

Aurobindo Pharma Q4 FY23 Earnings Conference Call May 29, 2023

Dr. Satakarni Makkapati - CEO of Aurobindo Biosimilars, Vaccines and Peptide business.

Mr. Yugandhar Puvvala - CEO of Eugia Pharma Specialties Limited

Mr. Sanjeev Dani - COO, Head Formulations, Aurobindo Pharma Limited

Mr. Swami Iyer - CEO, Aurobindo Pharma USA

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

Ms. Deepti Thakur - Investor Relations & Corporate Communication, Aurobindo Pharma Limited



Moderator: Ladies and gentlemen, welcome to the Quarter 4 FY23 Earnings Conference Call of Aurobindo Pharma Limited. Please note that participants' line will be in the listen-only mode, and there will be an opportunity for you to ask questions after the opening remarks. Please note that this conference is being recorded.

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

Deepti Thakur: Thank you, Vandit. Good morning and a warm welcome to our 4th Quarter FY23 earnings call. I am Deepti Thakur from the investor relations team. We hope you have received the Q4 FY23 financials and the press release that were sent out on Saturday. These are also available on our website.

I would like to introduce my senior management team today on the call with us, represented by Dr. Satakarni Makkapati - CEO of Aurobindo's Biosimilars, Vaccines and Peptides Businesses, Mr. Yugandhar Puvvala - CEO of Eugia Pharma Specialties Limited, Mr. Sanjeev Dani - COO and Head-Formulations, Aurobindo Pharma Ltd., Mr. Swami Iyer - CEO, Aurobindo Pharma USA, 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 limitation statements relating to the implementation of strategic actions and other affirmation 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 future any 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 Deepti, and good morning and welcome to all of you for joining this earnings call. This year has been very challenging due to various factors, namely, challenging macro environment and competitive industry landscape, etc. Despite these issues, we have delivered a good result in this fiscal year.

We'll now discuss the results for the 4th quarter of FY22-23 declared by the company. For Q4, the company registered a revenue of 6,473 crores, with an increase of 11.4% year on year. The EBITDA before forex and other income grew by 2.8% year on year, and by 5% quarter on quarter to Rs. 1,002.2 crores. EBITDA margin for the quarter was 15.5% and for FY23 was 15.1%. Net Profit increased by 3% quarter on quarter to Rs. 505.9 crores. EBITDA margin before R&D is 21.8% for the quarter against 21.4% of the last quarter.

In terms of the business breakdown, Formulation business in Q4 FY23 witnessed a growth of 11.4% year on year to 5,455 crores and contributed around 84.3% of the total revenue. API business contributed around 15.7% and clocked a revenue of 1,017 crores for the quarter, registering a growth of 11.4% on a year-on-year basis, led by improved demand for some of the key products. For the quarter, the revenue from US Formulation increased by 11.6% year



on year to 3,045 crores. On a constant currency basis, US revenue increased by 2% year on year basis to USD 370 million.

We have received final approval of 26 ANDAs and launched 10 products during the quarter under review. We have filed 12 ANDAs including 3 injectables during the quarter. Revenue for Aurobindo Pharma USA, the company making oral products in USA, has increased by 1% quarter of quarter. Revenue of US injectable products in US, increased by 3% year on year and 18% quarter on quarter to USD 71.9 million in Q4 FY23. The total Eugia speciality sales in US, including the speciality OSD amounted to USD 81 million. During the quarter, Eugia performance in various financial parameters were better than that of last quarter. We have a total of 171 injectables filed as of 31st March, 2023, out of which, 126 have been received in final approval, and remaining 45 are under review, or have tentative approval.

The company as on 31st March, 2023 has 774 ANDAs filed with the US FDA on a cumulative basis, out of which 565 have final approval and 34 have tentative approval, including 8 ANDAs which are tentatively approved under PEPFAR and the balance 175 ANDAs are under review. For the quarter, US Formulation clocked revenues of Rs. 1,660 crores, an increase of 7.7% year on year. In constant currency terms, Europe business clocked a revenue of Euro 188 million against Euro 183 million of last year for Q4. For the quarter, growth market revenue increased by 18.6% quarter and quarter and witnessing a growth of 51.2% year on year to Rs. 592 crores. This includes PLI incentive of Rs. 48 crores against 8 crores of the last quarter due to improved sales of eligible products during the quarter.

For the quarter, ARV formulation business clocked a revenue of Rs. 159.3 crores year as a whole. We reached an amount USD 119 million against an estimate of USD 120 million. R&D expenditure is at 411.7 crores during the quarter, which is 6.3% of the revenue. This is similar to last quarter R&D revenue of Rs. 415 crores. The average raw material cost remained flat during the quarter, and the freight cost also reduced during the quarter. Net capex for the quarter is around USD 105 million, of which capex for existing businesses 62 million, including USD 14 million for ANDA purchases. PLI capex of USD 31 million and capex for new business for new markets amounts to USD 12 million. The PLI cumulative capex till March 2023 amounts to USD 121 million. The average forex rate was 82.1936 in Q4 FY23 against 82.10 for Q3 FY23. The average finance cost for FY23 was at 4% mainly due to availing multiple currency loan.

We have clocked an income from investment of Rs. 74 crores for the quarter, and cumulatively it is Rs. 148 crores for the year. This is accounted in Other Income. This needs to be read in conjunction along with the Finance Charges.

The business generated a free cash flow of USD 61 million during the quarter, as result of strong cash flows generated during the quarter. The Net cash flow, including investments at the end of March 2023 was at USD 194 million. The gross debt is USD 591.7 million. Our endeavour is to bring down the debt going forward. The high cash was due to some good collections in the month of March 2023, by the US business.

Board Composition – During the quarter, we have inducted one new Independent Director in the parent company and one new Independent Director in Apitoria Pharma, the API arm of



the company. With this, the total number of Independent Directors in the company is now 5 out of total 10 directors. Also, we have appointed CEO for the API arm Apitoria. We'll be appointing one more new Independent Director in Apitoria.

Facility Status – Out of the total 8 US FDA regulated API units, 6 units have VAI status, 1 unit recently got inspected, earlier it was in VAI status, and the balance 1 is under Warning Letter. We are putting our efforts to get it cleared. All the total 11 US FDA approved FDF units are under VAI status as on date.

Major plans are under commissioning - We have three plans, including one Eugia plan under commissioning in US. Of these, a part of the US Raleigh facility was commissioned in March 2023. The balance is expected to get commissioned by FY23 or during FY25. The China plant is fully installed and is expected to be commissioned in Q1 FY25. We are in the process of manufacturing the exhibit batches. The Lyfius plant which will produce Pen-G, is expected to be commissioned by '23, however it is our endeavour to complete ahead of schedule. We are conducting clinical research study phase 3 for biosimilar product, and the biosimilar plant is expected to commission by FY23. So far, including the R&D revenue expenditure in biosimilars, we have invested more than 1,900 crores on biosimilar till date.

Outlook — While our financial performance FY23 indicates our resilience to withstand economic adversity on the back of our strong fundamentals, we remain focused on continuing our growth and we are cautiously optimistic on the business growth going forward. We are committed to deliver good performance in the coming quarters, while adhering to the regulatory and quality standards.

Some of the key focus areas for the coming quarters are summarised as below:

- PLI implementation will be as per schedule as informed earlier. Post PLI implementation by March 2024, most of the major capex will be done. To improve the capacity utilisation across the plants, we may be doing some debottlenecking on the maintenance capex. We will continue to acquire ANDAs from market authorisations to leverage the existing capacity and resources.
- Our differentiated business, biosimilar, is expected to contribute to margin enhancement from FY25. New pipeline approvals will include high margin new generation product categories like peptides, biosimilars, etc.
- Pricing has stabilised in the US, and there is price normalcy in the market. Both RM cost and logistics cost have reduced during the quarter, overall resulting and emanating a better business situation for the coming year.
- Eugia continues to do well and achieved various financial parameters, which are better than those of the last quarter. We expect to continue this.
- We expect to see some good cash generation from FY25 onwards after capitalising all the assets which have been enumerated above.

This is all from our end, and my colleagues will give a better clarity in our Q&A session. We are happy to take your questions now. Thank you.



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

The first question is from Damyanti K. Rai.

Damyanti Rai: Hi, good morning everyone. Thank you for the opportunity. Sir, my first question is on your generic injectable portfolio. For the US, we have been seeing sales hovering somewhere around USD 70-75 million a quarter. And similarly, branded oncology sales is hovering somewhere around USD 30 million in the last few quarters. So, how do you see these injectable sales picking up ahead, given the approval rate is very healthy. Would you say, you would be achieving your guidance provided earlier with this kind of run rate, or do you see pick up ahead?

Yugandhar Puvvala: Hi, Damyanti. In fact, I stick to my earlier guidance of double-digit growth. As you rightly said, we are doing as per our plan and we'll be continuing our journey with double-digit growth, on the back of healthy approvals, we feel that it is achievable. That's on the generic injectable side. Swami, in case you want to address on branded injectables?

Swami lyer: So, on the branded injectables i.e. Acrotech, this is an asset we acquired from Spectrum, and we have a larger plan here to market other products too. We have got into business development deals with couple of other companies, this could take some time. But right now, we're looking at maintaining this kind of revenue line at about USD 20-30 million a quarter.

Damyanti Rai: So sir, you already have some products which you have identified which will be part of your portfolio ahead, and then you might see a pick up from the current run rate?

Swami Iyer: Yes, but that could take a little time, yeah.

Damyanti Rai: Okay. And, if you can also update on the status of the Vizag plant, which I think was mainly intended for European supplies.

Yugandhar Puvvala: Damyanti, like we started doing the exhibit batches in the Vizag plant as per plan, and the first filing is expected to be in September 2023. It is not only for European and Emerging Markets. We have identified multiple products even for US filing, because this plant is big and we have lot of scope for expansion. So, we wanted to use this as a global plant rather than for a specific market plant. But, it's on track and as per the project timelines, because it's almost, all the lines are up and running and we started doing the products.

Damyanti Rai: Okay, thank you. And my last question is if you can comment on your R&D spend ahead? How do you see it moving ahead in the coming quarters?

Santhanam Subramanian: The R&D spend for the quarter was 6.3%, and the year was around 5.7%. We will be having something around 6% to 6.5% anywhere. But more than that, I would say, we'd be incurring around Rs. 400 crores per quarter, is very likely, irrespective of how the turnover is going to be.



Damyanti Rai: Rs. 400 crores R&D spend?

Santhanam Subramanian: Per quarter.

Damyanti Rai: Okay. Thank you, sir. I'll get back in queue.

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

Kunal Dhamesha: Hi, good morning. Thank you for taking my question. So, first on the Pen-G PLI scheme, would you provide some update as to what would be... how cost competitive we would be versus, let's say, the Chinese players, and what kind of scenarios would you have assumed while going for this plant? In terms of pricing, right now it remains high. But, do you expect it to become more competitive once you enter the market?

Santhanam Subramanian: I think this question has been asked in the last quarter, wherein I said we'll be able to give a picture only in the month of November. There is no point in guessing a price which is going to happen in April 2024, right? But certainly, we believe with our financial metrics, etc, we are very cost competitive, and we'll be able to withstand any of the price erosion also. So, we will see it only at that time.

Kunal Dhamesha: Sure. And then, on the US price erosion, you said in your opening remarks, it has kind of stabilised, normalcy has returned. But would you be able to quantify what kind of price erosion we saw in the quarter on a sequential basis, or on a year on year basis? That would be helpful.

Swami lyer: Hi Kunal. On the US price erosion, if you ask for a year on year basis, in the first three quarters we had a fair amount of price erosion, and then the 4th quarter was somewhat stable and we see the continuity. Right now, we are pretty stable, I would say. So, if you talk about year on year, yes, first 3 quarters was fairly high and, I don't want to hazard a guess exactly how it is, because we had some changes in the 4th quarter, we had requested some changes. So overall, net-net, I would think we are in a better position today. That's what I would like to say. today, we are pretty stable.

Kunal Dhamesha: And, let's say, the trend that you saw in Q4, would that have continued in April and May as well?

Swami lyer: Yes.

Kunal Dhamesha: Sure, perfect. I have more questions, I'll join back in the queue.

Swami lyer: Sure.

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

Neha Manpuria: Yeah, thanks for taking my question. Swami sir, on the US oral solid business, despite the fact that pricing erosion has normalised, as you mentioned. We've seen launches.



Data shows that Aurobindo is gaining share in lot of the disrupted products. We haven't seen the commensurate increase in revenue in oral solid. So, could you give us some colour there? Do you expect more of this to reflect going forward, because it's pretty much flat. I think it's up 1% quarter on quarter.

Swami lyer: Sure. So, you know the 4th quarter was, that's when we got some of the awards and we have ramped up some of the supplies. I think, we would see more of this starting this Q1, and I think the impact would be more Q2 timeframe. Even though we got the awards, we had to give a quick turnaround. It will be a little difficult, especially for the kind of product that we got. We did see some surge in terms of sales, but it's not completely reflected, I would say, based on the awards that we received.

Neha Manpuria: So, you're saying the bulk of the benefit of the incremental volumes that we've been awarded, will be seen in the 2^{nd} quarter; not even in the 1^{st} quarter?

Swami lyer: 1st quarter, we would have some and then it would continue from there. If you recall, in the last two earnings call we'd mentioned that we're also launching some newer products. So, the new products would also contribute to our top line in the next 12 months.

Neha Manpuria: Got it. and sir, overall, on the market environment in the US, do you think these NBO opportunities, as we call them, is more short-term, or do you see this being slightly more part of the base business and not necessarily a one-time opportunity? How would you see the environment?

Swami lyer: You know, the one-time opportunities, that I'll leave apart from the NBOs. NBOs have been pretty decent, and I would not assume that these are short-term, I would assume that these are medium-term. I think the customers are looking for stable supplies and we have been able to provide them that.

Neha Manpuria: Got it, thank you so much and Subbu sir, on the gross margins, despite the fact that price erosion has stabilised the ARV sales are lower, injectable sales are higher, we didn't see a gross margin improvement in the quarter, and we had the PLI benefit. So, was there any factor impacting gross margins?

Santhanam Subramanian: We had certain one-off items which have reflected in the reduced the top line item, because of some claw back taxes in one of the European countries, which has really reduced the overall gross margins, sales as well as the gross margins, this is also one of the reasons, from the EBITDA margin perspective. Also we have taken some one-off write-off, around Rs. 20 crores. Overall, if you really see, around Rs. 45-50 crores is the one-off amounts we have taken during the quarter.

Neha Manpuria: Sorry sir, I missed that number. Rs. 40-45 crores?

Santhanam Subramanian: Rs. 45-50 crores is the one-off write-offs we have taken during the quarter.

Neha Manpuria: This is both on the cost and the revenue?



Santhanam Subramanian: Yeah, both on the cost and on the revenue, maybe in equal proportion...ie 30:20 type.

Neha Manpuria: Okay, got it. Thank you so much sir.

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

Prakash Agarwal: Yeah hi, good morning. A question on the outlook. Last 2 years, obviously, a lot has happened, growth has come down, gross margins have come down and so have the EBITDA margins. Multiple factors, or US pricing pressures, some US FDA issues. So, how do you think the next couple of years will shape up? What are the big building blocks? If you can share which segment in your differentiated R&D assets will start coming out first, and how do you see the margin trajectory?

Santhanam Subramanian: So, I'll give the broad direction and my colleagues will be able to explain in detail. Swami has already explained that sales is expected to move in the 1st quarter followed by 2nd quarter. The range of sales is going to increase, right? If you go into 3rd quarter, 4th quarter. Mr. Yugandhar has already said in the last meeting itself, that he will be launching Revlimid, which is also going to contribute to that. Next year if you really see, probably in Q4 some biosimilar product may get launched, and next year by April quarter onwards we can start seeing the Pen-G delivering. We will start to see some more biosimilar impact coming. I mean, the full year impact will start coming rather than some one-quarter impact of this year. So, I would request Yugandhar and other colleagues to explain this in detail.

Yugandhar Puvvala: I think Subbu you covered most of the things. From generic injectables which is under Eugia, we will continue to grow and our endeavour is to grow double-digit. We will keep Revlimid as one-off and that we will count as over and above the base business for the next 3 years. But, the base business, with a slew of launches and filings, we expect quarter on quarter, we should have at least five approvals and five launches. We just wanted to do 20 launches a year going forward every year and that should provide us that double-digit growth. We will keep Revlimid as a one-off opportunity.

Prakash Agarwal: So, you're saying in your base business in US you're expecting double-digit growth in fiscal '25 on a large base?

Yugandhar Puvvala: That's right. That's for the Eugia business, which is a generic injectable business.

Prakash Agarwal: No, your generic business, I was asking?

Yugandhar Puvvala: That's right. That is for injectables and speciality products.

Santhanam Subramanian: Which is USD 81 million for this quarter, which I explained in the opening remarks.



Prakash Agarwal: Yeah, but a little colour on the US generic business ex-injectable will also help sir.

Yugandhar Puvvala: Swami, would you like to take it?

Swami lyer: Yeah. Prakash, we talked about new products being commercialised during the current fiscal. All that I can say is, that we would have steady growth. We anticipate about 40 ANDAs to be commercialised during the year; that's a fairly conservative number, and that would add decent amount of dollars to the top line. And, I think we would consistently, at least for the next few quarters, we would see this kind of product being commercialised based on the approvals that we are expected to receive.

Prakash Agarwal: So, approvals we are still getting a lot, sir. I'm just trying to understand little quantitative idea also, that with this high base, can we expect high single-digit or atleast mid single-digit growth on the US generic base business? Or, given the erosion and the state the US generic market is, that will be difficult? Or, with the R&D pipeline, we can manage?

Swami lyer: So, all that I can say is, prices have stabilised. We are able to able to ramp up volume. There's a good demand. So, on an overall basis, I think we should see a pretty decent demand. I don't want to put a number to it, but I think it would be fairly decent. It could be probably in the higher single-digits, that's something we expect and we are very optimistic about it.

Prakash Agarwal: Okay, thank you. And Subbu sir for you, on the margins, if you could give some qualitative and quantitative....

Santhanam Subramanian: I think, before that, if I request Satakarni to talk about his launches, etc, because that is also going to make an impact on the overall margin profile improving in the coming years. Over to Satakarni.

Satakarni Makkapati: Yeah, hi Prakash. So, continuing our journey to build on a differentiated portfolio, one of the key elements to us to achieve margin enhancement in future and also sustainable growth, is bringing in biosimilars into the regulated market(s). So, we are fairly confident that towards the end of this year, we will have at least one product in the market. Next year, we see at least 2 to 3 products in the European market with our first filing happening in the US market (in this period). So, I really see the inflection point for biosimilars to start from FY 2025-26. The amount of effort that had gone into conducting these clinical trials for biosimilars, we (now) have a robust portfolio of biosimilars. As we talk now, we have two product filings which are already made with European Medicines Agency, we had three product filings made with the MHRA in the UK, and we have two product filings with Health Canada. I expect the regulatory procedures and the procedural nuances to conclude anytime between Q2 of this year to Q2 of the next year. That will bring in a series of launches in regulated markets.

Now, staying on the same subject and continuing my guidance for the last three quarters' earnings calls till now, I'm happy to state that we have completed the treatment phase of (clinical) trial in 690 metastatic breast cancer subjects of a Trastuzumab biosimilar, biosimilar



to Herceptin, where our test product was tested for efficacy, safety and immunogenicity *versus* the innovator's Herceptin. After the completion of treatment phase and after initial read of the raw data, we are confident the study (which is a three-year long study) has achieved similar objective response rate to that of the innovator's product in women with HER2-positive metastatic breast cancer. We are confident that the filing process in Emerging Markets will begin in June-July. The first filing will happen in India. We will file with European Medicines Agency by September and we will file with the US FDA by Q4 (this FY). We are prioritising the filing of this very important life-saving biosimilar in India, with an aspiration to launch it in our country this year. We believe that more women will benefit from this life-saving oncology therapy on the back of such extensive clinical data in 690 patients, usually not heard of in submissions that are done domestically. We believe, it will give the oncologists and the patients an access to a good and reliable cancer therapy option for treating our women, our mothers and sisters. So, this is my update on Trastuzumab.

Likewise, as the discussions on differentiated portfolio (go), as the filing process for our oncology biosimilar across markets is slated to begin, we are showing signs of advancing our differentiated portfolio to various autoimmune diseases. Autoimmune diseases are a huge market in the US. I'm pleased to state that a full-fledged global phase 3 clinical trial of a biosimilar Xolair (we are announcing the name of the biosimilar for the first time) i.e. the phase 3 clinical trial of biosimilar Xolair, which is Omalizumab has begun. Our (clinical) trials sites are being readied now and our subject's recruitment is ongoing. The patent expires in US in November 2025. We have followed the due process of submitting the clinical trial plan and application for our biosimilar candidate (in Europe) and this is a phase 3 clinical trial, a comparative study on the efficacy, pharmacokinetics, pharmacodynamics, safety and immunogenicity, which is being conducted in 600 subjects with chronic spontaneous urticaria. The reason why I bring this up is to tie in this discussion with what Swami is saying. (The) Arcotech Biopharma, which is our brand(s) business in the US, is investing in dermatology. Now, if you look at our biosimilars and how we are positioning them in immunology and autoimmune diseases (read: also, dermatology), this adds to our commercial front end and the business that we are establishing and nurturing in the US with a long-term view to increase margins and to sustain our margins in the US. We believe that this biosimilar presents a sizeable opportunity in a potential market of USD 4 billion with very limited biosimilars competition. It is our intent to file this product in 2025 just in time, maybe two quarters ahead of the formulation patent that expires in US in (Nov) 2025.

Further to share on the differentiated portfolio, we are strengthening our immunology pipeline competitiveness in the autoimmune therapy segment by kicking off a phase I three arm PK, PD, (and) safety study of another biosimilar aimed at treating osteoporosis. This is also (an) immunology biosimilar; this will also fit very well into the portfolio for both our US and European commercial front end teams. Phase 3 clinical trial application for this product is being submitted (as we talk) in this week to European Medicines Agency and we are gearing up to initiate a phase III trial by Q3 of this year. Likewise, a third immunology biosimilar, (again a strong focus of the entire company on differentiated portfolio) we have already begun a phase III clinical trial where we completed around 40% of the recruitment already. We plan to file this product in the next fiscal year in India and Emerging Markets, to start with.



So, to answer your question, (overall) as a company and as biosimilars (company), we are nurturing our R&D so that we can sustain our business in the future especially with an eye on the regulated markets – especially, Europe and US. Prakash, I hope this answers?

Prakash Agarwal: This is very elaborate. Thank you so much and some color on the margins will also help?

Satakarni Makkapati: It will be too early.

Prakash Agarwal: The overall community level Sir?

Satakarni Makkapati: Then Subbu would answer that. Subbu?

Santhanam Subramanian: The overall company level, if you have really seen last quarter we ended with around 15.5%. We will not be limping, but certainly we will go in an incremental fashion. Probably, I don't think a step jump approach will happen this year right, so incrementally probably we may not touch 20%, but could be the mid-point in this year is what my feeling.

Prakash Agarwal: Okay. Thank you very much and all the best.

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

Shyam Srinivasan: Yeah, good morning and thank you for taking my question. Just the first one on the Eugia, what is the full year number now for the revenue I think USD 81 million per quarter also has some global part which is non-US, I assume and that is for the quarter, so what's the full year number and did I miss it in terms of the guidance that we are talking about double-digit growth. So, the 650-700 million would that come with the generic Revlimid on top, sorry if you can help us reconcile with the past on how we were thinking about this business?

Yugandhar Puvvala: Even though like we don't give specific numbers on Eugia, but I'll just give you a proper guidance in terms of we closed around Rs. 3,300 crores of top line, which is roughly around USD 411 million this year, this is a flat growth compared to FY22, but we didn't decline. In fact, in a challenging environment we could able to grow a single digit and going forward I am guiding based on the current pipeline what we have that we will continue on Rs. 3,300 crores of base. We will continue our journey of double-digit growth and on top of it Revlimid will get added, that's how it is here.

Shyam Srinivasan: Got it Mr. Yugandhar. So, just help us understand on the base business you're talking about launches, like you said 20 launches I think in your previous comment, so just want to understand how is the I think we've got a lot of questions on the oral solid side of things on price erosion, but what is happening on generic injectables anything that you can comment, what explains the flattish growth right I'm still assuming OSD is a very small percentage of your overall thing and largely injectable, so just help us understand pricing environment on the generic injectable side?



Yugandhar Puvvala: I mean like first two quarters of FY23 were really like challenging and I think the first time when the market opened up post-COVID in the Q1-Q2 of last financial year, this is FY23, we had almost a double digit price decline which was unseen, unheard in an injectable and specialty business, but from Q3 onwards things have stabilized and right now the competitive environment is I think, let me put it this way that we are in a good footing with respect to the competitive environment is concerned and last two quarters the pricing decline, has been almost negligible, and that is what we feel that going forward with and also one more thing which is helping us is in terms of unfortunately the drug shortages in the US are at the highest level in its history and all these things and on top of it slew of launches will help us grow the business and as guided earlier our gross margins in Eugia should be between 60% to 70% and EBITDA levels will be around 25% to 35%. It's a broad range okay, one quarter we might be here, one quarter we might be there depending on how launches will shape up.

Shyam Srinivasan: Got it, Sir and just follow up on Revlimid, is there anything that you've disclosed in terms of the timeline for the launch, how large it is will likely be for you in terms of because it's a crowded space, is there still elbow room for everyone 6-7-8 players now right, so just want to understand your thoughts on generic Revlimid?

Yugandhar Puvvala: In generic Revlimid, we already secured the final approval as per the settlement, we will be launching in October, but we cannot disclose the percentage of settlement, so I will leave it there, it won't be a significant part of my revenue, it will be like pretty good bottom line for my business and as it is as that like this is going to be limited share for multiple players, so we expect the price pricings to be stable and it doesn't matter before Jan 2026 whoever or a number of launches might happen, but like only thing is we don't expect because each player is it will be restricted by the percentage of like share what we settle for and we expect the pricing to be stable up to Jan 2026.

Shyam Srinivasan: Got it Sir, last question is in growth markets. I think you've seen a good bump up there 18%-19% quarter-on-quarter growth, so what is driving some of this growth, is it sustainable? I think 9% now is domestic formulations in India, so some qualitative color on that business? Thank you.

Santhanam Subramanian: I have already said in the opening remarks itself Shyam, this quarter we have got a good PLI incentive of around Rs. 48 crores against last quarter Rs. 8 crore the incentive is depending upon the eligible product which has been approved by the ministry and this quarter the sales of the eligible products have picked up a lot and because of that we got this Rs. 48 crores, we are in line with the overall number agreed with the ministry and it is the number which has been achieved.

Shyam Srinivasan: So, Subbu Sir, you classify the PLI income as domestic formulation.

Santhanam Subramanian: Yeah, because it is only for the Indian subsidiaries, - achieved by the Indian subsidies they don't give it for the US or any other sales achieved in other foreign country, only for domestic.

Shyam Srinivasan: Okay Sir and last follow up, Sir if I may quickly when you're talking about mid-teens margin, are we talking exit quarter or full year fiscal 24? Thank you.



Santhanam Subramanian: You're asking to Yugandhar?

Shyam Srinivasan: No, no, I'm asking you, Sir. When you talk about between 15.5% and 20% you talked about the margins being that, are we looking at an on a quarterly exit basis, are we looking at full year fiscal 24 EBITDA margins? Thank you.

Santhanam Subramanian: I have taken it only quarterly basis because we do not know at this stage as Yugandhar has clearly pointed out, the Revlimid will happen only in the Q3, which will have a significant addition to the bottom line. At this stage I'm saying moving on excluding the Revlimid etc. we should be in midpoint between current and 20%, that's what I feel at this stage.

Santhanam Subramanian: We will see the shift next quarter. Every quarter we will revisit.

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

Tarang Agarwal: Hi, good morning. I have three questions, Sir. One, Subbu Sir you in your opening commentary you suggested that the free cash generation for the business would perhaps begin from FY27.

Santhanam Subramanian: I said FY25, not FY27 okay.

Tarang Agarwal: My bad, my bad.

Santhanam Subramanian: The Pen-G plant will be completed by March 24, by the time we would have incurred most of the Capex and there is no other big project which we are thinking of as on date of this size or magnitude to incur in the couple of years and the Pen-G should give good cash generation. So, because of various factors I feel there will be a good cash generation starting next year onwards.

Tarang Agarwal: I understand Sir, I misheard it for FY27, apologies. Dr. Satakarni on biosimilars and peptides, one if you could give us a sense on the status of regulatory inspections and second some sense on what's happening on peptides?

Satakarni Makkapati: On the regulatory inspections, I gave you guidance in the last earnings call that with the two filings that we had with EMEA, we are expecting a regulatory inspection which had happened (now) and we are waiting for a formal report of the precommercial audit or the inspection from EMEA. We believe this will become part of the day 180 clock stop procedure and response from EMEA, so we are expecting that. With the delay in the audit, let me also give you a guidance because we have submitted this file last year, we are close to exhausting the time on the procedural clock stop that EMEA or CHMP allows us. We have a clock stop until June 20th, so once we receive the draft observations of GMP inspection from the agency, we will have to work with CHMP on the way forward and how can we provide any additional data if they require within the time frame allowed by the clock stop for the (Day 180) procedure. Now, this is the guidance on EMEA inspection. Now, with Health Canada, I told you last time that we are expecting a Health Canada inspection. The review process of



our products had begun (with Health Canada), so we were expecting an onsite evaluation as communicated by Health Canada, but because of the paucity of the auditors, the auditors have pushed the dates back. We are expecting (now) the Health Canada audit inspection to coincide with the review procedure, which is around November, so that's my expectation. But again, I'm pre-empting. I need to talk with Health Canada over a period of next 2-3 months, engage with them as the review procedure unfolds to see when I can have the inspection from Health Canada. With MHRA unfortunately, with all the three filings that we had, for example (more importantly) with one of our monoclonal antibody filing, we have concluded day 150, which is at the point of approval and we still did not get any inspection date from MHRA. We are following it up with them. So, this is about the update on the inspections. What was your second question Tarang?

Tarang Agarwal: Status on peptides?

Satakarni Makkapati: On the peptides, as I told you, we are now focusing on two majority segments in peptides API development, which is essentially Oncology peptides and (Antidiabetic) diabetology peptides. So, last October if I did not give this guidance earlier, we have filed a Drug Master File for liraglutide, which is now an active DMF. We are hoping to file a DMF for another GLP 1 analogue by the end of this year. So, I'm reasonably pleased with how the peptides business is shaping up. It is also contributing to Eugia's injectables. I think we have two ANDAs approved this year. Yugandhar may correct it (and) may give you the right picture. So, we are convinced about how we are working on peptides and the focus that we have on diabetology and oncology segments in peptides.

Tarang Agarwal: That's helpful. Thank you. The third question to Swami Sir, Sir just wanted to get a sense today about 774 ANDAs field, I mean in your view what will be Aurobindo's coverage for the generic market in the US just to get a sense because my sense is by volumes you're probably the largest dispenser, so I just wanted to get a sense on how big the uncovered market is for you and how should we see this number moving forward over the next two or three years?

Swami lyer: So, if you talk about approvals, if you talk about the potential, yes, there is a fair amount of uncovered market and today we are covered the market to the extent we can and we are launching new products. So, the priorities change depending on the profitability of the product and then how quickly we can do this product. I think there is a lot of scope for coverage that's all I would like to say at this point. Even today we have number of approvals that we are in the process of launching, month after month we have launches. So, it would be at this point I can only tell you that we have a fair amount of market that we have not covered yet.

Tarang Agarwal: Would it be more than 50%, the uncovered market?

Swami lyer: I wouldn't hazard a guess, but on the overall term we you know we have the largest, I would not put such a high percentage, all that I can tell you is we have uncovered market, today we are a large player. Obviously, being a large player, you cannot compound the growth with huge percentage, but I think we have a fair amount of market to recover.



Tarang Agarwal: Okay. That's all Sir. Thank you.

Santhanam Subramanian: I would request everyone to ask only one question because quite a lot of people are waiting and restrict to one question, please. Thank you.

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

Nitin Agarwal: Hi, thanks for taking my question. Sir, if you can provide any more color on our plans and outlook for the Chinese business given the fact that you said the plant should be in place by next year sometime?

Santhanam Subramanian: Yeah, as we said we have more or less installed the plant and we have been doing the exhibit batches, we will be filing around five products from the China plant and we'll be starting with the European despatches because it takes quite a lot of time to get the regulatory approval from the Chinese regulators, so we'll be starting with the European manufacturing starting first quarter FY25, that is April next year followed with probably by third quarter or fourth quarter for the Chinese market, so this is our plan for China plant.

Nitin Agarwal: And Sir on the products that you're looking to file from this facility are the injectables, these are inhalers.

Santhanam Subramanian: As of today, we are doing only OSDs.

Nitin Agarwal: Okay Sir, okay. Thanks.

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

Bino: Hi, good morning and good evening. Just a clarification on the Capex, on PLI so far we have spent about \$120 million, how much of that would be for the Pen-G project?

Santhanam Subramanian: Entirely for the Pen-G.

Bino: It is entirely Pen-G plant okay and how much more will be done in this year for Pen-G?

Santhanam Subramanian: I think this year means the FY24 if I'm right?

Bino: Correct.

Santhanam Subramanian: As I said now, most of the capex will be done by FY24 that mean Pen-G project as on date it is estimated around USD 250 to 265 million plus or minus contingencies right. So that much of amount will be spent by the end of the year that means another USD 130 to 140 million will be spent this year.

Bino: Understood okay. Any significant Capex plans in biosimilars for this year?



Santhanam Subramanian: No, see already the plan for biosimilars in place already, as we inform to the exchange sometime back in October, we want to put one unit, which we will take, we have already informed, but the timing wise Satakarni will decide when to start that plant, but that may not be a very big plan like Rs. 2,000 crore, it must be around Rs. 300-400 crores only.

Bino: Understood okay and all put together what would be the total Capex for FY24?

Santhanam Subramanian: See, as I said the maintenance capex will be very less in terms it will be around one USD 120 to 130 million existing plants capex. Any new products, new market etc., which is going to give you a return in terms of the new turnover, new profits everything that will be depending upon what we close it by end of the year, that could be anywhere I'm just guessing anywhere between USD 75 to 100 million. You see that I think it's too early because our objective is to complete the existing projects.

Bino: Right, sounds good. Thank you.

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

Surya: Yeah. Thanks for the opportunity. Sir, my specific question about this thing is that it's about Eugia is that so after doing all this integration and all what all means what kind of benefit of integration that we have started witnessing and how is that going to help you incrementally going ahead that is one and just if you can also clarify on the Pen-G, having seen the kind of changed price, dynamic price as well as demand dynamic recent past how has that changed your potential as well as outlook for the project and starting from which month or which quarter or which period that you are expecting contribution from the Pen-G project?

Santhanam Subramanian: It is expected from Q1FY25 that is April 24 onwards we need to start generating the revenue from that project. How fast the ramp up can take place etc, we will be able to tell only in the November or maybe in February quarter, as it is in the process of installation. The installation is likely to complete only by October-November and then after that we will do some pilot batches to ensure the product is coming out successfully. In terms of the demand forecast etc., we don't need to guess for the product, which is going to be launched one year down the line. Maybe we will address this at a later date.

Surya: Okay, sure Sir. Regards the integration benefits of this Eugia putting all the assets relevant assets into that and the integration advantage what is that you're trying to see going ahead if you can talk about?

Santhanam Subramanian: As we said in the Stock Exchange notification, so the purpose of it to bring, a) focused management to improve the performance which Yugandhar has been explaining very nicely what is his plan, double digit growth and other things, those are all the things and b) also to have a control on the quality standards. Yugandhar you may like to add more?

Yugandhar Puvvala: No.



Surya: Basically Sir, I just wanted to have a sense about the contribution at the margin level or the profitability level because many of the assets would be also seeing developmental cost and all that which is currently and may not be compensated by incremental revenue that is one and even the two injectable facility what we have been building up in US, one in India, so when are they likely to contribute incrementally, so this segment how should it really be contributing to the overall profit or margin improvement of the company?

Santhanam Subramanian: The answer has already been given by Yugandhar very clearly. He said, he will grow the base business, existing business by double digit and he also said Revlimid will be over in addition to that. He said there is a significant profit and addition in the profit will come from Revlimid. Plus he also said that what are all the new projects on Vizag plant etc., when he is going to launch. I think all the questions which have been answered already. Yugandhar has given you all answers what is the EBITDA margin etc., band also he has given.

Surya: Okay, so then Sir specifically if you can just indicate let's say what is the kind of cash burn that we are seeing because of the kind of initial activity, the developmental activities one and then incrementally this US plant is likely to see the revenue because that is currently possibly in the filing stage right?

Santhanam Subramanian: Yeah, that Yugandhar can answer it?

Yugandhar Puvvala: Yeah, it is in the filing stage. We already did the first filing, so we have plans to do around 5-6 filings from that plant during this fiscal and in case if FDA triggers the audit, it will get commercialized in FY25. In case if the FDA delays the audit, we don't know, but our anticipation at this point is that in FY25 this plant should get commercialized.

Surya: Okay and the India plant is a FY26 opportunity Sir?

Yugandhar Puvvala: It is also will be FY25, not FY26. I have four commercial plants under Eugia and two new plants. One plant is in Vizag and one plant is in the US. These are the two non-commercial plants. We expect both these two new plants to be delivering some revenue starting from FY25.

Surya: Okay, yeah sure Sir.

Moderator: Thank you. The next question is from Vishal Manchanda.

Vishal Manchanda: Hi. Sir, my question is, have we witnessed any failure to supply penalties during the year?

Santhanam Subramanian: Swami.

Swami lyer: No failure to supply is normal commercial practice that the suppliers generally get into failing to supply. As you know there are several types one is the service level penalty, other one is actual failure to supply. So, all this comes under the broad gamut of failure to supply. We do that have as a practice and we do incur that.



Vishal Manchanda: Sir, can you kind of share whether it was higher YoY or the trend is broadly similar on a YoY basis?

Swami lyer: You see, it's too early to say how exactly this panned out because, first and foremost for the last year, there were many customers who did not, who gave some kind of leeway because it was post-COVID and there were other issues. So, it's not comparable that's number #1 and #2, if there's a failure to supply it doesn't mean that you're actually going to pay that kind of money because you are going to contest it, if we give you a failure to supply on a product that you don't supply to him at all which you supply two years back or so these are all questions it gets normally settled after a point of time, but yes there could be failure to supply and this is a normal commercial practice. Our idea is to try and control it to the extent we can.

Vishal Manchanda: Got it. Sir you provide for it in your numbers?

Swami Iyer: Yes, absolutely.

Vishal Manchanda: Got it.

Vishal Manchanda: Just one more

Santhanam Subramanian: There are another three people waiting Mr. Vishal if you don't

mind.

Vishal Manchanda: Okay. Thank you.

Moderator: Thank you. The next question is from Puneet Pujara.

Puneet Pujara: Yeah, hi, thanks for taking my question. So, my questions are for Dr. Satakarni. Now, I understand you are developing a global biosimilars portfolio, but my questions are just for the US part of it. first question is, do you think it makes sense to incur additional cost for say interchangeability, not for the currently filed products, but the products that you'll file later on and that's first and second what are your thoughts around the regulatory framework around the interchangeability converging with what we have in the European market? These are my questions.

Satakarni Makkapati: Puneet, it's a good question. It actually requires a huge discussion because the regulators, the policymakers, and the industry is engaged in a major debate across the regulated markets. But, I will try and give my perspective or Aurobindo's perspective on (the subject of) interchangeability. One, I think going by what is happening in other regulated markets, if you see what I have predicted before, interchangeability as a scientific norm doesn't make any sense for biosimilars. So, it has been my policy that I would not invest in any interchangeability clinical trials for the time being because I believe as Europe and MHRA has shown the way, going forward maybe towards the end of this decade interchangeability as a concept for additional clinical trial will be nullified even at the US FDA. Now, this is my personal opinion and the opinion on which CuraTeQ designs its clinical trial.



What is interchangeability's relevance in biosimilars? There is a good debate, there is a bad (read: needless) debate around it. The good debate is that in chronic segment, when I say chronic segment - where a patient uses has to use a drug for a longer period of time. Say for example, in diabetes you are using an insulin. So, the patient should be armed with an interchangeable data, so that he can confidently switch from one drug to another drug. Now, by definition we don't agree to it as scientists because by definition biosimilar (when approved) is in all means a similar to innovator biologic. Now, again after proving that there is no residual uncertainty, and proving totality of evidence through a stage wise development that is doing preclinical trials, (establishing) analytical biosimilarity, (demonstrating equivalence by conducting) phase I. (PK/ PD) and phase III (safety efficacy, and immunogenicity) trials, why is there an additional need to show interchangeability is the question that industry is asking?

Now, this (interchangeability) has been widely accepted already and you are seeing signs of it in countries like Canada, Europe etc., I think US will also follow suit. So, in a nutshell, at Aurobindo and CuraTeQ, I don't do any interchangeability trials for my biosimilars. I don't think it will significantly impact me in the market. Maybe in the first 2 to 3 years (in the market), because I have to always create a new customer base and I will not be able to switch the old customers into my product (owing to lack of interchangeability trial data). But, towards the end of this decade, I believe interchangeability as a definition, interchangeability as a concept will die down from a requirement of doing an additional clinical trial. I hope that answers?

Puneet Pujara: Sir, that's very helpful. Thanks. I'll join back in the queue.

Satakarni Makkapati: Thank you.

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

Alankar: Yeah, hi. Thank you for the opportunity. Sir, just one question. Couple of quarters back so you had spoken about the possibility of some kind of buyback or higher dividend, so just wanted to check are we still thinking on both sides, any update on that thing?

Santhanam Subramanian: That is a good question. We are discussing that, but the timing wise it has not been decided because we are accelerating the Pen-G project and also we are looking at the possibility of moving the cash, which is available in various parts of the globe especially Europe. We are sitting on around USD 200 million cash, but the exchange rates are not very conducive to bring it at this stage. So, we are working on all these things so that we are able to ensure that we are optimizing that. Probably, we may do it at some point of time, when- Board only will know.

Puneet Pujara: Got it Sir. Thank you.

Satakarni Makkapati: Give me a second. This is Satakarni. I would go back to Puneet and leave a punchline, by definition we at Aurobindo and CuraTeQ believe "all (approved) biosimilars should be interchangeable." I will leave with that thought. Thank you.



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

Deepti Thakur: 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 in due course. Thank you and have a great day.

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

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