



“Aurobindo Pharma Limited Q3 FY17 Earnings Conference  
Call”

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**Moderator:** Good morning, Ladies and Gentlemen and Welcome to the Q3 FY17 Earnings Conference Call of Aurobindo Pharma Limited. As a reminder, all participant lines will be in the listen-only mode. And there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal an operator by pressing '\*' then '0' on your touchtone phone. Please note that this conference is being recorded. I now hand the conference over to Mr. Krishna Kiran – Investor Relations, Aurobindo Pharma Limited. Thank you and over to you, sir.

**Krishna Kiran:** Thank you Margret. Good morning and Welcome everyone to our Third Quarter FY17 Earnings Call. With me we have our Senior Management Team, represented by Mr. N. Govindarajan – Managing Director; Mr. Robert Cunard – CEO, Aurobindo USA; Mr. Sanjeev Dani – COO & Head, Formulations and Mr. Santhanam Subramanian – CFO.

We will begin the call with opening remarks from the Management, followed by an interactive Q&A session. The Company from 1<sup>st</sup> April 2016 has adopted Indian Accounting Standards (Ind AS), and hence financials we will discuss today are in accordance with that. For comparison purpose the Q3 FY16 numbers are also restated as per Ind AS. 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 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 differ materially from our expectations. Aurobindo Pharma undertakes no obligation to publicly revise any forward-looking statements to reflect future events or circumstances.

And with that, I will hand over the call to Mr. Govindarajan for his opening remarks. Over to you Govind.

**N. Govindarajan:** Thank you Krishna. Good morning, everyone. We are here to discuss the Third Quarter Financial Year 2016-2017 Results declared by the Company. The Company registered a revenue growth of 11.4% year-on-year to Rs. 3,906 crores. The EBITDA increased by 9.4% to Rs. 894.8 crores, and profit after tax increased by 5.6% to Rs. 575.8 crores.

In terms of the business breakdown – Formulations business contributed to 80% of the total gross sales. The gross formulations sales for the quarter stood at Rs. 3,130 crores, registering a 11.4% growth year-on-year. API business accounted for the balance Rs. 776 crores for the quarter, registering a growth of 11.6% year-on-year. In the Formulations business, the total sales from the US market and European market stood at Rs. 1,745 crores and Rs. 855 crores during the quarter respectively. The US business registered a healthy growth of 12% year-on-year during the quarter despite pricing pressure in the oral products base business. Injectable business continued its growth momentum.

Aurobindo USA, the company marketing oral products in US has witnessed a 9% decline quarter-on-quarter due to high pricing erosion in the base business. Price erosion amounted to 7% and one-off impact amounted to around 4%, partially offset by new launches. We launched eight new products taking our total launches to 19 products in the first nine months of FY17. We received 20 approvals, including three tentative approvals during the quarter. We have filed five ANDAs during the quarter. AuroLife, our US manufacturing arm continued to witness increase in demand from government tenders. In order to meet further increase in demand as well as further expansion of the US controlled substance portfolio, we are tripling our capacity over the next couple of years.

AuroMedics, the injectable business maintained its growth momentum during the quarter with sales at \$ 42.5 million, posting a growth of 91% year-on-year. We launched three new products during the quarter, taking the total launches to 10 during the first nine months of this year.

Under the Injectable segment, including Ophthalmics, we have filed a total of 89 products as on December 31, 2016 out of which 50 have received approval, including two tentative approvals, and the balance are awaiting approvals. We received two approvals during the quarter. We have a large number of complex products under development namely Hormones, Oncology, Inhalation, Topical, Liposomal and Microsphere based depot injections which we plan to start filing over the next three to six quarters.

AuroHealth, which manufactures and markets Pharma OTC products in the US continued to gain penetration into several key national retailers, as well as select regional accounts. Currently, AuroHealth is shipping to 22 customers and having a product basket of 85 products. Natrol, the acquired branded nutraceutical entity is performing as expected.

We are pleased to announce an acquisition of four cell culture derived biosimilar products from TL Biopharmaceutical AG. As part of this agreement, Aurobindo and or its affiliates will develop, commercialize and market these products globally. The branded market size of these four biosimilars is around \$20 billion in 2016. The Company, as on December 31, 2016, has filed 421 ANDAs on a cumulative basis; out of which 262 have final approval and 41 having tentative approvals, including 19 ANDAs which are tentatively approved under PEPFAR. The balance 118 ANDAs are under review.

The unit wise filing and approvals are as follows: From Unit III - 125 filed, 99 approved. Unit VII -158 filed, 79 approved. AuroLife - 26 filed, 16 approved. Unit IV - 75 filed, 38 approved. Unit XII -20 filed, 19 approved. Unit VI - 11 filed and all approved. Unit X - two filed. And AuroNext - four products have been filed so far. Unit III, VII, X and AuroLife manufactures oral non-Betalactam products. Unit IV manufactures general Injectable and Ophthalmic products. Unit VI and Unit XII manufactures Cephalosporins and semi-synthetic Penicillins respectively. AuroNext, which has its facility in Bhiwadi in Rajasthan manufactures Penem Injectable products.

Europe Formulations sales were at Rs. 855 crores in Q3 FY2016 - FY2017, an increase of 9.2% growth year-on-year. The acquired business continued to see profitability during the quarter. As on December 31, 2016, we have transferred manufacturing of 63 products from Europe to India. Emerging markets Formulations sales stood at Rs. 188 crores during the quarter, with a growth of 15.8% year-on-year. ARV Formulations sales were at Rs. 342 crores during the quarter. In terms of segmental classification, US Formulations contributed to 45% of the overall revenues in Q3 FY2016 - FY2017 versus 44% in Q3 FY2015 -FY2016. Share of EU Formulations remains at 22% in Q3 FY2016 - FY2017, while the share of emerging markets remained at 5%. ARV segment sales represent 9% of the total sales in Q3 2016 - 2017 and API business contributed to 20% of the total revenues in the same quarter.

Our EBITDA before FOREX for the quarter is at Rs. 894.8 crores, representing an operating margin of 22.9% for the quarter, against 23.3% from the corresponding period last year. R&D expenses is at Rs. 130 crores during the quarter, which is 3.3% of the sales. The closing rupee versus US dollar rate was at Rs. 67.925 in December 2016, and Rs. 66.615 in September 2016. CAPEX for the quarter is around US\$55 million. The effective tax rate for the quarter is 27.4% of PBT. The net debt stood at US\$410 million as on December 31, 2016, against US\$484 million in September 2016. The majority of the Company's debt is denominated in foreign currency. The cash and bank balance is at US\$ 129 million.

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

**Moderator:** Thank you very much. We will now begin with question-and-answer session. We have the first question from the line of Manoj Garg from Bank of America. Please go ahead.

**Manoj Garg:** Mr. Govind, you have indicated that the net debt sequentially has come down by almost around \$74 million, this is despite the fact that we have \$55 million kind of CAPEX in the quarter. So, can you give a little more color in terms of what is the net debt reduction which happened during the quarter?

**N. Govindarajan:** Sure. I would rather ask Subbu to clarify this, Manoj.

**Santhanam Subramanian:** we had net debt of around \$484 million at the end of September quarter, and now it ended at \$410 million. The main contribution has come from the improved working capital, and we also added a little bit of factoring, it is a very small amount. So there is a real improvement in the working capital and the cash flow generation during the quarter.

**Manoj Garg:** And the second thing sir, on this Biosimilar portfolio, since we have acquired those four assets and you indicated one of the asset is in advanced stage. So, if you can give a little more color in terms of clinical trials and what is our thought with regard to this overall Biosimilar portfolio? And which are the target market which we are initially focusing for this segment?

**N. Govindarajan:** Our strategy is doing the clinical trial for the regulated markets, which will also be used for the rest of the world, including the emerging markets. This way when our potential out licensing when explored, it would be easier for us to do it. And as far as timeline is concerned, we expect to file our first lead molecule by 2020. The partner has done a fantastic development and it is ready for scalability. In fact, we can do the batches for clinical trials. Our manufacturing facility is expected to be ready by June - July timeline by which we will start manufacturing the lead molecule and immediately we would be going for the clinical trial.

**Manoj Garg:** And here sir like a lot of other Indian companies who have focused on partnership kind of a model for the regulated market in terms of development given, there are high costs associated with the clinical trials. And all and I do not know whether we are aiming for interchangeability to start with, or we are also looking from a promotional perspective where we may need the front-end kind of promotional requirements. So what is the strategy in terms of go-to-market for this kind, while it is a little early at this point of time?

**N. Govindarajan:** It is right now premature to talk about the front end since we got it done only yesterday and we would be able to provide clarity as we progress. The one aspect I would like to clearly say is that if we had started our development on our own then we would have taken much longer time in terms of reaching the state where the partner has already reached. So, we are able to shorten the timeline in terms of our overall timeline for development towards clinical and filing, so that is the advantage of this portfolio.

**Manoj Garg:** And the last question from my side before I get into the queue, sir. In your prepared remarks you indicated about 4% kind of one-off expenditure during the quarter, I think, which has come from the US through rebate and charge-backs. Can you provide a little more color on that, and you feel that why this is not recurring in nature, because I think charge-backs and all those things are part and parcel of the business?

**Robert Cunard:** Manoj, thanks for the question. As you indicated, there are a lot of moving parts in the US market, particularly around the charge-backs. And one of the things that we have seen over the past couple of years is a growing representation of wholesaler as a percent of the business. So, one of the things we continue to do is an ongoing reconciliation process looking at inventories in the field with wholesaler, what contracts that volume may flow back through and they all have different discount rates. So, when we did that reconciliation this past quarter, we had some clean-up that needed to be done, as indicated, we view it as a one-time thing and not a recurring issue.

**Moderator:** Thank you. Our next question is from the line of Neha Manpuria from JP Morgan. Please go ahead.

**Neha Manpuria:** Bob, on the US number, when we look at fourth quarter and FY18, while our approval momentum has remained strong and given how the pricing environment is, could you probably

outline two or three things outside of the Injectable portfolio which could improve our US run rate which has been stuck in the sort of range over the last few quarters?

**Robert Cunard:**

Clearly, as you indicated we have got a couple of different headwinds. What is happening in US market with this customer consolidation and the number of players getting into the market and the FDA efficiency on getting those approvals through. So, we have had success over the past five years and growing our market penetration and having a broader impact with the customers and our share of the market. And unfortunately that creates some exposure underneath as other people come in. But a couple of things that we haven't seen a full effect of, we mentioned Esomeprazole in the past, there was a very small representation in the third quarter, we did not get a significant customer. So that is still out there in fourth quarter and as we move forward. There is a couple of more significant items we think that they can have a material impact. If you remember when we go back the whole way in the fourth quarter when we had this backlog of ANDAs, I think it was about 19 where we had approvals, but they had not been monetized. We will have the last six of those that get into the marketplace here in the fourth quarter, and it could be a mix. As we have talked in the past, each product kind of stands on its own as far as what the competitive situation is. But just like we are seeing complication on the base business that is applying to the new product introductions as well. So, some of those when we get there we see what the market looks like. But the volume will continue to drive and the portfolio will continue to expand.

**Neha Manpuria:**

And Bob, again a follow-up. If I look at approvals for next year, we have been doing okay, 50 plus. But would you point out some largest approvals that could move this number significantly over the next few quarters?

**Robert Cunard:**

There are couple of things out there, the Metoprolol ER is a product that we are pretty bullish on and that gets near the end of next year. Generic Fortamet, Metformin ER is a product we have a targeted action date for August, more than likely as it stands right now that would be a tentative approval as we have a 30-month date out in June 2019. But we are optimistic that there is an opportunity to pull that in and get that into the market potentially in fiscal 2018. And as we get the full complement of some of our recent Ophthalmics into the marketplace those could potentially be some nice drivers for us as well.

**Neha Manpuria:**

And on our Injectable business, Ron if you could just, how do you see that panning out? Will have been seeing very good growth there, we still have a decent pipeline pending for approval. So, are we still on track with the improvement in business that we had guided to last year?

**Robert Cunard:**

Yes. This is going to be Bob again. I am going to do my best to fill in for Ron. He had a scheduling conflict and couldn't make this quarter's call. But regarding the Injectable, at the highest level is, yes. We think everything is on track to maintain that guidance of 50% year-over-year growth and that is for the next several years. That is highly likely how we finish fiscal 2017 and also 2018 as well. So, as Govind indicated in his comments, we had three

additional launches in the quarter for a total of 10 for first nine months. We estimate another three products that get into the market in the fourth quarter and we had a very nice approval in the levetiracetam bags that are in the market now. So, we are still very bullish and optimistic on that business and it continues to perform well.

**Moderator:** Thank you. We have the next question from the line of Anubhav Agarwal from Credit Suisse. Please go ahead.

**Anubhav Agarwal:** Govind sir, on the Biosimilar acquired portfolio, how are you trying to phase the four molecules, you will do trial of one and once that finishes or is about to finish, you will start the other one? Objective here is to understand that total R&D that we spend is about \$80 million on an absolute number, do you think with this first trial going in, can it move by like 20% - 25%?

**N. Govindarajan:** Our lead molecule, we would like to file it by 2020. So, obviously the clinical would be phased between calendar year 2018 and 2019 is what I would say. So, first of all, I do not expect the entire impact to happen on one year, that is one aspect of it. And the second is, we are also conscious about not getting the R&D expenses out of bound, so we are also looking at options of once we cross the Phase-I, we can always look at options of out-licensing certain markets where we are not very strong. To give an example, let's say emerging markets, we are not the strongest in terms of certain markets, we can always look at exploring those out-licenses. So, first to answer you, yes definitely these molecules would be phased out. It would not happen in one year. Even for the single molecule it will be spread over two years. If you take an example of our lead molecule itself, between Phase-I and Phase -III, we expected to go over a period of 18 months to 24 months. I mean, taking 24 months it will be spread over two years, Anubhav.

**Anubhav Agarwal:** And sir, what is the rationale for the partner or let's say the TL Biopharmaceutical to sell this out? I mean, they were short of development resources because we are also new in terms of how to design clinical trials here. So, what was the rationale for them to sell out?

**N. Govindarajan:** I think their rationale is not short of resources at all, I think they are one of the largest developer in the world, so definitely it is not lack of resources. Beyond that, I may not be able to comment on the rationale in terms of why they exited this portfolio, Anubhav.

**Anubhav Agarwal:** Just some more questions, one on Natrol. Can you help, I do not understand the business very well, and that how this business will grow? Do you have sufficient number of products in the pipeline or is it that the products that we have in the market, the under-penetration is so much that it can continue to give us growth for next four - five years?

**N. Govindarajan:** It is a combination of both, Anubhav. On the short-term, obviously, we are able to enhance the penetration better for the existing molecules. Having said that, we are also enriching the

pipeline, and again, when we are talking about enriching the pipeline, we are working on two-phased approach or two-pronged approach. One is in-terms of innovation which is more incremental, which is happening under dietary supplement space. The second level of innovation is more impactful. In fact one of our Directors in the Board himself is leading the effort of assembling a team of people which would collaborate with Natrol to bring some tectonic innovation. So, we are working on a short-to-medium to medium-to-long approach in terms of the innovation itself. But having said that, in the short-to-medium term, our existing portfolio enhanced penetration itself would sustain the growth, by the time I think the new portfolio would kick in. And one of the objective for us also, we are conscious that we do not want to be milking only the existing portfolio because there is a risk involved. So we are also conscious of measuring how much we are minimizing our dependency on that portfolio by growing the rest of the portfolio as well.

**Anubhav Agarwal:** So let us say, just to get the numbers right. I think in the past you mentioned that this portfolio can grow at 15% CAGR. So, would you say that without getting the new pipeline in existing portfolio can sustain that CAGR for next two-three years?

**N. Govindarajan:** Yes, that is possible

**Anubhav Agarwal:** And you also mentioned about AuroLife increasing capacity, so we are spending right now \$200 million CAPEX. So with capacity almost tripling what kind of CAPEX are talking about for next one or two years?

**N. Govindarajan:** No, I think partially that amount has been figure into this, Anubhav. And having said that, I would like to tell you that we are conscious about relooking at our entire CAPEX for next couple of years. One more thing you need to remember is, as we move forward we also have to be looking at certain geopolitical aspects of where we need to invest as well. So the clarity on the next couple of years CAPEX would be available by next quarter rather than current quarter, Anubhav.

**Anubhav Agarwal:** Last clarity, DTG launch, ARVs have done well in this quarter, DTG in some form a contributor there or...?

**N. Govindarajan:** No, not at all, Anubhav. I think you will start seeing DTG sale from the beginning of next financial year. In the first quarter itself, some numbers would come in. Currently the manufacturing is on at the API level, it will move to the finished dosage during the current quarter. The sale would happen between April to June, but still it would not be significant. The major sale you can start seeing from the third and fourth quarter of next financial year is what I would say, but a full year impact level in terms of DTG and its combination you would see it the subsequent year.



**Moderator:** Thank you. Our next question is from the line of Ranjit Kapadia from Centrum Broking. Please go ahead.

**Ranjit Kapadia:** My question relates to TL Biopharma, acquisition of four molecules. What was the upfront payment and what is the milestone and royalty payments which are decided? And you have said that clinical trial costs will be \$80 million spread over three to four years. So going further, these molecules, will it require a clinical trials done at various locations or only in the single location you are planning to do?

**N. Govindarajan:** Ranjit, we have not disclosed any specific numbers, but I can tell you that the numbers are not really huge. That much I can say and leave it there as far as numbers are concerned. As far as the clinical trial is concerned, one of your colleagues had mentioned about the \$80 million spread over four years. I would at this juncture say that there would be certain clinical trial costs, but it would not happen in the first full year itself because we are phasing out. Typically each molecule clinical cost itself would be spread over two years. Our objective is to do the clinical trials with 70-30 wherein 70% of study might happen in let's say in India and 30% might be in the West, take an example of say Europe. So to that way I think we can still keep the cost at control. At the same time, we would be able to address the need of the regulators of the global market. This will also help us in terms of out-licensing to the MNC companies where they would be looking at a certain standard which would suffice the need in terms of whatever we are attempting to do. And any other question I have left out, Ranjit?

**Ranjit Kapadia:** No. Only that establishing global Biosimilar portfolio, we are still looking at other assets for the time being?

**N. Govindarajan:** We are also developing our own portfolio of eight products. And typically we are looking at four large areas like Oncology, Rheumatology, Ophthalmology and Respiratory. Apart from the first four molecules we are also developing eight products on our own. So you can say portfolio of 12 is what we are starting with.

**Ranjit Kapadia:** And there is another question related to Natrol. Are we facing a capacity constraint? Because we are growing at almost 15% as you have mentioned, and is there any plan to move manufacturing out of the USA because there was a plan to move it to Middle East to establish a facility?

**N. Govindarajan:** No, I think the Middle East facility has nothing to do with Natrol. That is for our own finished dosage because by producing in Middle East we could serve Middle East as well as certain African markets. So that is a completely unrelated subject to Natrol as far as the Middle East facility is concerned. When we took over Natrol, actually the capacity was underutilized, Ranjit. To that extent, we have also added powder line which is under commissioning. So, we at this juncture do not see any capacity constrain per se. And the second one is, we are also not looking at moving that out because there is an edge in terms of a Made in USA product being

exported to certain countries. And at this juncture since we have the capacity and we have an edge, we do not see that gets necessitated.

**Moderator:** Thank you. Our next question is from the line of Girish Bakhru from HSBC. Please go ahead.

**Girish Bakhru:** Govind, any update on dolutegravir what is the run rate and any update there?

**N. Govindarajan:** Dolutegravir currently our manufacturing is on for the API and the finished dosage would get converted during this quarter. And the sale would start happening from next quarter. And currently, we are also discussing with certain sponsors in terms of looking at certain contracts for couple of years, which would start from next year only. What is more important in dolutegravir is to wait for the combination approval, which we are expecting it over next six months to nine months. After the combination approval comes in then you will start seeing traction in terms of this business, Girish.

**Girish Bakhru:** And in combination, are there other filers also expected?

**N. Govindarajan:** Yes, definitely there would be other filers who would come in, but we have a slight edge, how much is the edge depends on when we get the approval, Girish.

**Girish Bakhru:** And on the US side, I mean, Bob you mentioned AuroMedics, still guidance is strong. I mean, I do not know on the Isosulfan are you still selling the product in the US after the recent development in the case?

**Robert Cunard:** Yes, we are currently not selling it while the preliminary injunction is under appeal.

**Girish Bakhru:** And just if you could give guidelines on launch of Epzicom and Viread, that would be helpful.

**N. Govindarajan:** While Bob is looking at it, Girish, I would like to clarify that in spite of this product on which you and Bob discussed about, we would be able to still maintain our growth momentum and there is nothing which changes the growth momentum of the entire portfolio.

**Girish Bakhru:** Govind, I am just trying to look at the overall piece today. I mean, you will easily cross \$1 billion in US, so do you think 20% growth is still very much visible given the set of products that you have in FY2018 - FY2019?

**N. Govindarajan:** We never give forward-looking statement or a projection. But having said that, even though there is pressure in terms of the oral solid and the advantage which Aurobindo enjoys is that we are very well spread, apart from the oral solid. The injectable is growing and then Natrol is also growing. Over and above that, there are couple of interesting molecules which we are expecting approval before the end of this year in terms of AuroHealth as well. As you have heard from us, AuroLife is also growing. So we would be able to maintain the growth

momentum is what our confidence is, Girish, in spite of pressure in terms of the oral solid business.

**Moderator:** Thank you. Our next question is from the line of Chirag Dagli from HDFC Mutual Fund. Please go ahead.

**Chirag Dagli:** Sir, in your prepared remarks you mentioned about oral solids' price erosion. I actually did not pick up the numbers, if you can just repeat them?

**Robert Cunard:** So on the price erosion we saw about 7%.

**Chirag Dagli:** This is quarter-on-quarter, sir?

**Robert Cunard:** That is correct.

**Chirag Dagli:** And what would be that number YoY?

**Robert Cunard:** YoY, we are...

**N. Govindarajan:** I am sorry Chirag, we did not map that way, so let Bob quickly look at it.

**Chirag Dagli:** Sure, no problem, sir. And sir, this rebate or this one-time impact on sales of 4%, so if this impact would not have been there then the US sales would have been 4% higher than the current number, that is what you are trying to say?

**Robert Cunard:** That is correct. And it looks like it would be about 13% YoY.

**Chirag Dagli:** 13% YoY. And what is leading to this 13% kind of a number, sir?

**Robert Cunard:** That is a really long answer. There are a lot of things happening, obviously, we have seen this hyper consolidation on the customer side, while really no slowing in terms of number of generic competitors and FDA approvals. So, it created very much a hyper-competitive situation. The other thing, even though there has been some regulatory activity in the marketplace, we really have not seen any significant shortages or anything else in the market that would have created a pause in the pricing pressures from the customers' standpoint. So it is a competitive market and there is also a lot of downstream pressures. As far as what our customers are dealing with from both the wholesale and the retail side, you have probably seen that. And looking at some of the releases of the three major wholesalers where that has become more competitive as they are out there, vying for the same customer base and also reimbursement pressure at the retail pharmacy side. So, all of those things have lent to this hyper-competitive market on the retail Rx base.

- Chirag Dagli:** And do you think in the near future this will normalize, flat-out or should we sort of pencil in similar kind of a number going forward?
- Robert Cunard:** It is a little difficult to say. I would be very surprised if we continue to see an acceleration of this rate, particularly if we look at our base business. And I think every company is going to be unique with what their portfolio looks like and where their revenues are spread across. But in the near-term, we probably expect to see some continued erosion. There are some significant customers that are going through a bid process right now, that will have the immediate impact of the bid and then there is a little bit of an echo affect as there are any supplier disruptions as they go out and look for additional business. So, I would expect we will continue to see some price pressures through the first six months of the calendar year.
- Chirag Dagli:** And sir, just a couple of clarifications. This foreign exchange gain that we report, this is all operational, right? Because in your notes to accounts you are mentioning that there is no interest cost which is included in the foreign exchange bit.
- Santhanam Subramanian:** These are all operational numbers.
- Chirag Dagli:** And this transfer of 42 products in Europe, what is this, in a total pot of how many products would you want to eventually transfer?
- Sanjeev Dani:** As a first wave we had planned for 42 products and then through second wave last quarter, we had announced about another 72 products. So, totally 114 products. Out of which last quarter, that is quarter three, in all we have transferred 26 products additional. So, the cumulative number is 63. And if you look at whole universe then, there are 200 products in the market already and then, some more are being launched ex-India. So that universe will keep on expanding.
- Moderator:** Thank you. Our next question is from the line of Shyam Srinivasan from Goldman Sachs. Please go ahead.
- Shyam Srinivasan:** First one is on other expenses less R&D. I think you have seen a sequential like 10% kind of a jump QoQ. Is there anything that you can share there on that line item?
- Santhanam Subramanian:** This quarter we had made some additional provision of around \$4.5 million for certain customer penalties as a matter of caution. While we have been disputing that amount, as abundant caution and prudence we have provided for that. We believe it is a non-recurring event.
- Shyam Srinivasan:** So this is like you have taken 100% of the entire dispute that amount is it, is that what you are talking about?
- Santhanam Subramanian:** Yes, we have taken.

- Shyam Srinivasan:** On the Penem franchise, can you provide some kind of an update?
- N. Govindarajan:** Okay. As far as our Penem is concerned, we are still awaiting the approval of Meropenem which should happen anytime. There are two inspections which had happened and incidentally we received the EIR for both the inspections as well. So currently that facility is manufacturing and selling to Europe, Mexico and Brazil. And once the Meropenem approval for US happens, we are already preparing and rather we are partially ready even for the launch, so whenever the approval comes I think our folks would be able to launch Meropenem.
- Shyam Srinivasan:** Nothing on the other two, Ertapenem, or that is still in the...?
- N. Govindarajan:** So, technically the second inspection happened for one more product. I think we would await the approval because having seen the timeline which had taken for the Meropenem approval, like we would like to evaluate how it progresses in terms of subsequent products. But we are fairly confident once this one or two Penem approval happens, I think that facility would be able to generate enough top and bottom line.
- Shyam Srinivasan:** And the last thing is a clarification, I think last quarter we had said that you expect price erosion to be 6% to 8%. So this QoQ and the 7% is in that range, is my understanding correct?
- Robert Cunard:** That is correct.
- Moderator:** Thank you. Our next question is from the line of Rakesh Jhunjhunwala from Rare Enterprises. Please go ahead.
- Rakesh Jhunjhunwala:** My question has been answered. Thank you.
- Shyam Srinivasan:** Thank you. Our next question is from the line of Prakash Agarwal from Axis Capital. Please go ahead.
- Prakash Agarwal:** My question relates to the growth that is softening a bit. We saw 15% plus growth in the US dollar terms in the first half and about 10% in the Q3. Now you have mentioned about pricing pressure which was there last few quarters as well, and this one-off impact which is likely to be there in case of going concern having bigger products. I am trying to understand would there been a possibility of capacity constraints given the strong approval that you all getting, you are not able to launch all of them because you just launched about eight in orals and three in injectable. So, is there a possibility that more launches are expected in Q4 or Q1 of next year wherein the growth shall accelerate?
- Robert Cunard:** Well, I will take that in a couple pieces. As far as the launches on our retail Rx, we do expect that to continue at a very strong pace. For the fourth quarter, right now we expect 13 new products in the marketplace. And we have talked about this a little bit over the year-to-date as far as capacity and we are really in a pretty good position right now. Earlier in the year, at the

end of fourth quarter and early in the first quarter there were some things that were lagging as far as some capacity build out and some of the transition plans that we had for some of the European business that was in Unit VII, but we are in a very good position right now. As a matter of fact, that facility continues to outperform every month. I think we have four or five months now with record output from Unit VII. So we are in a good position in that regard and we will continue to get the broad portfolio of products in the market. We think that is key for us as, again. For that typical retail business being a broad line supplier, having our degree of vertical integration, some of these things are happening in the pricing environment, it is difficult to control that, but we feel we are still one of the most efficient manufacturers out there and we are in a good position to capitalize on these new launches.

**Prakash Agarwal:** Sir, should we see this lower growth of 10% as an aberration and growth to bounce back?

**Robert Cunard:** The growth rate, I think we have talked about that before on the retail side, that rate definitely slows from a couple things. The base continues to get larger and now we have perhaps an additional headwind with the pricing environment. So, we have talked earlier in the year, we thought that is more mid-teens and that is probably a little less now, as we see the growth rate. A lot of it I think is on some of the new products that could be a significant bump-up to what we see in that space.

**Prakash Agarwal:** And if you could help us update on the new capacity at Naidupet? When is this expected and the new injectable lines that you talked about launching Vancomycin and other products, if there is any update there?

**N. Govindarajan:** As far as Naidupet is concerned, we already filed two products, Prakash. And we would be conscious in terms of having some critical mass before we start really billing from this unit to take advantage of the SEZ. And as far as Vancomycin is concerned, already Ron had mentioned about getting it towards the next year is what he had mentioned. I think whatever I am trying to recollect is towards like second quarter or so, I will just qualify it later Prakash.

**Prakash Agarwal:** Okay. So what I understand, there is no capacity issue as such between the huge approvals that you are getting and due to capacity issues we are not able to convert that into launches, is that right understanding?

**N. Govindarajan:** That is true and I will qualify that further on whatever Bob had said. In the past I think our Unit VII would have been loaded more because even it has to share the capacity for new product filing as well as the existing products. And also till the European facility came up even the European products has to be accommodated in Unit VII only. Now, with the Unit X coming up most of the new products would get there, because it makes more sense for us to transfer the new products there. So that is one level of capacity which has been made available in Unit VII. Apart from that, the European facility is also like as Sanjeev had mentioned about the transfer of products and which otherwise was whatever is getting accommodated in Unit VII

will also get shifted more focused towards Europe into that Vizag facility. On Capacity front, as rightly mentioned by Bob, would not be an issue as we move forward.

**Prakash Agarwal:** And just a clarification here, when you say products have been transferred, assuming the dossiers have been transferred, the manufacturing is expected to start soon or if you can just highlight when it's going to start?

**Sanjeev Dani:** Yes, actually the dispatches have started. That is how we count. So when I say 63 products, actually 63 products cumulative December 2016 have been dispatched from India.

**Prakash Agarwal:** To Europe markets?

**Sanjeev Dani:** Yes, that is right. So first launch in any European country is taken as a tick mark. Thereafter some more countries will launch as and when their inventory is exhausted.

**Prakash Agarwal:** This is from the new unit?

**Sanjeev Dani:** No, in fact, they are all going from current units, that is Unit III, VII and Unit XV. But we will be ramping up for Unit XV (new unit) from this quarter, i.e. quarter four.

**Prakash Agarwal:** To the new unit?

**Sanjeev Dani:** That is right, but not all of them will go to new unit.

**Prakash Agarwal:** And last question before I join, on the debt side, so we have very well reduced the debt. If you could just give the kind of year-end debt number given there will be some increase of \$150 million because of the acquisition, what is the debt number by the end of the year we are looking at?

**Santhanam Subramanian:** If you recollect, Prakash, in the last earnings call we said we will be ending net debt less than \$600 million by the end of the year. Because, today it is \$410 million, we will be paying for the European acquisition plus we also acquired Orocal brand from Teva. So all put together we will be ending less than \$600 million. We started the year with \$640 million.

**Moderator:** Thank you. Our next question is from the line of Nitin Agarwal from IDFC Securities. Please go ahead.

**Nitin Agarwal:** Sir, on the EU products transfer you talked about, can you give us some sense of the kind of cost savings or the synergies that can come through? Say for example, the 63 products that you transferred, I mean, what kind of financial impact does it really translate into once these products are fully transferred?

- Sanjeev Dani:** Actually, it is not possible to give you product-by-product breakup because each product is different. So you can see, in overall EU performance it has been reflected, it was negative EBITDA three years back and we have switched the first product about two years back. And now we have reached 6% to 8% of our sales as EBITDA. So that swing has been possible mainly because of the product transfers.
- Nitin Agarwal:** And where do you see this European EBITDA sort of trending over the next couple of years?
- Sanjeev Dani:** Nitin, right now we are ahead of curve of our guidance, which we had given three years back and that will be completing in March 2017. And I think we will just estimate again and come back to you for the future EBITDA guidance, but obviously it will show improving trend.
- Nitin Agarwal:** And sir, on the \$4 million to \$5 million impact, one-time impact you talked about, this is the same thing as a 4% one-time hit we talked about in the gross margin, 4% impact of one-time or are these two different items?
- Santhanam Subramanian:** These two are different items please.
- Nitin Agarwal:** So this \$4 million to \$5 million is the impact that is built into other expenses?
- Santhanam Subramanian:** Yes, that is different compared to what Bob has explained to you at beginning.
- Nitin Agarwal:** And Bob, you had mentioned, looking on the Viread and Epzicom launches, what is our sense, when do we come to those markets with those products?
- Robert Cunard:** Epzicom should be April 2017, the first quarter next fiscal year. And I am sorry, what was the second product?
- Nitin Agarwal:** Viread.
- N. Govindarajan:** It's Tenofovir, Bob.
- Robert Cunard:** Tenofovir, that is probably going to be fourth quarter next fiscal year, so in the January timeframe.
- Moderator:** Thank you. Our next question is from the line of Prakash Agarwal from Axis Capital. Please go ahead.
- Prakash Agarwal:** Just trying to understand the R&D numbers going ahead. So, I mean R&D is about 3.5% as we speak. We spoke about last quarter on some of the Liposomal trials to start next fiscal as well as now Biosimilars. So if you could just give us the two year kind of guidance on the R&D side?



- N. Govindarajan:** Over the next couple of years the current 3.5% should reach 5% to 6% Prakash. For a simple reason that we were still re-looking at the entire R&D expenses, keeping in mind our biopharmaceutical acquisition. Also keeping in mind in terms of potential out-licensing. With all the other aspects of it, we need to look at it rather than isolated. Having said that, we had maintained last time also that when the clinical trial start, at the peak it would be around 8% to 9%. And please remember the 8% to 9% what we talked about is also on the enhanced sales figure and that also we are not expecting that to be permanently 8% to 9% year-on-year, we expect that to come back to the 5% range once that particular normalization happens, Prakash.
- Prakash Agarwal:** So it will peak out in fiscal 2018 and then drop in fiscal 2019 is what I understand.
- N. Govindarajan:** I will put it this way, the fiscal 2018 it should be around 5% to 6%. That also as we progress, we will get more clarity. At this juncture we are still saying it's 5% to 6%. Next financial year, we are not talking about 9% at this juncture.
- Prakash Agarwal:** And lastly on the Europe side we have seen growth going high-single-digit. I see Euro depreciation also only 1%. So 8% growth CC term, is that right? And what has led to this kind of growth?
- Sanjeev Dani:** Yes, you are right. It is 8% growth and actually even on nine-months basis also it is very close to that. And basically, we have put system and processes in place, our organization structure has been streamlined and we are more focused on growing business. So, I guess being closer to the customer is what is leading to this growth. Some of the Day-1 launches are going to happen now. But that is not so much reflected there.
- Prakash Agarwal:** So we can see a better growth from this business ~ 8% to 9% kind of run rate?
- Sanjeev Dani:** See, actually we are looking at consolidating our business and improving the margins and that has been the single minded focus. I guess 5% sales growth is what we had committed, I would still retain that as a benchmark because there are impacting factors on product margins which can happen and, it depends also on some tender products sales. Our overall focus is on the bottom-line, to improve the bottom-line percentage.
- Prakash Agarwal:** So current run rate of EBITDA margin is 5%?
- Sanjeev Dani:** No, it is more than that now. It is between 6% and 8%.
- Prakash Agarwal:** And the new acquisition that you've done that is about 20% kind of margin?
- Sanjeev Dani:** Yes, that is 20% plus, in fact.
- Moderator:** Thank you. Our next question is from the line of Kartik Mehta from Deutsche Bank. Please go ahead.

- Kartik Mehta:** I want to hear your views on the recent comments by the new US Administration on border tax. So where do we have and how do we plan to hedge ourself in case we need to shift manufacturing?
- Robert Cunard:** Well, I certainly have an opinion and Govind, you may want to weigh on. It is one of the things that we are watching closely as Aurobindo as well as the US generic industry. We already have a significant presence in the US and we are in the middle of expansion of that as well. So, if there is an increased impetus to have additional manufacturing in the US, I think we have a foot-up on that and the ability to potentially accelerate some of those plants to do that quicker. I think it is going to be very much an evolving landscape in the months ahead. And as indicated, we are becoming more active as Aurobindo and also working through our generic association as well to stay ahead of the trends.
- Kartik Mehta:** So broadly if we have to compare capacity for dosage and injectable in India vis-à-vis the US, where are we and where would be the utilization, I just want a broad idea here?
- Robert Cunard:** Well, if you look at on the retail Rx space, about 12% of our volume right now is coming out of our US manufacturing. And again, we have the ability to increase that as need be for the right products. Obviously, some things when we look at our beta-lactam or antibiotic business, I do not see a scenario where that would ever be made domestically here in the US. Regarding the Injectable, we do not have any current Injectable manufacturing in the US, but we do have plans to begin construction and build-out a sterile facility at our East Windsor campus.
- Kartik Mehta:** And the next question was on the tax rate, how much should we budget for the next two years or at least for FY2017 and FY2018?
- Santhanam Subramanian:** Tax rate, for 9MFY17 we are at 26.7%, I think we will be around that range by end of this year. Next year also it should be around 27% . .
- Moderator:** Thank you. Our next question is from the line of Surjit Pal from Prabhudas Liladhar. Please go ahead.
- Surjit Pal:** I have few questions. Govind, if you can clarify on the legality part of Fortamet, as well as Isosulfan Blue? I mean, we understood is that Isosulfan for you guys have filed appeal court and expecting in say next 14 days of any kind of summary judgment on that. But if you can tell us that what could be the penalty provision if there is any? Or is there any kind of challenges were there when you filed the drug from Mylan side?
- N. Govindarajan:** No, what I suggest is Bob has responded to both, I would rather allow him to handle this. If there are anything residual I can always come back Surjit. Go ahead Bob.
- Robert Cunard:** Yes, regarding the active litigation, obviously you can appreciate we do not comment a whole lot on that. As mentioned with the Isosulfan Blue, there was a preliminary injunction that was

awarded. We are currently not selling the product while that decision is under appeal. And I think that we will just continue in litigation process and we will provide updates as appropriate. And very similar for the generic Fortamet, the Metformin ER. Again, just to reiterate that we have a targeted action date from the FDA of August 2017. We anticipate that will be a tentative approval at that point. Our 30 month stay in the litigation will complete in June 2019. But we think there is some opportunity to get that resolved and get that product in the market sooner. We are working towards that and we consider that upside at this point.

**Surjit Pal:** So, you mean is that you can launch before June 2019, I mean, before 30 months expiry?

**Robert Cunard:** Well, that would be our goal. We are not committing to anything now, but that would be a goal to get into the market before that.

**Surjit Pal:** If you can throw some light on the many ARV product have quite sizable market size going off patent. So in FY2018 and FY2019 any meaty product in every segment you are expecting to be launched from your side?

**Robert Cunard:** Yes, there are a few products as indicated earlier. Epzicom, an estimated April launch, which should be a good product for us, few other products later in the year. We mentioned that Tenofovir, that is almost at the end of next fiscal year, so some significant products they all kind of standalone. Historically, in the US market with the ARV some of those have been very attractive. There is historically a more limited number of players, but all the products are unique. So we will see when we get to the actual launch dates.

**Surjit Pal:** It would have been helpful, if you take some name of the products, which could be expected in FY2018 and FY2019?

**Robert Cunard:** I will follow up with the complete list, we have 118 pending with the agency, so there is quite a few. As far as just high level when we look at 2018, we anticipate we will probably be somewhere in the 40 to 45 launches overall in the retail space. So it will be a very active year, but we will be happy to follow up with some other key items.

**Surjit Pal:** The last question is about Lidocaine. I mean, I am sure you have many, not many but few products have in shortage category, one is Tazopip, and one is Lidocaine. I mean, any update on these two products?

**Robert Cunard:** Yes, so Lidocaine was a significant product for us. It continues to be, it is probably one of the top-10 products in the AuroMedics line and should continue to be a key contributor for us.

**Surjit Pal:** And Tazopip?

**N. Govindarajan:** As well as Tazopip is concerned, we are already supplying and we would be able to ramp-up as it progress. I think probably we will have more volume on that as well.

- Moderator:** Thank you. Our next question is from the line of Surya Patra from Phillip Capital. Please go ahead.
- Surya Patra:** A couple of clarification, whether we have authorized generic for Nuvigil for US recently?
- Robert Cunard:** Yes, we did that. That was back in July, we launched an authorized generic of just the 200 mg strength.
- Surya Patra:** And what is the kind of opportunity that you are visualizing in Fortamet opportunity currently?
- Robert Cunard:** Well, we can't speak on the Fortamet opportunity right now as it is in 30 month stay through June 2019. So, it is involved in litigation and we have to find an alternative to pull that date forward.
- Surya Patra:** No, I mean to say, what is the kind of market size that you would be targeting whenever you launch?
- Robert Cunard:** Well, obviously, that could be a big gamut when we look at something that is potentially two years out, but it is about a \$2 billion market currently as far as the addressable market per IMS. If we were able to do that earlier, we would certainly expect that would be on the higher percentages as far as market share and well into the double digits.
- Surya Patra:** So that means including all the Metformin formulation that you indicated that could be the size. Is that correct or...?
- Robert Cunard:** Again, that is just what we consider the addressable market per IMS on the Fortamet generics, right now about \$2 billion.
- Surya Patra:** And regards this AuroLife expansion what we have indicated, from where that we are getting the confidence whether it is the controlled substances business or it is the government tender business that is looking very, means, what is giving you confidence for that kind of capacity expansion what we have indicated? And what is the kind of current base, annual base of AuroLife business sir?
- Robert Cunard:** So currently, the AuroLife business as you mentioned the VA national contract that is Federal Government tender business is right about \$50 million to \$55 million for the year and trending to that. So, as far as the growth opportunities there, I think it is three-fold, one, the ability to continue to bid on those contracts and expand in that space. When we look at the controlled substances, we currently have 10 applications pending and we anticipate another 15 filings in fiscal 2018, so that portfolio is expanding. And then as we talked earlier with the current landscape of what is happening with the White House Administration, some of the things that may change there. Clearly having capacity in the US, we do not think would be detrimental at this point.

- Surya Patra:** So, that means we can maintain in AuroLife strong double-digit kind of growth beyond 20% what we have been seeing since sometime?
- Robert Cunard:** Yes, we think there is a nice growth opportunity there. Those typically with our controlled products as well there about 50% higher than what we'd say the balance of our retail generic products in terms of pricing.
- Moderator:** Thank you. Our next question is from the line of Manoj Garg from Bank of America. Please go ahead.
- Manoj Garg:** Bob, couple of clarification. A. you have indicated that you are expecting around 5% to 7% high single-digit kind of price deflation on a quarter-on-quarter basis. And if I sum up all those four quarter that means, what we are talking about 20% - 25% kind of price erosion on a year-on-year basis. And on the top of that we are still saying that we can have a healthy double-digit kind of growth. Are we talking about then almost around 35% - 40% kind of growth coming from the new products in the US?
- Robert Cunard:** Well, we have such a significant number of new products as indicated, I think we have 40 to 45 approvals this coming year, so that is equal to or greater than what we had this past. I think what we have seen in pricing, what we will see in the future, it is really unclear right now. Clearly, when you look at some of the products, we are not going to see that kind of erosion across the board. The other thing that I think is important if we look at this again, when you look at our level of control across this portfolio and our degree of integration. So, we are more than 70% across our entire book of business, but when we look at this retail Rx business, we are greater than 90% as far as our own material. So the ability to go back and continue to drive efficiency on those products and we think there is some leverage points there as well continue to grow that. If you look at the past quarter, we were flat as far as our volume growth as well maybe down a little bit, which that was one thing. Historically, we have seen that be an offset to that price erosion as well as that volume gain and the base business. I think that is returned in the fourth quarter and moving forward as well as and we look at the share of extended units in the TRx and the IMS data that continues to grow at a really healthy rate. So, I think there is a few other offsets to that pure price pressure.
- Manoj Garg:** Because I think 20% kind of year-on-year price erosion seems to be a very steep number, given the background that the margins we have started seeing a lot of positive comments coming from many other channel partners and other generic companies, which are still maintaining that maybe mid-to-high single-digit kind of price deflation versus what we are talking about almost high double-digit kind of range.
- Robert Cunard:** Yes, I do not see that erosion rate continue for the full next 12 months. I talked about the next couple quarters because we are in the middle of these significant bid processes. But clearly some of these will reach a bottom.

- Manoj Garg:** And secondly on Fortamet, as we indicated that we are currently under litigation and the patent which we have challenge is primarily of March 2021 instead of March 2018 patent. So what gives us the confidence that it could be a likely opportunity for fiscal year 2018 given that Synovia is still selling the product and if they allow any other incremental generic competition, even it can have an impact on the revenues as well?
- Robert Cunard:** Well, again, I think we are looking at that as an upside, so we would not put that into our base case for 2018. That is one of the things we are working on and try to find a way forward to pull that into as early as possible.
- Manoj Garg:** But have you seen any precedence that when a product is under litigation with the 30-month kind of mandatory stay period where FDA would not give the final approvals, without court coming up with the final judgment FDA approve the drug before 30 months' expiry?
- Robert Cunard:** There have been some cases in the event of a settlement.
- Moderator:** Thank you. Our next question is from the line of Nishid Shah from Ambika Fincap. Please go ahead.
- Nishid Shah:** Most of the questions have been answered, but it will be useful if you could guide us on when do you see the Lansoprazole and Vancomycin injection launches?
- N. Govindarajan:** While Bob is looking for it, Nishid, do you any other queries?
- Nishid Shah:** No, basically the color on the injectable portfolio with Vancomycin, Lansoprazole and Meropenem coming in next year, it would be useful, if you could give some color on FY18 one injectable portfolio?
- N. Govindarajan:** So, we do not give specific numbers, but I can only tell as far as Injectable portfolio is concerned, we have been growing at a very good rate and we would be able to maintain the rate of growth. Also we are having enough diversified portfolio both in terms of what has been filed and what is coming up and we are comfortable about maintaining the growth rate, Nishid.
- Robert Cunard:** Just a follow-up, we expect both those launches in the second quarter of fiscal 2018.
- Moderator:** Thank you. Ladies and Gentlemen, that was the last question. I now hand the conference over to Mr. Krishna Kiran for closing comments. ---
- Krishna Kiran:** Thank you all for joining us on the call. If you have any questions unanswered, please feel free to keep in touch with the Investor Relations. The transcript of this call will be uploaded on our website [www.aurobindo.com](http://www.aurobindo.com) in due course. Thank you.



*Aurobindo Pharma Limited  
February 10, 2017*

**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.