Aurobindo Pharma Q2 FY24 Earnings Conference Call
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Mr. Yugandhar Puvvala - CEO of Eugia Pharma Specialities Limited

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

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

Mr. Swami Iyer - CEO, Aurobindo Pharma USA

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Moderator: Welcome to Aurobindo Pharma Q2FY24 Earnings Call. Please note that all participants' line will be in '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 management for opening remarks. Thank you and over to you Sir.

Shriniwas Dange: Thank you, Vandit. Good morning and a warm welcome to our Second Quarter FY24 Earnings Call. I am Shriniwas Dange from the Investor Relations team. We hope you have received the Q2FY24 financials and the press release that was sent out yesterday. These are also available on our website.

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

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

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

Santhanam Subramanian: Thank you Shriniwas. Good morning and a warm welcome to our Q2FY24 earnings call. I am extremely delighted to inform it has been yet another quarter with highest ever sales. The sales growth was seen across the market and businesses. This is further augmented by the highest EBITDA in the past 12 quarters. Now let me take you through the details of the results for the 2nd quarter of FY24 declared by the company.

For Q2, the company registered a revenue of Rs. 7,219 crores with an increase of 25.8% year-on-year. The EBITDA before forex and other income grew by 67.7% year-on-year and by 21.9% quarter-on-quarter, to Rs. 1,403 crores. EBITDA margin for the quarter was at 19.4% against 16.8% for the last quarter. Net profit increased by 83.6% year-on-year and by 31.7% quarter-on-quarter, to Rs. 752 crores.

In terms of the business breakdown, formulation business excluding Puerto Rico in Q2 FY24 witnessed a growth of 29% year-on-year to Rs. 5,968 crores and contributed around 82.7% to the total revenue.

API business contributed around 16.2% and clocked a revenue of Rs. 1,166 crores for the quarter, registering a growth of 20.3% on a year-on-year basis. The growth is mainly driven by higher volumes on account of the improved asset utilization and de-bottlenecking.

For the quarter, the revenue from U.S. formulations without Puerto Rico increased by 35.7% year-on-year to Rs. 3,385 crores. On a constant currency basis, U.S. revenue increased by 30.7% year-on-year basis to USD 409 million. Please note that these numbers are without gRevlimid which have started to contribute during Q3 FY24. The growth was mainly driven by volume gains, stable demand and new product launches. Price erosion has moderated and continues to be neutral. Our wide range of approved baskets has helped us optimally manage the price erosion.

We have received final approval for 15 ANDAs and launched 19 products in Q2 FY24. We have filed 10 ANDAs during the quarter.

Revenue of Aurobindo Pharma USA, the company marketing oral products in USA, has increased by 23.3% year-on-year to USD 212 million in Q2 FY24. Revenue of Eugia Pharma Specialities Ltd. in the U.S. increased by 64.2% year-on-year. The year-on-year growth was driven by improved volumes of existing products and new product launches. This was coupled with a stable pricing scenario in this quarter with a low single-digit price erosion. The total Eugia Specialities sales in U.S. including the Specialty OSD amounted to USD 91 million.

During the quarter, the Eugia performance in various financial parameters were better than the last quarter. As informed by my colleague during the previous quarter earnings call, we are on track to achieve the USD 560 million globally for the Eugia Specialities for FY24.

We have a total of 169 injectable ANDA filings on 30th September out of which 133 have received final approval and the remaining 36 are under review or have tentative approval.

The company as on 30th September 2023 has 817 ANDAs filed with the U.S. FDA on a cumulative basis out of which 628 have final approval and 32 have tentative approval including 6 ANDAs which are tentatively approved under PEPFAR and the remaining 157 ANDAs are under review.

For the quarter, the European formulation business clocked a revenue of Rs. 1,769 crores, an increase of 16.7% year-on-year growth. In constant currency terms, Europe clocked a revenue of EUR 197 million against EUR 189 million of last year Q2.

For the quarter, growth market revenue increased by 24.7% year-on-year to Rs. 564 crores. In U.S. dollar terms, revenue grew to USD 68 million in Q2 from USD 58 million in Q1. For the quarter, ARV formulation business revenue increased by 52.1% year-on-year to Rs. 250 crores or USD 30 million.

During the quarter, the raw material cost and freight cost have improved further aiding our gross contribution which stood at Rs. 3,983 crores. Gross margin for the quarter was higher at 55.2% against 53.9% last quarter mainly due to low material cost and favourable product/ business mix.

R&D expenditure stood at Rs. 300 crores during the quarter which is 4.2% of the revenue. Previous quarter expenditure was high on account of clinical trial expenses for multiple projects.

Capacity utilization has gone up well this quarter driving the operating leverage. Consequently, EBITDA has improved to Rs. 1,403 crores reflecting a margin of 19.4%.

As on date, out of the 18 U.S. FDA regulated units, 15 units have classification of VAI, 2 units have received one observation each and 1 unit is under warning letter.

Net CAPEX for the quarter is USD 154 million which mainly includes USD 48 million towards acquisition of marketing authorization in Indonesia and USD 42 million towards PLI CAPEX. Cumulative CAPEX for Pen-G PLI project till September 30 amounts to USD 188 million.

The average USD-INR exchange rate is 82.68 in Q2 against 82.15 in Q1, FY24. The average finance cost was 5.3% mainly due to availing multiple currency loans.

The business generated a free cash flow of USD 48 million during this quarter before the PLI investments and the investments in new markets.

Our API business was transferred to the new subsidiary Apitoria Pharma Private Limited effective 1st October 2023.

Outlook: Our financial performance in Q2 was on the back of a positive business environment across our market as well as our continued focus on driving growth and efficiency. We are confident of continuing the growth trajectory across the top line and bottom line fuelled by new launches, cost efficiencies, healthy product pipeline and new business opportunities. We remain committed to strong execution. Our structural strength through the significant volumes and pricing are the underpinnings of the U.S.-generic growth.

Some of the key highlights for the coming quarters are summarized below.

- We launched Generic Revlimid in October 2023.

- In Q2, U.S. continued to improve, price erosion remained neutral. All raw material costs and logistics are continued to reduce. We remain optimistic in Q3 in terms of margins.

- We are on track to achieve the 20% plus EBITDA margin target set internally for the year.

- We have the following plants under commissioning.

  - China plant is fully installed and has received the EU GMP approval. It is expected to start revenue generation from end of Q4 FY24 or early Q1 FY25.
  - The Pen-G plant and the 6-APA plant are under installation and are expected to be operational from Q4 FY24 or Q1 FY25..
  - Further, we are conducting clinical studies for our biosimilar products and the plant is expected to be commissioned by FY25 or early FY26.

- With the above actions including commercialization of Pen-G plant and other projects over a period of time and stabilization of the manufacturing processes, base EBITDA margin is expected to improve considering the current market conditions. This margin is without considering the margin for biosimilars, etc.

- We are strongly focused on biosimilars and peptides and these are significant levers for the future. Strategic partnerships like Merck announced recently will continue to fuel growth and margins for the future beyond FY25. My colleague Satakarni will provide more insights.

- We will continue to explore opportunities for any bolt-on acquisition aligned with our company strategy, especially acquisition of ANDAs and market authorization based on market opportunities, thereby reducing the gestation period. Indonesia opportunity is one such. Sanjeev will talk about it.

- The CAPEX of Generics over the near to medium term, except towards the major plants as mentioned earlier, will be more focused towards the debottlenecking, some additional lines and maintenance, thereby increasing the manufacturing capacity and the efficiency.

This is all from my end. My colleagues in the panel will give more clarity on any specific aspects in our Q&A session. We are happy to take your questions now. Thank you.

Moderator: Thank you very much. We will now begin the Question & Answer session. Anyone who wishes to ask a question may raise your hand from the 'Participant' tab on your screen. Participants are requested to use headphones or earphones while asking the question. Requesting everyone to refrain to two questions at a time.

The first question is from Kunal Dhamesha.

Kunal: Hi, good morning. Thank you for the opportunity and congratulations on a good set of numbers. So first one on the LOI that we have signed with MSD. I just wanted to understand what's the kind of investment that we could be looking here as well as what kind of capacities that we would be putting and what is our right to win versus already established players, I mean, regionally or even globally like Lonza, Samsung Bio. That would be the first question.

Dr. Satakarni Makkapati: Kunal, this is Satakarni. So, to answer your question, I'll provide you some context into it. The limited letter of intent that we signed with MSD entity allows us to create infrastructure for contract manufacturing of innovator biologics. Now, the market for the originator biologics right now is about 300 to 350 billion US dollars. With more biologics approvals and their success that we are seeing in treating debilitating diseases worldwide, the need for reliable manufacturing, improving lead time efficiencies and reducing supply chain lengths is becoming more relevant than ever in this industry. Personally, I believe biologics contract manufacturing industry is growing immensely and is poised to grow to about 30 to 40 billion US dollars by 2030.

Now, if you look at the landscape of, that's part B of your question, the landscape of competition, most of these innovator biologics or innovator companies opt for contract manufacturing in the West. You have contract manufacturers like the Lonza, like Bohringer-Ingelheim, Patheon, etc. In Asia, you have companies like the WuXi Biologics, the LG Life Sciences and the Samsung. Now, the kind of capacities that we are installing for mammalian cell culture manufacturing are over 15KL bioreactor scales. Now, this is way-way higher than the capacities that you see in India in contract manufacturing.

So, the ideation here is to essentially have a large mammalian cell culture drug substance manufacturing facility with a series of 15KL bioreactors and which is also complete with fill and finish capabilities. Now, in contract manufacturing space, either you see drug substance manufacturing capabilities in biologics or the fill and finish capabilities and it is very rare for a customer to come in and do both drug substance and the finished product in one site. So, in this regard, I believe this is a unique proposition vis-a-vis the competition. It is being positioned to supply the product commercially right from day one to the collaborators or the partners. So, we are positioning this to compete with the CMOs, the large CMOs in Asia and outside over a period of time. But the objective and the intent is that.

Now, in terms of investments, as we have made a press release and disclosure to the exchanges, we have signed a limited letter of intent, and we are continuing to negotiate the final terms with the partner. We hope to conclude these negotiations by 31st of March 2024, which is when we will have a clear idea of the sort of investments that we are going to have in this plant. But right now, we are going ahead with some investments. The final investments that we will be making to complete this plant, there are a few items which are still to be sorted out between us and I will be able to provide a clear picture four to five months from now. I hope this answers your question.

Kunal: Yes, Sir. These answers my questions to a great extent. So, we are seeing that unique USP is drug substance plus drug product. At some point, we are going for the scale.

Dr. Satakarni Makkapati: Yes. Because if you look at the Indian contract manufacturing space, Kunal, I am sure you have checked it. There is no one of this scale in biologics who are positioning it and trying to call in. See, we need an anchor industry here. I mean, India needs a WuXi sort of a moment to make sure that we have a contract manufacturing setup that can compete globally. And for us, I think we have done to a great extent the right steps. We have a good anchor, who is a partner. And then we are investing in good scales. And we are planning to get into commercial space right from the first supplies. So, let's see how this

unfolds. I am thoroughly excited by it. Aurobindo is excited by it. It's now the time for execution of this project in the next two to two and a half years. And we'll keep you posted on the progress that we make with this project.

Kunal: Sure, sir. Thank you. And one for Subbu sir, if I see Gross Debt has gone up by almost around $160 million. And I see that we have done some acquisition in Indonesia as well. So, could you throw some light as to what that acquisition, how that fits into our number and where do we see the Gross Debt number by the year end?

Santhanam Subramanian: See, the Net cash we are having, we had end of June was around $179 million, if I'm right, or say $180 million. And today we are having around $130 million net cash, predominantly that $50 million has gone for the acquisition finance. So, in terms of the cash generated from the business, etc., we have effectively ploughed back into the PLI project, which is in the fag end of the completion of the project. We need to complete the project by March. Before that, everything will be expended. And the existing accruals which is happening will be spent towards the PLI projects and other things. So, the Gross Debt and cash put together, probably by end of the year, will be anywhere between $0 to $50 million. That's what I think. Because after that, once the PLI project has been commissioned, which is the biggest project from next year, first quarter onwards, we will start able to generate the profit. Once again, it will help us to get the net cash back to $200 million over a period of maybe in a year's time, or maybe 6 to 9 months' time.

Kunal: Sure. And just one clarification, this 20% EBITDA margin guidance for FY24 includes gRevlimid contribution?

Santhanam Subramanian: Absolutely. Today we are having 18.2% is the YTD EBITDA margin. So, thanks to Revlimid and the entire Eugia team, we should be able to make it 20% year as a whole. That's what we are working on.

Kunal: Great. Thank you and all the best and Happy Diwali.

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

Neha: Yeah, thanks for taking my question. Sir, on the US business, if I were to strip out the Puerto Rico, there seems to be very strong traction that we've seen in the Oral Solid business. So, one, is there any one-off sale which is there in this number or should we assume that the gRevlimid build happens on the existing base of US sales? And what happened in Oral Solid?

And second, we haven't seen any improvement in the injectable business quarter on quarter, you know, the generic injectable business in the US. So, you know, what's our expectation in the second half of that business? Is this the new base for injectable? Will we get any large approval? You know, any colour there would help.

Santhanam Subramanian: Swami

Swami Iyer: Yeah, Subbu. Okay. So, let me handle the Oral Solid. Thanks Neha. We had earlier talked about in the earnings call, we talked about the introduction of newer products,

launching of the newer products and/or surge in volumes generally in the Oral Solid area. We have been having steady improvement in terms of volume growth and we've been able to leverage our large manufacturing capabilities and our demand has also been very steady. You know, we have a very broad portfolio. So, we continue to grow and surge which volumes across our broad and diverse portfolio. And this is driven by new launches plus the base business. We've also seen some positive outcome in new opportunities. Thus, I think we are fairly positioned for a steady performance in future.

Neha: So, there isn't any one-off in this number, right? That's the right way to…

Swami Iyer: No.

Neha: So, we build on the existing base as we launch new products.

Swami Iyer: That's correct.

Neha: And I think in the opening remarks, sir mentioned that Oral Solid pricing was neutral for the quarter.

Swami Iyer: Yeah.

Neha: Okay. And on the injectable business, if Yugandhar sir can help.

Swami Iyer: Yeah, Yugandhar will take the question.

Yugandhar Puvvala: Hi, Neha. Yeah, you're right. In fact, injectable business from year on year, it is a significant growth but quarter on quarter, it is single digit growth. And from a base level of overall injectables, we have gone from a USD 100 million run rate to USD 120 plus million run rate and we expect the same trend to continue. So, it will be a… if you compare Quarter 1 to Quarter 2, it's USD 122 to USD 127 million at a global level. But if you compare year on year, it is 60 plus percent growth. And all these are without any one-offs. And obviously, we have launched gRevlimid in October. And we expect gRevlimid to continue to give us good revenues from Quarter 3 and Quarter 4. But base business will continue to be in the range of USD 120 million plus globally.

Neha: Yes, Yugandhar sir, I understand the Eugia number and gRevlimid contribution. I'm talking about generic injectable business, right? Because, we had guided to that base improving as we are launching more products, you know, pricing there is also improved.
So, the $81 million that you've got for the generic injectable business, not the Eugia number, can that improve as we go ahead? Or is this the new base where we get some large product revenues?

Yugandhar Puvvala: So, at this juncture, it is generic injectable business has stabilized around USD 80 million per quarter for the US market. And we expect that it can go up to 90. But as you see, like we are getting significant number of approvals. And we expect that this run rate can go up from USD 80 to USD 85 million and USD 90 million.

Neha: Understood. And Subbu Sir, on the margin number that you've mentioned, I think that our R&D spend is trending below what we saw in the second half, you know, last year. So, should the R&D be at the current level, for 5% that we've done in the first half?

Santhanam Subramanian: See, our R&D spent approximately in a quarter will be around Rs. 375 crores. This quarter, it's Rs. 300 crores. Because some of the major clinical trial studies which has happened has been completed in the month of June. Before the next phase starts, which may take place starting October. And some of the milestones are being met in October, November only. So, we'll be back to around anywhere between Rs. 350 to Rs. 400 crores in the third quarter.

Neha: Okay, got it. And your 20% margin guidance is after assuming a higher R&D number?

Santhanam Subramanian: Yeah, obviously.

Neha: Okay.

Santhanam Subramanian: It is not guidance, that is our internal target set ourselves and we'll be working on that.

Neha: Got it. Thank you so much, sir.

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

Surya Patra: Hello. Yeah, thank you, sir. Congratulations for the great set of numbers and their broad-based performance across segments and across line items. My first question is on the strong double-digit growth, what we are witnessing in the US oral solid business. Whether this is a kind of temporary momentum, as you mentioned that you are witnessing volume growth as well as new product launches and all that. But is it a temporary momentum that you are witnessing, or it is kind of a sustainable run rate that we are now having? And can we maintain near double-digit growth consistently in the near future for the oral solid business, Sir?

Swami Iyer: I'll take this question, Subbu. Thanks, Surya. There are a couple of questions that you asked whether our growth is temporary. I think that's a question Neha had also asked. We don't have in a different way. We don't have a one-off in this. This is the actual demand and this is the actual sale. Based on that, these are the numbers that we achieve. And we have been talking about this in each of the earnings call that we expect growth in the US market because we were expecting approvals. And we did mention that we will be launching 40 new products. I mean 40 products over the next 12 months. And we are on track with that. And this is one which is a new product launch. Apart from that, even in our existing business, we have been given new opportunities and there have been some positive outcomes. And then this is positioned as well for the current quarter. And I believe that in future too. But, you know, these are markets which you can never say. As more people come into the market, there could be competition and then we have to beat the competition. We believe we are well positioned because we have got that kind of manufacturing capability. And we have a

very broad portfolio. Somewhere you lose, somewhere you win. Net-net, I think we are in a better shape with a broader portfolio. That's all I would like to say.

Surya Patra: Okay. Okay. Thank you, Sir. And secondly, on the injectable front, basically the gRevlimid. Sir, you have launched the gRevlimid this quarter. But any sense whether our volume share are likely to be kind of average of the existing players? And the pricings are similar to the existing players? I mean, some sense if you can give?

Yugandhar Puvvala: Frankly, like it is, we can't disclose in terms of the settlement terms. So, I will leave that there. But the pricing seems to be almost similar.

Surya Patra: Okay. And do you think, Sir, it will be a kind of streamlined revenue? I mean, even a distributed revenue stream for you or it would be a kind of lumpy one within the year?

Yugandhar Puvvala: No, it is not going to be lumpy. It will be distributed across quarters throughout the settlement period.

Surya Patra: Okay. And in fact, my next question is about this PLI project. Now we are inching ahead towards the completion of the project. And we should be positioning ourselves also commercially. So, Subbu Sir, if you can give some more clarity at this juncture, what you have about that? And whether you have mentioned in the opening remark that you will get the payback in the first year itself for the project?

Santhanam Subramanian: I never said we will get the payback in the first year. What I said is we are likely to complete the entire project and we will commercialize on 1st April as planned. And we will be starting the project. The phase by phase, the project starting will take place from next year onwards.

Surya Patra: Okay. Okay. In terms of utilization volume, any sense that you can provide, Sir, because you would possibly be making arrangements for commercial launch and all that?

Santhanam Subramanian: No, Surya, actually we have said in the past also, we are out of the 15,000-ton capacity which we are having, 45 to 50% will be self-consumed. Okay. And to that extent, we are better positioned to take out the project. And it is too early for us to talk about it. I mean, we'll talk about how we are going to do that, which are all the parties, how the commercial for external parties will take place, etc. We'll get a better clarity once the trial runs are completed successfully in the month of January and February for the fermentation process.

Surya Patra: Okay. Okay. My last question is on the European market, Sir. See, in the previous quarter, we had got a kind of a very positive remark that the business which used to hover around to 12 odd percentage kind of margin it has already surpassed kind of mid teen levels. So, if you can update about the European business in terms of growth, growth outlook where from that we are seeing this double-digit kind of growth and what is the margin levels that we are currently at and what outlook that we are having, let's say for next year driven by the injectable launches, what is in plan for you?

Sanjeev Dani: Yeah, hi, good morning, Surya. European business on the top line has grown by 4.2% on constant currency, but if you discount the discontinued business in a couple of market last year, then it will improve by about 1%. And the margins are growing faster than the top line and our focus is because we are lower than the average company's EBITDA, our focus mainly is on improving the margins and our EBITDA remains in the mid-teens' percentage. So, even though this quarter seasonality is lower in Europe, but still we have with the fixed cost that we have also we have maintained the EBITDA margins. So, that has been the performance and obviously, the margins are growing in double digit. Top line growing double digit is not expected in a market which is growing 2 to 3% per annum. And we are fine with that, unless, some different dynamics happen like withdrawal of some products from major competitor or otherwise, there will not be such opportunity. Going forward, I think that our focus is to grow profit, EBITDA margin in double digit that is what our main objective is.

Surya Patra: Sir, is it ever possible to achieve the company level margins for our European business?

Sanjeev Dani: Yeah, that is our desire and the goal 20% is what we should be looking at. And the scale will allow that to happen. We are looking at I mean, as you know that for biosimilar, as well as oncology, the distribution platform is this European companies that we have. So, we hope that with specialty product launched, we will further improve the top line.

Santhanam Subramanian: Vandit, as there are a lot of people in the queue. I would suggest only two questions are allowed. Many people are waiting.

Moderator: Requesting, Surya to fall back in line.

Surya Patra: Of course, Sir, thank you.

Moderator: Thank you. Next question is from Tarang, requesting everyone to please introduce themselves and refrain to two questions at a time.

Tarang: Hi, good morning, couple of questions on Europe and Indonesia, and then probably one more on Eugia. Particularly with respect to the Vizag plant coming in Sanjeev sir, and hopefully China coming through, how do you see this business evolving, say, from FY25 onwards. Because it does take care of a lot of bottlenecks that were there in the system?

Sanjeev Dani: Yes, that is true. Actually, our top line would have been better if we had more stocks available, that is true. So, demand was higher than what the P&L will reflect. And we are very hopeful, in fact, the unit 15 expansion is also getting over in December- January. Plus, Europe is sourcing from unit three and unit seven. So actually, there is some de-clogging and expansion happening in those areas also. So, we think that our stock situation in oral solid should improve in the next 2-4 months. And of course, China facilities backup but we are taking one at a time and the facility is already approved for European Union. Injectables, Vizag will definitely allow us to supply some of the products which are already approved in Europe, and plus the new filing will happen.

Tarang: Okay, Yugandhar Sir, how are you seeing FY25? When you know, do you see Vizag contributing meaningfully to the business to the bottom line?

Yugandhar: I don't think FY 25 will have a meaningful impact but I think it'll be FY 26.

Tarang: Okay, and just the last one Indonesia, if you could give us a sense on the market, and how does this acquisition help you and how should we see this business evolving?

Sanjeev Dani: Yeah. So Tarang I'll just answer very briefly, but if you have more question, I can answer that. So, Indonesia, you know, is the fourth largest populous country and its economy is doing well. And expected to do well, has a lot of other opportunities. And it is having a universal health insurance scheme, but the acquisition that we have made is the branded products of Pfizer, and they are sold in a private market through the medical representatives and the patients purchase from the pharmacies and these are 16 products. And there are, quite a well-known brand like Lipitor, Norvasc, Viagra, Lyrica, Neurontin etc. And the people strength is about 160. The top line is USD 31 million and with a very good margin, and we expect to close the acquisition in this quarter.

Tarang: Okay, I'll join back the queue. Thank you.

Moderator: Thank you. The next question is from Marcel Lewis.

Marcel Lewis: Yeah. My question is that currently how many sites are under US FDA restriction, and what's our like roadmap to get it through?

Santhanam Subramanian: There is no restriction on any of the units, only one unit is having a warning letter. But still, we are supplying the material and there are no major filings in that. And the two units having VAI status have been inspected on one observation each has been given we are yet to get the EIR. So, there are no major issues for us in terms of the compliance. And we look forward to resolve all the issues in consultation with the FDA.

Marcel Lewis: Regarding our power brands, so like what kind of growth prospect do we look in the current quarter from the power brands coming from the like a specific territory or about any new loans or about any 180 days for example, exclusivity

Santhanam Subramanian: Yeah. See we don’t have specifically power brands, but if you can put it Swami can reply.

Marcel Lewis: So, but like, do we have any like, did you have any 180 days exclusivity, like in the last quarter or like quarter to come by like, are we going to have 180 days exclusivity, like selling rights for any off-patent thing?

Swami Iyer: No, when you say exclusivity right, we will have something called CGT, right. So, that's for about 180 days. So, we'll have for that, you know, that kind of approvals will be there for maybe a few products, three, four products. At least in the last few quarters we've been having it. Otherwise, brands wise, we have some brands in the US for the oncology division, branded injectables. And then we have a small branded consumer division that was

acquisition in the last two years. Other than that, we don't have anything with the brand and exclusivity wise at least from the US side, there is nothing else other than some CGT items.

Marcel Lewis: And, what kind of turnover growth and EBITDA growth do you see in the current quarter and the next quarter as compared to September quarter?

Santhanam Subramanian: Yeah, we have been working on growing the business on high single digit in US continuously and that is what has been said in the last earnings call and we continue to maintain that. Having said that, it is not that we are restricting ourselves to high single digit growth. Wherever there is an opportunity, the sales team will be looking for more growth. Okay.

Marcel Lewis: Okay. Thank you.

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

Bino: Hi, good morning. Subbu, this Puerto Rico revenue, as I understand was reported earlier as part of US sales, is it? And why have you separated that out now? And has it got something to do with the restructuring you're doing in Puerto Rico?

Santhanam Subramanian: Yeah, we have said know in the last, you know we are shutting down the operation to do the restructuring and modifying the plant and other things. We are planning to put CapEx in a couple of years' time. So, we are scaling down the operations and then bringing it to a close. That is the reason we don't want to club it, because this is the revenue which has been done as a contract manufacturing for the business of Viatris. That is a reason. Now having completed all our commitments at the time, we may not be doing that, hence we are showing it separately.

Bino: Okay, so these particular sales will not be there from next quarter onwards.

Santhanam Subramanian: That is what, yeah.

Bino: Okay. Just on two products in the US Mirabegron and Macitentan, on which I believe you have to first to file a status are these products which we can expect in the next 12 to 18 months or so?

Swami Iyer: Bino, I think this question you raised last time also and I did mention that these are under settlement, and we don't expect a launch in the short term. When we say short term anything below 12 months or 12 months is short term. We don't expect to launch.

Bino: Understood and Subbu, just a bookkeeping question. The depreciation number seems to have jumped quite a bit from the previous few quarters. What has led to that and is this a new level of depreciation we'll see going forward?

Santhanam Subramanian: Periodically we do the impairment assessment in consultation with statutory auditors. The statutory auditors have advised us to make some impairment provision for some of the assets. So, we have done the provision.

Bino: Okay. So, is this level going to continue or this was just this one quarter?

Santhanam Subramanian: The base depreciation will be around Rs. 350 crores and whatever is the extra is the impairment and we will continue to have Rs. 350 crores every quarter and if there are any suggestions or advice given by the auditors, we will stick around to that.

Bino: Understood. Thank you very much.

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

Nitin: Thanks for taking my question. Sir, my question is we have about Rs. 6,000 crores of CWIP which is there on the books as of September. Can you give us some sense on the phasing of the capitalization of this CWIP over what period of time some of this will get capitalized?

Santhanam Subramanian: The Rs. 6,000 crore is tantamount to around USD 700 million Capital Work in Progress. Out of that if you really see the Pen G project itself is nearing USD 185 million dollars as on this day, which will get capitalized by March quarter. And probably China also part of it if we are able to successfully start the operation by Q4, probably we may capitalize some of the portion of China, I mean, the number of lines which we will be using, it will be capitalized like that. And the other projects I don't think like, Vizag, Yugandhar said we will do it only FY25 end or FY26 and biosimilar will be in FY26 and then you have Aurolife and the Eugia manufacturing US, which will be done in FY26. Part of it has been capitalized in Aurolife that is the Raleigh plant, part of it has been capitalized and balance whatever maybe it will be capitalized either by end FY25 or FY26, so that is a broad thing. The main thing is around USD 185 million is for the Pen-G project which will get capitalized by Q4.

Nitin: Okay. And sir secondly on the biologics CDMO business that we talked about. Sir, what is the date of commissioning of this business in terms of where do we start revenues coming through and at what stage do we onboard clients barring MSD in this business, in our assessment?

Dr. Satakarni Makkapati: Nitin, so we expect the plant to be fully commissioned by 26 or early 26. And we expect the revenue streams to flow in the calendar year 2026 or the fiscal year 2027. The steady state of supplies, commercial supplies, I expect these to begin to the potential partner from 2027 onwards. The reason being that when you do a technology transfer into a new plant, you need to carry out the validation batches, which results in the filing in multiple territories. And the procedure unfolds anywhere between 6 to 15 months depending on the markets that the partner would intend to file. So, I expect steady supply, steady revenues to come in from 2027 onwards. So that's one part of your question. What was the other part of your question?

Nitin: Sir, at what stage, do we in your assessment begin to onboard more clients or this is intended to be a single client business opportunity?

Dr. Satakarni Makkapati: No, no, it is not intended to be a single client endeavour at all. But as you know, when you want it to leapfrog into the CMO ecosystem, that has evolved in the

West, and that has not evolved in India to the levels that we see in the West or in countries like Singapore and Korea. It is important that we have an anchor and here the anchor is the first strategic partner, which you know, so we would like to develop a client base over a period of time. But having said that, I would like to experience this partnership for at least three years before I go to bigger clients or similar clients. But to answer your question, it is not going to be a single client endeavour at all.

Nitin: Okay sir. Thank you and best of luck.

Dr. Satakarni Makkapati: Thank you.

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

Damyanti: Hi, thank you for the opportunity. So, you have seen strong performance across segments. So, I have a question on two segments, specifically API and ARV. So, in ARV have you seen improvement that has helped this quarter number? And also, API is it a sustainable number or is some kind of seasonal benefit which has come in for second quarter?

Santhanam Subramanian: See, Damyanti this question I've answered in the past also we repeat the same thing. The ARV business, we are looking at your sales on the quarter of around USD 25 million plus or minus five. And we don't see there is a huge growth in case if you're not able to supply the material in a particular quarter, right, that probably it may hit the next quarter that's the reason why you're seeing USD 30 million. But ideally, you should take the ARV sales around USD 25 million, probably plus or minus USD 5 million. That's the way you want to take it.

Damyanti: Okay, and on the API part?

Santhanam Subramanian: API part there is a continuous improvement has been taking place since April and last quarter we have done around Rs. 1,033 crores or something like that. And this quarter we have grown to Rs. 1,166 crores, our capacity utilization has been very good. And apart from that, they are also able to supply to the captive consumption for the formulation business because the formulation business has been requiring more APIs in view of the improved demand in US, which Swami has explained earlier and APIs business continue to do well.

Damyanti: Okay. My second question is, can you update us on some of the complex or differentiated opportunities in the injectable part, specifically the anti-diabetic portfolio which will open up the next few years.

Yugandhar Puvvala: In fact, Damyanti it is obviously our endeavour is to continue to file significant products and we have a big pipeline of 100+ products and also antidiabetic is part of that. So, we are working on it as in when like we file and as and when we get approvals will keep informing all the investors.

Damyanti: But most likely these would be said more of medium-term opportunity, right rather than something in short term?

Yugandhar Puvvala: Yeah, obviously nothing in short term.

Damyanti: Okay, thank you. That's helpful.

Moderator: Thank you. The next question is from Parth Shah.

Nitya Bala Subramanian: Hi, this is Nitya Bala Subramanian from Bernstein, can you give us an update on your PEG and Filgrastim filings in Europe?

Dr. Satakarni Makkapati: Hello Nitya. So, as you know that we had a technicality last time that the audit got delayed into day 180 where we were not left with more than two weeks. So, we had to, in consultation with CHMP, we had to withdraw and resubmit the files. Now, we had our meetings with CHMP and we have started the process of re-submission. In fact, we have submitted one product already to CHMP and the second product we are waiting for the assignment of rapporteurs. And the sooner that our rapporteurs get assigned, it will be submitted as well. So, I expect all the three biosimilars Pegylated filgrastim, Filgrastim and the important product, the breast cancer drug that we have Trastuzumab, for which we have announced a successful completion of phase three clinical outcome, all three will be aligned and filed before the end of January 2024. For already one product had been filed, and the other two will also be filed in the next four to six weeks' time, or eight weeks' time.

Nitya Bala Subramanian: And it's a 250 odd day cycle and therefore these are FY26 revenue opportunities, right?

Dr. Satakarni Makkapati: It's roughly going to be day to thin. We expect things to move faster, because for Filgrastim and Peg filgrastim, I expect the clock to really move faster in terms of the time required for us to respond. Because these files are going through the second time and in our discussions with CHMP we don't foresee any time more than two or three weeks for us to respond to their queries. The only thing pending on Filgrastim and Peg filgrastim will be the audit, which we expect CHMP is intending to audit us sometime in Q1 next year. As soon as we file within three to four months. That's the hope. The Trastuzumab, maybe Q4. But the other two, I expect to be faster, because there are absolutely no queries on those files that we foresee coming through. Trastuzumab being the first filing in Europe, we expect queries and some time that we take to respond to the queries within the clock stop. So yeah, to answer your question, Trastuzumab could be Q3 and Q4. The other two can be at least a quarter faster than Trastuzumab.

Nitya Bala Subramanian: Got it. On the CDMO business would Merck's product be occupying both your 15KL bio reactors?

Dr. Satakarni Makkapati: Absolutely.

Nitya Bala Subramanian: Okay. Thank you and is Merck's product currently pre-commercial or is that an asset that's already in the market?

Dr. Satakarni Makkapati: I am bound by my confidentiality norms. I can't disclose it at this point of time with you unfortunately, but at an appropriate time, we will be making the disclosure.

Nitya Bala Subramanian: Fair enough, thank you so much.

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

Tushar: I missed the comments. So, R&D for the quarter was lower at 4% of sales or even at absolute basis Rs. 300 crore. So how much R&D spend will be there in second half FY24 and FY25.

Santhanam Subramanian: Look Tushar as I said, we estimate around Rs.750 to Rs. 800 crores in the second half, that's what we are estimating. But having said that, it depends upon how the things pan out in the next two quarters in terms of the clinical trial CROs guys meeting the milestones.

Tushar: Got you sir, that's it from my side. Thank You.

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

Santhanam Subramanian: You can move on.

Ritesh: Hello. Hello, am I audible?

Moderator: Yes.

Ritesh: Can you guide on your organic CapEx given first half you already done $80-83 million kind of a number?

Santhanam Subramanian: Yeah, this year probably I mean we specifically we don't give the organic CapEx because it includes there are a lot of strategic CapEx also and many projects nearly 7-8 plants are under installation/commissioning. But if you ask what for the existing plants, what is the CapEx etc which we may be needing in probably we have been doing it around USD 125 to 150 million. Any new Greenfield plant etc. is not included in there. Plus, we are also embarking as I said in my earlier on, we are also trying to acquire some ANDA, market authorizations, etc., which will be over and above this.

Ritesh: Yeah, which is why my second question is, last year you spend USD 74 million in acquiring such for new business or business acquisitions or new market. This year, you have already first half you have done USD 95 million dollars. So, would this number be there continuing for FY25-26? Like you will keep doing this kind of at USD80 to USD100 million annually to enter into new markets new business over and above your organic CapEx?

Santhanam Subramanian: If you really see Ritesh, we have already new market includes China market, which we already explained what is happening there. And Indonesia is another market where we are not present, right. So, we don't see any new major market but we do

not know if some good opportunity comes where it makes a lot of sense either new market or new product, new business model, etc., which we can always look into that. So long, it is allowing us to grow significantly over a period of time.

Ritesh: Okay, and this existing plant CapEx of USD120 to USD150 million, that would sustain in FY25-26 or there is a possibility of that coming down.

Santhanam Subramanian: May not be that much. As I explained, we are not embarking on any new major Greenfield plant, right. We are trying to add new lines, debottlenecking. Like that, we are trying to do that by which we are trying to reduce the gestation period. If you put a greenfield plant, whatever we say, it takes around four to five years' time. So, what we are trying to do is we are trying to add new lines in the existing plant provided we have adequate space. So, that is the way we are going to put it and also China also we are going to have around a significant capacity, right? That also will help us to serve various US market, Europe market, may not be US immediately, maybe over a period of time later. But immediately Europe and China we will be doing that and later, if the capacity is still available, we will take it to US market and Sanjeev has clearly explained. He is expanding the unit 15 by which he will take out some of the capacity which has been occupied by Europe in Unit 3 and 7 which will be shifted to unit 15 by which more capacity available for the US market. So, we have been continuously, depending upon the growth of which Swami has been demonstrating, which we have been trying to increase the capacity to meet the demand as on date our capacity utilization for formulation is significantly high.

Ritesh: Sir, my question intent was is there a possibility of this coming down dramatically in FY25-26?

Santhanam Subramanian: Obviously, will come because this major CapEx which is taking place is on account of the greenfield like Eugia Vizag then we have the thing. But strategic CapEx will be there always. Strategic CapEx will always be there 100 and 150 million will be the like biosimilars. Satakarni has explained neatly what is going to happen and CMO, etc., these are all the CapEx which is meant for the future, but for the existing generic business we will be adding lines we may not be doing any major CapEx.

Ritesh: Okay. That's it from my side. Thank you.

Moderator: Yeah sure. The next question is from Ayush Bansari.

Ayush Bansari: Thank you. Thank you for taking the question. I just wanted to ask what are the corporate governance initiatives that the company has taken after the incidents which happened last year. Because even after the good performances that the company has kept up over the last three-four quarters, the valuations, still seems to be a bit depressed compared to the other peer companies.

Santhanam Subramanian: What is your question, Ayush?

Ayush Bansari: So, from last year are there any corporate governance initiatives that the company has taken?

Santhanam Subramanian: For corporate governance, we have inducted the new directors etc., we have got CEOs in all the verticals which is driven effectively, and we have inducted Dr. Satakarni who is a specialist in Chemistry. He has got into the board, by which board is getting more information and knowledge. So, we have been doing continuously, this a continuous process.

Ayush Bansari: Okay, Thank you.

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

Shriniwas Dange: Thank you all for joining us on the call today. If you have any of your questions unanswered, please feel free to keep in touch with the investor relations team. The transcript of this call will be uploaded on our website, www.aurobindo.com in due course. Thank you and have a great day!

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

(END OF TRANSCRIPT)