



*“Aurobindo Pharma Q2 FY23 Earnings Conference Call”*  
**November 14, 2022**

**Dr. Satakarni Makkapati** – CEO of Aurobindo Biosimilars, Vaccines and Peptides businesses

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

**Mr. Sanjeev Dani** – COO & Head Formulations, Aurobindo Pharma Limited

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

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

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

**Moderator:** Hello and good morning. Welcome to Aurobindo Pharma Q2 FY23 Earnings Call. Please note that all 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 Deepti Thakur for the opening remarks. Thank you and over to you.

**Deepti Thakur:** Thank you, Aditya. Good morning and a warm welcome to our Second Quarter FY23 Earnings Call. I am Deepti Thakur from the Investor Relations team.

I would like to introduce my senior management team today on the call with us, represented by Dr. Satakarni Makkapati – CEO of Aurobindo Biosimilars, Vaccines and Peptide Businesses, Mr. Yugandhar Puvvala - CEO of Eugia Pharma Specialties Limited, Mr. Sanjeev Dani, CEO, Head Formulations, Aurobindo Pharma Limited, Mr. S Subramanian – CFO and Mr. Swami Iyer - CEO, Aurobindo Pharma, USA.

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

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

**S. Subramanian:** Good morning, everyone. We are here to discuss the results for the Second Quarter of the Fiscal Year FY23 declared by the company. For Q2 FY23, the company registered a revenue of Rs. 5,739 crores; a decrease of 3.4% over last year. The EBITDA before Forex and other income was Rs. 836.9 crores. EBITDA margin for the quarter was 14.6%. The Net Profit decreased and for the quarter stood at Rs. 409.4 crores.

In terms of the business breakdown, formulation business in Q2 FY23 witnessed sales of Rs. 4,770 crores and contributed around 83.1% of the total revenue. API business contributed around 16.9% and clocked a revenue of Rs. 969.4 crores for the year.

For the quarter, revenue from US Market declined by 11% year-on-year to Rs. 2,637.6 crores. We have received final approval for nine ANDAs and launched six products in the quarter under review. We have filed 14 ANDAs including two injectables during the quarter.

Revenue for Aurobindo Pharma USA, the company making the overall products in the US has decreased by 19% year-on-year for the quarter in US Dollar terms. Revenue for Eugia US, formally known as Auro Medics, the Injectable business decreased by 27.6% year-on-year to \$49 million for the quarter.

The company as on 30<sup>th</sup> September'2022 has filed 756 ANDAs and on cumulative basis of which 527 has the final approval and 36 having a tentative approval including 8 ANDAs which are tentatively approved under PEPFAR and the balance 193 ANDAs under review.

For the quarter, the European formulation clocked to Rs. 1,516.2 crores; a decrease of 8.8% year-on-year mainly due to Euro currency depreciation. On base currency business, the revenue was Euro 189 million against Euro 191 million on year-on-year basis.

For the quarter, the Growth Market witnessed a growth of 17% year-on-year to Rs. 451.9 crores. The quarter performance was led by strong growth in Canada. Also, this includes domestic Indian sales of Rs. 65 crores

For the quarter, ARV Business stood at Rs. 164.3 crores; a growth of 13.3% year-on-year.

R&D expenditure is at Rs. 276 crores during the quarter which is 4.8% of the revenue.

Net Organic CapEx during the quarter is ~\$82 million.

The average forex rate was Rs.79.6123 in September'22 and Rs.76.9795 in June'22.

Net Cash including investment at the end of September'22 was \$337 million.

The average finance cost is 1.9% mainly due to availing multiple currency growth.

The business generated a free cashflow before CapEx and other items of \$82 million during this quarter. This was spent towards CapEx including \$31 million for PLI Penicillin G Project. With this, so far, the investment in PLI Penicillin G Project around \$63 million against the budget of \$235 million dollars.

This is all from our end and we are very happy to take your questions now. Thank you.

**Moderator:** Thank you very much. We will now begin the Question-and-Answer session. Anyone who wishes to ask a question may use the raise hand from the 'Participants' tab on your screen. Participants are requested to use headphone or earphone while asking a question.

Ladies and gentlemen, we will wait for a moment while the question queue assembles.

First question is from Mr. Damayanti.

**Damayanti:** Hi, Good morning. I hope I am audible.

**Moderator:** Yes.

**S. Subramanian:** Yes.

**Damayanti:** Okay, thank you. Thank you for the opportunity. Sir, my first question is on the US Business. So, what has happened like this quarter was obviously much lower than what we have seen in the previous quarter? And, especially, if you can comment on the EUGIA's performance and how do we sales moving in coming quarters? And my second question will be, do you maintain your guidance for global generic injectable sales what you have provided earlier \$650-700 million by FY24?

**S. Subramanian:** Swami.

**Swami Iyer:** First you would want to take Injectables?

**Damayanti:** No Sir, first please comment on the US like what has happened and how do we see things moving.

**Swami Iyer:** Yes, okay. So, thank you, Damayanti for the question. Now, there are two components to this, obviously, the Oral Solids and the Injectables. I will talk about Oral Solids. We have seen lot of competition and then this led to price erosion during the quarter and shelf-stock adjustment. So, we also saw some drop in volume or demand for certain key products which could be seasonal because we don't think this is long-term. This is the main reason for the shortfall in the revenue for the quarter.

**Damayanti:** Okay. So, that's under Oral Solids portfolio specific or same is true for Injectables Business also?

**Yugandhar Puvvala:** I will comment on this, Damayanti. I think, you asked two questions. One is on quarter performance for the Injectables. Let me put it as speciality, overall speciality business and the future guidance. Let me address both of the things. Number one, yes, Q2 is a bad quarter and in fact we have seen 2-3 effects. Number one, we have seen volume drop to the tune of around 20% and also, we have seen price erosion but that is in single digits. But we also had to take some shelf-stock adjustments on Vasopressin, from Q1 to Q2. That has decreased the revenue. But, in general, we don't see this as trend going forward but this is one-off quarter that's what we feel.

**Damayanti:** Okay.

**Yugandhar Puvvala:** It should come back to the normal run rate. Number two, going forward our future guidance, going by the current events what's happening is we are still observing what's going on in terms of the elective surgeries and everything, hospitals are full and what we are seeing is there's a significant volume drop not only for us in Q1 and Q2, we have seen that for multiple competitors. So, probably, it has to do with some inventory adjustment and it should come back. But our guidance, based on current events, we feel it might get delayed by a year unless something substantial and some upside happens. But going by the current events we feel like it might go into FY25.

**Damayanti:** Okay, Sir. I think that's very helpful. And, my last question is, if you can update on the Vizag Plant in terms of where the plant is currently standing, whether it started supply etc. Yes.

**Yugandhar Puvvala:** No, in fact the construction is complete and we are doing the line qualifications and as I mentioned in the last quarter we will be taking exhibit batches in this year and we will start filing in H1 of FY24 and we still are confident that by end of FY24 it should start generating some revenues. We will be filing it for all markets – US, Europe and Emerging Markets from this plant. The plant construction is complete and lines are under qualification right now.

**Damayanti:** Okay, Thank you very much for your answers.

**Yugandhar Puvvala:** Thank you.

**Moderator:** Thank you. Next question is from Alankar.

**Alankar:** Hi. Good morning, everyone. Sir, my first question is on the recent promoter development. Given that Mr. Sarath has been relieved from his executive responsibilities can you, please, explain what were his exact roles and responsibilities in the first place and who will be taking charge of his responsibilities?

**S. Subramanian:** Yes, Mr. Sarath has been looking after the Information Technology, Engineering purchases as well as the logistics. So, that has been allocated between the whole-time directors and that will be continued.

**Alankar:** And, Sir, any particular reason for retaining him as a Director considering that his ability to discharge those responsibilities as well would be limited now?

**S. Subramanian:** No, he's not going to be an Executive Director. So, he will continue to be Director on the Board as Promoter-Director.

**Alankar:** Alright, okay. And maybe one other question on this front, Sir, any other member from the promoter family who is involved in some of the non-Aurobindo businesses wherein Mr. Sarath was involved because we have been getting those questions from investors? Any clarity on this would be really helpful, Sir.

**S. Subramanian:** See, let's me put it like this - the matter is under sub judice. We don't want to talk about this matter and to the best of my knowledge no other Directors are involved in that business.

**Alankar:** Alright, Sir. And my second question is, given that shareholder wealth creation has been an issue for the last 5-6 years now, how are we thinking about this as well as capital allocation? Now considering that we have been generating good cash for the last few years, is the Board incrementally open to buybacks?

**S. Subramanian:** So, let me put it like this. See, as on date we are having around \$337 million Net Cash and if you really see we have embarked on couple of projects which are very important both from the company point of view as well as from the nation point of view especially the Pen-G Project which involves a capital outlay of around Rs. 2,000 crores, right. Probably, we are thinking of 'Can we be able to accelerate that?'. So, at this stage probably unless some clarity comes on that and we move forward, this issue relating to the capital allocation like buyback etc. will not be taken up.

**Alankar:** Understood, Subbu Sir. That's all from my side. Thank you.

**S. Subramanian:** Probably, maybe in another 6 months we will get some better clarity on the Pen-G project.

**Alankar:** Understood, Sir. That's all. Thank you.

**Moderator:** Thank you. Next question is from Neha Manpuria.

**Neha Manpuria:** Thanks for taking my question. Sir, when you say clarity on the Pen-G Project, I mean Rs. 235 million is already earmarked for that, right. So, do you mean additional CapEx on the Pen-G Project over and above what is year marked?

**S. Subramanian:** \$235 million is the budget based on the current currency exchange rates etc. and what we mean is we have not taken any bank loan etc. as on date. So, what we are saying is if we are able to accelerate probably the \$337 million Net Cash we are carrying in the books will come down. Going forward in the next two quarters, the major outflow will happen and based on that outflow and what is the new cash generation etc. will be known. We also committed, if you have really seen, we are going to put additional Biosimilar plant ~Rs. 300 crores apart from other projects. So, keeping in mind various projects it will be deferred and will be reviewed only in the May Board Meeting in my view.

**Neha Manpuria:** Okay. So, basically, any additional buyback or dividend etc. will be considered only in the May Board Meeting?

**S. Subramanian:** I am not saying it will be considered. It will not be taken till the time.

**Neha Manpuria:** Alright, understood. Thank you so much. Sir, on the US Business given there was a fair bit of shelf stock adjustment in both the Oral Solid and Injectable business would it be possible to quantify that number for the entire US Business? I know you can't mention product-specific, hence I am asking. Just wanted to understand, you know, how much of the impact that we have seen quarter on quarter is actually one-off and what is the new base for the US Business.

**Swami Iyer:** So, first let me take the Oral Solids. After that, Yugandhar can talk about the Injectables. So, the Oral Solids shelf stock adjustment has been pretty normal the way it happens. Only thing is, since we had the price erosion which was little higher, so the shelf stock adjustment would be proportionately higher otherwise I would think that there's no abnormal increase in shelf stock as far as the Oral Solids are concerned.

**Yugandhar Puvvala** Yes, I think, it is the same, it is one-off product which we had to take the shelf stock adjustment. It is not a general phenomenon and, as I said, it is driven by the 3 factors. One, is the volume drop and which we feel with the way things are going and all the business back to normal in all the hospitals, we feel the volume should go up going forward. Two, is related to the price decline what we have seen in single digit and third is, on-off shelf stock adjustment. Mainly, I can say that it is on Vasopressin. So we had to take that. That's why I said this quarter is bad, but we are very positive going forward.

**Neha Manpuria:** Sir, you know, sorry to harp about this but in that case is it fair to assume that the \$330 million that we have reported this quarter becomes the base for the US Business? And I am just trying to understand our ability to regain the volume that we have lost, is this Market Share loss both in the Oral Solid and the Injectable business? Or, you know, how much of it is actually something that we can get back in the subsequent quarters?

**Yugandhar Puvvala:** Like as I said, number one is, we haven't lost market share. We have seen a significant volume drop across various categories. It has nothing to do with the market share loss. We haven't lost the market share. What we are seeing is a general lesser offtake in this quarter both in Oral Solids as well as Injectable and which has nothing to do with the market share loss. That's why we feel it will come back.

**Neha Manpuria:** Understood, okay. And my second question is, you know, on the Injectable you mentioned that the speciality guidance has been delayed by a year but in terms of a more one year outlook, do you see Injectable momentum...Now, you know, we have not even gone back to pre-COVID levels, so how confident are we of our pipeline coming through to go back to the \$70 million run rate that we were doing pre-COVID?

**Yugandhar Puvvala** Yes, number one is from a perspective of future outlook, we have been launching significant number of products and I expect to launch roughly around 20 odd products in this financial year and we are filing 20 odd products every year. So, from a pipeline point of view we have been very robust and substantial in terms of the filings. Number two is, we are expecting some limited competition product approvals hopefully starting from next week and I am sure that that should give us a significant impact going forward. Third is, as you know, like we do have a settlement on Lenalidomide and that will give us the impetus which is required for us to go towards FY25 and our delayed guidance because some of the upsides what I thought would pan out didn't pan out the way they were supposed to. That's why I am just saying that it might get delayed by a year.

**Neha Manpuria:** Understood, Sir. Thank you so much.

**Moderator:** Thank you. Anyone who wishes to ask a question may raise your hand from the 'Participants' tab on your screen. Next question is from Surya Patra. Yes, Mr. Surya, you can unmute yourself and ask the question.

**Surya Patra:** Yes, okay. Thank you for this opportunity, Sir. when you said about across board volume decline in the US Is it an industry wide phenomena sir?

**Swami Iyer:** So, I will say this from Oral Solids side. We cater to certain portfolio of products. Among the top 20 products that we have seen for overall product decline, we have seen some decline there. I don't want to comment on industry, but we are talking about the products that we are dealing with.

**Yugandhar Puvvala:** Surya, it is similar because we don't want to comment on the overall industry but what we are seeing is, the category of products what we are dealing with. I have seen a decline in volumes, it is general. It can be one-off here, and there might be some market share loss, but mainly driven by at this juncture our guess is, it is lower op rate and probably related to inventory adjustments at wholesalers and distributors. But the way things are going we feel that the volumes will come back.

**Surya Patra:** Ok. Sir, my 2<sup>nd</sup> question is on the branded oncology business. So, trend wise what we are witnessing is, there is a gradual drag although it is not very significant from the time of acquisition. So, this portfolio, how should we think going ahead? Whether our specialty product will be complementing this one or we will continue to see a kind of a drag till sometime when our specialty will probably start contributing beyond FY 24 or so?

**Swami Iyer:** Yes, thank you. I will take that question. We are talking about the oncology branded product. Correct?

**Surya Patra:** Ya.

**Swami Iyer:** So, the oncology branded product has been steady, that's what I would say and it continues to be steady. We have been looking for businesses development opportunities outside and we have been successful in tying up with a few of them and we expect some of these products to start generating business sometime in late FY24 and early FY25. I would say. For FY25, we expect some business to be generated in other products. We are very optimistic about the branded products. We have few other things which are under development. So, we feel very optimistic about it.

**Surya Patra:** Ok. Regards the US injectable plant and its piling momentum sir, can you update us, what is the status there? And also, if you can provide some update about your speciality project, let's say biosimilar, vaccines, like that.

**Yugandhar Puvvala:** I think I will just talk about the US plant and I will ask my colleague Satakarni to talk on the Biologics part. US plant you know, we have completed the project and we have already done exhibit batches and we expect to start filing from Q1 of next financial year and we have a pipeline of 20 odd products which we have identified. Every quarter, our target is, we want to do 3 products and the 1<sup>st</sup> product we will start filing from May'23 and after that it will keep going on. That's on the US plant. So, both Vizag plant and US plant, the timelines will be similar in terms of filing products. Satakarni, would you like to comment on biologics?



**Satakarni Makkapati:**

Yes, thanks Yugandhar. Thanks for the question on biosimilars. I would answer your question in 2 parts. One for the biosimilars and one for the vaccine. The 3 biosimilars in phase 3 efficacy trials are progressing as desired. If you remember my last update, I had talked about the oncology biosimilar and the large trial that we have been doing in metastatic breast cancer patients even during the covid headwinds period. Now, I am pleased to inform that we have completed randomization of all 690 metastatic breast cancer subjects in our phase 3 efficacy trial comparing CuraTeQ's version of biosimilar to the innovator's product. We plan to unblind the clinical trial data starting end Q3 this financial year, with a series of filings to begin from Q1/Q2 in the next fiscal year, starting with India and Emerging Markets before June 2023 and the big filings of EMA, which we expect to close by August or September 2023, and FDA filing by October or November 2023. So, that's a big filing that we are looking at in the next year.

The other two biosimilars in phase 3 clinical trials are also progressing really well. What is important to note is also that from earlier oncology therapeutic segment focus, we are now also advancing our immunology pipeline. One of our immunology products which we think, we are one of the first 3 or 4 to be filing in FY24 or FY25 is now closing on its phase 1 trial in Australia and New Zealand. This is a product which serves both respiratory as well as in dermatology segments. The dermatology segment is very important to our portfolio of products for Aurobindo's (portfolio) differentiation. We will be entering into phase 3 first patient injection milestone by Q4 of this fiscal year for this immunology program. This is a large trial which will be carried out in around 13 countries and in 85 sites. We are excited about the prospects that we will be able to close this trial somewhere by Q1 of FY24 and initiate the filing process in Europe and US. So, that's (the update) about biosimilars.

With respect to the vaccines question, in the area of vaccines, I am also happy to inform that our PCV-15 vaccine comprising of the 15 serotypes conjugated to carrier protein CRM 197 had shown to be immunogenic and generated the functional antibodies for all vaccines serotypes, in the 3+0 trial that we conducted in paediatric population. 13 serotypes that we were evaluating vs. Pfizer's Prevnar 13 showed similar or slightly higher immune response and the clinical end points have been met. The two other serotypes which we additionally have other than those in Prevnar 13 have also shown non-inferiority. We have submitted this filing last week for a (Market Authorization) approval to the Indian regulator. I expect the regulatory process for approval to unfold in the next 2-4 months' time. Meanwhile, as part of the regulatory requirement and as part of our aspirations to make it a WHO program, we have also initiated on this 7<sup>th</sup> October, a 2+1 regimen paediatric trial in India. At this time, I think we are well on track to get this product approved in India followed by our continued impetus to make this product better and increase the safety database by conducting an additional 2+1 trial and building on another trial for the WHO markets and we believe that we will have a WHO filing in 2024. We will provide a guidance on this product as the regulatory queuing procedure (unfolds) in accordance with the Indian regulator. Probably in the next earnings call, I will be able to provide you good news on this product.

The other early-stage vaccine programs are progressing as expected. I hope I have answered your question.

**Surya Patra:** So, sir, is it fair to believe that the contribution of this speciality project from the advanced market is likely in let's say FY26 or so?

**Satakarni Makkapati:** Can you elaborate your question a bit more?

**Surya Patra:** From the advanced market let's say Europe and US, that is the target market if you consider, then those are like the incremental business from those advanced markets from these specialty products is likely in FY26 or FY27 or beyond 25, FY25. Is it so?

**Satakarni Makkapati:**

So, in the area of biosimilars, we are expecting a product approval next year with the filings that we have in Europe. So, we expect the revenues to kick in sometime in Q3 or Q4 of the next year. So That's when we will see the commercialization to begin for biosimilars in certain regulated markets. With the ongoing clinical trials, the three large antibody clinical trials that we are doing globally, (FY24 end or) FY25 is a fair assessment for the revenues to kick in because the regulatory process takes anywhere between 9-15 months in Europe and US (after filing).

**Surya Patra:** Ok. Just one last question from my side. So here, about the European market and in general about the margin profile of the consolidated operations, so obviously generally the cost pressure what we are witnessing, it is common for all the markets and our key market which is a key earning contributor that US is facing is obviously the pricing pressure as well as the cost pressure. So same should be there even in the European market I believe should have pressurized the overall margin. So here, if you can share some idea about what is the current situation and the current challenges that you are facing in the European markets and how long that can have similar kind of impact on the overall margin profile. And having kind of seen a correction in the gross margin level from last year for the consolidated operation, how should one really build in the gross margin scenario for Aurobindo going ahead for this year and say next year?

**Sanjeev Dani:** So, on the European business I will answer, and CFO will answer on the overall for Aurobindo. During the quarter, we have not seen a margin compression. In fact, our margins have strengthened because of the various opportunities which were thrown up because of the supply chain disruption in Europe with other competitors. So, if you really see, our business or top line has been rock steady at about 190 million in Euro terms and we discontinued two loss making country's business in the first 6 months. So actually, if you discount for the last year's base of these 2 companies, we have grown by 3% in the top line and our EBITDA has strengthened actually to 13% to net sales. I do agree that there is a pressure on gross margin and also maybe expenses, but we are better positioned versus competition.

**Surya Patra:** Sure sir.

**S. Subramanian:** Surya, as Sanjeev said, if you really recollect, last year we have been telling about the low teens and the position has slightly improved and going forward with the Euro appreciating, (hopefully it will get appreciated), I think we can see some improvements only. In terms of the overall company, the percentage of the overall European business remains at

around 26% and continues to remain in the same position. So overall if you really see the Company as a whole, the gross margin and EBITDA margins will slightly improve based on the performance of the European business.

**Surya Patra:** Ok, yes sir. Thank you. Thanks a lot.

**S. Subramanian:** But it may not be very significant, in bps, around 10-20-30 bps, like that it can start to move up.

**Surya Patra:** But next year should be different sir.

**S. Subramanian:** See at this stage, we would not want to comment on the European business.

**Surya Patra:** Generally for the consolidated operations.

**S. Subramanian:** For Consolidated operations, quite a significant manufacturing has been started in India if you recollect in the last 3-4yrs, they have really taken around, if I am right Sanjeev can confirm, we have already moved around 50% of the products to India.

**Sanjeev Dani:** Ya, it is about 55%

**S. Subramanian:** Ya, 55% cost effective manner and this process is being continued. Sanjeev, would you like to talk about European business, injectable moving to Europe, biosimilars etc. Do you want to elaborate?

**Sanjeev Dani:** Ya, actually going forward, we have seen that our business has been growing double the market growth rate. So, we expect 5-7% growth to continue. Secondly, we are developing more than 200 products which includes injectables, biosimilars but mainly broadening the product portfolio of Oral Solid also. So, over the next 2yrs, we will be launching these products. So, we see that there are a lot of opportunities which are coming up because of competition, we are not able to maintain the steady stocks in the market.

**Surya Patra:** Ok, Ya. Sure sir. Thank you. Wish you all the best.

**Moderator:** Thank you. Next question is from Kunal Dhamesha.

**Kunal Damesha:** Good morning. Thank you for the opportunity. First on the Pen-G project where we are planning to invest \$235 million dollars. Can you provide colour on what are the major parts to that \$235 million dollar including let's say equipment, the outer infra, the land cost etc.

**S. Subramanian:** The overall project of \$235 million, the major will be, we are planning to put a de-salination plant, the fermentation process, power blocks, etc. like multiple sub-projects are being done and those purchase orders have been issued and work is being done by the respective suppliers etc. The material is expected to receive in this quarter and the next quarter. Significant portions of the buildings and blocks have been done. So, we believe

by next September or October, the installation should be over. After that, the trial or the pilot batches will take place starting October next year onwards. So, our target is to complete the projects by March'24 and it's our endeavour to advance it.

**Kunal Damesha:** Ok. And the capacity of production – how much will be the production capacity?

**S. Subramanian:** The production capacity will be around 15,000 Metric Tonnes.

**Kunal Dhamesha:** 15,000 Metric Tonnes. Ok. Sure. Coming to the R&D expense which seems to be kind of guided between 5-6% of the revenue and this quarter its 4.8%. Do we expect it to go up given that we now have phase 3 trial for biosimilar running or would you say that the majority of cost for those phase 3 trials are already on and you would see similar run rate?

**S. Subramanian:** Kunal, you are absolutely right. Coming quarter I think, December quarter and the March quarter, some of the phase 3 trials are being conducted as Satakarni explained very clearly. So, we expect the overall percentage to go up and probably it may go up to 6% level. This quarter is 5% because of the timing of the expenditures and other things but certainly we are looking at 6%.

**Kunal Damesha:** Sure. One follow up on the profitability of the biosimilar business specially in Europe where the price erosion seems very strong. So, what are your views? Currently we are doing low double digits in the Europe. Once the biosimilar business comes in, could that have a material delta or how should we think about it?

**Sanjeev Dani:** Yes, Europe business, even without this specialty products will strengthen the EBITDA margin that is what our endeavours are with the launch of more new products. But biosimilar, oncology and injectable will definitely help to improve the margins. However, it depends on the expectations, but we think that it should reach beyond 15% In the coming quarters.

**Kunal Dhamesha:** And the last one on the biosimilar, we have said again, we are investing another Rs. 300 crore, what kind of bioreactor capacity we are looking at with that investment?

**Satakarni Makkapati:** So, Kunal we are looking at about (multiple) 15KL manufacturing bioreactor (capacity) that probably makes it the largest monoclonal antibody manufacturing capacities when it becomes fully operational in the country. We also think the 15KL manufacturing capacity would provide the foundation for our company's contract manufacturing aspirations and also add in additional capacities for our own products. We look at this plant becoming operational and ready for commercial supplies in FY25-26.

**Kunal Dhamesha:** And what would we have current capacity for biosimilars and current gross block?

**Satakarni Makkapati:** At present, we are having 140,000 square feet manufacturing footprint with four 2,500 litre (mammalian cell culture) bioreactors that is around 10 KL capacities for our internal programs. So, for the first two or three monoclonal antibodies that will come out of our CuraTeQ facility, we are well aligned to capture up to 5% to 10% of the market share without any (capacity) hiccups. If you can go through the press release that we have made about this Rs. 300 Crore investment, this is primarily to stretch our aspirations into contract manufacturing, creating a huge manufacturing footprint that allows us to make solid foundation to attract contract manufacturing opportunities in this segment.

**Kunal Dhamesha:** Sure, thank you. I'll move back in the queue.

**Moderator:** Thank you. Next question is from Prashant Poddar.

**Prashant Poddar:** Hi guys, thank you very much for the opportunity. Subbu, first of all, there are two concerns I will point out. First one is on the governance standards given the experience of the Chairman in compliance, investors who have been with you for more than five years, a decade, etc. would expect better governance standards, wherein the side businesses of directors should also be reported and should be public rather than we coming to know about it much later. The second one is on your use of cash; I just could not understand your response, honestly. We don't want a buyback or anything to be announced immediately. Obviously, the use of cash is something that the board of directors have to decide, but your confidence in saying that this money will be needed till May you do not have any clarity on that, and the response that the capital expenditure will suddenly be increased. I just could not understand that bit. \$337 million cash and Rs. 800 crores a quarter EBITDA it just does not, I mean, we can't understand how this cash can be so quickly utilized and we don't want it to be used for buybacks or anything but your lack of clarity on what it will be used for, you just could not add numbers for me. So honestly, this is a disappointment from our perspective. We just want a candid feedback and we need better communication from Aurobindo on all these things.

**S. Subramanian:** Yes, Prashant your point is taken. In terms of the Pen-G plant, we are already putting around Rs. 2,000 crores and out of that we have spent around Rs. 500 crores, Rs. 1,500 crores are going to be spent in the coming year. We like to accelerate it as much as possible. Second point if you really see once we get a clarity, we are already having a gross debt of ~\$490 million we would like to use the cash and reduce it. It is not the entire cash that is going to get used, the cash is kept as a reserve and there is a gross debt of nearly Rs. 4,000 crores, which has been forming part of the earnings presentation also, we would like to use it and reduce the debt. So, we are working on that. In this quarter we could not do because of the volatility we do not know when we need to bring it and whether the rupee will touch the 85 rupee or not, we don't want to bring it at a low price and then later rupee getting depreciated. The third point which I want to say is we talked about Rs. 300 crores which has already been announced and Satakarni has explained that. Apart from above money, which is expected to complete and we are already guided in the past, we will be doing a CapEx of around \$125 to \$150 million every year, since we are already having around 23 plants and

some more plants will come into operations in the coming year also. So, because of these reasons, we are a little bit conservative, and we'll like to look at it in the month of May. When I say May, it is during the March results.

**Prashant Poddar:** Yes, we understand that Subbu. Only that at the beginning of every year, you know, when the Board of Directors meet, like any large company needs to do, you need to, you know, be very, very clear about the use of cash rather than thinking it through as it happens, the CapEx is not you know, it's not easy to just increase the CapEx as I mean, as you said as much as we can. So, the use of cash, you know, large shareholders would only want it to be more stable, to get a more stable outlook on that rather than a very, you know, quick changing once. And last one, the corporate governance, you know, serious work needs to be done there about what directors are doing etc. I mean, just because some of them are promoters, they cannot do anything that they want, right? I mean, such a responsible position that of a director of a large company, which is making more than \$400 million EBITDA year and such large responsibility as an exporter, the largest exporter of pharma from the country, largest manufacturer or supplier to the drug industry, the drug consuming industry of the US, it is disappointing to, you know, because this would not even work well with your buyers. I mean, they would also want you to abide by certain corporate governance, I would believe. That's all from my side. Thank you very much.

**Moderator:** Thank you. Next question is from Rahul Jeevani.

**Rahul Jeevani:** Yes, hope I'm audible, sir?

**Moderator:** Yes.

**Rahul Jeevani:** Yes, sir. I just wanted one clarification. Your injectables speciality revenue guidance from \$650 to \$700 million dollar, does that factor in contribution from Revlimid as well?

**S. Subramanian:** Yes, it does.

**Rahul Jeevani:** Okay sir. So, then how do you see the revenue momentum on the injectables business to sustain given that Revlimid will be a short-term opportunity for most of the players so that opportunity might last only two-to-three-year period. But beyond that, how do you then see the growth on the injectables business?

**Yugandhar Puvvala:** What we have done is based on what we feel is based on our filings and the approvals what we are getting, we feel double digit growth, on a regular basis even if I take out Revlimid, growth will continue to happen, quarter and quarter, that is what we have baked in and we have good enough pipeline to take care of that. Also, we have added significant capacities looking at the future growth of this business at a double-digit growth.

**Rahul Jeevani:** Sure sir.

**Yugandhar Puvvala:** So, I'm also keeping Revlimid as well, it will start from FY24 and it will remain till FY26 or FY27. So, I'm just keeping that three-four years of opportunity. I'm keeping that aside, going forward, whatever it is, it's a regular, normal trending of business should happen in double digits.

**Rahul Jeevani:** Sure sir. So, if you can just come in, what was the global injectables revenue for the quarter? I missed that number.

**Yugandhar Puvvala:** In fact, we don't put it as segment wise results, but it is in the range of around \$100 million.

**Rahul Jeevani:** Okay, sure sir and at least the thought process which I was working with, was that given Revlimid at the end of the day is an oral product although I know you classify speciality or Onco as part of your global speciality business but my sense was that the \$650–\$700million growth will be driven by the injectables portfolio rather than Revlimid being such a large contributor to the growth, which we're talking about.

**Yugandhar Puvvala:** Yes, I appreciate that. But that's why like, if you see Revlimid initially, based on our settlement, we were supposed to launch only in October 2023. So, in FY24 revenue, Revlimid would have been an insignificant portion from an overall number's perspective. But, and most of the numbers were supposed to come from the regular portfolio of products. But the guidance I'm giving as I said, like it is going into FY25 is mainly that regular portfolio also should go to that level. But we need to wait and watch at this juncture, it is too early for me to comment based on the last two quarters events.

**Rahul Jeevani:** Sure sir. So, then that implies that your contribution assumption from Revlimid would have been very negligible, given that you were launching only in second half of FY24.

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

**Rahul Jivani:** Okay. Sure. Thank you. That's it from my side.

**Moderator:** Thank you. Next question is from Tarang Agarwal. Tarang, please unmute yourself.

**Tarang Agarwal:** Hi, good morning, am I audible.

**Moderator:** Yes.

**Tarang Agarwal:** Okay. Just a couple of follow ups. One did Yugandhar did you suggest, that you would be properly launching 20 products in this financial year?

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

**Tarang Agarwal:** So, in the next half a year, we should see 20 products. Is that how I should look at it?

**Yugandhar Puvvala:** Yes, overall, this year, we should have around 20 launches.

**Tarang Agarwal:** Okay, that's one. Second, if you could give us a sense on what's happening on the Depot business? Is it status quo from your earlier update or has there been any developments there?

**Yugandhar Puvvala:** It is status quo there and as I mentioned, last time, we have finished one product and that is on stability. The other two products also, we should complete it in this year and post that we expect the filings to happen from FY24 onwards, and status quo, literally. Everything is going as per what I updated last time.

**Tarang Agarwal:** Thank you. Dr.Satakarni, just wanted to get a sense on, I mean, I think the three Biosimilar products that have been filed, they've been filed somewhere in September and January. Any status on Product Approvals Inspection (PAI) from the regulator?

**Satakarni Makkapati:** That's a good question, Tarang. So, we had two filings with the European Medicines Agency (EMA) in the oncology space with an abbreviated clinical path. We have (adopted) the EMA suggested clock stop for seven months (after) we have completed all the procedures and responses leading up to Day 120. But, because of the paucity of auditors to come and do a GMP inspection, the clock has been stopped by EMA. So that's something which is not under our control. The clock stop will be until the June of 2023 (for two programs). If the situation changes, the inspectors are (become) available ahead of time, then (I believe) EMA will give us a notice in months' time for the GMP inspection. With respect to our filing for non-squamous small cell lung cancer drug biosimilar with MHRA in the UK where we filed this product with only phase 1 data, (i.e.) three arm phase one data of our test biosimilar versus the US and EU registered reference products, this is (possibly) the first time ever that the monoclonal antibody has been filed with only phase 1 and not including the phase 3 (data) of the efficacy trial. So, you should understand that we are pushing the regulatory barriers here. But I'm pleased to inform that the Day 80 (which is an equivalent to Day 180) with EMA (the Day 80 procedure) has been adopted by MHRA and it is highly likely and now this is a forward-looking statement, it is very highly likely that this may become the world's first monoclonal antibody biosimilar that may be approved by the developed market's regulatory agency without the need for a phase 3 efficacy trial. I'll keep you posted on it. You should understand that this is a forward-looking statement and that we are pushing the regulatory barriers here. But the only point that is left after Day 80 is the GMP inspection. So, we are waiting for a GMP inspection for all the EMA as well as the MHRA filings. We will keep you posted as and when things evolve.

**Tarang Agarwal:** Correct, just a follow up. So, on the Europe filings, would it therefore, given that the regulator, there's a paucity of inspectors or impediments from the regulators end, would it therefore mean that your product approval inspection might perhaps been pushed to June 2023?



**Satakarni Makkapati:** No, what we have been told, what we have been communicated by them is to take a clock stop until June 2023. They are expecting the regulators scheduled to be available starting Q1 of the next calendar year. If the situation changes, they will keep us informed and carry out the inspection with one month's notice (I believe). But based on the formal letter, we expect the inspection to happen in June. But, an inspection between January to June cannot be ruled out, Tarang.

**Tarang Agarwal:** Got it. That's simple and Swami sir just wanted to check, I mean, this is again to an earlier question. Does the base which is the US base between OSDs, injectables, OTCs and everything will just come down to about \$330 million, would it be fair to presume that this \$330 million would be the new base going forward or different numbers as a base just for us to understand how, if we were to ignore the one-offs of this quarter, how should this number or how should this business look like going forward from Q3 onwards?

**Swami Iyer:** Yes, so, actually, we need to split this into two. One is the injectable side and then the other one is others, speciality side and others. Because as you know injectable business, we are considering separately from Eugia, this speciality. But with regard to the other business, as far as the oral solids are concerned, the generic market would continue to remain competitive in the next few quarters. We believe that this could be due to overcapacity or number of approvals that's coming in. But you know, we have a very broad and strong base portfolio and we have a fairly robust pipeline. And recently we got the Unit VII clearance, we also have other ANDA which are ready to be launched. So, we are looking at a potential launch of around 40 products for the next 12 months. So, we think that we should be able to regain from the market in terms of value. We have such a broad portfolio of products, we also see some time surge in demand. Right now, we are seeing good surge in demand as far as antibiotics are concerned with the onset of flu season. I think overall our base should be better when we should go back to the earlier base or at least to that level, that's what we think. With regard to the OTC product, they are doing well and they continue to do well. So, we have no issues at this point. Yes, I think Yugandhar, he has already answered on the injectable part.

**Tarang Agarwal:** Yes, that's been answered. Yes. Thank you.

**Moderator:** Thank you. That was the last question. 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 [ww.aurobindo.com](http://ww.aurobindo.com) in due course. Thank you and have a great day.

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

**(END OF TRANSCRIPT)**