“Indoco Remedies Limited

Q3 FY '25 Earnings Conference Call”

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MODERATOR: **MS. RASHMI SHETTY – DOLAT CAPITAL MARKETS PRIVATE LIMITED**

Moderator: Ladies and gentlemen, good day, and welcome to Indoco Remedies Q3 FY '25 Earnings Conference Call hosted by Dolat Capital Markets Private Limited. As a reminder, all participant lines will be in the listen-only mode, and there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal an operator by pressing star then zero on your touchtone phone.

I now hand the conference over to Ms. Rashmi Shetty from Dolat Capital. Thank you, and over to you.

Rashmi Shetty: Thank you, Steve. Good afternoon, everyone. I, Rashmi Shetty, on behalf of Dolat Capital, welcome you all on the Q3 FY '25 Earnings Con Call of Indoco Remedies. I would like to thank the management of Indoco Remedies for giving us this opportunity to host the call. Today from the management team, we have with us Ms. Aditi Panandikar, Managing Director; Mr. Sundeep Bambolkar, Joint Managing Director; and Mr. Pramod Ghorpade, CFO.

I now hand over the call to the management for the opening remarks. Over to you, sir.

Pramod Ghorpade: Rashmi, thank you very much. Good afternoon, everyone. Thank you for joining this call today. Let me draw your attention to the fact that, on this call, our discussion will include certain forward-looking statements, which are projections or estimates about our future events. These estimates reflect the management's current expectation of the future performance of the company. Please note that these estimates involve several risks and uncertainties that could cause our actual results to differ materially from what is expressed or implied. Indoco does not undertake any obligation to publicly update any forward-looking statement, whether as a result of new confirmation, future events or otherwise.

Thank you so much. I'll hand over mic to Aditi Madam.

Aditi Panandikar: Good afternoon, everybody, and thank you for joining us on this call to discuss performance for the third quarter of financial year 2025. Our business has primarily two aspects to it: demand generation and demand satisfaction. For the second quarter in a row, we remain impacted on the supply side for our international formulations business.

With the earnings impacted the way they have been for the third quarter of FY '25, it would be easy for anybody who is not familiar with our business to wonder if fundamentals of the organization are in place or not. Let me, therefore, share a few positive highlights on the demand generation side first.

You'll be pleased to know that our order book for international formulations business to Europe and US today stands at about INR180 crores. In the India business, there are many winners. Cyclopam, the largest brand of the company on the MAC basis in IQVIA today is at INR175 crores with a growth in excess of 20%.

When one compares IRL, Indoco Remedies Limited, with the covered market, across most of the top brands, we are doing better than the covered market on growth, and our market shares have also seen a gain. Almost all our top brands, except for ATM, azithromycin, which is, in

any case, doing better than its market, is marginally in negative. New introductions now form 4.8% of top line vis-a-vis the industry benchmark of 2.8%.

As I said in the beginning, most of our issues have been on the supply side, and supplies of finished formulations to the regulated markets for both US and EU have been severely affected in this quarter. While certain delays are on account of the implementation of corrections at facilities as part of the master manufacturing plan, which is designed to optimize operations.

Others and largely are on account of the warning letter that came on the sterile plant, Plant II in Goa by FDA. These two factors have primarily resulted in us not being able to supply. And if you compare sales to the regulated markets of US and EU, on a Y-o-Y basis for this quarter, we are down by INR90 crores in sales and revenues. And all the while costs, which are incurred at plant of a fixed nature have continued.

We are working with the US FDA to address the concerns listed in the warning letter and feel confident that in a -- over a period of time, we will be able to get out of this situation. On quarter 4, as it is a warning letter impact, I have to be cautious and say that US will stay partly impacted. EU, on the other hand, which was impacted because of delays of production rollout of solid orals at Baddi sites should be back on its feet. And from API, India domestic sales and services, I have an expectation that they will go all out. Other than this, there are certain other positives in this quarter, I would like to share with you.

In this quarter, we launched five new products, Iceraft, a suspension, which is for affinity; Afebrex drops and Afebrex syrup, both of which are two drug combinations without paracetamol in the Febrex range; Biltal-DX Syrup and Winbrinza, which is a brinzolamide/brimonidine combination.

In this quarter, we also received final ANDA approval from US FDA for Cetirizine Hydrochloride tablets 10 milligram, which is OTC. We also received final ANDA approval from US FDA for Varenicline tablets 0.5 mg and 1 mg, a product used for -- to aid smoking cessation treatment. Also happy to share that this quarter, Indoco entered into a strategic distribution partnership with Clarity Pharma U.K. These are some of the positives.

I now hand over to Mr. Sundeep to take you through the financials of third quarter.

Sundeep Bambolkar: Thank you, Aditi. Good afternoon, everyone. Hope you all are doing fine and thank you for joining the call. Let me first begin with the business highlights.

Net revenues of the company for the third quarter FY '24-'25 are at INR3,649 million compared to INR4,484 million for the same quarter last year. EBITDA to net sales for the quarter is 5.5% at INR201 million compared to 14.6% at INR653 million. The above numbers are on stand-alone basis. We have declared results with consolidation, which includes results of subsidiaries.

The domestic formulation business, revenues from this business for the quarter grew by 5.5% at INR2,242 million as compared to INR2,126 million. Major therapeutic segments, namely Vitamins, Minerals, Nutrients; Cardiac; Urology; and Gastrointestinal performed well during the quarter as compared to the same quarter last year.

Now on the International Formulation business front, revenues from international business are at INR1,074 million compared to INR1,947 million for the same quarter last year, as has been explained by Aditi earlier. Revenues from regulated markets for the quarter are at INR684 million as against INR1,475 million for the same quarter last year. Revenues from US business for the quarter are at INR280 million as against INR863 million. And revenues from Europe for the quarter are at INR354 million as against INR582 million.

Revenues from South Africa, Australia and New Zealand for the quarter are INR49 million against INR30 million. And revenues from emerging markets for the quarter are at INR390 million against INR472 million. Revenues from API business for the quarter are at INR28 million against INR33 million; and from services, AnaCipher CRO and Indoco Analytical Solutions are at INR6 million against INR8 million. That is all about the business highlights for the third quarter.

And I now request the participants to put forward their questions. Thank you.

Moderator: Thank you very much. We will now begin the question-and-answer session. The first question is from the line of Gautam Rajesh from Everflow Partners.

Gautam Rajesh: I have one question. What is the status of the refurbishment of the plants for Europe and USA. Can you update on which lines are operational now? And by when will the balance of the lines be operational?

Sundeep Bambolkar: From the Plant II, that is a sterile plant, Line 1 is fully operational, and we have been exporting 1 terminally sterilized product to the US from that line. Line 2, we are taking exhibit batches. That is also operational but has not been inspected by the FDA. So we can go ahead and take exhibit batches of all the planned products for the future that we are doing already. Line 3 will be ready by the first week of February to go commercial and Line 4 will be ready by first week of March. This is the schedule of all the sterile plant, all the lines in the sterile plant.

Aditi Panandikar: Coming to solid orals, for solid orals, the main plant is Plant I in Goa, which currently largely manufactures for US And we also have Baddi I and Baddi III, as we call it, two plants in Baddi doing solid orals. Of these, the master manufacturing plant is completely rolled out and work is completed in the third quarter for Plant 1. So impact from supplies -- regular supplies from Plant I will be seen in the fourth quarter. Baddi, on the other hand, as we speak, we are rolling out, meaning we would have lost 1 month in the fourth quarter for Baddi. Does that answer your question?

Moderator: The next question is from the line of Sajal Kapoor from Antifragile Thinking.

Sajal Kapoor: Aditi ma'am and Sundeep sir, both of you, the question is on the India business. What kind of digital initiatives do you plan to undertake or currently exploring for the India business?

Aditi Panandikar: Yes. Very good question. So there is a -- I mean, when you say digital, it's about digitization and digitalization. So just to share with you that over the last 18 months, the company has already got into digitization mode where out of the 3,000 field employees, now almost 2,000 use iPads

to promote products to doctors. That allows us to give a lot of additional data and a lot of audiovisual kind of representation studies. So on that part, of course, digitization is done.

Regarding digitalization of India business, other areas, we are -- of course, through SAP and other things, the data is already digitalized and digitalized. And we have been using some software for some time, which has been helping us to -- for the field to report calls as they happen. We also use other software, which helps any field employee to be updated within 10 minutes, every 10 minutes of the status on his achievement on a product-to-product basis versus the targets taken. Does that answer your question?

Sajal Kapoor: Yes, that's helpful, Aditi ma'am. And just a follow-on really. I mean, what's your sort of current thought process and experience with this GenAI and AI in general? I mean, how can that new technology impact Indoco's manufacturing and operations because we could perhaps use this to improve product quality and compliance, things like detecting faults, automating inspections or almost kind of predicting any quality issues. So are you thinking along those lines because there's a lot of upgrade and capacity expansion happening?

Aditi Panandikar: Right, right. So again, very interesting. So for all the new projects, whether it is the project at Auric of toothpaste block or APIs, or all the new lines, which are coming in at Plant II, from day zero, the equipment that's coming in is aligned to be part of anything digital by way of -- for us to sort of collate data and help us to work on AI/ML basis. The challenge really comes in the equipment and machinery that is already there in the system because the OEM vendors are all very different. Each of them is at different stages of their readiness to support data collection, collision, etcetera.

However, coming to departments like quality, stability, R&D, where we already generate a whole lot of data, which is in the system, we have already started using small applications to help us do more predictive work. Also in a very small way, work has also started in F&D. In fact, we are looking at any and every other department in the company where a whole host of data is sitting today, which we can work on to help us get efficiency.

Sajal Kapoor: No, that's helpful. And the implementation of SAP S/4HANA, that -- is that integration fully complete within the organization? And with that kind of an infrastructure back end and the digital initiatives that you spoke about, I mean, is it fair to assume that the efficiency and productivity will take a significant jump going ahead?

Sundeep Bambolkar: Yes, definitely. The SAP S/4HANA implementation happened almost 2 years back, and we did it in record time of less than 8 months, and we won an award from the SAP. So that is well settled, and that has made the entire organization very efficient.

Sajal Kapoor: So once these compliance challenges are behind us, I mean, no one can predict the timing of the US FDA audit because there will be a physical audit at some point. But at some point, we'll get over those challenges. And then at that point in time, as we start scaling up this, I mean, there should be better productivity compared to where we were before these issues erupted, right?

Sundeep Bambolkar: Definitely, yes.

Sajal Kapoor: Yes, yes. Okay. And lastly, on this Florida Pharma, I mean, how much is the -- so from simple perspective, I think our fixed costs have increased because we have acquired this front end in the US and we are kind of facing a near-term pain because of that increase in fixed cost and our output is not commensurate with that increase in fixed cost. So I'm just trying to understand what is that amount that we are bleeding? Is it INR10 crores, INR20 crores? What is that additional fixed cost that is currently hitting our P&L, but it's not giving us the output because of supply challenges?

Pramod Ghorpade: Yes. So Sajal, I'll just take this question. FPP, though we are incurring certain additional spend there, but if you see from a revenue perspective, we have started generating revenue starting from day 1. That is on account of 2. One is about certain current -- the existing arrangements with third-party suppliers and sales from FPP, that is one. And secondly, our supplies, Indoco supplies to FPP. So that is helping us to cover up certain fixed costs. But still, there is on an average, about INR6 crores to INR7 crores per quarter is the fixed cost, which currently we are incurring. Certain portion we are recovering from sales.

Sajal Kapoor: And do we expect this fixed cost of 7, 8 quarters -- INR7 crores, INR8 crores per quarter or, let's say, INR30 crores on an annualized basis, is it expected to go up maybe because of we plan to hire more people or salary increments, that kind of a thing?

Aditi Panandikar: No, no. So there are just 6 employees in FPP, and it is more of KOL management of generics. So there is no expectation to increase number of employees.

Sajal Kapoor: Sure. And finally, ma'am, is it still kind of 60-40 ratio that we expect 60% to go through our own front end in the US and 40% would still be through partners?

Aditi Panandikar: Yes.

Moderator: The next question is from the line of Sudarshan Padmanabhan from JM Financial.

Sudarshan Padmanabhan: Ma'am, I would like to understand qualitatively where do we stand on the US FDA as far as remediation is concerned? And when do we start seeing the approvals and kind of a ramp-up that we initially expected?

Aditi Panandikar: Yes. So as I discussed already, we've just got the warning letter and our response -- initial response to the warning letter has gone off. And we have committed a certain time period in which we will be giving a more concrete plan. In the interim, we are constantly now in communication with the FDA to keep checking whether we can supply -- which products we can supply safely.

We are also in constant touch with all our customers who are all auditing us to evaluate the risk in taking product from our site. Coming qualitatively to the issues in the plant, the team is looking at each of them in greater detail. And we have already hired remediation partners, and they're working with the team as we speak.

Sudarshan Padmanabhan: And in terms of cost curve, ma'am, I mean, broadly, since we have higher -- the concession, I would assume that a fair amount of cost will basically be spread between the third and the fourth quarter. And probably post that, it should come out.

Aditi Panandikar: Yes. That's a correct assumption. Rather than third, I think because it came towards the fag end of third quarter, I would expect it more to be in the fourth quarter this year and the first quarter of next year.

Sudarshan Padmanabhan: Sure. And any idea what would be the quantum, ma'am?

Aditi Panandikar: Difficult to say at this stage as we are still evaluating the amount of work to be done.

Sudarshan Padmanabhan: Sure. And just persisting a little bit more on the US I mean we also have certain interesting products like Combigan and brinzolamide, is there a way where we will continue to supply or is this an opportunity that we will still benefit from in FY '26?

Aditi Panandikar: So what we have done is, as in any business, once you see the risk, and it is not after this has happened, for some time now, we have recognized that we have only one site for sterile. And the company has started strategically working on creating other manufacturing locations from where we can source it, but it will take some time.

Sudarshan Padmanabhan: Sure. And just moving on to European business. I mean, as you said, this quarter has various issues, but the order book looks good for the near term. Qualitatively, say FY '26, FY '27, I mean, I understand US is a little bit of a difficult project given that the regulatory issues have to get detangled. But how do we see Europe kind of driving growth in that side?

Aditi Panandikar: We are actually not giving much guidance, to be honest. But one would have to expect close to 15% at least.

Sudarshan Padmanabhan: Sure. And with respect to the semi-regulated markets, I mean, what was the specific issue that we saw this quarter, ma'am?

Aditi Panandikar: No, semi-regulated is a typical model where we are actually selling our brands. So if you see the secondary performance, it is pretty constant. It is just because of the distributor model as and when they sort of give you orders and you get to sort of sell out, then you get the primaries. So as such, it is typically a business, which is very heavy in the fourth quarter. We have got the team to start working on making it more predictable around the year.

Sudarshan Padmanabhan: And also, spending a little time on taking cues from the previous participant on the cost side. I mean, this quarter or specifically the last few quarters, it has been a confluence of negative operating leverage and various costs. But say, if I'm saying the next 2 years or so, means our gross margin is good, which means that the majority of the impact is below the gross margin. So as we see the ramp-up, how do we see the margin expanding? I mean...

Aditi Panandikar: So we've come down from EBITDA at the level of 18% and 20% to 15% last year, averaging 13% this year. And with the shocker of this quarter, it has come down on -- for a 9-month basis down to, I think, 10.5% or 11%. So naturally, 1 quarter like that really puts you back a bit, quite

a bit. So we had said very clearly that this year, we were confident of maintaining close to 13% -- between 13% and 14%, but that has gone for a toss. So now we'll have to work back slowly and steadily. But as you rightly said, fundamentally, there is nothing why we should -- I mean, we will not allow another such quarter where so many sort of headwinds hit us at one time.

Sudarshan Padmanabhan: Ma'am, can you talk a little bit more on the cost cutting strategy because, I mean, I understand that the business has come off. And we also are seeing some kind of escalation on the fixed cost. I mean that is from a longer-term perspective. But is there any kind of a fact you see in the system that has impact, which can kind of allay the kind of issues that you are seeing on the negative operating leverage...

Aditi Panandikar: Yes. So like I said in the opening, when you sort of have a deficit of close to INR100 crores in sales, but the fixed costs of the plants and sites stay the way they are, that has been the reason for this quarter. Going forward, as part of the master manufacturing plan, in any case, cost per unit was to go down. So I see in the fourth quarter itself, we'll be able to see on geographical business basis, we'll start seeing some improvement for sure. Also in the India business, given that we are not increasing the number of people, we will also see an improvement in per head yield, PHY, that should help.

And certain costs, especially of the -- like other expenses, where there is a lot of work being put in right now to sort of contain them, check, etcetera, those will come under control. As you rightly said, in the next two quarters because of the extra cost on remediation, this impact we may not be able to see correctly. But I think after such a quarter, we will, in future calls, try to give more data on operational efficiency that we are achieving at sites, yes.

Sudarshan Padmanabhan: Sure. Ma'am, on the domestic business, I mean, since you've taken a lot of measures to improve the efficiency, digital as well as on the MR side, I mean, how do we see the prescription -- the penetration of our products? The kind of market share or the mind share that we are seeing?

And if you can just elaborate it specifically with certain products, especially if you're talking about the top three products, how do we see that picking up? And also with respect to the new launches? I mean, how do we see the new launches also driving?

Aditi Panandikar: Yes. So just to give you a glimpse for -- because we get prescription data from outside sources is a bit delayed. So I can talk for the October, November period. So October, November 2024 over same period last year, prescriptions of Cyclopam have grown by 23%. And IQVIA has classified Cyclopam as one of in the top 100 brands growing fastest in prescription. Rexidin-M, which is a dental product, prescriptions have grown by 18.7%. Sensodent-K, which is actually we took OTC through Warren Remedies, the prescriptions have grown by 23%.

On Oxipod-CV, it is growing by 40%. So typically, if you see the prescription trend is across the legacy products, we are really concentrating on the fundamentals of the business. So the prescription growth is very much same. On the new products also, if you look at products like Noxa, they have done exceedingly well.

And let me just try and give you some details. Cloben-G and Azole product is number one prescribed antifungal by ENTs. Cital is the number one prescribed urinary alkalizer by urologists and GPs. Cital and Cital-Uti together have crossed INR100 crores MAT December.

Your Ninaf -- Noxa is number one prescribed ozenoxacin antifungal -- new launched antifungal. So a lot of good happening in the India business. And this has come through both good strategies and good strategies being implemented properly as well as sales effectiveness improvement.

Sudarshan Padmanabhan: One final question before I join back in the queue is now that we have certain losses, what is the kind of tax rate that we should be looking at?

Pramod Ghorpade: Tax rate.

Aditi Panandikar: Tax rate? We are already at the lowest tax.

Pramod Ghorpade: New regime.

Aditi Panandikar: And the losses are only for this quarter.

Pramod Ghorpade: Only this quarter.

Aditi Panandikar: On YTD, we are still positive. So we will have to pay tax.

Moderator: The next question is from the line of Vishal Manchanda from Systematix. Mr. Vishal, your line has been unmuted. Please go ahead with your question.

Sundeep Bambolkar: No, no, Vishal. You are not audible at all.

Moderator: We will move on to the next question. It's from the line of Anush Mokashi from Yadnya Academy Private Limited.

Anush Mokashi: So ma'am, I was actually looking at our fixed asset turnover ratio. It was around 2.5x in FY '24. And now it is around at 2-ish, like 1.9x. And considering both the PPE and all the intangibles both. And now going by the way, that we have spent about INR800 crores to INR1,000-odd crores into our capex. So do you feel -- I mean, do you have any number in your mind? I mean, can it reach back to those levels given everything is behind us about all these warning letters and all?

Aditi Panandikar: We should at least do 2x.

Anush Mokashi: Okay. 2x is what...

Aditi Panandikar: At least.

Anush Mokashi: Okay. And next question was about the margins. So given as compared to peers, we are at a bit lower side. And I'm assuming that is because of some lower chronic mix. And I heard you saying that you want to increase the chronic mix going ahead. So any guidance on what our target number you're looking about chronic mix going ahead?

Aditi Panandikar: No. So the sales may not be lower because of the chronic mix. But we have always grown India business in a stealthy fashion. So I really didn't get your question. Are you saying that because we don't have chronic, we are lower in size. Is that your question?

Anush Mokashi: No, I'm actually assessing the impact on margins. Maybe I'm missaying that?

Aditi Panandikar: No, on margins, whether it's chronic or acute, in fact, legacy products are much better on margin because the brand is far more established in the market.

Anush Mokashi: Okay. So going ahead, I mean, is there any chronic mix percentage you're targeting?

Aditi Panandikar: We have been -- right now it is around 9% to 10%. It can inch up. But when the other side also is growing rampantly, it would not be correct to talk of increase in contribution from chronic, okay?

Moderator: The next question is from the line of Vishal Manchanda from Systematix.

Vishal Manchanda: Yes, sorry for that. So basically, with respect to your collaboration with Clarity Pharma, you expect to sell around 18 products in the next -- sorry, I think, 18 products over the next 18 months. Is that right? Hello?

Aditi Panandikar: Yes, yes, can you hear me?

Vishal Manchanda: Yes, I can hear you.

Aditi Panandikar: Yes, yes. Yes, a basket of 18 SKUs over 18 months. I mean, gradually get added. Yes.

Vishal Manchanda: So are these products already approved for you and whether you own the dossier or Clarity Pharma would own?

Aditi Panandikar: No, no, no. We have the dossiers. Over the last 20 years, we inched up from being pure contract manufacturers to eventually owning the IP to eventually owning the dossiers and MFs, okay? It's only that we weren't supplying to others. So now we supply to Clarity, which is our partner. So we have a state, yes.

Sundeep Bambolkar: Clarity will be only a distribution partner.

Vishal Manchanda: Understood. Okay. So you have these products approved and supplies would start in the next -- over the next 18 months to the partner?

Aditi Panandikar: Yes.

Vishal Manchanda: And any sense on what revenue can this generate, maybe a range, if not a number?

Aditi Panandikar: No, we are not giving out numbers at this stage.

Vishal Manchanda: Okay. Okay. And second, on the US, the new lines that have been refurbished. I just wanted to understand what was the need to refurbish the lines? Whether these lines were kind of obsolete and that led you to refurbish? Or was it for compliance reasons?

Aditi Panandikar: Yes, compliance. So we had audits last February and then this July. So the last February audits were initially when we gave responses, where we got the OAI. In those responses, we committed to -- so there were some on sterility -- sterile practices as in how the workers moved inside because of lack of space in areas, etcetera, such things were identified. Also certain improvements towards sterility like glove ports and going for isolators, larger LAFs, those commitments we made and, therefore, the refurbishments.

Vishal Manchanda: Okay. So you would have replaced the entire line in that case. And the old line has been removed from the space?

Aditi Panandikar: No, we have not replaced the line. We have not replaced the line. We have refurbished the area and sort of upgraded the lines wherever required.

Vishal Manchanda: Okay. And the total capex that we would have incurred for this?

Pramod Ghorpade: In this year, we have incurred close to about INR200 crores, including some new machines upgradation, all the projects, some advances.

Vishal Manchanda: And specifically for this refurbishment project?

Aditi Panandikar: Sorry, Vishal, just to give you more clarity. For the line upgradation, it was more of a repairs and maintenance cost. So it is not entirely capex. Certain -- of course, certain components we got, which is a part of capex.

Vishal Manchanda: Okay. And just one final one. The other expenses line is quite elevated this quarter, around INR165 crores. I think about 15% jump and probably the highest ever we have seen. So any details there?

Aditi Panandikar: So some amount of remediation costs have started coming in. There was also, I think, a good amount of payout on incentives for India business. And as Pramod correctly said, repairs and maintenance has absorbed a lot of the remediation for the lines in plant 2.

Pramod Ghorpade: While Vishal, when you talk about INR165 crores, that is at consolidated level, which includes certain expenses related to Warren, FPP and Indoco. At Indoco stand-alone, if you see our average this quarter, we are at INR139 crores. So -- which we had indicated. Like our average is between INR120 crores to INR130 crores. But because of certain additional costs related to remediation, we are at INR140 crores at this point of time.

Vishal Manchanda: Okay. Okay. And we -- like how should we expect this to be in the future, the other expense line, around INR150 crores, INR140 crores or INR150 crores levels?

Pramod Ghorpade: No, no, no. Certainly, you will have a range of about INR120 crores to INR130 crores.

Vishal Manchanda: At a consolidated level, I mean?

Pramod Ghorpade: Consolidation level adds around another INR20 crores for other two entities, FPP and Warren. So about INR150 crores.

Moderator: The next question is from the line of Narendra from RoboCapital.

Narendra: So I'm new to the company, so pardon me if the questions become a little repetitive. Just wanted to know that the recent warning letter that we have received, what is it regarding? And what kind of products are we still allowed to supply to the US? That's my first question.

Aditi Panandikar: So we are, at this time, as I said earlier, we are in communication with FDA to find out what we can and cannot supply with zero risk, some risk, etcetera, and we're also talking to our customers. So sterile products are basically of two kinds, aseptic filling and terminal sterilized. Terminally sterilized products have very low risk because they are sterilized at the end.

So we are going ahead manufacturing and supplying those products, but they form a very small percentage of our portfolio. So we are still waiting for okay to start manufacturing the aseptically filled products. Since our outline response has gone to FDA, we have to give them some time before they come back to us and we can start getting clarifications from there on.

Narendra: Okay. Okay. Understood. And what -- why are we seeing softness in the European region? Any reason for that?

Aditi Panandikar: Yes. So I think in the beginning, we spoke of this that a couple of our sites where the master manufacturing plan is being rolled out, there were delays in certain completion of projects because of which supply from those sites got impacted. That's it.

Narendra: Okay. So going ahead from FY '26 onwards, except Europe -- except US, all of our geographies should go back to the earlier levels of performance, right?

Aditi Panandikar: Yes.

Narendra: Okay. Okay. Great. And on the margin front, right? So this quarter, it was only because of these 2 reasons? Or was there any other factor that contributed to this? And also a related point, would it be possible to give out a range of what kind of margins do we make in the US business on a steady-state basis?

Aditi Panandikar: No, it would be very difficult for us to give you that, and we are anyway not giving out that kind of data. But your question is correct. As I said, it was only because of non-supply of product in this quarter that the margins were so severely impacted.

Narendra: Okay. Okay. Understood. And on the capex, which you have done, I can see around INR400-odd crores in the past 2 years. So is it fully for the refurbishment? Or is there any component other than that as well?

Aditi Panandikar: No, there is refurbishment. We have set up a new unit at Auric, which is for making cosmetic toothpaste, where we now manufacture the OTC toothpaste. We also have added a block for increasing capacity of API because otherwise, we were dependent on our old site at Patalganga alone. That is largely where the capex has happened. And some amount of capex has gone into the -- into sort of going for newer equipment in order to increase efficiency at the solid oral side.

Moderator: The next question is from the line of Ankit Minocha from Adezi Ventures.

Ankit Minocha: I mean, margins this quarter, obviously, you've mentioned the reasons, but margins in the previous quarter were also on the lower side. I mean, if I was to kind of understand when do we move back with all your issues with remediation, with all the issues with supply into the existing markets. If I was to look at the next four quarters, say, Q4 -- upcoming Q4 and then Q1, Q2, Q3 of the next year, when do we think we kind of will move back to business as usual and maybe like touch 15% EBITDA margins in this time period?

Aditi Panandikar: So as I said, the next two quarters, we will stay impacted at least for the warning letter related issues and sales to US from the sterile plant. So nothing before that, I don't expect we will be able to come back to 15% for sure. But the 13% we were going at, possibly by Q3 of next year, we could start seeing some early signs of it.

Ankit Minocha: Okay. And this 13% you're mentioning, say, if it's by Q3, then would you have an estimated, say, some sort of a target for the entire Europe to...

Aditi Panandikar: Let's just not talk of any estimates. Nobody -- you can understand the kind of pressure the organization is under right now with the warning letter and 2 more quarters of having to sort of not be able to supply product, but we hope against hope that from FDA, we will hear something and be allowed to make more. If that happens, we can try to do better. So no commitments, no guidance's.

Ankit Minocha: Sure. And in terms of the warning letter, I mean, do we think the worst -- we've seen the worst in terms of this quarter? Or could the following quarter be even worse coming ahead?

Aditi Panandikar: No, I think this is the bottom because we couldn't supply anything this quarter, so -- at least from sterile product perspective.

Ankit Minocha: Right. And finally, these remediation costs, which are kind of coming up extensively, do these costs now start to taper out slightly and reduce slightly?

Aditi Panandikar: No, the remediation costs will continue for at least two quarters. And after that also in a certain measure.

Moderator: The next question is from the line of Pratik Kulkarni from KamayaKya.

Pratik Kulkarni: I just wanted to ask that even after all the compliance challenges and the remediation things going on or the master manufacturing plant going on, I see that the company is currently in complete re-haul and revamp in its business process. But as it is taking some delay, so I just wanted to know that how much per quarter revenue are we losing because of these delays?

Aditi Panandikar: So as we said, in this quarter alone, we have not -- we have seen a sales drop from the reg market of close to INR90 crores. And I said in the beginning that we have orders of INR180 crores in hand. So that INR90 crores could have easily gone to INR100 crores. So the largest impact has been seen only in this quarter, where INR100 crores additional revenues could have been collected.

Moderator: The next question is from the line of Harsh Shah from Reera Holdings.

Harsh Shah: So my question is related to the previous question asked by one of the participants. Since we are losing out on a certain amount of revenue because of the remediation measures and even also because of the US FDA issues, someone else would be filling in the market since we are not supplying?

So just want to get a sense that once we get back on track, how do we get that market back because I'm sure there would be multiple competitors who would be operating in similar drugs would be supplying the market. So when we get back on track, how do we regain that market again?

Aditi Panandikar: Yes. So our business to international markets, reg markets is of two kinds. One where we contract manufacture for others and other where we have our products front-ended. So even if it's FPP or Clarity, they are our products. So there, we are pretty much in control of the whole chain directly or indirectly. And here, of course, in the shortest run, there may not be much impact because there is also stock carrying in these markets. So that will not cause too much problem.

I see more impact possibly in the contract manufacturing side if our partners lose confidence in us, where I have to say our business teams are doing an exceptional job. Also within limitations, whatever we are able to supply, we are trying to satisfy everyone to a little extent so that they do not -- any one single party does not get too much impact.

Harsh Shah: Okay. So currently, your customers would be engaging with some other vendors to fill in the...

Aditi Panandikar: They always have, Harsh. We are in business for making paracetamol for U.K. for the last 20 years. And the parties we supply to, they are taking product from many other parties. So question is whether they will want to come back to us or no, whether they will stay with us or no. That pretty much depends on, a, the relationship and reputation we have built over so many years working with them. Also the cost.

And I have seen at least that for a few pennies, they have not moved because the partnership and sort of logistic kind of support, which we have faltered for the first time in 20 years where we probably have not given people what they have wanted. This is the first time it has happened. And I am very hopeful that we should not lose long-term business because of this.

Moderator: The next question is from the line of Rajat from Tata Mutual Fund.

Rajat: Aditi, ma'am, just one question from my side. If I look at your employee expenses for 9 months, that seems to be pretty much flat on a Y-o-Y basis. Could you just elaborate what has led to this? There is absolutely no increment. Is there any rationalization in the field force or the incentive -- there is some reclassification of incentive, what has happened here?

Aditi Panandikar: Yes. So we have been watching employee costs for a long time. And as part of the checks and controls to bring in efficiency at sites, there is a great improvement seen, especially in areas like R&D and some of the areas like contract workmen and others where there is improvement certainly seen in employee costs. And even in the field, while we have not cut down the number,

our new restructured divisions like the second division of ophthal or any -- like we recently launched a division in the North, it has come from reconstituting existing field force.

Rajat: Sure. So we should not expect any material jump in employee expenses in terms of incentives in the last quarter, right? It should not be materially different from this quarter?

Aditi Panandikar: No, no.

Moderator: Yes, sir. Does that answer your question?

Rajat: Yes, I'm done.

Moderator: Thank you. As there are no further questions from the participants, I now hand the conference over to the management for their closing comments.

Aditi Panandikar: Yes. Thank you, everyone, for your active participation and all your questions. And thank you for joining us today. Yes, thank you very much.

Sundeep Bambolkar: Thank you.

Pramod Ghorpade: Thank you.

Moderator: On behalf of Dolat Capital Markets Private Limited, that concludes this conference. Thank you for joining us, and you may now disconnect your lines.