

May 31, 2024

To Listing Department, <b>NATIONAL STOCK EXCHANGE OF INDIA LIMITED</b> Exchange Plaza, Bandra Kurla Complex, Bandra (E), <b>MUMBAI -400 051</b> <b>Company Code No. AUROPHARMA</b>	To The Corporate Relations Department <b>BSE LIMITED</b> Phiroz Jeejeebhoy Towers, 25 <sup>th</sup> floor, Dalal Street, <b>MUMBAI -400 001</b> <b>Company Code No. 524804</b>
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Dear Sir/ Madam,

**Sub: Transcript of Q4 FY24 earnings call.**

Please refer to our letter dated May 17, 2024, wherein we intimated about the schedule of Investors/ Analysts call on May 27, 2024. We are attaching herewith the Transcript of the said analyst / investor call on the Audited Financial Results of the Company for the fourth quarter and year ended March 31, 2024, and the same is being uploaded on the website of the Company and is available in the following web link.

<https://www.aurobindo.com/investors/disclosures-under-regulation-46/investor-meet/conference-call-transcripts/>

Please take the information on record.

Thanking you,

Yours faithfully,

**For AUROBINDO PHARMA LIMITED**

**B. Adi Reddy**  
**Company Secretary**

Encl: As above.



## **Q4 FY24 Earnings Conference Call**

**May 2024**

**Dr. Satakarni Makkapati** – CEO of Aurobindo Biosimilars & Director of Aurobindo Pharma Limited

**Mr. Yugandhar Puvvala** - CEO of Eugia Pharma Specialties Limited

**Mr. Santhanam Subramanian** - Chief Financial Officer, Aurobindo Pharma Limited

**Mr. Swami Iyer** - CEO, Aurobindo Pharma, USA

**Mr. V. Muralidharan** – President, Europe Formulations Business

**Mr. Shriniwas Dange** - Investor Relations, Aurobindo Pharma Limited

**Moderator:** Welcome to Aurobindo Pharma Q4 FY24 earnings call. Please note that all participant lines 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 fourth quarter FY24 earnings call. I am Shriniwas Dange from the investor relations team. We hope you have received the Q4 FY24 financials and a 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 and 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 the 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 obligation 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 Q4 and full year FY24 earnings call. It has been a good year performance across the businesses mainly driven by volume gains, new product launches, our expansion in to new growth markets and stable pricing. The profitability of the company has improved significantly backed by softening of raw material prices, favourable product and business mix and improved operating efficiency with better capacity utilization. We had the highest ever sales and EBITDA for the quarter and the year. For the year FY24, we achieved 29,002 crore of sales exceeding our internal target of Rs.28,500 crores plus and achieved an EBITDA margin of 20.1% against our guidance of 20%.

Now let me take you through the details for the results of the Q4 FY24 and full year FY24 declared by the company. For Q4, the company registered a revenue of sum of 7,580cr., with an increase of 17% year on year. The EBITDA before forex and other income grew by 68% year on year and by 5% quarter on quarter to Rs.1,687cr. The EBITDA margin for the quarter was at 22.3% against 15.5% for the last year, same quarter. Net profit increased by 80% year on year and decreased by 3.% quarter on quarter to Rs. 909cr. The quarter on quarter decline was mainly on account of the onetime exceptional loss of Rs. 122cr. For the full year FY24, the company registered a revenue of Rs. 29,002cr. with an increase of 17% year on year supported by growth across the business. The EBITDA before forex and other income grew by 55% year on year to Rs.5,843cr. EBITDA margin for the year was 20.1% against 15.1% of last year. Net profit increased by 65% year on year to Rs. 3,173cr.

In terms of the business breakdown, formulation business excluding Puerto Rico in Q4 witnessed a growth of 21% year on year to Rs. 6,510cr. and contributed around 86% of the total revenue. The revenues are mainly supported by growth across the growth markets and Europe. For the full year FY24, formulation business including excluding Puerto Rico witnessed a growth of 19% year on year to Rs. 24,419cr. and contributed around 84% of the total revenue.

For the quarter, API business contributed around 13% and the revenue remained flat year on year at Rs. 1,019cr. For the full year FY24, API business contributed around 15% and clocked a revenue of Rs. 4,241cr. registering a growth of 10% year on year basis. The growth in the API business is mainly driven by higher volumes on account of improved asset utilization and debottlenecking.

For the quarter, the revenue from US Formulations excluding Puerto Rico increased by 22% year on year to Rs. 3,588cr. On a constant currency basis, US revenue increased by 20% year on year basis to US\$432 million. The growth was mainly driven by volume gain, stable demand and new product launches. Our large product portfolio basket helped us to optimally maintain the price stability. The Q-o-Q decline of around 4% however was mainly on account of lower sales from Eugia and seasonality. The sales volume in US are expected to pick up during the quarter [Q1FY25]. Revenue from US Formulations for the year increased by 23% to Rs.13,867cr. or US\$1,675mn.

During the quarter, we have filed 11 new ANDAs, received approval of 17 new ANDAs and launched 7 new products. Revenue from oral generic product in USA has increased by 23% year on year to US\$279mn in Q4FY24. Also, for the full year, the revenue from oral generic products in USA increased by 18% to US\$1,078mn.

Revenue from injectable and specialty business in USA increased by 28% year on year to US\$104mn. The year on year growth was driven by new product launches and volume gain. Albeit, the quarter on quarter decline was mainly on account of the Eugia-3 plant temporary shutdown. The total injectable and specialty sales globally increased by 26% year on year and stood at US\$143mn for Q4. For the full year revenue, the revenue from injectable and specialty business in USA increased by 38% year on year to US\$397mn. The total global injectable and specialty sale for the year increased by 31% year on year and stood at US\$541mn for the year against last year's US\$414mn. We have a total of 223 injectable and

specialties ANDA for the year ending 31<sup>st</sup> March 24. Out of that, we received 169 final approval and remaining 54 under review or tentative approval. The company as on 31<sup>st</sup> March has 830 ANDAs, out of which 658 have final approval and 27 have tentative approval.

For the quarter, European Formulation clocked a revenue of Rs.1,832cr., an increase of 10% year on year. In constant currency terms, the Europe revenue was Euro 203mn as against Euro 188mn of last year Q4. For the full year, the European Formulation revenue grew by 12% and clocked a revenue of Euro 798mn. For the quarter, growth markets revenues increased by 50% year on year to Rs. 852cr. In US\$ terms, revenue grew to US\$ 103mn in Q4 FY24. The revenue increase is mainly driven by sales across the markets. For the growth markets, revenue increased by 29% to Rs. 2,517cr. In US dollar terms, revenue grew to US\$281 million in FY24 from US\$243mn in the previous year.

For the quarter year, ARV formulations revenue increased by 31% to Rs. 238cr. or US\$29mn. For the year, ARV business decreased by 11% to Rs. 868cr. or US\$105mn mainly due to pricing pressures partially offset by volume gain.

During the quarter, the raw material cost eased up further supporting our gross contribution which stood at Rs.4,519cr. Gross margin for the quarter of 59.6% against 57.1% of the previous quarter which is supported favourably by the favourable business and product mix.

For the year, the gross contribution stood at Rs. 16,399cr. with a gross margin of 56.5% against 54.6% of last year. R&D expenditure stood at Rs. 392cr. for the quarter which is 5.2% of the revenue. For the year, the R&D expenditure stood at Rs. 1,480cr. which is 5.1% of revenue.

Improved capacity utilization seen during the last few quarters has resulted in continued operating leverage benefit during Q4. Consequently EBITDA improved to Rs. 1,687cr. For the full year, the operating leverage benefit has reflected in 20.1% against 15.1%. The net capex for the quarter is US\$70mn which mainly includes approximately US\$33mn towards the Pen-G projects. Net capex for the year is US\$422mn which includes approximately US\$146mn towards Pen-G projects. Cumulative capex for the Pen-G projects amounts to US\$285mn. The average USD INR exchange rate is 83.04 against 83.24 in Q3 FY24. The business has a net cash flow of US\$12mn during this quarter before the Pen-G investments and investments in new market. As a result, the net cash including the investments at the end of March'24 was US\$18mn. The gross debt is US\$758mn.

Recent changes in the composition of the board - Our board structure comprises of 10 board members out of which 5 are independent directors including 2 women directors. Mr. M.R. Kumar, ex-chairman LIC India has been appointed as the Chairman of Board of Directors for the company from April 01, 2024. Dr. Deepali Pant Joshi, retired as Executive Director from RBI, joined the Board of Directors during the year.

Outlook - Our financial performance in Q4 FY24 and the full year FY24 was driven by higher sales on the back of new products launches, expansion into new growth market, volume gains and stable pricing. During the quarter, we commercialized 4 manufacturing facilities including Pen-G, 6-APA and injectables. During the next few quarters, we expect the operation of these plants to ramp up and start contributing to the top and bottom line meaningfully. With

continued investment in R&D, we continue to develop strong growth pipeline. We are focusing on our key strategic priorities to enable a long-term growth. Our growth levers include:

- Backward integration to build resilient supply chain for key raw material reflected in the recent commercialization of Pen-G and 6APA facility
- Expanding manufacturing footprint with capacity enhancement, debottlenecking the existing capacities and newer facility creation. At present we are manufacturing around 47 billion units of formulation.
- Expanding growth market with a recent foray into the Indonesian market with acquisition of 17 brands
- Long term growth with biosimilars. Our biosimilar and complex products portfolio is progressing. The clinical trials are advancing. Mr. Satakarani, CEO, will elaborate on that.
- Ensuring a well-diversified product portfolio reflected in 830 USA ANDA filings and continued focus on R&D investment.

With a continued ramp-up of our recently added capacity, R&D efforts and focus on strategic growth [levers], we are confident of continuing our growth trajectory during FY25 as well. We expect to achieve around 21-22% of EBITDA margin and target set internally for the year. This is all from my end. Now our business leaders will give more clarity on any specific aspects in the 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 questions, may raise your hand from the participant tab on your screen. Participants are requested to use headphones or earphones while asking the question. 1<sup>st</sup> question is from Kunal Dhamesha.

**Kunal Dhamesha:** Hi, good morning! can you hear me?

**Moderator:** Yes.

**Kunal Dhamesha:** Ya. Thank you for the opportunity and congratulations on a good set of numbers. Just one of the 1<sup>st</sup> questions on the growth outlook for FY25. While we said that we will continue to grow, would you be able to give any range for the outlook FY25?

**Santhanam Subramanian:** We are not giving any growth outlook overall as a company but our respective business leaders will talk about it when they are addressing their businesses.

**Kunal Dhamesha:** Ok sure. Given that how Eugia 3 is classified as an OAI and there are 29 pending ANDAs, what is our plan to de-risk our growth in the next couple of years till we are able to resolve this official action indicated?

**Yugandhar Puvvala:** Hi Kunal, good morning! I am sure you are aware that we have built the Vizag plant as a backup, de-risking plant for Eugia-3. Now, Vizag plant audit is completed and hopefully we should get our first approval sometime very soon. So we will start filing more products from our Vizag plant. We also have plan to de-risk Eugia-3 by doing dual filings from

Vizag. So that's been the plan from almost 2 yrs. and now it is getting actualized with the audit getting over.

**Kunal Dhamesha:** How many filings (because of this OAI) for let's say next 2yrs will get stuck from Eugia 3 out of this 29?

**Yugandhar Puvvala:** Let's say around 20+ will get stuck but we have taken all proactive actions and we have never waited for FDA to come back and we hope that we will be in a position to show to FDA that we are in state of compliance. I expect at least 1yr. getting impacted but hopefully in the 2<sup>nd</sup> year, we should come back. That's our internal estimates on this.

**Kunal Dhamesha:** Sure Sir. Thank you. Second question is for Satakarni Sir on the biologics CMO LOI that we have signed with the MSD. Any update on LOI to contract signing as of now? Whatever capex we are putting, capacities etc., are we through in terms of basic infra? What is the update there?

**Dr. Satakarni Makkapati:** Hello Kunal! With respect to the limited Letter of Intent that we signed with Merck, I have updated the exchanges that I would attempt to close the definitive agreement by 31<sup>st</sup> of May. Now, I think, we are truly on track to close the definitive agreement with MSD, Singapore entity by 31<sup>st</sup> of May. I don't see any showstoppers there. Sure[ly] there are a few nitty-gritties that we are still ironing out but I am optimistic about closing it by 31<sup>st</sup> of May. If there are any delays by a couple of weeks, then we will keep the exchanges informed about it. But at this point, I don't see any showstoppers. What is your 2<sup>nd</sup> question Kunal?

**Kunal Dhamesha:** In terms of capacities, how many litres worth of bio-reactors we are putting and what's the capex that we are planning for that contract? And what's the outlook, I mean in terms of where it is in terms of finalizing?

**Dr. Satakarni Makkapati:** We have already started our project work. As I have told before, this is a large mammalian cell culture manufacturing facility which is being done in 2 phases. The Phase 1 capacities would be 2\*15KL mammalian cell culture stainless steel bioreactors with associated purification lines to manufacture the drug substance as well as isolator-based vial filling line to convert the drug substance into the finished product. So this is an integrated CMO offering end to end services in manufacturing, both drug substance, the drug product and the QC release. The project is shaping well. If you remember the details about my limited Letter of Intent, we have capped ourselves to an exposure of around US\$24.5mn to the point where we sign the definitive agreement. In case we, for any reason we don't sign the definitive agreement, we are covered for the US\$24.5mn. So right now, we are well within the cap and I think the deal is going through, so exciting times for us. This is the update that I have on the project. It's going well. It's on time. It has already been 5 months since we have started the civil work and by 2026, the capacities will be aligned and commissioned to start the water and engineering runs in the facility at Theranym.

**Kunal Dhamesha:** Perfect and thank you. All the best Sir.

**Dr. Satakarni Makkapati:** Thank you.

**Moderator:** Thank you. The next question is from Damayanti.

**Damayanti:** Hi and Good morning! I hope I am audible.

**Moderator:** Yes.

**Damayanti:** Ok, thank you. So my first question is again on Eugia-3. So as Mr. Yugandhar mentioned that the de-risking process is on and dual filing is one of the process that you are taking. So just want to understand, out of the 29 ANDAs which are pending from the Eugia-3 plant, have you filed any product from Vizag so far or this or this process will start now?

**Yugandhar Puvvala:** It will start now, Damayanti. All the new filings and some of the site transfer projects is what we are planning to do in Vizag but we have no plans of transferring the existing filings of Eugia-3 to Vizag. I hope that clarifies your question. We are still confident that we will be in a position to resolve issues and we will secure approvals for Eugia-3. That's our internal confidence level at this point.

**Damayanti:** Ok. In terms of remediation, what kind of timelines you are anticipating, say you already started when the FDA update came first and you took obviously some precautionary measures etc. In terms of resolution, what are the plans, you will be hiring 3<sup>rd</sup> party consultant and what will be the approximate timelines anticipated by your team within which you can resolve the FDA queries satisfactorily?

**Yugandhar Puvvala:** We have taken the remediations even in the middle of the audit itself. In fact when we voluntarily stopped the manufacturing, that was our 1<sup>st</sup> step when we observed there are some deficiencies. Our remediation activities started immediately after the audit. We are already into the 4<sup>th</sup> month of remediation and we expect probably that it will go on for another 3-4 months. Post that, as and when the management feels confident that we have addressed all the concerns raised by the auditors, we will approach the FDA again.

**Damayanti:** Got it. Very broadly, in terms of the impact, in terms of sales, the 4<sup>th</sup> quarter number is broadly representative of what we may say for the next few quarters while remediation is on or it could come down?

**Yugandhar Puvvala:** No. 4<sup>th</sup> quarter, I have taken the hit. I think, I told this last time to one of the analyst that because we stopped the manufacturing, we stopped the distribution, out of abundant caution, and we got everything retested and with full confidence, we started releasing the products. So we have taken whatever sales hit we wanted to take in Q4. Q1 onwards it should be normal. So we expect a run rate of about US\$ 150mn every quarter across the globe. That's the Eugia run rate now and we feel that we will maintain that.

**Damayanti:** Ok, that's clear. Thank you. My 2<sup>nd</sup> question is for Dr. Satakarni. if you can update us on some of the key biologic projects in terms of approval timelines etc. and when we should be seeing the first product coming in the market?



**Dr. Satakarni Makkapati:** Hello Damayanti. I would like to update the progress that we are making in the biosimilars business with the recent trastuzumab marketing authorization received in India. This is our 1<sup>st</sup> product authorization. We have promptly applied for a manufacturing license which we expect to obtain very soon. So, the plan is to manufacture the batches and launch the product in the second half of this year [FY25] into the domestic market. This product, [which] is used in treating early and metastatic breast cancers that are HER-2 positives, is also filed with the European Medicines Agency and the review procedure has already started. We are getting slightly delayed with the USFDA filing for this product as we could only complete a Type-IV, a mandatory Type- IV pre-submission meeting with the FDA, in May. So, the Type-IV pre-submission meeting went really well. I believe we should be able to complete the USFDA filing also in the next 3 months. So, I don't see any further showstoppers. If the procedure unfolds well with the European Medicines Agency without any glitches or without any additional data requirements, then I see a decision coming out somewhere towards the end of Q3 or early Q4 [FY25] for this product. So, this is about the first product.

Then we have two more biosimilars, both in the Oncology space, which were also filed with the European Medicines Agency. Again, the guidance on these two biosimilars will also be somewhere towards the end Q3 or early Q4 [FY25]. If the regulatory procedure unfolds without any procedural clock stops, that require any remediations etc. where I extend my clock stops, then we are expecting a Q3, Q4 [FY25] approval for these products or otherwise.

So, that's about the three biosimilars which are filed. Now, with the other biosimilars, as you know, I have told in the last Earnings Call that we have advanced two immunology biosimilars. And also gave a press release last quarter, I think in February, that we are working on a biosimilar to Xolair, which successfully met its PK/PD end points in a 3-arm Phase-I study conducted in 165 healthy volunteers. The results are extremely encouraging. We met both the key parameters of PK and PD within the equivalence ranges that we expect. I think this product is now in Phase-III across multiple European countries and is progressing well to conclude the recruitment phase by Sep-Oct. So, I expect to file this product both with the EMIA as well as the FDA sometime in Q2, Q3 of the next fiscal [FY26].

Likewise, our Denosumab biosimilar, which also I talked about in the last Earnings Call, I'm happy to state that we have completed the Phase-III recruitment across 40 sites in Europe for this product. So, this is about 436 osteoporosis patients that we completed the recruitment for. The primary objective of this study is to compare efficacy of our Biosimilar versus the originator's Prolia and I hope that I would be able to submit this product also with the EMIA and FDA between Q2 and Q3 of the next fiscal year [FY26].

Along with these two, there are two more products, an Ophthalmic product and an Oncology product, in Phase-III for a long time now. The Oncology product is inching towards the closure of recruitment. I hope to complete the recruitment by October this year and the filing phase would be Q4 the next fiscal [FY26]. The Ophthalmic product will be delayed. The Ophthalmic product, the recruitment rate is slow across Europe. So, I would be able to probably hoping to file this product only in FY26-27.

So, that's about the Biosimilar's products and what's happening with my 7 products in Wave-I and Wave-II.

**Damayanti:** Dr. Satakarni, that's very helpful. Thank you for your response. I'll get back in the queue.

**Dr. Satakarni Makkapati:** Great, thanks.

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

**Neha Manpuria:** Yeah, thanks for taking my question. My first question, Yugandhar Sir, on Eugia or broader Injectables, is it fair to assume that this will be a year of very little growth outside of generic Revlimid for the injectable business because, you know, even with Vizag, et cetera, your first approvals probably start coming through in the second half of the year? In your view, how should we look at growth of the business because the US\$ 150 million per quarter that you've mentioned is very similar to the number that you're doing, you know, you've done the fourth quarter?

**Yugandhar Puvvala:** You're right, Neha. In fact, it will be a year of muted growth. So, we do expect a double digit growth but definitely not the way like we have grown from FY23 to FY24 and that was always the plan. Like this year FY25 was supposed to be a year of a muted growth because there are no blockbuster products, approvals expected in FY25 as per the original plan itself. So, we expect things to be much better starting FY26 when Oncology OSDs and other significant filings where the settlements are been done will come. So, FY25 is going to be a muted growth.

**Neha Manpuria:** Understood. And, in terms of remediation, because we've been doing this for four months, in your view what additionally does the FDA expect Aurobindo Eugia to do on that facility for which you think it will take another 3-4 months? If you could give us some colour on that.

**Yugandhar Puvvala:** No, in fact, FDA never said anything. In fact, whatever we have done, we have done it voluntarily based on the observations and we expect to continue the same things. Obviously, there are some things which we would have completed in two months, some things which take four months, some things which take six months. This is all absolutely voluntary. FDA never advised us what to be done because when we received the letter OAI, they didn't say anything. So, it is, basically, I'm assuming that whatever we have committed as part of our response, they're fine with it. I have to complete it. That's all.

**Neha Manpuria:** Understood. And my second question is on the European business. You know, we've been able to grow the European business base. Constant currency growth this time was around 8%. With the commissioning of Vizag and also the China facility, how should we look at the growth trajectory for Europe in the next year?

**Mr. V. Muralidharan:** Yeah. Good morning and happy to answer this. Yes, in Europe, at this moment, we are definitely growing little ahead of the market growth rate and the Vizag unit's

contribution is going to be substantial. And, of course, China unit is yet to commence supplies. We expect that to happen in FY25.

**Neha Manpuria:** Understood. And one last question, if I can squeeze in one more. Subbu Sir, in FY25 given that global speciality isn't growing as much, is it fair to assume that margin expansion might be limited to additional generic Revlimid? How should we look at margins for FY25?

**Mr. Santhanam Subramanian:** So, Neha, as I said earlier, we are targeting to achieve EBITDA margin of 21%-22%. We are working on the ramping up of the Pen-G and it will be complete by September. So, we will be able to give a better number in the month of November Earnings Call. Once we know what all the issues are and what is the sort of margins we are getting in the Pen-G business, et cetera, we'll be able to tell but we are very positive about the gross margin for this year as well as the EBITDA margin.

**Neha Manpuria:** Got it. Thank you so much, Sir.

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

**Surya Patra:** Yeah. Thanks for the opportunity and congrats for the great set of numbers, Sir. My first question is on the, let's say, Pen-G. What are the kind of operation or utilization level that it has reached or what are the kind of utilization that we are targeting for the current year? And have you really commercialized the plant? And have you seen any kind of price impact in the market for Pen-G?

**Mr. Santhanam Subramanian:** Surya, the last one, price of Pen-G is hovering around \$25 per kg. Having said that, our consumption or Indian consumption of Pen-G is not very big actually. It is only 50%. What is more important is the conversion of the Pen-G into 6-APA, which we have successfully done it. That consumption is more and that price remained stable in the last two years. And it is commensurate with the Pen-G prices now.

In terms of the entire Pen-G business, we have taken a test batch in the month of March and it has come out well. We have done one big batch and it is also going well. And, hopefully, starting in the next two days, we'll be doing a little bit expanding the number of batches, et cetera. So, the entire lot of batches at the same time running all the fermenters will take place in the month of September because the fermentation is not an easy process. It's a very complicated process and there are multiple issues we are coming across and we have been resolving one by one and we were able to succeed in the first major batch. Hopefully, in another 2-3 days we will come to know the outcome of that, okay.

**Surya:** Sure. But is there any sense about the yield that you have so far got, Sir?

**Mr. Santhanam Subramanian:** No. See, the first thing is, from test batch we have to take a bigger batch. And after the bigger batch, expand the same bigger batch into multiple batches. We are having 10 sets of starting batches. So, we will expand from 1 to nearly 5 and after that we will expand to 10. So, yield is not the main issue right now. Yield we will be addressing only in the month of September.

**Surya Patra:** Sure-sure, okay. My second question is about, possibly Yugandhar Sir, you can respond. Our preparedness about the launch of Ryzneuta in the U.S., you have already indicated that launch is likely to happen in the second half of the current financial year. So, how important this launch could be for us? And how important it could be as a trigger? Knowing the fact that this is a kind of a US\$1.8 billion size, what is your preparedness for this launch? And how important that you do think about it?

**Mr. Swami Iyer:** No, Yugandhar, I think I'll take this question. I think he's referring to the product that we are getting from Evive. So, we have briefly talked about it in the last call. So, we expect to launch it in the second half of the current calendar year, that is sometime in July. And we also mentioned that there are a number of competitors in the market and we had also indicated that we don't believe that the volume or the pricing is going to be so high. But we'll have to see as we launch this product. We are somewhat guarded and we are somewhat not so optimistic, I mean, in terms of what you're saying with regard to the value. But we think it's a good product. Once we launch, we'll have a better feel of it.

**Surya Patra:** Ok. Sir, just, if I need some more clarification about it, see if the size of the product is, let's say \$1.7-\$1.8 billion and the competition is generally from the biosimilars and we know that the penetration of the biosimilar is kind of not so great. And, generally, the interest of the payer, in U.S. biosimilar business if you see, is not generally aligned with biosimilar manufacturer. Rather, it is more aligned with the innovators. And since it is an innovative molecule, is it not fair to believe more positively than what you have indicated?

**Mr. Swami Iyer:** So, I leave that to you on how you want to look at it. But we have done a study and typically we like to do it conservatively and we have a fairly conservative estimate. This is a non-biologic product, as you're aware, and this is something different. So, we have to see as we go.

**Surya Patra:** This is not a biologic molecule, Sir?

**Mr. Swami Iyer:** I don't believe so. [Please refer to the later comment, in the transcript, by Mr Swami Iyer for a clarification]

**Surya Patra:** Okay. So, my third question is about the Biosimilar opportunity as a whole, Sir. So far what are the kind of money that we have spent towards this biosimilar portfolio creation and all that, Sir? And whether this cost is currently capitalized or it is expensed currently? And once you start commercializing the product, what is the likelihood that it will have some impact on the overall margins of the company? So, if you can give some sense about it.

**Mr. Santhanam Subramanian:** I will provide some light on the numbers but the impact will be informed by Satakarni. We have spent around US\$ 340 million so far and the only we have capitalized around US\$ 75 million and balance has been charged to P&L, right. Overall impact on that, Satakarni we will be able to answer.

**Dr. Satakarni Makkapati:** Surya, the spend numbers have been provided by Subbu. Now in terms of impact, as you can see, we have completed the licensure clinical trials for three Biosimilars. We should also realize that we have been in existence only from 2018-19 seriously. So, we completed 3 clinical trials and filed three products. Now, we have four more in global Phase-III clinical trials.

Now, if you see how much does the competition spend versus what we spend on developing a product all the way from cell line to bringing it to clinical efficacy trials, it's very prudent, it's very objective. We are very guarded in what we spend because we push the regulatory barriers when we design our clinical trials.

Now in terms of the impact, while I hate to put certain numbers against these products, there is a good opportunity with both Wave-I and Wave-II of the products if they get launched in Europe and if U.S. also comes by. Especially I am very optimistic about a product like Omalizumab where we will be probably one of the four companies to vie for the U.S. and the European market. And it's a US\$4 billion product with probably four players in it by FY26-27. So, I expect a good revenue stream once the product gets into the European and the U.S. market. So, all these seven products, well, I hate to put any numbers against it, our business is sustainable, the cost of goods ensures that we have a margin base of around at least 60%-80% depending on which market we are.

And to your question about how much will this increase the margin points of Aurobindo overall, there will be an impact depending on what share of the business that we get in. But biosimilars with a higher margin will definitely increase, to a certain extent, the margin base of Aurobindo as a whole. But I expect it to make substantial contributions from the year FY29-30, the Biosimilar s business, to the overall Aurobindo margin base.

**Surya Patra:** Okay. Just last, Sir. In fact, are you really worried about the fact that the progress of biosimilars for Adalimumab what we have seen in the U.S.? Looking at that scenario, are you worried about your pipeline or your entry into the U.S. business with your pipeline?

**Dr. Satakarni Makkapati:** To be honest, no, because the biosimilar landscape, especially the market opportunity and the market landscape, is fast evolving. Adalimumab is a specific case that people would like to discuss but I would like to look at the better growth stories that we have. For example, you look at Pegfilgrastim space where a biosimilar player has taken at least US\$700-800 million of the revenues from the U.S. market alone. So, Adalimumab is a curious case because it is a chronic segment product, which means that you need repeated doses of the product. And in chronic segment, I expect, the markets to behave in a slightly disruptive manner, especially if someone comes in with a disruptive pricing strategy. But whether that will happen across all the products and primarily across products and oncology, I personally don't think so.

Come what may, our business model has been built in a manner that we will be resilient with respect to any price disruptions that happen. For example, we are building our price model versus the Europe right now where you are already seeing in the chronic segment a bleeding of around 85% and 80% from the innovator pricing. Even if there is such a price erosion, our products will be able to still sustain the margin of around 50%-75% very easily even if there is

further price erosion. Only then we are developing the product and hope to enter into the market.

So, as much as you are very cautious about what's happening in the U.S., I am also watching that space closely. But, I think, biosimilars are required in the U.S., especially to reduce the healthcare burden and the normalization will happen very soon. Adalimumab is a one off case. And it might happen in the chronic segment where products like Adalimumab are prescribed. But in Oncology segment, I still think there will be very healthy margins in the U.S, not so much in the Europe.

**Surya Patra:** Sure, Sir. Yeah, thank you. Wish you all the best.

**Dr. Satakarni Makkapati:** Thank you.

**Mr. Swami Iyer:** Surya, just to clarify. My apologies, it's biologic, I'm sorry. I meant it's not a biosimilar, right. So, this is something different. It's a biologic. So, we are competing against number of players who are there in the biosimilars.

**Dr. Satakarni Makkapati:** I would just add a point there to what Swami said, Surya. It is a biologic but it's a biologic going against the Filgrastim and the Pegfilgrastim. So, that's the reason why Swami is conservative with his numbers. Once he gets a feel of the market when he launches it, then he will tell you how the product is shaping up. I mean, it is as good as a guess that you have that we have also in the U.S. market with this product.

**Moderator:** Thank you. As we have a long queue of questions, I would request everyone to restrict to two questions per participants. The next question is from Shyam Srinivasan.

**Shyam Srinivasan:** Yeah, good morning. Thank you for taking my question. Just a quick about housekeeping, the specialty and injectable revenue in the US\$104 million. Yugandhar Sir, this had the US\$ 20 million hit, right? I'm just trying to get the number right in terms of what we stopped for Q4.

**Yugandhar Puvvala:** That's right.

**Shyam Srinivasan:** Okay. And when you're now guiding for it to go back to US\$ 150. I'm assuming about US\$ 110 was the last quarter number.

**Yugandhar Puvvala:** It's actually like it's a global number versus a local U.S. number. So, the global number what we expect is a global revenue of US\$150 million.

**Shyam Srinivasan:** Understood.

**Yugandhar Puvvala:** U.S. will continue to be in the range of US\$100-110mn. That's the range out of that US\$150mn.

**Shyam Srinivasan:** Understood. And do you expect a ramp up in Revlimid for next year? FY25 I mean.

**Yugandhar Puvvala:** Yeah, depending on the settlement percentages, normally we do expect a slight improvement maybe.

**Shyam Srinivasan:** Sure. Okay, that's helpful. Second question is on the gross margins. Subbu sir, I think has reached almost if I round up 60%. So this is a number we're not seeing for some time. So just want to get the sense of what is sustainable, which are the cyclical elements in it, which will probably go away, maybe like whatever low raw material cost you called out earlier? What can sustain from a mixed perspective? And when we do the 21% to 22% guidance from EBITDA margins, what are the things that could be below the gross margin lines that could be growing faster?

**Santhanam Subramanian:** Last year, we did around 20.1%. So against, that when you're saying 21 to 22%, one is the overall gross margin has improved considerably by about 2- 3%. Right. Between last quarter to this quarter, if you recollect, last quarter we had a big hit on account of the clawback tax, which we have explained to you; around EUR13 million we have taken a hit. That is around Rs. 122 crores, if I recollect, which has been given in the press release. Against that we are around Rs.35 to 40crores only this quarter. So, this is expected to continue. Because the French government has come with a clawback notification, which helps us to have a lower clawback tax this year. That is one thing.

In terms of the raw material price, the prices have come down considerably in the last four quarters, and it is now remaining slightly lower to flat. I don't see a major improvement or decrease in the raw material prices. But what is more important is, as we said, the US business is doing well, and they are continuing to ramp up and which has helped us to drive the operating efficiencies, which can help us to improve the overall EBITDA margin. And also, as Swami has explained or touched upon it, there are a lot of new product launches which he has done, which is also helping us, and the pricing environment is stable. So, we don't see a major down in the EBITDA margin, as well as the gross margin. Once the Pen-G comes, which I explained in the month of September, what is the additional gross margin improvement which will come out of the Pen-G, will be disclosed sometime in November earnings call.

**Shyam Srinivasan:** Understood. Sir, my last question again, you talked about Pen-G prices at US\$25. Last calendar year, this was US\$30. So are you seeing action from some of the Big 3, Big 4 in Pen-G already in anticipation of your 15,000 metric ton total. I'm saying maybe global will be lower. But just are you seeing some signs that they are starting to drop prices? At what dollar per kilogram or ton do you think it starts becoming less feasible? Like, if it goes below US\$20, let's assume, does this become difficult? So, I'll stop there. Thank you.

**Santhanam Subramanian:** My chief buyer does not believe there will be a big drop in the Pen-G prices. Having said that, the Pen-G price has no relevance in terms of the overall consumption of the entire Penicillin G, because we are going to consume it- convert it, and then consume it as 6-APA or some other product, other forward derivatives. So really, the Pen-G price has no meaning actually, because we are not importing any Pen-G at all. We are importing single digit kgs only. So Pen-G price has no relevance for us. What is important is

how much we are going to convert it into 6-APA, how much we are able to further convert it into amoxicillin bulk and then sell it in the market or sell it as 6-APA, is what really matters. And that price, 6-APA price is always stable. So let's forget what is the Pen-G price. Pen-G price has no relevance actually.

**Shyam Srinivasan:** Got it, sir. Helpful. Thank you and all the best.

**Moderator:** Thank you. The next question is from Tarang Agarwal.

**Tarang Agarwal:** Hi, good morning and congrats on an extremely strong FY24. A couple of questions, one on Capex. You know, quite a few projects have been commercialized, Pen-G, 6-APA, Vizag, Granulation, China. If you could give us a sense on when, you've suggested Pen-G will probably start in September, both Pen-G and 6-APA, but if you could give us a sense on the other three projects, when will they start to meaningfully contribute?

And further, CWIP as on March 31st, 2024 was about Rs.2,750 crores. And Intangibles under development was about Rs.1,130 crores. So if you could just give us some sense on what are they referring to? What plants or what specific products are they referring to? My sense is, US\$75 million of biosimilar capitalization, a large part of it would be under Intangibles under development, but I'll leave for you to comment on that. And then I have a couple of questions. Thank you.

**Santhanam Subramanian:** We have four projects commissioned in the last quarter, one is the Pen-G and the second is the 6-APA. That meaningful contribution will start coming from Q3 onwards. And we also capitalized part of Vizag Injectable facility, and Auroactive project. We have done only partial capitalization, the front end only. So as Yugandhar already informed, the inspection took place and is waiting for the next steps. In terms of the Auroactive, it will also start moving up by August- September. In terms of the total overall [CWIP] of Rs. 2,739 crores or US\$325 mn, as you rightly said, CuraTeQ forms around \$78 mn and USA, Dayton facility will be around US\$70mn. And we have other projects, which are very small.

In terms of the intangible asset under development, which you said around Rs.1,129 crores or US\$135 million, once again, there are certain, Acrotech products, which are under WIP, Acrotech, which is around US\$75 million, which they are doing clinical trials. And Eugia Specialities, which Yugandhar has already explained that is after the settlement, etc. It will go by FY26. The other things are very small. So actually, our plate is very clear and we will be capitalizing and we will be seeing a meaningful contribution starting September, October onwards.

**Tarang Agarwal:** Perfect. Okay. Thank you. On US and Europe, I mean, US, can we expect the current OSD run rate of about \$280 million to edge up to about US\$300mn as we move forward? And similarly for Europe, EUR 200mn seems to be the new base. How should we look at it for FY25?

**Swami Iyer:** So on the US, we are fairly optimistic about the outlook for the coming fiscal with new launches being the main drivers. I think, I cannot quantify any particular amount, but you



know, we have a large base and compounding growth on this base will be difficult. But we do believe that there is a reason to be optimistic about the growth.

**Tarang Agarwal:** On Europe?

**V. Muralidharan:** On Europe, yeah, Tarang, as you rightly said, EUR 200mn plus is a new base. At least we have started hitting this in the last two quarters, even though in Q3 it was short of EUR 200mn, but you account for the clawback. We were crossing EUR 200mn and this quarter also we could do it. So the expectation in FY25, all the quarters will be doing north of EUR 200mn, and the idea is to grow further.

**Tarang Agarwal:** Perfect. Last question, sir. You know, Auro Peptides as a business was incorporated somewhere in 2013-14. And while we see an exhaustive list of peptide DMFs on your website, we're not sure what's happening in this business in terms of what is the traction that Auro has, both on the API and the formulation space. So if you could just give us a sense on where this business is? Its vintage has been quite long, about 10 years now.

**Dr. Satakarni Makkapati:** Tarang, hi, I would take the question. I would start with an update on Auro Peptides. Auro Peptides, the manufacturing facility was inspected by the US FDA from 12th Feb to 16<sup>th</sup> Feb [2024]. And FDA has determined that the inspection is closed with zero observations. We are particularly glad for this outcome. As you have rightly mentioned in your question, that we have been steadfast in developing synthetic peptides, these are very difficult peptides, for over 10 to 12 years now. We have 14 DMFs filed cutting across oncology segments and others. And some of these have contributed to five ANDA approvals for our customers, including Aurobindo and Eugia.

Right now, our work is primarily in oncology and diabetics. Our work in GLP-1s compared to our industry peers is very less talked about. We have an active DMF for one of the GLP-1 products, and our second GLP-1 product is now fully developed with the process validated as well. We hope to file a DMF in the next 2 or 3 months for this product.

Right now, we are expanding our synthesis and purification capabilities for GLP-1s as we are aligning some additional capacities that will become available by early next year. So, in all, our focus on diabetes and oncology segments will hopefully build momentum in this business. I am quietly confident and pleased at how we are starting to relook at our peptides business, mixed with a bit of caution when it comes to GLP-1s. At the same time, with both optimism and prudence in how we reinvigorated our pipeline.

One more update is that, recently through APL, through Aurobindo, we have received an approval for Linaclotide. Linaclotide is a peptide, a synthetic 14 amino acid cyclic peptide. It is used in the treatment of constipation and irritable bowel syndrome. So, we are going to launch that product through a very trusted partner. This is a first-in-class peptide to be available for Indian population, probably becomes the first launch in the next 3-4 months' space. So, you can see that we are shaping up the business. We are trying to do a few things there. And going forward, you will get constant updates on what we are doing in our peptides.

**Tarang Agarwal:** Got it. Just last, I mean, in terms of accounting, the peptides revenues would be bunched up in the API business or would be bunched up elsewhere?

**Santhanam Subramanian:** Yeah. See, as on date, if the ANDA is in the name of Aurobindo, it will go into that. But we'll look into the possibility of putting it as part of the peptide. We'll do some work on that. Ideally, we'd like it to go into peptide, but let's look into the issues beyond that.

**Tarang Agarwal:** Okay. Thank you.

**Moderator:** Thank you. The next question is from Harit Ahmed.

**Harit Ahmed:** Hi. Good morning. Thanks for the opportunity. On biosimilars, you touched on your filing plans for Trastuzumab in the US. Can you share that again? I missed that. And for Pegfilgrastim, how should we think about our US plans? Because as you mentioned, the market opportunity is quite significant, and it's been a while since we filed in Europe, but we haven't talked about any US filings till now.

**Dr. Satakarni Makkapati:** I think the part two of the question is very interesting, but I would address the Trastuzumab one, which is easier. Trastuzumab with the US FDA, we have completed a Type-2 followed by a Type-4 meeting. A Type-4 meeting is considered to be the pre-submission meeting, where any differences or any additional data requirements from the FDA will be pronounced. We had a successful Type-4 pre-submission meeting. Now, what does this mean? A successful Type-4 pre-submission meeting means that we can go ahead and file the product. So, I'm expecting to file the product and make some changes to the dossier as required by the FDA in the next two months. Probably by next quarter end, we should be filing this product with the FDA. And the procedure unfolds, the procedure would be anywhere between 9 to 12 months' time.

Now, with respect to PEG-filgrastim, Harit, as you know, that we haven't done an extensive Phase-I, Phase-III clinical trial for Filgrastim or PEGylated Filgrastim. We have gone with an abbreviated clinical pathway, where we have only conducted a Phase I PK-PD study in healthy volunteers, that too, a very small number and push the regulatory barrier, especially in Europe and with MHRA, to file this product with them. Now, FDA, in terms of their totality of evidence approach that is required for the biosimilars, they will ask for a Phase I and Phase III. With Filgrastim and PEGylated Filgrastim, it is slightly different. We haven't ever developed this product for the US market. The thought is very recent that while we had a meeting with FDA and FDA is convinced with our approach of doing a Phase I, they wanted a small additional immunogenicity trial, while they were okay with us not doing a Phase III efficacy trial. So in the sense that, the data that we have generated for the European trial is good enough, plus some additional data on immunogenicity has to be generated in healthy volunteers, and then, the PEG-filgrastim will also be readied for the US FDA filing.

Now, the timing of it, originally, I was thinking that I will file it somewhere before Q3 this year, but that might get slightly pushed into Q4 or into Q1 next year. But PEG-filgrastim, we are definitely going to take it to the US market. We will take it not just the PFS to the US market, we would like to take the autoinjector also to the US market. We are working with the agency

very closely. We have completed a Type 2 meeting on PEGylated Filgrastim. I am hoping to have a Type-4 meeting, a pre-submission meeting also with the FDA, sometime in the next quarter. Does that answer your question, Harit? I think he's on mute.

**Harit Ahmed:** All right. I'll get in the queue, thanks.

**Moderator:** Thanks. Thank you, Harit. Next question is from Nitin Agarwal.

**Nitin Agarwal:** Thanks for taking my question. Sir, two quick ones. Sir, what Capex should we assume for FY25?

**Santhanam Subramanian:** We are not planning to put any big Capex, because all the major Capex have been done and then capitalized. So probably, we must be having around sustenance capital and the de-bottlenecking initiatives, etc., must be around US\$200 mn, is what we are thinking. Plus, any market authorization, if it comes very lucrative, etc., we will do that.

**Nitin Agarwal:** Sir, on this inorganic, we've been acquiring about US\$100 mn or thereabouts of assets as and when the market opportunities have been attractive. I mean, is there a number that we have in mind to spend on buying out?

**Santhanam Subramanian:** No, no, it is not like that. If any opportunity comes only, we will look into that. We are not scouting for any market authorizations on our own. If it comes, we'll look into it.

**Nitin Agarwal:** And sir, last one. The other growth markets did extremely well this quarter. This number which you've done in this quarter, US\$100mn plus, how should we think about it as a base for. Should we look at it as a base now for the next year onwards?

**Santhanam Subramanian:** I think we have done well this quarter. Probably we must be doing something like US\$75mn [per quarter], I mean, around US\$300mn is what we should be aiming for [the year].

**Nitin Agarwal:** Okay, sir. Thanks.

**Moderator:** Thank you. The next question is from Sangeeta.

**Andre/Sangeeta:** Hi, this is Andre, Sangeeta's partner. I had two questions on biosimilars. One was that, can you explain to me generally, what are the trends in the US and Europe towards biosimilars, particularly when the competition is not a biosimilar? What are the advantages, etc, of a biosimilar that may be trending the market in favour of biosimilars? That was the first question.

And the second question was that, could you give some more color as to when will the biosimilar, the opportunity, be effectively monetized? What should our assumption be? Are we talking about FY26 or FY27 or calendar year 2027 or 2026? You know, could you give us

some kind of idea on the timelines of whether we can expect the biosimilar opportunity to be monetized?

**Dr. Satakarni Makkapati:** To answer your question, one, to be very honest, I did not understand the question one in entirety, but I will try and answer that. A biosimilar is against an innovator product, an existing biological entity. So, I did not understand that because you have a biological entity, which is already there, and it goes off patent when you launch a biosimilar into the market. So, does it answer your question, or do you want it to phrase it differently?

**Andre/Sangeeta:** No, my question was, what are the trends in the US that are favouring biosimilars, if any, in Europe?

**Dr. Satakarni Makkapati:** Essentially, the biologics was a huge healthcare burden with the pricing and all. So not just the US, but all the developed countries across the world would like to have cost effective alternatives to the biologics. And that's the reason why biosimilars find traction in these markets. Now, with the case of products like Adalimumab, where the innovator also becomes very disruptive over a period of time, because he had made his margins. And when the biosimilars come in, then there will be additional price debates, etc. And to switch from a biologic to a biosimilar requires interchangeability studies with the FDA, etc. That slows down the uptake of biosimilars. But right now, the trends have been encouraging. There are a lot of good companies which are doing well in the US with respect to biosimilars. So, I expect with the next wave of patent cliff, more biosimilars will be in the market, especially across oncology and immunology segments. And the US market continues to be favorable in terms of the uptake of biosimilars. I see the regulatory guidelines also easing out a bit over the next 6 to 7 years that that prompts more biosimilar players to come into the market. That's part one of the question.

What is part two of your question?

**Andre/Sangeeta:** Part two was as to when you expect to start monetizing the biosimilar opportunity? Rough timelines.

**Dr. Satakarni Makkapati:** The real opportunity for us in terms of the commercial space starts from one quarter of this year [Q3 or Q4] possibly and from the next year. I would say you should wait for at least 2 to 4 years' time frame around 2027, 2028 would be the opportunity to monetize this. Subbu, do you want to add to that?

**Santhanam Subramanian:** As Satakarni said, Q3 or Q4 we will launch in the Indian market. Probably that's a very small portion, Indian market, but the major things are going to come from Europe and the US which is around 2026-27. Am I right Satakarni?

**Dr. Satakarni Makkapati:** That's right.

**Andre/Sangeeta:** Okay. Thank you very much.

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

**Shrinivas Dange:** Thank you all for joining us on the call today. 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](http://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. You may now disconnect your lines and exit the webinar. Thank you.

**(END OF TRANSCRIPT)**