our intimation dated 20 May, 2024 with regard to the Q4 FY24 Conference call held on Friday, 24 May 2024 at 1.00 PM IST, please find the enclosed transcript of the call.

Thanking you,

**For Shilpa Medicare Limited,**

**Ritu Tiwary**  
**Company Secretary & Compliance Officer**



# “Shilpa Medicare Limited Q4 FY24 Earnings Conference Call”

**May 24, 2024**



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

**Moderator:** Ladies and gentlemen, good day and welcome to Shilpa Medicare Earnings Call for Q4 FY24.

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 “\*” then “0” on your touchtone phone. Please note that this conference is being recorded.

I now hand the conference over to Mr. Nachiket Kale from Ernst & Young Investor Relations. Thank you and over to you, Mr. Kale.

**Nachiket Kale:** Good afternoon everyone and welcome to the conference call hosted by the management of Shilpa Medicare Limited to discuss the 4th Quarter and Financial Year ‘2024 performance. The management is being represented by Mr. Omprakash Inani – Chairman of the Company, Mr. Keshav Bhutada and Mr. Alpesh Dalal.

The discussion will be led by Mr. Keshav Bhutada with his perspectives on “Business Performance” and “Strategic Overview”. He will be followed by Mr. Alpesh Dalal – Chief Financial Officer of the Company to give his perspective on “Financial Performance”. After the management’s comments, there will be an opportunity for all your queries to be answered.

Before we proceed, I would like to state that some of the statements made on today’s concall could be forward-looking in nature. A detailed disclaimer in this regard has been mentioned in the conference call invitation which is available on the Stock Exchange. We have also published results presentation prior to the call. I hope everyone had a chance to go through it.

I would now like to hand over the call to Mr. Keshav Bhutada to take this discussion forward. Thank you and over to you, sir.

**Vishnukant Bhutada:** There is a small correction I am going to draw this Vishnukant Bhutada here. Welcome to our Call to discuss the Performance of the Shilpa Medicare during the 4th Quarter of the Year ‘23-24. As always, I shall commence with the highlights of the “Operating Performance” and touch upon “Segments Wise Initiatives” and Mr. Alpesh Dalal – CFO, will share perspective on the “Financial Performance” by the Company. Following our opening comments, we shall invite queries from the participant in order to address it comprehensively.

I will begin with the update from the API business which is the most important division for us. Building upon our strengths in developing and commercializing products, we are moving up on the value chain in our API business.

For non-oncology API segments, we are exploring products which have a high growth potential or can serve as an import substitute API. During the quarter, we have added 3 molecules in our portfolio, Methotrexate, Liraglutide and Teriparatide, which are at the validation stage and are likely to be completed during Q1 FY25. We are also enhancing the capacity of one of our key



molecules Tranexamic acid from 15 metric ton to 25 metric ton per month with tentative completions in 2024. For another key molecules, UDCA we are witnessing the significant improvements in volume pickup. And with the filing of our USDMF and EU for the GMP, we feel that this molecule will have a significant improvement in the volume.

We are progressing fairly on the polymer initiative as well, where our focus is on innovators seeking quality products and we have already developed one product for the US-based clients and supplied them with the pilot and the validation quantity.

On oncology APIs, we are developing almost 8 API, which will come at the plant level before FY26 for API CDMO services, which are growing with the great potential, which provides a significant growth opportunity in upcoming years.

Moving on our formulations, we launched successfully our first NDA product with our partner in the US market under the J-code in the US market by Amneal. Another significant product will be our innovative product NUD07 Phase-3 studies have been initiated and the recruitment of NAFLD patients, fibrotic stage F2 and F3 for Phase-3 trials have been completed across multiple centers. Phase-3 clinical study dosing is expected to be completed by end of the Q1 FY25 and study is likely to be concluded by end of Q2 25.

We also completed the Phase-2 trials of another product which is a tropical lotion SMLTOP09 for the treatment of Androgenic Alopecia. We are now planning to initiate the phase three trials in July-August 24. Additionally, we have expanded our geographical reach by entering into emerging markets through our marketing partners for launching our approved products portfolio, providing access to the private market and enabling us to participate in the local tenders as well. We have successfully completed the inspection by the AGES, Austria in January 24. Our Jadcherla facility has been issued GMP certification, which will facilitate continued supply to various countries of the European Union from this unit. For our Jadcherla facility, which has undergone a USFDA inspection in November 23, I would like to share that we have submitted all compliance for the 10 observations that were issued. We are closely working with the FDA to meet the expectations of the FDA in a current regulation. We are also appointed some additional consultants for our GAAP reports which was found out by the FDA during the November 23 inspection.

Coming to the ODF post-US launches of various ODF products, we are entering into the emerging market where we have signed licensing and supply deals in the key market and also exploring further partnerships. And in US also we are trying to launch even the Paracetamol film into the US market under the ODF category. Our efforts to introduce transdermal-patch based offering on track. We have partnered for the Rotigotine, which is the most complex product in Europe and the emerging market.

Clinical studies completed for the EU market and skin irritation studies completed on the Indian subjects and ongoing at abroad. Plan to complete in Q2 FY25, followed by the filing in EU and emerging market.

Apart from this, we have partnered another two products for EU and emerging market. Rotigotine we are planning to take to the US market also, which is used in a Parkinson's disease.

Speaking now about the Shilpa Biologics, we are monitoring the volume growth in high concentration product, piggybacking on the India approvals and launch for strategy extended to tap into the various international markets with this product. Also, additional indications approval submitted to the Indian Authority. For our NBE Recombinant albumin the Phase-1 studies have been completed, and we are working for submitting the data to the CDSO for further Phase-3 pathway.

For Aflibercept CDSCO approval for the Phase-3 has been received and manufacturing of CT batches will be done in the Q2. Additionally, our first biologic CDMO project for microbial fermentation has been moved to the second level and we have signed the further one more CDMO projects in the biologics. To conclude, we are working towards into the various markets and also having innovative products along with the regular generics.

I just draw my opinion and remarks to a close and ask Alpesh, our CFO to continue these discussions with his comments on the financial performance. Thank you.

**Alpesh Dalal:**

Good afternoon everybody. I will now provide the financial highlights for the 4th Quarter and full year ended 31st March 2024. From a revenue perspective, we reported a steady quarter with consolidated revenues of Rs. 294 crores registering a growth of 11% year-on-year and with an EBITDA of Rs. 72.5 crores as compared to Rs. 68 crores in the last quarter and Rs. 40 crores during the same quarter in the last year. This is the sixth consecutive quarter where we have seen improvement in our sequential EBITDA, thus reflecting improved business mix and continuous endeavor to rationalize our cost and increase our operational efficiency. And this enhanced EBITDA has also translated into an improved profit after tax with quarterly PAT of Rs. 24.5 crores as compared to Rs. 4 crores during the previous quarter and that is against a loss of Rs. 8.1 crores during Q4 of last year.

Now I will quickly take you through some financial highlights for the full year of FY24 where our revenues for the period stood at Rs. 1,160 crores reflecting an increase of 9% compared to FY23 and EBITDA was at Rs. 252.7 crores registering a growth of 111% over the previous year. So, previous year our EBITDA was at about Rs. 119-120 crores and this is more than doubling of EBITDA there.

And on the other financial parameters our net debt as at 31st March was Rs. 912 crores and net CAPEX that we have incurred has been Rs. 172 crores, majority of which has been in our upcoming albumin manufacturing facility to the tune of roughly about Rs. 150 crores. During

the year, we also generated operating cash flow of Rs. 172 crores, so we have been moving in the right direction as far as control financial performance is also concerned.

Another important development, I am very happy to report that we have recently in the month of April raised equity funding of Rs. 500 crores through QIP issue and this has been subscribed to by some marquee investors and this QIP issue has helped us in deleveraging our balance sheet and also provide us the requisite growth funding to enable our future growth and the further journey ahead. With those closing remarks, I would like to now open up the session for Q&A. Over to you.

**Moderator:** Thank you very much, sir. We will now begin the question and answer session. The first question is from the line of Rahil Dasani from Mittal Analytics. Please go ahead.

**Rahil Dasani:** So, first of all, I need you to understand the balance sheet that is the goodwill, the intangibles and the intangibles under development these are very significant, approximately Rs. 500 crores. So, last few years, the overall P&L has been hit, but now that it is getting better, any plans to write down the goodwill and take a hit in any 1 year? And if I am not wrong, the intangible under development and the intangibles are related to the R&D, so why have we not expensed this? What sort of judgment has been taken here from the management to include it in the balance sheet? That is the first question.

**Alpesh Dalal:** As far as the goodwill is concerned, goodwill basically is acquired goodwill when we have acquired certain entities and as a matter of process under Ind-AS, there has got to be an impairment testing done of the goodwill. So, on the impairment testing of goodwill we do not have any charge that is required or that comes up and hence it continues. If in any impairment testing if you are required to write down the goodwill, we will do the same. As far as intangibles are concerned, we have a very clearly defined policy where any product, any development which is still at development stage and has a risk of development involved in it is charged off to P&L. Once the product development has been completed and we see a commercially viable path for the product, all the expenses incurred after that till the time the product is commercialized are capitalized and this is what we have been doing consistently. We have not had any situation where we have followed a different accounting policy because we had difficult years. We have been following consistent accounting policies which have been very clearly laid down and laid out in each of our annual reports also you can check out all those accounting policies in relation to R&D, what gets capitalized and what doesn't get, what gets charged to P&L, so we are following that consistently. It is not based on whether we are having a good year or a bad year that we keep changing our accounting policy.

**Rahil Dasani:** So, the next question is about the Pemetrexed injection, what is the update for this product? It was launched in Q1 FY23 in Europe, since then, how have the numbers grown from there? Also, we were to launch it in April in the US, so what has been our off take to Amneal in March? And how have the sales grown from April and May?

- Vishnukant Bhutada:** Here Pemetrexed will be as expected. We have already mentioned that it has been launched in the month of April and the number is yet to come, so currently commenting on numbers may not be possible, but yes, successfully we have launched in the month of April. So, once the quadrant is over, probably we will be doing the number on this.
- Rahil Dasani:** But that is for the US side and we launched this product in Europe in Q1 FY20 if I am not wrong?
- Vishnukant Bhutada:** No, we have not launched in FY20.
- Rahil Dasani:** No, we had launched this product in Europe in Q1 FY23?
- Vishnukant Bhutada:** Yes, that is there.
- Rahil Dasani:** So, that is what I am asking, how have the numbers grown from there?
- Vishnukant Bhutada:** In the Europe and US this is a totally different approach. In US it is a 505(b)2 J-Code. In Europe it is again generic. So, it is not 505(b)2 or something is there in that or there is no J-Code specifications. It is normally we are competing against generic.
- Alpesh Dalal:** We generally do not provide product level sales details and all, so this is like any other normal product that we have got. It is as Vishnuji was mentioning it is not a differentiated product as it would get classified in the US. It doesn't get classified as a differentiated product in the EU market, so for all the generic products we anyways don't provide product level pick up of sales.
- Rahil Dasani:** My next question is on albumin if you can go in a bit of detail from a scientific perspective and explain via form of NAVYA was able to crack it and considering the huge market potential and shortage why other MNCs who are a lot more liquid with a larger R&D workforce not pursuing it?
- Vishnukant Bhutada:** No, I cannot comment on why other MNCs are not pursuing. I can comment on my this one that we are pursuing this. We completed the Phase-1 and the Phase-1 study will be submitted to CDSCO, and probably we will submit for the Phase-3 approval also. And as you mentioned, that the size is huge, the demand is huge. Why others are not pursuing and all, I think it is not possible for me to comment, but yes, it is a complex product not easy to be developed, not easy to see that as the cost competitive against the plasma product. That is why we are putting up the huge facility of the fermentations also into the near to the Raichur, where we want to manufacture this particular product once we get Phase-3 approval. We have a commercial manufacturing capacity also for manufacturing this albumin.
- Rahil Dasani:** Secondly, we have to register the DMF for the excipient grade and start selling it this year. So, what is the capacity we have for the excipient grade? And since the plant is to start by July or August, can we expect increased excipient grade sales or will we only utilize the plant once the pharma grade is approved?

- Vishnukant Bhutada:** On excipient grade we are submitting the DMF for sure, but submitting the DMF doesn't mean that immediately the sales will start. People will use our excipient grade albumin in their formulation put it for the stability because albumin itself is not a drug, means it will not be used in excipient. They will use in various formulations that formulation then in that also Phase-1, Phase-3, so it is a long term process. It is not that immediately the sales revenue will come on that. But yes, the people will at least start using our excipient grade and we will start giving them the development and some pilot quantity.
- Moderator:** Thank you, sir. We will move on to the next question, which is from the line of Vishal Manchanda from Systematix. Please go ahead.
- Vishal Manchanda:** Sir on albumin could you kind of share some color on what could be the price differential between a recombinant one and a blood derived one?
- Vishnukant Bhutada:** The price difference currently stating is difficult because in a various market the excipient grade and the therapeutic grade has a various pricing. Of course, excipient grade has a much more value than the therapeutic grade. But in US, Europe even therapeutic grades, in India therapeutic grades, in ROW market therapeutic grades has a different pricing. That is the reason why we feel that we have to compete including the India pricing. This is the reason why we have put the largest capacity on that, so that once you are competitive in India market also on a therapeutic grade, definitely we will be competitive in other markets. This is what our goal.
- Vishal Manchanda:** So, you would definitely be lower than the blood-derived albumin in terms of the pricing? Would that be?
- Vishnukant Bhutada:** Yes, our intention is that only.
- Vishal Manchanda:** And it should be significantly lower kind of get a market share here?
- Vishnukant Bhutada:** First of all, definition of significantly lower itself is questionable, but I can tell you that this is a shortage product. Once you have this quality of the product with the 99% plus purity and consistency of not having any impurities from the other blood derived products, definitely our product will be little premium, not the more premium on this in the therapeutic grade also. So, we are working on all aspects. Keeping that into the mind only, this product development has been taken and the facility has started building up.
- Vishal Manchanda:** So, you will initially target India and then go global with this product?
- Vishnukant Bhutada:** I think India and ROW for sure immediately, parallely because we are using the EU RLD against this, even in our India trials. That will allow us to penetrate into the India and ROW market. Of course, Europe and US also parallely it is there, but once we are seeing this India, now phase-1 is completed. Now with this, can we go with the parallely into the US and Europe that still it is not decided, but India and ROW for sure.



- Vishal Manchanda:** Are there other companies globally who have either tried this recombinant albumin and successfully done that?
- Vishnukant Bhutada:** Excipient grade, yes, one or two companies are there, but on therapeutic, I think we have not heard anyone.
- Vishal Manchanda:** And sir second one on the US, you have a para IV filing on a product called LENVIMA and probably you are the first to file or SUN Pharma and you have it along with SUN Pharma. Could you share timelines on when potentially could be the launch of this product?
- Vishnukant Bhutada:** It is Lenvatinib we and the SUN are the only 2 filers for the first to file. I don't know more on this, but I think publicly probably it is known that the SUN has settled with them on this. But still we are litigating, the litigation is ongoing. So, commenting on that will be a ....
- Vishal Manchanda:** Shilpa Medicare has not settled yet?
- Vishnukant Bhutada:** No, we are not settled. We are still continuing and we fairly feel that we are non-intriguing. So, that still litigations are going on and commenting on that on litigation will be very difficult for me today on this, but yes, answering your specific questions, the litigation is ongoing. So, what time they launch, when it will happen, still it is very difficult to comment on that.
- Vishal Manchanda:** Just final one would you be able to share what would be your total investment on the gross block on the biologic front, excluding albumin just on the other biosimilars like Adalimumab and others?
- Alpesh Dalal:** On biologics front, our gross block for our biologics is about Rs. 450 crores.
- Moderator:** Thank you. The next question is from the line of Aditya Sen from RoboCapital. Please go ahead.
- Aditya Sen:** So, we have got a few products such as the Aflibercept, Albumin and Adalimumab in the line and we believe they are of huge market size, so once we decide the products, do we have any aspirational market share in our mind while proceeding with the product that we want to achieve?
- Vishnukant Bhutada:** Normally, we are not doing direct marketing by ourselves, except for Adalimumab we have done in India, but rest all markets we partner with the strongest partner in that particular division in the various region, so this is what we do. In India, as it is known that we have partnered this Adalimumab with the SUN Pharma and they are known for taking the bigger market share.
- Aditya Sen:** I am new to this Company, so just to understand how do we anticipate the incremental growth from the new products of Aflibercept, albumin and Adalimumab I understood, but specifically about a Aflibercept and albumin?
- Vishnukant Bhutada:** Yes, of course that is the reason why we selected such a complex product.

- Aditya Sen:** And about the margins of our 3 segments, Formulations, API and Biologics, can you please let us know how much margin we did in each segment and any guidance going forward on all 3 segments?
- Alpesh Dalal:** Basically, we generally do not provide segment level margin per se, but if you look at our standalone business, which is our Formulation business, you can get an idea about the margins over there for our standalone business and for our API business, we are typically operating at an EBITDA margin of about 25% to 27% I cannot give you the exact numbers over there, but that is the range in which we operate.
- Vishnukant Bhutada:** And I think guidance we are not providing.
- Alpesh Dalal:** Guidance we are not providing, but this is the general thing.
- Aditya Sen:** The last one, the biologics margin, if you can?
- Alpesh Dalal:** Biologics is basically, it is at an initial stage, so there not the entire costs get absorbed operationally in a full-fledged operation. So, at this stage, it may not be appropriate to look at the margin profile of biologics separately.
- Moderator:** Thank you. The next question is from the line of Krishna Kansara, an Individual Investor. Please go ahead.
- Krishna Kansara:** First of all congratulations on a good set of numbers. My first question is on the QIP money that we have raised around Rs. 500 crores, so as far as I know our prepayment option is opening up in July this year, so can we expect the bullet repayment to happen in July because that will save around Rs. 45 crores to Rs. 50 crores of interest expense, which is huge. So, when can we expect the debt repayment to happen?
- Alpesh Dalal:** So, I think we need to wait till not July, but till mid of August to make a partial payment. We have already planned to make a partial payment towards that NCD and of the QIP money that we have received the QIP funding that has come in portion of that has been already kept in FD for the repayment that comes up, that we can make in the month of August. There is no repayment obligation, but we are planning to make repayment of partial amounts. So, a significant chunk of the NCD will be reduced. We will be carrying some small portion maybe we will try and settle it out or pay it out in next 1.5 years to 2 years' time maximum.
- Krishna Kansara:** So, majority will be repaid in August?
- Alpesh Dalal:** Yes.
- Krishna Kansara:** And another question is on the import alert, so how long will USFDA take to issue the compliance certificate? I am asking this because majority of our delta in let us say next 1 years or 2 years is expected to come from formulation segment, so do you think that any risk could

arise in future because of this? Of course we have completed all the remediation expenses, but when will the final notification from USFDA is expected to come?

**Vishnukant Bhutada:** Commenting on the final when they will give it is very difficult, but yes we are working. Now we are at the stage where we are almost trying to complete this all whatever their expectations are there, so that much I can tell you and the risk mitigations and the delta what we are thinking for the US see like Pemetrexed were launched from the other side. Another product we have filed 505(b)2 for the Bortezomib that also probably we have already shifted, and the review is going on that is from other sides. So, any products which we feel have a risk mitigation, we already have two sites. So, whatever the largest chunk of our products which are like a 505(b)2 or very complex, we are parallelly keeping one more site also, so that is the reason I don't think that any such risk we are caring for our future growth.

**Krishna Kansara:** For Pemetrexed, we are using our own site, or are we using some other Company's site on contract manufacturing basis?

**Vishnukant Bhutada:** It is a CDMO site, another site we have used.

**Krishna Kansara:** Another question on formulation, so what kind of products have we already developed in this segment, which we plan to monetize over a period of next 1-2 years? I wanted to understand a potential sales number which this formulation product can generate as a licensing fee in the next 1-2years?

**Vishnukant Bhutada:** Our policy is there to develop the complex products. So, the licensing revenue will come always it will be there every year. That is the reason why you are seeing that there is a licensing revenue. Until and unless somebody sees the potential of this molecule, nobody is going to give you licensing fees. So, we are continuing to do such a complex project. So, from that, how much revenue and all will come is very difficult to tell today. But like Bortezomib 505(b)2 what we doing you can see the IMS data also. So, currently nobody is there in a subcutaneous RTU. We have developed that product and we have already filed 505(b)2 and the review is going on. Another product, whichever products we are trying to do it, either it should be a very complex product, like Lenvatinib first to file we had done it. SUN and we only two people were there. It is a 1.2 billion product since settlement has not done with us, but we normally do the non-infringement or the complex or the patient compliance product we try to select in-house and try to see that such unmet need is always scattered. Then only people will come here for the licensing and will be interested in to launch not only in the US, Europe, and other part of the world.

**Krishna Kansara:** Just not the potential field, if you can just tell us the number, let us say how many agreements have we currently already signed? If you can tell the quantum of that, that would be helpful?

**Vishnukant Bhutada:** It is a difficult now to tell because in the ROW market if I am able to tell you. See in each product there is a different agreement is happening. It is not one product, one Company and one Company and then we sign 10 products with them we never do that. We specialize like

somebody specializes in Onco, somebody specializes in non-onco, somebody specializes into the OTC segments where we do our farming, the ODF and the TDF, so accordingly we work with the various companies. We have a flexibility of working such type of companies and then licensing deal happens. But particularly telling about how many licensing agreements we have signed and all, but we have signed number of that, that much I can tell you.

**Moderator:** Thank you. We will take the next question from the line of Harsh Bhatia from Bandhan AMC. Please go ahead.

**Harsh Bhatia:** I just have 2 quick questions, one just from accounting perspective in the audited statements, again this is standalone versus consolidated, licensing and service income is Rs. 58.4 crores in the consolidated and Rs. 28 crores in the standalone level. And in the presentation under formulations, it is somewhere around Rs. 32 crores- Rs. 33 crores for this quarter. If you can help us sort of better understand how are these numbers getting segregated maybe standalone is where the formulation related licensing and service income is coming and therefore that is the difference, so maybe you can help us understand?

**Alpesh Dalal:** Harsh, basically licensing income, what you see in the presentation that is provided for the formulation business and we do receive licensing income in our other foreign subsidiary where we could have done the deal. So, especially in this particular year, there was some licensing income that was also received in the European territory in a separate subsidiary. So, what you see here is basically a formulation business and not a standalone business.

**Harsh Bhatia:** And in terms of this new facility for albumin that will probably come in this ongoing first quarter, without getting into the numbers, the incremental OpEx part do we feel anything incrementally that could come into picture? Obviously, I am not sure to what part of the construction is done and what part of the OpEx is there in the P&L, so could you just help us understand qualitatively?

**Vishnukant Bhutada:** We have completed almost all construction and the majority of the equipment at place. That is why probably next quarter we will start the trial batches. So, the majority CAPEX probably will be completed by the next quarter. So, another maybe Rs. 50 crores additionally we may have to spend it this is what I can tell you.

**Harsh Bhatia:** Man power cost is yet to come into picture?

**Vishnukant Bhutada:** That automatically will come, once we complete this and once we start the commercial production, that only it will be there more, but otherwise it will be less on the initial days. That is why we have not provided any guidance. We are saying that first after next year March only we should be able to get some revenue from this particular site. Till then, the stabilization, some of the batches, the exhibit batches we need to complete that all work will be completed in this current financial year.

- Harsh Bhatia:** One last clarification, I think there is some confusion at mind that the Pemetrexed related sales, nothing has been booked in March because the product has been launched in April, so your shipments must have gone out in March, maybe I am assuming, so it is fair to say that 4th Quarter didn't have any Pemetrexed related shipment because the US formulation has also shown an uptake, if I am not wrong?
- Vishnukant Bhutada:** Yes, you are correct. We have shipped this material in the month of March to the US, but please note that we are here giving on a transfer price to our US partner. There is a profit share arrangement once the sale starts. There is a substantial profit share arrangements.
- Alpesh Dalal:** Harsh, just to add on, the initial orders which were there have been shipped and have been booked in our US sales for Q4. That is where you see the uptake also over there and as Vishnuji was mentioning that once we have the entire reconciliation done for the profits that are generated during the quarter, then the profit share related portion will get booked at that point in time.
- Moderator:** Thank you. The next question is from the line of Dheeresh Pathak from White Oak Capital. Please go ahead.
- Dheeresh Pathak:** In slide 12, sir, you are talking about the third peptide molecule, so can you just explain the assets that you have here? This is I am assuming for USD MF filing, is that correct? And which are the other which you can talk about? And whether they have been filed in the US or not?
- Vishnukant Bhutada:** Which, for the peptide you are talking?
- Dheeresh Pathak:** Yes, slide 12 mentions Liraglutide, right? Which is our third peptide molecule trial that has successfully completed meeting the USD MF. we are going to file this already filed in the US. I am more interested in USD MF filing, so have we filed there and the other 2 also have filed there as well? And which of those other 2 if can you explain?
- Vishnukant Bhutada:** No, Liraglutide still we have not filed in the US. We completed the batches and probably with the stability data, we will file now to the US. Of course, our intentions are there to complete this validation and all. Our intention was there to file globally, including USA. The other two molecules are still already earlier are there, but we are trying to take this Semaglutide, Tirzepatide also in the future.
- Dheeresh Pathak:** So, this is our first GLP-1, the other 2 would be non-GLP-1, the other 2 peptides?
- Vishnukant Bhutada:** Yes, both GLP only.
- Dheeresh Pathak:** Sema and Tirzepatide that you will file now. Lira, you are already completing the studies.
- Vishnukant Bhutada:** No, we have not filed. Please, we have Sema and we are still under development. Only Lira will be filed.

- Dheeresh Pathak:** Our third peptide molecule, you referring to all the three GLPs or you talking about some other non-GLP peptide molecule when you refer to Lira as third?
- Vishnukant Bhutada:** No, another 2 is non-GLP.
- Dheeresh Pathak:** This type for DMF filing for albumin that you will do once the commercial plant is ready from then, you will take stability batches, and you will file from the current capacity?
- Vishnukant Bhutada:** For the API or formulation?
- Dheeresh Pathak:** So, Albumin USDMF filing that you will do once the plant is ready, commercial plant is ready, then you would file from the existing capacity?
- Vishnukant Bhutada:** No, we will file from both sides. We will add both sides.
- Moderator:** Thank you. The next question is from the line of Sanjay Kumar from ithought PMS. Please go ahead.
- Sanjay Kumar:** First on the Pemetrexed injection, what is the agreement with Amneal if you could share? Do we get some kind of royalty or is it cost plus some profit share?
- Vishnukant Bhutada:** Agreement cannot be disclosed on this, but I think you are right that there is a cost plus there is a profit share.
- Sanjay Kumar:** Second just a follow up to the previous question, so you mentioned Semaglutide and Tirzepatide, when can we launch any timelines for all 3 GLP-1, Lira, Sema and Tirze?
- Vishnukant Bhutada:** No, Lira we have completed the exhibit batches. Sema and this Tirze is under development. Maybe another 1-1.5 years minimum it will take.
- Sanjay Kumar:** And on Albumin, why are we not focusing on developed markets parallelly and why we limit ourselves to India and ROW?
- Vishnukant Bhutada:** I have not said that we are not focusing on the developed market. We are definitely doing that. That is the reason why we are completing the study with the EU RLD. That means including Europe we are completing it. Once we see the results of the EU and the other, then we will parallelly work on the US.
- Sanjay Kumar:** Finally, on the fermentation CDMO, any special technology about this fermentation and how big can this segment be in the next few years for us? Is it very niche technology?
- Vishnukant Bhutada:** As you know, now the world is moving to the clean technology, so the demand for especially on the fermentation is very high. And current situation of the China because of the Red Sea fiasco, now the majority of people are moving to the other than the China, to have the CDMO work to

be done and the size of the fermentation facility, what we have put it, probably very few companies in India have such type of capabilities into the GMP environment. So, answering your specific questions that yes, there is a huge opportunity for this CDMO. We are working into the microbial facility, which is the demand for the enzymes and other products also and the food grade, including the albumin, all these things can be done in our facility, so it is a multipurpose plant and we see that there is a serious interest in the large size plant.

**Sanjay Kumar:** How big can this segment be? I think you mentioned Rs. 6 crores in the last call for the Phase-2 of the Korean order, but how big can the segment be in the next few years? And if you could talk about the US order also, that would be very helpful?

**Vishnukant Bhutada:** No, Rs. 6 crores is from biologics site, it is not that something from the albumin plant. That is from our biologics facility from the Dharwad not from this facility.

**Sanjay Kumar:** Any size, you could call out for let us say how big can this segment be for us in the next few years?

**Vishnukant Bhutada:** The size can be very huge that much I can tell you, but commenting on number will be difficult, but the size is much bigger when we have put around 230 KL fermentation facility and with the current prices of albumin, you can calculate and accordingly you can judge.

**Moderator:** Thank you. The next question is from the line of Tushar Bohra from MK Ventures. Please go ahead.

**Tushar Bohra:** The first question is on albumin, can you just confirm by when will we be able to file the Excipient grade DMF in albumin? Do we expect to do this in next month or couple of months?

**Vishnukant Bhutada:** Yes, I think this quarter end or early next quarter.

**Tushar Bohra:** So, later by Q2 of this financial year, we should be able to file? There is no dependency on the new facility starting for albumin for this DMF filing, right?

**Vishnukant Bhutada:** Not at all.

**Tushar Bohra:** Second just picking up from the previous participants question on CDMO, is it fair to assume that we can do more than 1x of the gross block at the biologics plant between our own products as well as CDMO in terms of revenue on a full-scale utilization basis?

**Vishnukant Bhutada:** No, biologics, which biologics you are talking? There is one Shilpa Biologics and Shilpa Biocare. Biocare is where we are trying to put the large commercial scale facility for the fermentation on the albumin and biologics is like Adalimumab, Aflibercept and of course the CDMO project. Which one you are talking?

**Tushar Bohra:** I am talking for the biologics for the mammalian facility.

- Vishnukant Bhutada:** The commercialized for Adalimumab and all facility. Is it correct? Once we start working onto the probably, comment number will be difficult, but it should happen because once we are doing this Adalimumab, Aflibercept and then the CDMO work, what we are trying to put it plus we have a facility for CDMO especially for the as I mentioned, microbial to the mammalian, plus clone development to the fill/finish. So, such type of the GMP-grade facility with all this infrastructure's availability and working on a CDMO is very rare to find. So, I think we are getting quite good interest. We have, as I mentioned in our presentation also, we have successfully completed one NCE for the Korean client. Now they are given the second, in that next stage they are given it to us. That shows that we have good capabilities working on that. And definitely we will get a CDMO as well as the other once we start completing the Aflibercept itself and Adalimumab getting it approved into the various markets. But it is a slow process, so I cannot say that immediately this will happen. But biologics is not the way it will happen overnight. It takes time.
- Tushar Bohra:** This second project that we have signed with the US client that is also a fermentation project or is it in the mammalian plant?
- Vishnukant Bhutada:** It is very difficult to tell but it is I think on the same microbial.
- Tushar Bohra:** So, just a follow up on this, I just like to understand for the biologics plant, not the fermentation but the other one, what are the initiatives that we are taking, what kind of inquiries we have, any qualitative details of the CDMO pipeline or opportunities being discussed and also on the regulatory status, are we looking at USFDA approvals for this facility, what is the regulatory status in next steps?
- Vishnukant Bhutada:** Currently we are not working on to the US for sure. So, we are trying to see that the Europe and the ROW market, including the ANVISA and the peak countries, European approvals, so that we are going to trigger it. US still we are not able to file it or anything. We don't have our intention to currently go to the US because the spending is huge and until unless we find some good partner in that and then we would want to take it. But initially, Europe and ROW market and India market we are focusing on this.
- Tushar Bohra:** The business development for CDMO projects?
- Vishnukant Bhutada:** Yes, we are doing a lot. We have appointed in the US, in Europe, in ROW, so we have now 3 business development people, those who are working in various regions to get the CDMO business.
- Moderator:** Thank you. The next question is from the line of Prashantkumar Hazariwala, an Individual Investor. Please go ahead.
- Prashant K. Hazariwala:** Congratulations on a good set of numbers. My question is how are we going to use QIP money that we have raised Rs. 500 crores?



- Vishnukant Bhutada:** Already it has been explained. I think you were not there during that. We have informed already.
- Prashant K. Hazariwala:** Just can you repeat for me, please?
- Alpesh Dalal:** See broadly what we are doing is we are predominantly using it to de-leverage our balance sheet. Large chunk of it is getting used towards partial repayment of the NCD that we had raised in the month of August and for that we need to wait for the partial repayment till mid of August. So, we have kept that much amount in FDs with bank, so we are not using up that particular money what is required to be repaid for the NCDs. So, predominantly it is getting used for de-leveraging the balance sheet and also to an extent using it for providing the growth requirement of the business.
- Prashant K. Hazariwala:** So, how much money will go for de-leveraging?
- Alpesh Dalal:** So, substantial chunk is going there and I think you will start seeing those results in the coming period.
- Moderator:** Thank you. We will take the next question from the line of Karan from Invexa. Please go ahead.
- Karan:** I have two questions on formulation segment, so for further can you expect the profit share to come in quarter 1 of FY25?
- Vishnukant Bhutada:** Yes, I think we should be because in April we launched it, so maybe April, May, June, I think definitely there will be a sale. We can see from the next quarter onwards.
- Karan:** So, my question is on the formulation segment, so this quarter we have done Rs. 72 crores, so can we assume this as a new base going ahead?
- Vishnukant Bhutada:** Yes, you can assume.
- Karan:** Lastly, on the overall EBITDA, can we assume the EBITDA margins and the absolute EBITDA to grow from the base which we have set this quarter?
- Alpesh Dalal:** Basically, as I had mentioned earlier, that we are constantly working at improving the overall business mix, business quality, plus working on various other aspects of cost optimization and all, so ideally, those things should result into better results, but to what extent and what it would be, we can't provide that kind of guidance, but we have certainly looked to keep improving where we are currently.
- Moderator:** Thank you. The next question is from the line of Shashwata Chakraborty, an Individual Investor. Please go ahead.
- Shashwata Chakraborty:** Sir, I would like to know your CAPEX plan for the next upcoming year like the maintenance CAPEX you have or you have some growth CAPEX plan for the upcoming year?

- Vishnukant Bhutada:** As I mentioned in my opening commentary that we are building up the capacity enhancement for the Tranexamic acid from the 15 metric ton to 25 metric ton per month, so that will be there and the additional CAPEX to complete this plant of this Biocare for the fermentation of base that will be there. Rest all, I don't think we need anywhere in the CAPEX.
- Shashwata Chakraborty:** Can you tell any numbers regarding this? How much 1 year going to invest any particular amount for this particular project?
- Alpesh Dalal:** So, for this Tranexamic acid project, I think we are expecting to invest somewhere about Rs. 25 odd crores for this particular block capacity enhancement that we are doing, so that is not very significant in any case.
- Shashwata Chakraborty:** And second thing I would like to know, sir, like last one year back, the net profit margin was in negative, but this year it becomes positive. And the revenue was good, but is there anything happened in this year, like the price hike or any particular demand has increased because of that, the profit margin in positive, and in the future also you can see the positive. Can you please tell a bit or light on this particular topic?
- Alpesh Dalal:** See basically I had already mentioned in my opening remarks as well as in one of the answers that as a management team we have been looking at constantly opportunities to rationalize our cost structure as well as bringing operational efficiencies like the way we are increasing our Tranexamic acid capacity similarly, we have done similar things in the past. We have also to an extent been helped by softening of some of our input costs and all, but broadly if you see we have been fairly active on our cost specialization aspects and obviously also looking at improving the overall quality of the business. So, these things obviously have helped us in changing our profitability profile significantly and obviously we intend to continuously strive to improve this further to the extent feasible. But we can't really provide any specific guidance as to what extent will keep improving.
- Moderator:** Ladies and gentlemen this will be the last question for today which is from the line of Rahil Dasani from Mittal Analytics. Please go ahead.
- Rahil Dasani:** Sir quickly on Adalimumab, we not being the only manufacturer in our dosage concentration, how are we comparing in terms of prices for our product, especially when we have come in second in the market?
- Vishnukant Bhutada:** Yes, I was mentioning that the Adalimumab, we have already licensed to the SUN Pharma and with the additional indications which were applied for getting it approved from drug authority with that year-on-year we feel that the volume as well as the value will increase.
- Rahil Dasani:** On licensing, I wanted a very simple understanding for example, a milestone would be Rs. 100 crores or maybe 100 tons then you get a payment from the licensee. Then at 150, you get the

next payment and going on, but if the partners don't scale up from 100 to 150, then what happens, do your agreements have something built in around timelines and product off-take or how is it?

**Vishnukant Bhutada:** Answering specific will be difficult, but I think we have taken enough precautions to see that licensing revenue comes to us. But if there is a failure from either side, we have to look that this is not only from their side sometimes in a licensing revenue, we have to see from our side also. So, we take enough precautions while doing the licensing agreement that the importance is not getting the more licensing fees importance is getting the licensing fees at this stage and then increasing the ultimate sales is more important in this.

**Rahil Dasani:** So, sir that is what I am trying to understand because from what I have understood, we have recently licensed a lot of products and a significant chunk would be from the initiation fees. So, I wanted to understand if the partners are not able to scale up those licensing, our numbers will get stuck there, so if you can explain how will the partner be able to scale or something around it?

**Vishnukant Bhutada:** See, first of all, it depends on the product-to-product, so no product is mentioned that the licensing revenue from this, which initiation or the initiation will happen, but you have to see that whether that already developed, or we filed, or it is ready for the launch. Various product has a various aspect in this. Now we are not licensing at the very initial stage. We are licensing at the stage where we feel that the confident that this is in a 1 year to 2 years down the line, the product should get launched.

**Rahil Dasani:** And how many products have you licensed till now?

**Vishnukant Bhutada:** No, answering number will be difficult, but we have done quite number of products.

**Moderator:** Thank you. Ladies and gentlemen, as that was the last question for today, I would now like to hand the conference over to Mr. Nachiket Kale for closing comments. Over to you.

**Nachiket Kale:** Thanks everyone for joining the call. I would also like to thank the management for taking time out of their schedule and answering all the queries. EY IR is the Investor Relations Advisor to Shilpa Medicare. For any queries, please feel free to connect with us. Thank you everyone.

**Moderator:** Thank you, sir and thank you members of the management. Ladies and gentlemen, on behalf of Shilpa Medicare Limited that concludes this conference. We thank you for joining us and you may now disconnect your lines. Thank you.