



***“Aurobindo Pharma Q4 FY22 Earnings Conference Call”  
May 31, 2022***

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**Mr. Nithyananda Reddy** –Vice Chairman &Managing Director, Aurobindo Pharma Limited

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

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

**Dr. Satakarni Makkapati** - CEO of Aurobindo’s Biosimilars, Vaccines and Peptides businesses

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

**Moderator:** Ladies and gentlemen, welcome to the Quarter 4 FY22 Earnings Conference Call of Aurobindo Pharma Limited. All participants' line will be in the listen-only mode and there will be an opportunity for you to ask questions after the presentation concludes. In order to ask a question, please signal by using 'a raise hand' icon on the bottom of your screen.

I now hand the conference over to Ms. Deepti Thakur. Thank you and over to you.

**Deepti Thakur:** Thank you, Aditya. Good morning and a warm welcome to our 4<sup>th</sup> Quarter FY22 earnings call. I am Deepti Thakur from the investor relations team. We hope you have received the Q4 FY22 financials and the press release that were sent out yesterday. These are also available on our website.

I would like to introduce my senior management team today on the call with us, represented by Mr. P. V. Ram Prasad Reddy – Chairman, Aurobindo Pharma USA; Mr. K. Nithyananda Reddy - Vice Chairman and Managing Director of Aurobindo Pharma Limited; Mr. Santhanam Subramanian – CFO; Mr. Yugandhar Puvvala - CEO of Eugia Pharma Specialties Limited, and Dr. Satakarni Makkapati - CEO of Aurobindo's biosimilars, Vaccines and Peptides businesses.

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

**Santhanam Subramanian:** Thank you Deepti, and good morning and welcome to all of you for joining this earnings call. This year has been very challenging due to various factors namely COVID, steep crude price increases, global inflation, and second of geopolitical issues etc. Despite these issues, we have delivered a good set of results in this fiscal year. We will now discuss the results for the fourth quarter of fiscal year FY22 declared by the company. We'll be discussing ex-Natrol numbers throughout the call. For Q4, the company registered a revenue of 5,809 crores with the decrease of 3.2% quarter-on-quarter. The EBITDA before FOREX and other income declined by 23.6% year on year and declined by 4% quarter-on-quarter to ₹974.74 crores. EBITDA margin for the quarter was 16.8% and for the year FY22 was at 18.7%, however, EBITDA margin before R&D is 24.2% for the quarter against 23.5% of last quarter. Net profit decreased by 28.1% year on year and 4.7% quarter-on-quarter to ₹576 Crores. In terms of the business breakdown formulation business in Q4 FY22 witnessed a decline of 1.9% quarter-on-quarter to 4,896 crores and contributed around 84% of the total revenue. API business contributed around 16% and clocked the revenue of ₹913 crore for the quarter registering a growth of 15% on a YOY basis led by improved demand for some of our key products and declined at 9.6% quarter-on-quarter.

For the quarter, the revenue from the years formulation decreased by 4.5% year on year to ₹2,728 crores and 0.6% quarter-on-quarter. US revenue during the quarter is \$363 million in

absolute terms. We have received final approval for 3 ANDAs and launched four products in quarter under review. We have filed 14 ANDAs including three injectables during the quarter. The total number of filings at end of March 22 is 727. Revenue of Aurobindo USA, the company marketing oral products has decreased by 5% year on year for the quarter. Revenue of Auromedics, the injectable business increased by 4% year on year to \$70 million for the quarter. We had a total of 175 injectable ANDA filing as on 31st March, 22 out of which, 119 have received final approval and the balance 56 are under review or have tentative approval. The company as on 31st March, 22 has 727 ANDAs with the USFDA on a cumulative basis out of which 505 have final approval and 33 have tentative approvals including 8 ANDAs which are all tentatively approved under PEPFAR and the balance 189 ANDAs are under review.

For the quarter, European formulations revenue clocked ₹1,541 crore with a decrease of 0.8% year on year. For the quarter, the growth market witnessed a growth of 28% year on year to ₹391 crores. For the quarter, ARV business registered a 51.5% growth quarter-on-quarter at ₹236 crores, a de-growth of 52% YoY on a high base of last year. R&D expenditure is at 431 crores during the quarter which is 7.4% of the revenue. The average raw material cost increased by about 9% during the quarter and freight costs are more than 10% on year and quarter. The average raw material cost increased by 18% year as a whole and the freight cost by 42%. Net organic CAPEX for the quarter is around \$65 million. The average Forex rate is Rs. 75.09 in Q4 FY21, and 74.82 in Q3 FY22. The average finance cost is at 0.8% mainly due to availing multiple currency loans.

The business generated a free cash flow of \$38 million during this quarter. The net working capital for the quarter has been reduced by about \$98 million and \$126 million for the year mainly due to reduction in inventory. Inventory alone we have reduced \$200 million for the year. As a result of the strong cash flow generated during the quarter, the net cash position including investments at the end of March 22 improved to \$333 million. With this we'll be funding the PLI project mostly out of internal accruals. Also, we reduced the gross debt significantly to \$313 million from \$499 million end December 21. We have been reducing the gross debt quarter-on-quarter and will continue to do so. In nutshell, despite the hostile global environment and peak R&D expenditure, we were able to maintain our margin and also generated significant cash for future fund.

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

**Moderator:** Thank you. Thank you very much. We will now begin the question and answer session. Anyone who wishes to ask a question may raise the hand icon on the bottom of your screen. Once your name has been announced, you will be unmuted and you can ask the questions. Ladies and gentlemen, we will wait for a moment while the question queue assembles.

First question is from Nimish Patil.

**Nimish Patil:** Thank you for taking my question. Sir, My question is what is your guidance for the future, does it remain intact, I mean you know or is there any change or what is basically your guidance for the future?

**Santhanam Subramanian:** As a policy we don't give any guidance Nimish, however, while the detailed questions are being asked we'll try to give the direction as and when it is required.

**Nimish Patil:** Thank you.

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

**Neha Manpuria:** Yeah, thank you for taking my question. Sir my first question is on the gross margins, we've seen quite a bit of improvement quarter-on-quarter despite the fact that some of our lower margin businesses have you know have done well in this quarter and the oral solid business has you know sort of deteriorated. So, if you could give us some color on the gross margin trends and is the full impact of the cost inflation that we are seeing factored into in this quarter you expect this to moderate going forward.

**Santhanam Subramanian:** So Neha, last quarter itself we have answered this query. When we had 54.3% last year gross margin, it is mainly on account of the business mix skewed towards API in a significant manner by which around 1.25% is on account of the business mix. This quarter API business clocking around 900 crores, so it comes to the normal position by which around 1.25% gets released. The balance around 1% is on account of the product mix as well as the geographic mix between the various clusters, that is the main reason and we have factored in all the cost that whatever we have been buying. I believe these are all the peak and probably continue for a couple of quarters and this is the position as on date and we are trying to see how to improve upon it. Anyway, internally as a process we work on that continuously.

**Neha Manpuria:** Okay, so basically from what I understand the mix has changed back to its normal level and there has been some geographical mix which is health margins.

**Santhanam Subramanian:** Absolutely you are right.

**Neha Manpuria:** Sir on the API front you know have we been able to pass on the cost increases that we've seen in last few months to our customers or API margins have come down over the last year.

**Santhanam Subramanian:** In terms of the domestic industry, we are able to pass it on at least some significant portion of it.

**P. V. Ram Prasad Reddy:** Regarding Formulation, out of the total API sale/capitive consumption, around 55% of the sale is for formulation. 45% is outside. Whatever the 45% of the outside sale, we are able to pass at least 60%-70% of the price increase. But on the in-house one, everything we absorbed in the oral division.

**Neha Manpuria:** Got it Sir. On the second question on US you know there has been some commentary from our peers about portfolio rationalisation, we've seen moderation in the oral solid business even though injectable is improved. So, if you could one give us color on what we're seeing on the oral solid business in terms of price erosion has it sort of has been

flattish as it deteriorated from last quarter and injectables how should we look at growth from injectables given we are now getting closer to the pre COVID levels.

**P. V. Ram Prasad Reddy:** The injectable part, my colleague Yugandhar can explain. I can tell about the oral business and other businesses in US. We saw the price erosion is continuing and we felt that in Q4 there won't be much price erosion, but to our surprise the price erosion is in Q4, average for the whole year it is 9% and Q3 suppose around 9.5% and Q4 it is 11.5%, ie. another 2% was increased in Q4 and so the overall impact either price erosion or shelf stock adjustment together it is around 11%-11.5% and only price erosion in Q4 is around 10% between Q3 to Q4 around 2%-2.5% was further erosion and we expect this may not stop here, but it may be in slow phase, maybe for next two quarters this situation will continue that is what we are expecting.

**Yugandhar Puvvala:** Neha, in terms of the injectables as you can see like the price erosion continues it is not that, injectable businesses, which doesn't have a price erosion, it does have, but like we do have a good portfolio of launches which is actually like will offset some sort of a price decline and I do expect the growth momentum of injectable business to continue mainly the specialty business as overall both Oncology, hormonal, and the general injectables all put together, we do expect a double digit growth going forward into the next year.

**P. V. Ram Prasad Reddy :** Also in the overall business our volume has increased around 6% overall, but we know that the prices or the pricing pressure is continuing, there is no end for this, maybe for another two quarters and we have a good number of products even though it is a medium level products, we won't tell it is ever, first file our exclusive products or something, we have 30-40 products subject to some plant approvals also. So we hope in coming quarters after one or two quarters things will stabilize in the volume and the price.

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

**Moderator:** Thank you. Anyone who wishes to ask a question may use the raise hand icon on the bottom of your screen. Next question is from Tarang Agarwal.

**Tarang Agarwal:** Hello, Good morning. Thank you for taking my questions. Four from my side, first; between CWIP and intangibles under development which translates to roughly about 4,000 crores about 40% of companies net log seems to be on track to be capitalized. Over what period should we see this getting capitalized and how is management's revenue visibility on the assets?

**Santhanam Subramanian:** Out of the 3,000 crores which you are seeing Tarang, at least 1,500 crores is pertaining to both injectable as well as the oral plant and derma plant in US and overall the oral plant is likely to be commissioned before FY23 end and injectable probably may spill over to next year. And in terms of the other CWIP, other big one is the Auro Cure. Auro Cure is the Vizag injectable facility which the installation is more or less complete and the exhibit batches will take place and probably Yugandhar will explain it a little bit more and other things are more of brownfield expansion, small expansions etc. which it'll get capitalised over the course of time. So Yugandhar would you talk about the Auro Cure.

**Yugandhar Puvvala:** Yeah, Tarang you want to ask something else.

**Tarang Agarwal:** Yeah, so would it be fair to presume that over the next 15 to 18 months we should see a large proportion that getting capitalized.

**Yugandhar Puvvala:** Yeah, Tarang in terms of the injectable plants, we have two new injectable plants; one in Vizag and one in US, and we do expect the filing to start in FY23 and in case if everything goes well FY24 onwards we will start generating some revenue from Vizag and New Jersey both. In worst case it might spill over to FY25 first quarter.

**Tarang Agarwal:** Okay. The second question to you Mr. Puvvala, what's the global generic injectable sales for FY22 and the split between North America and others. Second, do you still stick to your earlier guidance of about \$650 billion by FY24 and if so can you give us a more calibrated pathway in terms of number of launches that could help us get there over next two years from this business.

**Yugandhar Puvvala:** Tarang, I think I did correct last time as well and I will continue to correct till the time your question starts changing from injectables to speciality. Yes, it is a specialty business including Oncology oral solid, hormonal oral solids, as well as the entire sterile business. At proforma level we closed around \$438 million in FY22 and we expect the double-digit growth to continue into FY23 and 24 and we stick to our guidance of 650 to 700 million by FY24 for the specialty business.

**Tarang Agarwal:** Sure. In terms of number of launches that we could see

**Yugandhar Puvvala:** Yeah, in fact this year in FY22, we had 11 launches and in FY23, I expect 15 to 20 launches. On filing and launches perspective our target is 20 filing and 20 launches every year that is what its going to be the trajectory.

**Tarang Agarwal:** Got it and Sir how should we see the CapEx intensity of Aurobindo as a whole going forward, I mean a reasonable amount of capacities created capital deployed, how should we see that going forward over the next two-three years.

**Yugandhar Puvvala:** Tarang, like I'll just take on in terms of the injectable portion of it. I think injectables most of the CapEx has been spent and as I said we have four commercial plants and two plants which are coming up and where already the CapEx has been spent. Other than the normal general capacity enhancements within the plant, I don't expect significant investment in capacity for the specialty business. Subbu, would you like to take on the other side of the business please.

**Santhanam Subramanian:** Aurobindo as a whole including the speciality injectable business, we expect around 125 million of CapEx. Already we have got a commitment of around 400 million including the PLI project which is the Pen-G project, so we expect this to be spent over the period of two years. So, we expect that other than the Pen- G product, I don't think we will be beyond 100-125 million, but however I would like Mr. Ram Prasad Reddy Garu or Mr. Nithyananda Reddy Garu to confirm.



**P. V. Ram Prasad Reddy:** There is not much CapEx and around 250 million or 230-240 million is the PLI, balance is 120-130 is one or two API plants, and in the oral formulation side there is not much CapEx. Maybe in US side, in Puerto Rico, we may require some CapEx, otherwise almost next two years other than the already approved CapEx not yet spent around 375 and it may be another 120 million in the CapEx side, not more than that.

**Santhanam Subramanian:** Tarang it includes the PLI also around 250 million.

**Tarang Agarwal:** Got it. Thank you.

**Moderator:** Thank you. Next question is from Mr. Tushar. Yes Tushar. Okay we can't hear you Tushar. We'll take you afterwards. Next question is from Kunal Randeria.

**Kunal Randeria:** Hi, good morning. Sir on the US price erosion you did share some numbers, could it be possible for you share some trends on how you are seeing price erosion in orals and injectables? The price erosion trends how do they differ between oral solids and injectable products.

**P. V. Ram Prasad Reddy:** Now I can tell about the oral. My colleague Yugandhar will tell about that injectable. As we told, the last four quarters average is around 9% and last quarter is 11%, but 11% includes the shelf stock adjustment and price erosion between the third quarter to last fourth quarter around 2%-2.25%. So such way we expect in a lower terms in next few quarters and a vice versa the shelf stock also will come along with the price erosion and already the prices lot of depression, not much is reducing now that we are not expecting, if at all further price goes down, so I don't know how the market will react either will drop some products or some price increases may happen, anything can happen afterwards.

**Yugandhar Puvvala:** Yeah. It is in the similarity trajectory, it is in the high single digits, not much different, but yeah, we do have significant launches coming up, so that is what like we'll take care of the future growth, but in terms of the price erosion, it continues to be in the similarly range like orals. It is 1% here and there, but it is in the similar levels.

**Kunal Randeria:** Got it Sir. Sir just one more, Sir you starting to build up a nice cash file now but given the challenges in developed markets does it make sense to keep acquiring there or are you sort of you know you could say maybe build a bigger cash file for some domestic acquisition in future.

**P. V. Ram Prasad Reddy:** Not at the present, we're not going very much big on acquisitions. We want to complete the existing projects. It is because the project completion is not the end that is the beginning again operationally, it has to become break even and profitable that will take another two - three years, so we have to protect the cash to the pending / existing approved projects as well as the completion of the existing projects, as well as the projects completed operationally break even and profitable projects, there almost 6-7 projects at various stages, like a biosimilars like vaccines and the China plant where we are filing a big way, we have lot of hope and Puerto Rico plant like that so we are not going to start anymore new plants that is what we wish in injectable two plants those things.

**Kunal Randeria:** Sure Sir. So, then we assume that there would be no big bang acquisition in future either in US or in India.

**P. V. Ram Prasad Reddy:** Not at all, at least in next two to three years that may not happen.

**Kunal Randeria:** Sure Sir. Perfect. Thank you very much.

**Moderator:** Thank you. Next question is from Surya Patra. Please unmute yourself. Okay, we will take the next one from Kunal Dhamesha.

**Kunal Dhamesha:** Hi, good morning and thanks for taking question. So, the first one on again on the US price erosion, have we done any withdrawals from the market and if yes how many? If no, what are the some of the key metrics that we look at and how frequently do we look at our products portfolio, whether to do withdrawals or not.

**P. V. Ram Prasad Reddy:** We are very closely monitoring, as on today we have not withdrawn any product and based on the situation of the next one or two quarters, we'll keep you informed, if anything is there. We hope that situation may not come because nobody will sell the product under loss, but we have seen few examples the less than the cost of production means less than the brand cost, also we are not able to cover in few products, so in such scenario drop may happen, but as on today such scenario is not there.

**Kunal Dhamesha:** Sure and second question when we now say that our injectable business is basically speciality business, so even the biosimilar part will be included in that specialty business is that the way to think about it.

**P. V. Ram Prasad Reddy :** No, Biosimilar is an independent business. Biosimilar and vaccine is an independent business.

**Kunal Dhamesha:** Okay, sure. Thank you.

**Moderator:** Thank you. The next question is from Surya Patra. Yes, Mr. Surya can you just unmute, yeah. I think there is an issue with your mic. We will take the next one. Next question is from Vishal Manchanda.

**Vishal Manchanda:** Thanks for the opportunity. Can you talk about the capacity utilization for your oral solid manufacturing units at a consolidated level?

**P. V. Ram Prasad Reddy:** Yeah, in US plants nothing has started production anyhow. US we have in Dayton and New Jersey, U block, B block is the overall plant that is going to start production at the end of this year; Dermatology and MDIs and patches is the plant which we are starting. We already started filing in the few products and some more products we are filing before 31<sup>st</sup> March and consequently and the Puerto Rico one we are doing approximately in 2023 and we will start our products. Overall, in the CapEx utilization in the major, I can tell oral plants approximately 70% of in the India side, 70% of the capacity we



have achieved. injectable, Yugandhar my colleague can tell, otherwise overall it is 68%-70% in India formulation plants.

**Vishal Manchanda:** So the point is like unless we kind of reach to full capacity utilization, we won't be thinking about dropping products which aren't profitable at including overhead so basically you would continue to manufacture as long as they cover the fixed costs and that would keep the prices low basically.

**P. V. Ram Prasad Reddy:** No, the question of dropping, there is no connection with the capacity and the dropping the products because still we have a good amount of capacity. In another 20%, we may not fill up at least in next 1-2 years this in the capacity side because afterwards we are getting our Puerto Rico plant coming into hand; and once the margins come down then only, we will take that extreme step, but we are not expecting, but anyhow we will continue wherever there is a positive contribution. As long as the positive contribution is there, we will continue, but we are losing then definitely we will keep you informed every quarter. As on today that situation we have not come across. Maybe few strengths and few excuse maybe, but if it is the same way around 11% next year also, the 10%-11% was the price erosion then definitely will happen, price drop, product drop.

**Vishal Manchanda:** Sir on R&D do we FY23 would this be around 7. - we are at 7.5% ballpark sales this quarter; would we be at the same levels for FY23.

**Santhanam Subramanian:** I think FY23 going forward no, because this quarter is a very high in Aurobindo's history. I think going forward we may not be having this much of percentage, it will be anywhere between, around 6%.

**Vishal Manchanda:** Okay and any color on the ARV business, so will that some bounce back to the FY21 levels.

**Nithyananda Reddy:** No at this juncture we expect the business to be maintained at the same level. We will strive towards the improvement. There's not much we maintain the same level of last quarter, here and there will maintain the same level.

**Vishal Manchanda:** And on the PEN- G facility that you are putting up, so would your customers need to kind of switch the supplier in their DMF files to procure from you or they can directly start procuring without any changes in their file.

**Nithyananda Reddy:** In the antibiotics, the DMF the regulatory quantity very minuscule, not much. Maybe CEP, Europe or something they may change, and we're not much initially we are not going to file the DMF – US DMF from that plant.

**Vishal Manchanda:** What I mean, so you won't be looking at the US markets.

**Nithyananda Reddy:** No, that is very small, it's 2.5% or 3% of the capacity of the plant is US market.

**Vishal Manchanda:** Okay and Sir customers who might be procuring from China they can directly switch to your product without any lag basically, so would this require some regulatory process for someone to change their source.

**Nithyananda Reddy:** Very minimal regulatory changes. We are not expecting any big change, there may not be a requirement.

**Vishal Manchanda:** Okay. Got it. Thank you. That's all from my side.

**Nithyananda Reddy:** Thank you.

**Moderator:** Thank you. Next question is from Nishit Shah.

**Nishit Shah:** Yeah, congratulations on a very good set of number when I compare with some of the peers especially who are operating in the US market. So first of all, congratulation's Mr. Reddy and his team for a splendid set of numbers. My first question is which I have been asking for almost last two years what is the status on that Depo injections, are we now at the stage of filing or what is the status there?

**Yugandhar Puvvala:** Nishit, we are at least one year away from filing. We will be doing the exhibits sometime in FY23 for all the Depo products and depending on bio studies and other stuff it will be in FY24 filing in the best case.

**Nishit Shah:** Sir, I want to know the reasons for the delay because these actually I go back to the two-year transcript also, it was a supposed to be done in one year's time, so what has led to the delay and why we are every time talking about one year later.

**Yugandhar Puvvala:** Nishit, if it would be so simple everyone would have filed it. So like obviously it is complex. Nishit let me just finish, it is complex. When we take batches, we do see some issues and we redo the batches and so it is a journey of continuous improvement in deeper products. It's not simple straightforward development and execution, we might have felt that like if we have cracked it and we are ready to take the batches and we have taken batches, but when we see – find some issues, we do redo the batches. So like now we feel more than 90% confident that whatever we'll be taking in FY23 will give us good set of results and that is when we will start the bio studies for these products and this is what is our best estimated at this point of time. Again, I might have a different answer six months down the line or 12 months down the line, but these are complex products.

**Nishit Shah:** So Yugandhar why I'm again raising this issue is that some of the large peers in India have failed to do this product that is why it is important to elaborate and explain if you are able to do it then it is a very big milestone, so that is why I'm again asking that are we now closer and how confident we are on doing this?

**Yugandhar Puvvala:** See I think we are closer than before and we are more than 80% confident at this point of time, but in these complex injectables unless you fully succeed, the success cannot be announced, the reason is they are complex.

**Nishit Shah:** Okay appreciate this. Now the second question is to Mr. Reddy, we have heard it in the past and we have seen several reports that we are trying to restructure the injectable business and bring in partners in this business, what is the status on that if you can elaborate to the extent you can elaborate on this subject.

**P.V Ram Prasad Reddy:** No this point my colleague Mr. Subramanian he will inform because he had a better answer along this, Subbu can you explain?

**Santhanam Subramanian:** Yeah. So Nishit bhai, this at the COID (Committee of Independent Directors) evaluated options and then appointed advisors. So, we are getting them through the restructuring process; if and when we reach a requisite stage that deserves to be announced, we will certainly do that. The evaluation process in today's context is in a very volatile environment and they're taking into consideration all the material aspects and also taking cognizance of the current environment. So it is being under process and the business is not looking; I mean irrespective of the restructuring or not, the business is committed to achieve the numbers and that's what Yugandhar has just said a few minutes back.

**Nishit Shah:** Thank you very much.

**Moderator:** Thank you Nishit.

**Moderator:** Next question is from Nitin Agarwal.

**Nitin Agarwal:** Hello. Sir my question is on the margins. So, the margins have come off a fair bit in this quarter, so how should we look at a margin improvement from these levels as we go to the next couple of years. I mean what are the levers for margin improvement for us and can we go back to the earlier levels that we've done in FY20-21.

**P.V. Ram Prasad Reddy:** Cannot tell at least next two quarters where we are and we want at least another two quarters to answer your question because margins are still, in some areas it is falling, some areas it is stable, and very few areas it is increasing, and we are waiting and see how the things will change in next one or two quarters. So, we can tell a better answer after two quarters, after a quarter or two quarters.

**Nitin Agarwal:** And Sir on that point, you know in the past you were expecting that the inventory liquidation process will get over by Q3, obviously this has not happened and price erosion will sort of reverse, but what has led to this has two things one is, is the inventory liquidation still going on and if it is stopped, then what else is driving the price drops then?

**P.V. Ram Prasad Reddy:** As far as the oral products, we are hearing from the distributors and all that, their inventory also come to the normal level and also the US companies their inventory also came normal level because it is already 1 year 1½ year, so either it will become normal level, or it is expired and destructed. So, where the issue is there that huge talks of API and intermediates in some products, so those things has to become normal. In some areas because otherwise that will impact in the especially those products the basic API

intermediates. Other than that majority of the stock issue as they passed that's what I feel, and we are hearing the same thing from the wholesalers also.

**Nitin Agarwal:** Okay Sir and Sir lastly on can you probably just help us understand what is happening in the vaccine business and what outlook for the vaccine business especially the pneumococcal vaccine, how do you look at that?

**P.V. Ram Prasad Reddy:** Satakarni.

**Satakarni Makkapati:** So, Nitin in terms of our vaccine business and bacterial vaccine that you have spoken about, we have concluded phase 3, 3 + 0 trial in India and we are in the process of analyzing the clinical samples. We will be able to provide more commentary on this program once we complete the clinical analysis and initiate the regulatory process in India. In all likelihood, the regulatory process in India will be initiated in Q3-Q4 of this year. In terms of the other vaccines, they are at early stages of development with one vaccine potentially moving forward to a proof-of-concept stage, preclinical, and then moving to a possible Phase 1 clinical study in the Q4 of this fiscal year.

**Nitin Agarwal:** Ok Sir. Thank you.

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

**Kaushik Poddar:** Yeah, you had announced your foray into the domestic formulation, I mean what is the status of that and what are the future plans for the next three to five years.

**P. V. Ram Prasad Reddy:** domestic one, now only we are completing the transaction, the integration is just in last one or two days only. – what Subbu the transaction has

**Santhanam Subramanian:** The transaction is in the closure, and we have been integrating all the people etc.

**P. V. Ram Prasad Reddy:** We are integrating this. Last week only we have closure and then integrating, first let us stabilize the existing and study the whole thing then we can take some decision what to do the next stage.

**Kaushik Poddar:** Okay. Thank you.

**Moderator:** Thank you. Next question is from Tushar Manudhane.

**Tushar Manudhane:** Thanks for the opportunity. Sir just on the inventory part, there's been significant reduction in the inventory for past six months and considering that the raw material prices have been on the rise at the same time, so how will you look at it on for next couple of quarters on the raw material side.

**Santhanam Subramanian:** Tushar, we explained we have been focusing on the inventory in the past; if you recollect in the August call itself explained and we have significantly reduced

in the last two qtrs. and given the nature of the price is going up and the availability of stocks right etc., we may not be reducing anything significant going forward. Apart from that the value of the materials itself has gone up, so whatever we're maintaining is equivalent to at least 1.1 times or 1.2 times of the past what we have been holding it previously. So, we may not be doing any significant reduction going forward.

**Tushar Manudhane:** Okay Sir. Thank you.

**Moderator:** Next question is from Tarang Agarwal.

**Tarang Agarwal:** Hi, just wanted to get a sense from Dr. Satakarni on the biosimilars business, if there is an update, if you could give us an update there, and second on the bacterial vaccine you said that the regulatory process submission should start from Q3-Q4. If it were to happen, how should we then anticipate the eventual launch of the vaccine in terms of timelines.

**Satakarni Makkapati:** It is a good question. So, I'll start with answering the part one of your question related to the biosimilars. In the Q4 of the last fiscal, our second Oncology biosimilar was with the EMA, so which is as per expectation. We are having three more biosimilars in clinical trials, out of which two of them are Oncology biosimilars at different stages of our Phase 3 licensure clinical trials. One of the Oncology biosimilars, we should be completing our 600 plus metastatic breast cancer patients recruitment probably in a month or two, which positions us to evaluate the efficacy and safety of this product potentially by Q4, which then leads to a series of filings in regulated and semi-regulated countries in the Q4 2023 or starting Q1 of the next fiscal year. What is also important to note in terms of our biosimilars for some of you following the business closely is that we are stronger in our pipeline with Oncology and Immunology biosimilars. An important update for all of you would be that right now our focus has been on Oncology, but we have advanced one our very important Immunology assets into Phase 1 clinical trial in ANZ in the Q4 of the last fiscal year with the potential of it moving into a global Phase 3 Immunology disease trial by Q3-Q4 of this year, which means that we will be probably in the top three to file this product by 2024-25 with a \$4 billion potential market opportunity when it opens up in Europe and US. So, we remain on track with the development of other biosimilars in our pipeline and I'm quite excited with the sort of development we are seeing and the progress we are making in the biosimilar space.

Does that answer your first question?

**Tarang Agarwal:** Yes Sir. Just a follow up on that as you said three more biosimilar Oncology in different states of phase III, one of which you should probably get some evaluation done by Q3-Q4, what about the balance to in terms of how should we see you actually filing for these products in terms of filings.

**Satakarni Makkapati:** So, out of the three biosimilars which are in global phase III clinical trials, two of them are Oncology assets. The first Oncology asset, I have given you guidance on when we are expecting the data review to happen and the filing procedure to begin with. The second Oncology biosimilar is also in a global phase III trial right now. We expect the filing to be towards Q4 of the next fiscal year, which essentially means that we expect a large

trial to take some time to conclude, but having said that we are discussing with certain regulatory agencies on the basis of our clinical data accumulated so far, we wanted to approach and push the regulatory barriers and file it with an abridged clinical pathway and when that happens, we will provide you guidance on what's happening on that product. But, we expect to file it towards the late 2023 or early 2024 because the nature of these clinical trials are very extensive and take longer duration.

With respect to our third biosimilar, which is in a Phase 3 global trial, we have just began recruiting subjects and dosing them in the Q4 of the last fiscal. It's a shorter clinical trial relatively; we expect the clinical trial to conclude in 23-24 with the expectation of filing either in Q4 23-24 and if all things go well, then the filing procedures might start as early as Q3, but again as you know the business of biosimilars, we had COVID headwinds over the last one and a half to two years. A major COVID headwind is on the clinical recruitment rate and the site preparedness, so that caused delay not just to us but across the clinical trials of biologics and biosimilars players.

**Tarang Agarwal:** This answers my first question.

**Satakarni Makkapati:** Can you take me through the second question one more time.

**Tarang Agarwal:** In case of your bacterial vaccine, you suggested that the regulatory filing should probably start by Q3-Q4 of FY23 depending on the analysis of phase III, if that were to happen typically how much time would this process take and how should we see that product actually come into market if all goes well.

**Satakarni Makkapati:** So, we are currently in the final leg of analyzing our Phase 3 clinical trial samples of the bacterial vaccine. We look forward to reporting the pivotal clinical data in Q3 of this fiscal year leading to necessary submission requirements to the Indian authorities either Q3 or Q4 of this fiscal year. Now what this means is there is a queuing procedure with the regulatory agencies and if the queuing procedure is 3 months leading to a review from the regulatory authority in India, then it would take another three months to have a final approval on this product. If the queuing procedure is four weeks or six weeks, then the review procedure is again 90-120 days, so we are looking at a window of anywhere four to six or four to seven months before the final approval happens. So, in next year i.e. 2023 Q1, I expect if everything goes well, Q1 would be a potential launch into the Indian market, if all the procedures go well at the best possible speed that we expect it to.

**Tarang Agarwal:** Got it. Thank you.

**Moderator:** Thank you. Next question is from Shyam Srinivasan.

**Shyam Srinivasan:** Yeah, hi. Good morning and thank you for taking my question. Just wanted some update on the Europe business, we have seen it come off sequentially, so just and you know what's the kind of outlook here, how you're looking at the different markets even from Price erosion or a tender perspective you could share something on the Europe business space.



**P.V. Ram Prasad Reddy:** Europe business is very stable, but in one or two countries where we bought the Apotex licenses, we took decision to write off those products. So actually, that's when we made some provision it became a little more than normal; this is in one or two countries in European Union. They're not doing well from the beginning when we bought the Apotex; these all Apotex businesses; so finally, we took the decision to write off the stocks and all these provisions. We hope the business stabilizes in the existing level of 11% is not the issue, but we are working very hard to improve. There are many products we are going to file, and we are hoping to reach the 15%, there are lot of people working very hard to improve from 10%-11% to 14%-15% EBITDA.

**Shyam Srinivasan:** Okay. So how many products have been moved to the Vizag plant if I recollect and you know so and do, we think at fiscal 23 it's possible to reach this mid-teens EBITDA margin.

**P. V. Ram Prasad Reddy:** simply changing that because we can change up to some extent only we have to change another 20-30 products, but still around 38% of the products will continue to be in Europe that there is no point in changing those product because of the volume and all these things, but the newer products where we filed around 60-65 products, we expect some because each country there are each product there are two to four countries, so those things it comes. Then the Vizag plant also now Vizag plant we are doing around 325 million tablets or capsules per month, and we will reach next year to another 100 million, then we are confident our EBITDA has to increase in the Europe.

**Shyam Srinivasan:** Got it, helpful. Some questions a little bit more philosophical, Aurobindo is always known to be a manufacturing powerhouse, so if I were to step back and look at your manufacturing footprint now, it's quite well diversified, I'm unable to get a specific message so for example when we close down a recent plant in the US in the New Jersey area, you're talking about the Puerto Rico plant, so is there some unified vision in terms of you know will we continue to divest certain non-performing plants versus open new and are we optimum there I know you give some sense about the utilization levels, but just from an overall perspective are we done in terms of how a footprint should look or is there more divestments or stoppages.

**P. V. Ram Prasad Reddy:** No because we already covered India plants around 70% and because there are so many products there where we bought some ANDAs and some of the pride products. so all these things comes as a safe side we kept and we recently bought the Puerto Rico; otherwise the New Jersey plant which we closed down is a 50 year old plant and in the recent typhoon there was last year, the leakages are there in one or two places continuously and not able to control, so we're moving the floor and we are re-flooring the thing, that is the reason we stopped this one because that will take around 8-9 months. So, in the same area, we have a B block that will be ready in December. There we will do around our 21 C2 products that we are going to manufacture one after other something. Other than that, we don't have any intention to expand in the oral side at least next three years.

**Shyam Srinivasan:** Got it. Last question, I know you didn't share any guidance at the start, but if there is some way, we could think about revenue growth going forward, so we have had

a flattish kind of year this year, but when is there likely to be a step change in growth, when can be likely see double digit growth for Aurobindo.

**P. V. Ram Prasad Reddy:** we can see the other divisions or other plans or something it will take another two to four quarters.

**Shyam Srinivasan:** Sir so given that your earlier comments on price erosion being high for the next, so the next two quarters are where the visibility is lowest and then

**P. V. Ram Prasad Reddy:** Yeah, no I have not told price erosion is high, maybe there is a possibility because I cannot tell that there is no price erosion. We felt in this fourth quarter there is not much price erosion, but the actual thing happened, other way round. So let us wait and see that is what we are taking a chance, we're taking a reasonable margin next to one to three quarters it will go, how it will change.

**Shyam Srinivasan:** Got it Sir. All the best.

**P. V. Ram Prasad Reddy:** Thank you Sir.

**Moderator:** Thank you. We will take the last question from Vikas Sharda. Vikas please unmute yourself.

**Vikas Sharda:** Yeah hi. Thanks for the opportunity. I have one question on the specialty business that for the full year how does the margin profile looks like, like supposing the full margins are 18.5% for the company, how would you split it say between specialty and non-specialty.

**Yugandhar Puvvala:** I think it's at a pro forma level, but in terms of the gross margins, we continue to be in the 65% to 70% and in terms of EBITDA it'll be around 35 to 40, but it is still at a pro forma level, not as a specific set of numbers, but that is what is good going to be the range.

**Vikas Sharda:** Understand. So just a follow up to Mr. Subbu then I mean when you look at the overall ROE of the company say in the mid-teens and then I mean the non-specialty business I mean what kind of returns does it make and how would you look at that business in terms of return profiles.

**Santhanam Subramanian:** See Vikas just now Satakarni has explained, we have a great future from the biosimilar business which is expected to deliver well. Even without the specialty business also the biosimilars will step in and improve the overall ROE.

**Vikas Sharda:** Understand, got it. Thank you.

**Santhanam Subramanian:** Thank you Sir.

**Moderator:** Thank you. I would now like to hand the conference over to Ms. Deepti Thakur for 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 investor relations team. The transcript of this call will be uploaded on our website [www.aurobindo.com](http://www.aurobindo.com) in due course. Thank you and have a great day.

**Moderator:** Thank you on behalf of Aurobindo Pharma Limited. That concludes this conference. Thank you for joining us and you may now disconnect your lines.

**End of Transcript**