Q3 FY24 Earnings Conference Call

12th February 2024

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Mr. Yugandhar Puvvala - CEO of Eugia Pharma Specialities Limited

Mr. Swami Iyer – CEO of Aurobindo Pharma, USA

Mr. V Muralidharan – President, Europe Formulations Business

Mr. S. Subramanian – CFO, Aurobindo Pharma Limited

Mr. Shriniwas Dange - Investor Relations, Aurobindo Pharma Limited

Moderator: Welcome to Aurobindo Pharma Q3 FY24 earnings call. Please note that all participant line will be in listen-only mode and there will be an opportunity for you to ask question after the opening remarks. Please note that this conference is being recorded.

I now hand the conference over to the management for opening remarks. Thank you and over to you Sir.

Shriniwas Dange: Thank you, Vandit! Good morning and a warm welcome to our third quarter FY24 Earnings Call. I am Shriniwas Dange from the Investor Relations team.

We hope you have received the Q3FY24 financials and the press release that was sent out on Saturday. These are also available on our website.

I would, now, like to introduce my senior management team on the call with us today, represented by –

- Dr. Satakarni Makkapati – CEO of Aurobindo Biosimilars, Vaccines and Peptide Businesses & Director Aurobindo Pharma Limited
- Mr. Yugandhar Puvvala - CEO of Eugia Pharma Specialities Limited
- Mr. Swami Iyer - CEO, Aurobindo Pharma USA
- Mr. V Muralidharan – President, Europe Formulations Business, and
- Mr S. Subramanian – CFO

We will begin the call with summary highlights from the management followed by an interactive Q&A session.

Please note that some of the matters, we will discuss today, are forward-looking, including and without limitations, statements relating to the implementation of strategic actions and other affirmations on our future business, business development and commercial performance. While these forward-looking statements exemplify our judgment and future expectations, concerning the development of our business, a number of risks, uncertainties and other important factors may cause actual developments and results to vary materially from our expectations. Aurobindo Pharma undertakes no obligations to publicly revise any forward-looking statements to reflect-in future events or circumstances.

With that, I will hand over the call to Mr. S. Subramanian for the highlights. Over to you, Sir.

Santhanam Subramanian: Thank you Shriniwas. Good morning and a warm welcome to our Q3 FY24 earnings call. It has been yet another quarter with the highest ever sales. The sales growth was seen across multiple markets and businesses. This is further augmented by the highest ever EBITDA.

Now, let me take you through the details of the results for the third quarter of FY24 declared by the company.

For Q3, the company registered a revenue of Rs. 7,352 crores with an increase of 14.7% year-on-year. [Audio issue starts] The EBITDA before FOREX and other income grew by 67.8% year-on-year and by 14.1% quarter on quarter to Rs. 1,601 crores. [Audio issue ends]. EBITDA margin for the quarter was at 21.8% against 19.4% for the last quarter. The net profit increased by 90.6% year-on-year and by 23.7% quarter-on-quarter to Rs. 936 crores.

The revenue of Rs. 7,352 crore was impacted [Audio issue starts] by claw-back tax of Rs. 121 Cr in Europe [Audio issue ends]. Otherwise, the revenue would have been Rs. 7,473 crores and EBITDA would have been Rs. 1,722 crores i.e. 23% margin.

In terms of the [Audit issue starts] the Business breakdown, Formulation business, excluding Puerto Rico, in Q3FY24 witnessed a growth of 17.2% Year-on-Year to Rs. 6,291 crores and contributed around 85.6% to the total revenue. [Audio issue ends].

API business contributed around [Audio issue starts] 13.9% and clocked a revenue of Rs. 1,022 crores for the quarter, registering a growth of 7.1% on a Year-on-Year basis. [Audio issue ends] The growth is mainly driven by higher volumes on account of improved asset utilization and debottlenecking. [Albeit], the quarter-on-quarter decline was [Audio issue starts] mostly on account of business restructuring impact.

For the quarter, the revenue from the US formulations, without Puerto Rico, increased by 28.9% year-on-year to Rs. 3,756. On a constant currency basis US revenue increased by 27.1% year-on-year to $451 million. [Audio issue ends] The growth was mainly driven by volume gains, stable demand and new product launches. Our wide range approved basket has helped us optimally manage the price erosion which remain neutral.

We have received final approval for 16 ANDAs and launched 21 products in Q3 FY24. We have filed 7 ANDAs during the quarter.

Revenue from oral generic products in USA has increased by 22.4% year-on-year to $287 million in Q3 FY24. Revenue from injectable and specialty business increased by 58% year-on-year to $112 million [in Q3FY24]. The year-on-year growth was driven by new product launches. The total injectable and specialty sales globally increased by 46.8% and stood at $ 150 million.

We have a total 216 injectable and specialty ANDA filings as on 31st December ’23, out of which 164 have received final approval, and the remaining 52 are under review or have tentative approval.

The company on 31st December ‘23 has 820 ANDAs filed with the US FDA on a cumulative basis, out of which 641 have final approval and 31 have tentative approvals, including 6 ANDAs which are tentatively approved under PEPFAR and the remaining 148 ANDAs are under review.

For the quarter, Europe formulation clocked a revenue of Rs. 1,728 crore, an increase of 1.6% year-on-year growth. In constant currency terms, the Europe revenue was € 193 million against € 203 million of last year [Q3]. The revenue was impacted by one-off clawback tax.

For the quarter, growth market revenue grew by 25.6% year-on-year to Rs. 627 crore. In US Dollar term, the revenue grew to $ 75 million in Q3 FY24 from $ 61 million in previous year Q3.

For the quarter, ARV business revenue declined by 28.6% year-on-year to Rs. 179 crore or $ 22 million. The drop in the revenue in this quarter is mainly due to sales deferment to Q4 in compliance with the Ind AS-115.

During the quarter, the raw material costs have improved further aiding our gross contribution which stood at Rs. 4,201 crores. Gross margin for the quarter was higher at 57.1%, against 55.2% of last quarter, mainly due to lower raw material costs and favourable business/product mix.

R&D expenditure stood at Rs. 398 crore during the quarter which is 5.4% of the revenue. During the current quarter, R&D expenditure was higher on account of the clinical trial expenses for multiple projects.

Capacity utilization has gone up well in this quarter driving the operating leverage. Consequently, EBITDA improved Rs. 1,601 crores reflecting a margin of 21.8%.

Net CapEx for the quarter was $103 million, which mainly includes approximately $37 million towards PLI project. The cumulative CapEx for the Pen-G project, till December 31st, amounts to approximately $230 million.

The average USD INR exchange rate is 83.24 in Q3 FY24 against 82.68 in Q2 FY24.

The business had a net cash outflow of $7 million during the quarter before the PLI investments and investments in new markets. As a result, the net cash position, including investments at the end of December ’23 was $49 million. The gross debt is $815 million.

Subsequent events –

US FDA inspection: further to our intimation regarding the US FDA inspection of Eugia Unit III dated February 2, 2024, we would like to provide the following updates –

- On February 2, 2024, FDA completed an onsite inspection of Eugia’s Unit III and issued a Form 483 with nine observations. We will submit a comprehensive written response by FDA’s deadline of February 26th, 2024.
- In an abundance of caution, the company temporarily paused manufacturing and distribution activities at the Unit III site. We have taken these aggressive measures because we believe it is the most responsible and appropriate course of action until we can conduct investigation and assessment to give FDA assurance that we are addressing its observations.
- We are continuing to distribute terminally sterilized and ophthalmic products manufactured at Unit III that we have already shipped to the US.

- We are working closely with FDA's drug shortage staff, and we have retained third party experts to assist us in conducting investigation, assessments and restart activities.
- With the progress we have achieved to date, we anticipate resuming production on non-aseptic lines around the end of the month, with a phased return to service on aseptic lines. Also available stocks are being retested and progressive release of tested stocks starts from the second fortnight of February '24.
- We will continuously work with the US FDA, and we will work tirelessly to achieve and sustain compliance with the FDA requirements and expectations.

My colleague will give further details on this in the Q&A.

Outlook – Our financial performance in Q3 was driven by operational and cost efficiencies. With our continued focus on developing strong pipeline and driving the commercialization of our key projects combined with positive business environment, we are confident of continuing the growth trajectory across the top line and bottom line. Some of the key highlights for the forthcoming quarters are summarized below -

- In Q3 at an overall level, US continued to have neutral price erosion. Also, raw material costs have continued to show reducing trend in Q3. We remain optimistic in Q4 in terms of the margins.
- While the growth in oral solids is expected to be strong and, we see positive signals in our OTC portfolio and steady continuity in branded oncology injectable business, My colleague Swamy will discuss about it when addressing the Q&A.
- We are confident of achieving 20% EBITDA margin target, set internally for the year, as mentioned in the previous quarters.
- Our new pipeline of approvals will include high margin, new generation product categories viz. biosimilars, peptides etc.

- We have the following plants under commissioning -
    - The China plant is fully installed and we have received EU-GMP approval. It is expected to start revenue generation from Q1 / Q2 FY25.
    - The Lyfius plant for Pen-G and the 6-APA plant are under installation. The trials are underway. Operations are expected to start from Q1 FY25.
    - The Vizag injectable plant is expected to be commercial in Q1 / Q2 FY25 growth markets. It is expected to start generating revenues from US and Europe by FY26.
    - Further, we are conducting clinical trial studies for our biosimilar products and the plant is expected to be commissioned by FY25 or early FY26.

- Considering the current market conditions, EBITDA margins are expected to improve with Pen-G plant commercialization and stabilization of the manufacturing process. The expected margin improvement will be without considering the margin from biosimilars.

- Apart from that, we will be incurring CapEx for the CMO business in biosimilars. My colleague Dr. Satakarni will provide more insights on the entire biosimilars and the other complex generic portfolio during Q&A.

This is all from my end.

I take this opportunity to introduce Mr. V. Muralidharan - President, European operations. He has been taking charge of Europe for the last 22 years and was instrumental in many M&A transactions in Europe. Welcome Murali for the earnings call.

Now my colleagues will give more clarity on any specific aspects in our Q&A session. We are happy to take your questions. Thank you.

Moderator: Thank you very much. We will now begin the question answer session. Anyone who wishes to ask question may raise your hand from the participant tab on your screen. Participants are requested to use headphones or earphones while asking the questions.

The first question is from Kunal Damesha.

Kumal Damesha: Hi, good morning and thank you for the opportunity. So the first one on the plant inspection, the Eugia III plant inspection. I think, I missed some of the comments. As of now, we have shut down the majority of production. Is [this the right] way to understand it? And then within that, the non-aseptic lines are expected to come back in Feb. And then aseptic lines. I didn't get the deadline there. But if you could provide some colour as to how many lines are aseptic lines and how many are non-aseptic lines, and also qualitatively, if you can direct at the contribution to revenue etc. would be helpful.

Yugandhar Puvvala: Yes, your understanding is right. In fact, the non-aseptic lines will start off sometime in next few weeks, and aseptic lines will take a month or two. And we expect that entire production to get streamlined by end of this financial year. We expect this stoppage can have an impact of around $20 million in Q4 of this financial year.

Kumal Damesha: Okay. And when you say streamlined by the end of the financial year, is FY 24 or FY 25 year?

Yugandhar Puvvala: I'm talking about FY24.

Kumal Damesha: FY24, okay. Sure. And then the second question on the EBITDA margin, which you have guided for 20% for this year and then we have also said that Pen-G plant at current prices etc. could help us improve that. Beyond that, what other levers do you see for the next year for the EBITDA margin improvement on a year-on-year basis?

Santhanam Subramanian: See, at this stage Kunal, we are talking about achieving 20% for the year. Already we are 19.4% and by end of this quarter, we will touch upon 20%, that we are confident. Apart from Pen-G, we are not saying anything at this stage. Probably next quarter we will be able to talk about it.

Kumal Damesha: Sure. And just last one again on the Eugia III. Do we have a lot of earnings concentration coming out of this plant, like few of the products making up for a lot of our revenue? If yes, can you guide us with top five products from the plant? What could be the revenue contribution?

Yugandhar Puvvala: See in general, this particular plant is important to us. [However] now we are a bit more distributed in terms of plant concentration, with Eugia-I also contributing significantly. But for Eugia business, this plant contributes to around 40% of revenue. And in fact, there are multiple products where we are market leaders in US, and that's where we are focusing in terms of how fast we can resolve and restart manufacturing.

Kunal Damesha: Sure. Thank you. I have more questions. I'll join back the queue.

Moderator: Thank you. The next question is from Neha Manpuria.

Neha Manpuria: Yeah, thanks for taking my question. Just an extension on Eugia Unit III. You know, if I remember, a few years back when we had shut down the bag line, it took us a very long time. I'm not even sure if we are back to the impact that we had seen at that point due to the shutdown. Now when we shut down the facility for an extended period of time, for the next 2-3 months and the revenue loss that you're mentioning, what is the confidence of bringing back the $20 odd million numbers, particularly since we are not going to see new approvals till the time we clear this facility also?

Yugandhar Puvvala: Neha, thanks for asking this question. The bag line issues might be different from the current observations. What we feel is the current observations are more to do with aseptic processing practices, some documentation gaps. We are confident that we are working with the most reputed consultants to ensure that we put the strongest response possible and also resolve the issues. That's where we feel that non-aseptic and aseptic, we are separating it out and ensuring that we start in a phased way both the things. Our assessment at this point in time is, this is going to take 1-2 months, and we will be back in full flow from April. That is our current assessment, Neha.

Neha Manpuria: I understand that. But my point is that the $20 million impact that you have mentioned, so there is obviously risk of market share loss in some of the larger products from this facility. What gives you the confidence of us being able to get back market share if we lose that in the next [quarter]. Is that a scenario that we are pencilling in at this point?

Yugandhar Puvvala: At this point of time, we do have stocks to cover up for the next 60 to 90 days, and we feel in some of the big products, we have enough coverage to take care of the market share. But if we lose, we will also gain, because these markets always give opportunities in terms of when you have 100 products, you lose in one and you gain in one. So in general, once we are back onto the full flow of production, we are expected to continue the similar run rate. There might be a $5 to $10 million gap in a quarterly level, but we are confident.

Neha Manpuria: Understood. And based on the data that you have given on the pipeline, it seems like bulk of our injectable pipeline is from this unit. But just want to understand the

approval pipeline in the next two years. How much of that pending 35-40 ANDAs is likely that we were building in for let's say, [FY]25-26.

Yugandhar Puvvala: See in [FY]25-26, anyway we were not expecting any major approvals from this plant. And as you know, we are putting most of our new products into the Vizag plant as a part of our de-risking strategy, we were always tech transferring and filing new products from a new plant because we also felt that we have put too many eggs in one plant. So we are just re-distributing and that has been going on for last 1-1 ½ years. And from a [FY]25-26 perspective, were not expecting any major approval from this plant.

Neha Manpuria: Okay. And sorry to harp up on this, Yugandhar. So where is our FY25-26 growth going to come from for the Eugia business, other than gRevlimid? From an injectable pipeline, where would that growth come from?

Yugandhar Puvvala: Yes, you said it right. It's mainly going to come from gRevlimid. But were expecting around $30 to $40 million of new products revenue coming from balance of the plants. As you know, we have total five plants, four commercial and one Vizag new plant. So were expecting 50% of the new product revenue coming from the balance plants and 50% new products revenue coming from this plant.

Neha Manpuria: Got it. Thank you so much.

Moderator: Thank you. The next question is from Shyam Srinivasan.

Shyam Srinivasan: Good morning and thank you for taking my question. Just on the disclosures of the US business, right? I think last quarter, specialty and injectable were around 90-91 million and now it is showing 112. Is a majority of this coming from the gRevlimid launch in the quarter?

Yugandhar Puvvala: Frankly, I'm not at a liberty to disclose as per our settlement terms with innovator the amount of Lenalidomide sales separately. But in general, yes, what you are saying is most of it is coming from gRevlimid.

Shyam Srinivasan: Got it. And the 20 million Yugandhar that you are calling out, so we should assume that on the injectable part of the business, that's where the 20 million goes away in Quarter four. Correct, right?

Yugandhar Puvvala: That's right.

Shyam Srinivasan: Got it. Understood. The second question for me is on the cash flow generation. So we had about Rs. 1,600 crores of EBITDA. But when I look at the slide 14, cash flow from business after working capital and others, it is about 45 million. So is there an adverse conversion cycle this quarter? Maybe 9 month numbers could be different. So if you could help us there.

Santhanam Subramanian: Yeah. Shyam, this quarter we have made some of the creditor payments [that] have been due across the group and we have paid nearly around $75 million in terms of the increased creditor over and above the gross current assets.

Shyam Srinivasan: Subbu Sir, you voice is low. Sorry, can you please repeat?

Santhanam Subramanian: In terms of the creditors during the quarter, our creditor payment is more than the gross current asset generated, to the extent of $ 75 million. That is the reason for the drop in the cash flow vs. the cash PAT.

Shyam Srinivasan: Understood, okay. So this is just a quarterly phenomenon you are saying?

Santhanam Subramanian: It is a quarterly phenomenon, because now the creditors have come down, we can sustain that additional 75 million which will get generated as part of the normal process

Shyam Srinivasan: Got it. My last question is just I think there is a slide on the biosimilars. Dr. Satakarni, if you could kind of walk us through the update on the biosimilars side, thank you.

Dr. Satakarni Makkapati: Good morning. So, on the biosimilars (front) we have an (SEC) approval for Trastuzumab, which is our anti-HER2 breast cancer drug in India. We have a SEC recommendation for marketing authorization. We are closing down on the final nitty-gritties before we receive a [final] marketing authorization to market in India. So, that's the first approval from CuraTeQ Biologics in the biosimilars business, with respect to the other programs, we have three filings done with European Medicines Agency including Trastuzumab. A spate of other filings with Trastuzumab is (are) likely to follow in emerging markets, including that of the US in the next quarter. So, that's an important update. It is likely (that) we have a couple of other filings made with MHRA and Health Canada. So, I expect the programs that are filed with the(se) regulatory agencies to go through the review process and materialize in the next financial year.

With respect to the ongoing (Phase 3) clinical trials, we have two programs, one in ophthalmology and one in oncology - two clinical trials happening globally. Both of them are progressing reasonably well.

As updated in the last quarter, we also have initiated a Phase 3 clinical trial of Omalizumab biosimilar in Europe across multiple countries and sites there. As you know Omalizumab references Xolair which is an injectable drug that targets and blocks immunoglobulin E. The product is approved for the treatment of adults and children with moderate to severe asthma and chronic spontaneous urticaria. The drug had worldwide sales, I believe, of around [$] 4.3 billion in 2023. So, our biosimilar version of this product is already in Phase 3 clinical trials. We hope to complete the recruitment by October 2024 and submit it to both Europe and US in the Q2 or Q3 of the next financial year. It is an important drug for us (and) so hopefully, we will be able to complete the clinical trials on time.

Our second immunology biosimilar also has received a green light from the European agency for conducting a Phase 3 clinical study in Osteoporosis patients. The study has actually begun

this month (read, January 2024). The study is being conducted across European region in multiple sites and the first patient was dosed in January. We hope to complete the recruitment of all 450 plus subjects in Osteoporosis trial inside Q2 of this year [June'24] and hope to advance the product to filings in the second half of next (calendar) year.

So, the reason why I bring this up is, you can see , from the wave one of products which was essentially having an oncology focus (to) a gradual and a nuanced shift into the immunology segment. With these two key products with a current market opportunity of around $ 12.5 billion making a shift into the immunology segment is what we aspire to achieve. Especially with Xolair (biosimilars), the competition is very limited and we also expect that there will be additional indications in treating accidental food allergies and hopefully will have a longer product cycle. Hence we are reasonably excited and are aspirational about this product.

So, that's about the guidance on the 7 biosimilars, three of them which concluded the trials and are in the filing phases or have already been filed with certain agencies and four of them in global Phase 3 trials. There is another immunology product that we are (only) developing, for emerging markets and India, which we will complete the (Phase 3) clinical trial in May this year and I expect it to be filed with DCGI first and other emerging markets by June-July this year.

So, Shyam, does that answer your question?

Shyam Srinivasan: Yeah, that's helpful, Dr. Satakarni. Just one follow up is on the opening remarks from Subbu Sir on the CMO with MSD. So, if you could give an update on that as well. Thank you.

Dr. Satakarni Makkapati: Yes. In the last quarter I mentioned that we have entered into a limited Letter of Intent with MSD Singapore entity enabling us to become a contract manufacturing provider for one of their products. Under the terms of the agreement, Theranym Biologics which is a wholly owned subsidiary of Aurobindo Pharma, will deliver cGMP batches of drug substance as well as drug products for supplies to MSD entity. We hope to start supplying from 2027-28. To this effect we are continuing to deliberate and engage with MSD entity on the terms of the definitive agreement, which I have stated in the last earnings call that we endeavour to close by the 31st March 2024. So far, we are progressing in the right direction and I believe we will be able to close the definitive agreement during this period. If there are any changes or extensions that I would take in terms of negotiating and closing and winding down this definitive agreement, I will provide an update in the next earnings call. But in a nutshell, it is progressing well and we hope to close the definitive agreement pretty soon.

Shyam Srinivasan: Thank you, got it and all the best.

Dr. Satakarni Makkapati: Thank you.

Moderator: Thank you. The next question is from Damyanti Kerai.

Damyanti: Good morning, all. My first question is again coming back to Eugia III. So, as we discussed you have been putting a lot of effort to bring the plant back to full production. But just want to understand in case it takes longer, so do you have any backup plans for shifting some of the key products to other facilities. If yes, which will be the facilities where you will be transferring your products, apart from the new ones which you said are filed from the Vizag unit.

Yugandhar Puvvala: Damyanti, in fact Vizag is built as a back up to Eugia III, so in case that situation arises we will try and tech transfer some of the key products to the Vizag plant.

Damyanti: And just want to understand, are these injectable plants fungible in nature or like you have to have different lines dedicated for some particular product.

Yugandhar Puvvala: No, we do have enough lines in Vizag, we have about 7 lines and as I have been saying in the past Vizag will act as a backup to Eugia III, also filing products from there, to some extent it is fungible because most of the lines what we planned was based on that direction only.

Damyanti: Okay. But just want to understand, you said Vizag plant will be ready for developed market some quarters down the line. I just want to understand from immediate perspective say in next 3 to 6 months if you want to transfer some products can you do that to Vizag or it is like not possible.

Yugandhar Puvvala: Damyanti, at Vizag plant we have already filed 2 products to US from that plant and we do expect inspection to happen any time in next few quarters. And normally any tech transfer takes time and takes time to get approvals from the new plants. But at this point of time, I think we are speculating too much, I think you need to give us time to respond to Eugia III observations and then we will see how it goes.

Damyanti: Sure, Sir, that's helpful. My second question is on gRevlimid, obviously you won't be commenting on the numbers, etc., but just want to understand from the sales contribution perspective will it be distributed across quarter, or you have some phase where you will be supplying most in a year and then in some quarters we won't be seeing much contribution coming in.

Yugandhar Puvvala: Our endeavour is to just make it a quarterly run rate, but sometimes depending on the pricing and customer request we might end up billing a bit more in that particular quarter, but in general it will be a distributed revenue across quarters. In case in one quarter it is more that will get knocked down in the next quarter, our endeavour is just to space out every quarter that is what we are planning to do. In general, Eugia we were doing around $100 million per quarter last year, this year first two quarters we were doing $120-$130 million and then like now we are reaching run rate of $150 million plus. So, our endeavour is just that in next few quarters we continue to maintain a run rate of $150 million plus.

Damyanti: Sure. My last question is due to these adverse geopolitical situations, Red Sea situation etc. are you seeing any notable pick up in your logistics cost. Like in near term should we expect operating cost will go up from current level.

Santhanam Subramanian: Damyanti, see the logistic cost as a percentage of the total sales is very, very low and at this point of time we see a decrease in the EBITDA margin to the tune of around 0.1 to 0.2 % at this particular point. It is not very significant at this point.

Damyanti: Okay as of now as you said it is miniscule and no impact as such.

Santhanam Subramanian: Yes.

Damyanti: Okay, Sir, thank you. I will get back in queue.

Moderator: Thank you. The next question is from Tushar Manudhane.

Tushar: Thanks for the opportunity. Sir, first one is PLI Scheme project, just would like to understand the pricing of Pen G maybe pre-Covid and what would be the profitability if the price goes below $20 per kg.

Santhanam Subramanian: Tushar, as I said last quarter also let us not speculate at this point of time. Our first objective is to complete the trial batches and start the business in the first quarter and the second challenge we will be doing is how fast we are ramping it up. We think we should be able to ramp it up between Q1/Q2. And once the full ramp up happens only the pricing issue will come because till that time the pricing issue will not come. So, we don't need worry about it for the next few quarters in my view. The current price will continue in my view.

Tushar: Just from a sensitivity perspective, let's say three quarters down the line when we start the external sales and at that point of time you know if at all you can elaborate what happens if the price goes beyond.

Santhanam Subramanian: Sensitivity modelling is your prerogative, how can I suggest that.

Tushar: Okay. Just one clarification gRevlimid is from Unit IV, right, as in Eugia Unit III.

Yugandhar Puvvala: It is Eugia I - which got audited in the month of July 2023 and we received zero observations and NAI classification for that facility.

Tushar: And lastly for FY25 given circumstances of the Eugia if you could call out what would be the sales guidance.

Yugandhar Puvvala: Tushar, I just mentioned that we are, in fact this quarter which is the quarter 3 we achieved $ 150 million of revenue for the quarter, and we expect to continue similar run rate in going forward in the next quarters. But Q4 might have slight impact as I mentioned, it can have an impact of $ 20 million but we will see how we can cover up that gap.

Tushar: Thank you for addressing my question.

Moderator: Thank you. The next question is from Bino.

Bino: Most of my questions have already been answered. Just one update on this product, Ryzneuta, which you in-licensed from Evive. Have you launched it in the US, and what are your targets like?

Yugandhar Puvvala: Sorry, we couldn't hear which product.

Bino: This Efbemalograstim product, Ryzneuta, in-licensed recently from Evive

Swami Iyer: So this product we are likely to launch in the second quarter of this coming fiscal or second half of this calendar year.

Bino: Given that it is a BLA would you need a sales force and all. How do you plan to sell it? Do you have any market share targets?

Swami Iyer: We have market shares, we have obviously budgeted for what we are going to sell. At this point I don't think we will be able to share that kind of sensitive information. But there is a 7 player market but we believe that we would also be one player and obviously it has got to be profitable for us. We hope to achieve a decent amount of sales. But it is too early to tell you about it.

Bino: But you are going to set up a sales force for this?

Swami Iyer: We already have a sales force and wherever it is required we will augment. I don't believe we are having any major ramp up for it.

Bino: Alright, got it, thank you.

Moderator: Thank you. The next question is from Surya Patra.

Surya Patra: Hello. Thanks for this opportunity, Sir. My first question is on the same question as the previous question basically, the in-licensed molecule. So, you indicated that second half of the current calendar year that you will be launching, but which are the markets that you are initially talking about. And do you see this as a kind of exact alternative of PEG-filgrastim?

Swami Iyer: That is something I cannot comment. We think that it is equivalent, it is non-biosimilar product. So, initially we will be launching in the US. We have plans to launch eventually in other markets.

Surya Patra: Starting with US or it is other than US market?

Swami Iyer: So, the product is already existing in China, but we are not marketing in China, we would be launching it first in the US.

Surya: Okay. And if you just add to its regulatory progress and process there, Sir, about that molecule?

Swami Iyer: We are confident of launching this product and the FDA had done the inspection in June '23. We have already received the FDA approval for it on 16th November I think last year. And then our potential launch is 2024, the product is under manufacture and we hope to CMO, we hope to launch in July 2024, we do not see any other hurdle at this point of time.

Surya Patra: Okay. So, considering the potential or the size of Pegfilgrastim, this could be one of the largest product opportunity for near term is that…

Swami Iyer: That is something I am not saying because there are like I said there are 7 biosimilar companies in the US and for this product we will have a very conservative estimate of what we are going to do. But I think economically it is a good product for us.

Surya Patra: Okay. Sir, my second clarification about the disposal of the US injectable plant. So, while we have been of the view that there is larger significant demand in the injectable side and we have a wider pipeline and that's why we had created two facilities, one in US and one in Vizag. So, US one was supposed to cater to the US increasing demand while the other one for Europe and emerging markets. So, now just before the disposal, what is the kind of thought process here?

Swami Iyer: I think Yugandhar should be answering this question. Yugandhar, you would like to take this.

Yugandhar Puvvala: Yes, yes. Sometimes what happens is initially we thought that Vizag will cater to emerging markets and Europe but subsequently two years back itself we changed the strategy that Vizag will also be backup to Eugia III and file new products from Vizag. So, with Vizag coming up and multiple lines being planned in Vizag - what we felt is US plant was becoming non-strategic and the capacities available were not sufficient to take care of the market share requirements of the US business. So, it is a strategic decision that we will take out the US plant and focus on all India plants. But at the same time the US plant will act as a contract manufacturer for us if needed with all the 4 products, in fact 2 products we filed from that facility and 2 more products we are planning to file from that facility and in case if there is a future need the contract manufacturing option is available.

Surya Patra: Okay. My third question is on the European business front. In fact, we have been saying that the European business has obviously seen margin profile beyond 15% since last couple of quarters. So, given the kind of shortage situation, improved pricing scenario for generics even in Europe what is the kind of margin profile of the business currently, that is one. And second question relating to Europe is that the European Union recently has come out with a large basket of products more than 200 which are critical for their requirement and they are expecting to create a kind of safety inventory and that's why the procurement is likely to start in this January. So, if I see the presence of Indian players in Europe obviously

Aurobindo is the largest, what would be our scope in that and what benefit you anticipate there.

Santhanam Subramanian: I would request Murali to talk about the second point, so that I can talk about the margin profile after that.

V. Muralidharan: So, I am happy to be part of this call. Coming to your question on the safety inventory advocated by EMA. Yes, we have analysed that list. We are also taking care to ramp up the inventory part (APIs and components) to supply sufficient quantities into Europe. Other than this also several regulators in our European foot-print countries do ask for certain safety net and we are working on it.

Surya Patra: Is it a sizable opportunity Sir, since it is a 300; means Sir 210 to 220 odd product basket?

V. Muralidharan: Yeah. It is almost 30% of the list of products. So, it is the sizable opportunity. Okay, yeah.

Santhanam Subramanian: Yeah. So, Surya, in terms of the margin, we've never given the margin profile of Europe, right, but having said that, we were earlier around 10% to 11% and certainly we moved up by 2% to 3% points already and with the growth we have been targeting, with the way cost structures have been looked at it certainly, we will make an attempt to touch upon the 15% plus.

Surya Patra: Okay, okay, and just lastly, any update on the pneumococcal vaccine supply opportunities, Sir?

Dr. Satakarni Makkapati: Yes, Surya, Satakarni here. On the pneumococcal vaccine, I have given an update, I think two earnings calls ago that we received SEC recommendation based on our 3 + 0 dosing regimen trial that we concluded in about 1,100 infants. We did not meet the timelines of the immunization (national) tender, because we still had the manufacturing license to obtain. So naturally, we couldn't become part of the national immunization tender that was floated. That time has passed now. During this period, we have conducted a 2 + 1 dosing regimen trial, which means the infants are given two doses followed by a booster dose 6 to 9 months later. Now, that [the] trial has completed, we submitted the findings to the SEC Committee last month.

In the private and retail market, we don't have any presence, which is an area that we would not like to enter at this point of time, because we wanted to generate more data to take the product to the WHO markets in 2026. It is the immunization (national) tender that probably is of interest to us, but we have passed that last year and I will keep you posted in case there is a strategic shift in what we think for the next tender cycle. At this point of time, in the next 2 to 3 quarters, I don't see us putting this product out in the market.

Surya Patra: Okay. Sure, Sir. Yeah. Thank you. Wish you all the best.

Dr. Satakarni Makkapati: Thank you.

Moderator: The next question is from Smith.

Smith: Thank you for the opportunity. My question is on US generics. How was the pricing environment in Q3 for injectable products?

Yugandhar Puvvala: It was a low single digit price erosion.

Smith: is it Q on Q or YoY?

Yugandhar Puvvala: It's Q on Q.

Smith: Okay. Thank you.

Moderator: Thank you. The next question is from Kiran Shah. Hi, Kiran, you are on mute. Okay, we move on to the next question. The next question is from Tarang Agarwal.

Tarang Agarwal: Hi, good morning. Couple of questions. Starting on Europe, if I were to adjust for the tax clawback, you're at about €206 million. How should we look at this business going forward here? Is this €200 million the new base for this business? and, in your response to an earlier participant, you commented you gave a metric, you said 30% of those 200 odd products. If you could elaborate in terms of what that 30% was?

V. Muralidharan: Yeah, 30% in the list of INNs that have been identified as potential shortage items and the manufacturers have to potentially ramp up the inventory and also we know in terms of the number, this much will come, but it's not based on value or other quantifications at this moment, but again we have communicated to our country teams to very closely look at these products and do the needful on the demand forecasting and purchase orders and similarly India team are also aware of it. So, I hope this answers your first question and relating to the clawback, Subbu, do you like to comment, or can I continue to?

Santhanam Subramanian: No, no he's talking about whether this is going to be the new phase against 206 of adjusted revenue for the quarter?

V. Muralidharan: Tarang's question was also whether are we going to clock this €200 million plus Q on Q and Tarang yes, we will be doing that for sure, that is the objective and of course this quarter because of the almost close to €14 million clawback, it's slightly impacted our Q3 revenues.

Tarang Agarwal: Sure. Thank you. On the ROW markets, if you could elaborate and I mean there's been a solid growth about 25% odd in INR terms in this business, any specific markets which are driving them, is it one off or the Rs. 600 crore or Rs. 625 crore quarterly run rate is something that we should work with moving on?

Santhanam Subramanian:: Tarang, ROW market as we call it growth markets is comprised of multiple countries including Canada, Brazil, South Africa, and China and many markets and we have been growing in all the markets at least. $1 million, $2 million like that we have been growing and it is expected to continue, especially China was not a player in the past and now they started contributing something, which we said will be doing single digit. Now, we are talking about moving to at least $10 million to $20 million in a year time and once the plant is commercialized say in Q2, it can go up only. So, this is where we are on the growth markets.

Tarang Agarwal: Got it, got it. And my last question on the US, Mr. Swami, if you could give us a sense on the outlook for the oral solids business, do things remain where they were say in Q2 or are you seeing an improvement in outlook or deterioration in outlook?

Swami Iyer: Yeah. We expect the strong momentum to continue underpinned by new product launches and surging volumes. We have taken a strategic decision to adopt volume-based plan to enhance our footprint. While the growth in the oral solid is expected to be strong, we also see some positive signals in our OTC portfolio and steady continuity in the branded Oncology injectable business. Overall, we are looking at decent growth going forward.

Tarang Agarwal: Okay. Thank you. All the best.

Moderator: Thank you. The next question is from Kunal Damesha.

Kunal Damesha: Thank you. Thank you for the opportunity again. Just one on the Eugia 3 since we have now added a third-party consultant etc. any view on the remediation cost we could have for the next year and more related to Eugia 3 again, so we are expecting this probably $20 million impact on revenue, but will there be any non-supply penalty since we are basically one of the biggest supplier to the US market? So, have you kind of factored in that as well?

Yugandhar Puvvala: Yeah, we expect $2 million to $3 million in the coming few months with respect to the third-party consultants working with us and we did evaluate in terms of what can be the penalties part of it. At this point of time, the way like we think it might not be significant, but in case if anything changes, I'll let you know.

Kunal Damesha: Sure, sure, and just on this clawback tax on Europe, this € 13.5 million would have, the complete amount would have impacted our EBITDA negatively, it's the way to think about it?

Santhanam Subramanian: Yes, yes, you're right.

Kunal Damesha: Okay, okay, perfect. Thank you and all the best.

Moderator: Thank you. The next question is from Nitin Agarwal.

Nitin Agarwal: Sir, my question is 2 things. One is on the biosimilar business. Dr. Satakarni has given us a sense on the pipeline, but if you can give us some more colour on how should

we see the commercialization part of the biosimilar business over the next say next 3 to 4 years and sort of which geographies do you anticipate where the revenue commercialization will start earlier? What kind of salience can this business really have in the overall things say 3-5 years down the line for us?

Dr. Satakarni Makkapati: Nitin, that's a good question. So, with the Trastuzumab SEC recommendation this year, we would hope to commercialize Trastuzumab in the Indian market in the next quarter or two. That's the start of commercialization phase for this breast cancer drug. Now, with three filings in regulated markets across Europe, Canada, MHRA, we expect [them] to translate into regulatory approvals towards the end of next fiscal year. [This] means that we would also begin the commercialization phase of these products in the next four to five quarters time. Now, with four more products in clinical trials, especially the big ones which is the Xolair biosimilar, with limited competition, and the second Immunology asset that recently advanced to Phase 3 clinical trial which is a Prolia biosimilar Denosumab, both of them will be filed in 2025 in Europe and other regulated markets, including the U.S., which provides us an opportunity to get into commercial phase in the following year, which is calendar year 2026. So, while I'm not a great fan of giving projections to what could be the size of the business with seven products, out of which three of them probably get to approvals in the U.S. before 2026 and at least three to four of them in Europe, and the filings in emerging markets are going to happen with trastuzumab and other programs, I see 2026 as an inflection point for this business. For the hard years that have been put in and the investment prudence that we have followed in shepherding these products through nuanced clinical trials over the last three to four years, I see 2026 should be the year from where a significant chunk of commercial opportunity or commercial revenues will start to come in. Now, with Xolair (biosimilar), I expect by 2028 we would be around $120 million to $180 million provided we will be able to get approvals both in U.S. and Europe, and another $20 million from the rest of the world. So, this is one product that I can give guidance about because there is limited competition. The other products, we are entering into a market which is already slightly formed. So, we know where we are getting in there. We really need to test the market, but the guidance after five years for Xolair (biosimilar) would be anywhere between $120 million to $180, $120 million in the worst case and $180 million in the best-case scenario with another $20 million coming out from the ROW markets. The most important thing to underscore here, Nitin, is the margin base that will increase with the introduction of biosimilars in the regulated markets. So, that's something which we are excited about four to five years from now and see how our efforts in investing as a company into differentiated portfolio of which biosimilars (business) is significant will translate into benefits and increased margins for Aurobindo as a whole. Does that answer your question?

Nitin Agarwal: That's very helpful. If I can just probably push one point taking reference from what you mentioned earlier, barring Xolair in most of the other products, we are probably going to be entering late aftermarket formation. I mean given the way dynamics in biosimilars have played out in Europe and the U.S., I mean what is your assessment in terms of what is our capability? What is the right to win even after we enter so late in some of the most of these products going forward?

Dr. Satakarni Makkapati: So, that's an interesting perspective. Now, in the first wave of products where we are already entering a formed market. A formed market is in a sense

where biosimilars have already formed the market. There is a price erosion that has already happened, for example, if you look at a Trastuzumab, I don't think it is going to erode further. In fact, the market started to pick up now because the outreach and availability of this biosimilar for multiple other patients or the patient base is increasing. So, when you enter a formed market, you make educated decisions. You say, okay, you have a price erosion of around 85% or 80% already in certain markets, so do I have the cost of goods to enter and still make a 80%-85% gross margin. So, only when we think we can enter a market which is already formed and if there is a further price erosion of 20%-30%, still we can make around 80% to 85% gross margin, only then we are entering into those markets and developing those products. So, we are sure while we are slightly late in certain products, With Denosumab, we will not be very late. With Denosumab, we will be in the 1st and 2nd wave of launches. With the first wave of products, it is a very strategic decision that we will enter into a low risk and already formed market. A low risk both in terms of the market as well as in terms of the IP risks. And we will test ourselves. So, for example in Europe, with so much price erosion we see with these products, I can safely tell you with the cost of goods that I'm having, I will still have a 85% gross margin.

Nitin Agarwal: Right Sir. Is it fair to assume that across all of these markets we would be leveraging our existing field forces to push these products. We would not be requiring additional SG&A investments in any meaningful way?

Dr. Satakarni Makkapati: That's wishful thinking. For example, in Europe we already have a field force and we will continue to engage with them and we will utilize that workforce. In U.S., Acrotech will become the arm for biosimilars commercialization. As you know, Swami has alluded to before, wherever there is a requirement, we already have a certain base there. [And] we are augmenting our field force depending on the nature of the products that we are going to launch. And to answer one of your colleagues question before, on the FC fused Filgrastim that we are going to launch in the U.S., there is already going to be a field force in the Oncology segment there, when we put out products in that market. So, we'll be using the same field force plus augment it, because the nature of biosimilars marketing is slightly different and still requires some sort of marketing. So, it will not be a grounds-up building or constructing or nurturing a field force there, we will leverage on what we have plus augment it with the skills that are required to take these products to their commercial success.

Nitin Agarwal: Got it. Thank you. It was useful. If I can squeeze probably one more, Sir on the Chinese plant, which you're talking about getting commissioned by Q2, Sir what is the strategy for this plan, is this going to be largely for Chinese consumption or we're looking at it as a base for other Reg markets? I mean and if you can probably highlight the thought process behind this Chinese manufacturing assets?

Santhanam Subramanian: Yeah. Nitin, Originally we are planning to do it for Europe and China. The products will be supplied for Europe immediately. The approval from the Chinese regulators may come around Q2 or Q3 of next fiscal year. Then, we will be supplying to China also. At this particular point of time, we are not saying U.S. as it will take at least 1 to 1½ years because the inspection will be triggered and approval to come etc., but as a whole, we will be using the plant to supply all the markets.

Nitin Agarwal: And Sir this is our orals plant or there are other lines also beyond the orals?

Santhanam Subramanian: This is only oral plant.

Nitin Agarwal: Okay. And Sir if I could take one last one, on the inhaler Sir, we had some products in the pipeline, any color on their commercialization or schedules?

Swami Iyer: Yeah. so, you're talking about the BFS product, so you're talking about the DPI / MDI kind of products?

Nitin Agarwal: Sir, the DPI/MDI products and the other one also if you can touch upon?

Swami Iyer: So, you know the DPI/MDI, we have a product that's under development. We have a query on it and then our team is responding to it, that would take some time and I think there are some legal issues too in launching that product. So, that's definitely going to take some time. As far as the BFS is concerned, Subbu mentioned in his starting remarks saying that one of our joint ventures is going to start manufacturing. So, we hope to have some news in the early part of fiscal 2025 on the manufacturing and commercial sale of some of the BFS products.

Nitin Agarwal: Okay, Sir. Thank you so much.

Moderator: Thank you. The last question is from Jigar Walia.

Jigar Walia: Hello, hi. Thank you for the opportunity. My first question is for the products approvals, we have received from the injectable side, how many would be from Eugia 3?

Yugandhar Puvvala: Most of it is from Eugia 3. Except for one product.

Jigar Walia: Got it. Second question, your perspective around the generic prices in the U.S. market, particularly around the current times?

Yugandhar Puvvala: We expect that at least on the specialties and injectable side, we expect a low single digit going forward into the next quarters.

Jigar Walia: Got it. Broadly, is there any concerns particularly from the U.S. market with regards to China sourcing, imports or generally China origination?

Yugandhar Puvvala: I don't see much of an impact, but that Swami can comment on it.

Swami Iyer: Subbu, would you like to comment on it.

Santhanam Subramanian: Yeah, I'll do that and then Swami will supplement it. Recently there was a report released and we have gone through the report and first of all we like to state upfront that we will only buy from the U.S. approved or acceptable vendors who have been with us for a long time, and we are not aware of the basic source of the report because

we see certain discrepancies. The first point I'd like to say is, the report talks about selling Valsartan. We are not selling Valsartan in the last 4-5 years. In fact, one of the suppliers mentioned in the report is supplying that and is having a market of around $1½ billion dollars. So, we are not clear about the source and we are also trying to find out if there is a sanctioned list of the suppliers but we are not able to find any. Having said that, the procurement from the suppliers in the list given in the report is very, very insignificant, in low single digits. So, we are not seeing any concern etc. from procurement of material from China. Also, once we get into manufacturing of Pen-G that percentage may also come down. So, we want to assure all our stakeholders that we are fully committed to upholding the highest standards on what we do, including the procurement, quality, everything.

Jigar Walia: Right. Thank you very much, Sir. Thank you and best wishes for the FD. Thank you.

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

Shriniwas Dange: Thank you all for joining us on the call today. We apologize for the mic and line related issues at the beginning of the call. If you have any of your questions unanswered, please feel free to keep in touch with the Investor Relations team. The transcript of this call will be uploaded on our website www.aurobindo.com, in due course. Thank you and have a great day.

Moderator: On behalf of Aurobindo Pharma, that concludes this conference. Thank you for joining us and you may now disconnect your line and exit the webinar.

(END OF TRANSCRIPT)