"Aurobindo Pharma Limited Q3FY15-16 Earnings Conference Call"

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**Moderator:** Ladies and Gentlemen, Good Day and Welcome to Aurobindo Pharma Q3FY15-16 Earnings Conference Call. As a reminder, all participants' 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 would now like to hand the conference over to Ms. Deepika Gupta Padhi. Thank you and over to you, mam.

**Deepika Gupta Padhi:** Thank you, Darryl. Good Evening and Welcome to our Third Quarter FY15-16 Earnings Call. With me we have our senior management team represented by Mr. N. Govindarajan – Managing Director; Mr. Robert Cunard – CEO, Aurobindo USA; Mr. Ronald Quadrel – CEO, Auromedics Pharma USA; Mr. Sanjeev Dani – COO & Head, Formulations and Mr. Santhanam Subramanian – CFO.

We will begin this call with the opening remarks from the management followed by an interactive Q&A Session. Please note that some of the matters we will discuss today are forward-looking including and without limitations statement relating to the implementation of strategic initiatives and other affirmations on our future business development and commercial performance. While these forward-looking statement 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 statement to reflect future events or circumstances.

With that, I will now hand over the call to Mr. N. Govindarajan for his opening remarks. Over to you, sir.

**N. Govindarajan:** Thank you, Deepika. We are here to discuss the Third Quarter FY2015-16 Unaudited Financial Results declared by the company. We have seen good

growth during the quarter on account of US market and new product launches. Our revenues for the quarter registered a growth of 10.4%, EBITDA increased by 34.4% and profit after tax increased by 39.2% year-on-year. Our consolidated net operating income in Q3FY15-16 is at Rs.3,496 crores.

In terms of the Business Breakdown: Formulations business contributed to 80% of the total gross sales at Rs.2,837 crores, registering 12.1% growth year-on-year; API business accounted for the balance of Rs.695 crores. In the Formulations business, the total sales from the US market stood at Rs.1,571 crores, registering a growth of 31% against the corresponding quarter last year.

Aurolife, our US manufacturing arm continue to witness increase in volume of production during the quarter mainly on account of increase in demand for government deliveries. The anticipated introduction of some of the newly FDA approved products and increased volumes for government is expected to keep the momentum going over the next few quarters.

AuroMedics, the company marketing the Injectable products in USA is experiencing a significant FDA activity in the review and approvals on filed ANDAs. We expect the momentum to continue and get more approvals during Q4 and the coming financial year as well. The Injectables business contributed to $23 million during the quarter, registering a growth of 26.9% against the corresponding quarter last year. Under the Injectables segment including Ophthalmics we have total 79 products filed as on 31st December 2015, out of which 31 are approved and the balance are awaiting approval. We have several complex products under development, namely Hormonal, Oncology products and Microsphere which we plan to file over the next few quarters.

AuroHealth which manufactures and markets Pharma OTC products in the US continue to gain penetration into several key national retailers as well as select regional accounts. We are now shifting to some of the top OTC

customers. The current portfolio consists of 77 Products and 119 SKUs developed to-date which are expected to be commercialized. Natrol, the acquired branded Neutraceutical entity is also performing as expected.

The company as on 31st December 2015 has filed 387 ANDAs on a cumulative basis, out of which 228 ANDAs are approved including 30 tentative approvals, out of which 21 are approved under PEPFAR which would not get commercialized in the US market and balance 159 ANDAs are under review.

The Unit wise filing and approvals are as follows: from Unit-3 119 filed, 112 approved; Unit-7 143 filed, 55 approved; Aurolife USA 26 filed, 10 approved; Unit-4 67 filed 21 approved; Unit-12 and 6, 19 and 11 filed and approved respectively and Auronext 2 products have been filed so far. Units-3, 7 and Aurolife manufactures Oral Non-Betalactam products; Unit-4 manufactures General Injectables and Ophthalmic products; Unit 6 and 12 manufactures Cephalosporin and Semi-Synthetic Penicillin respectively, and Auronext which has its facility at Bhiwadi in Rajasthan for manufacturing Penem Injectable products.

Europe Formulations sales were at Rs.779 crores in Q3FY16 down by 9.6% compared to the same period, primarily on account of currency impact as euro depreciated by 6.5% during the period. Emerging markets Formulations sales grew by 36.2% to Rs.182 crores in Q3FY16 over Rs.134 crores in Q3FY15. ARV Formulations sales registered a degrowth of 8.5% to Rs.305 crores during the quarter against Rs.334 crores in the same quarter of previous year.

In terms of Segmental Classification: US Formulations contributed to 55.4% to the overall Formulations revenues in Q3FY16 against 47.5% last year. The share of Europe decreased to 27.4% from 34% in the corresponding period last year while the share of the rest of the world remains the same at 6%. ARV segment sales represents 10.8% of the total Formulations sales in Q3FY16 compared to 13.2% in Q3FY15. Gross sales from API business have been at Rs.695 crores in Q3FY16 registering a growth of 3% over Q3FY15. Our EBITDA

before FOREX for the quarter is at Rs.823 crores which represents the operating margin of 23.5% and that has gone up from 19.3% in the corresponding period last year. The operating profit for nine months FY15-16 stands at Rs.2,323 crores resulting into the operating margin of 22.9%. R&D expenses of the company stands at Rs.110 crores which is 3.2% to sales. The company generated FOREX gain of INR 12.9 crores during the quarter. The closing rupee Vs US dollar rate was Rs.66.155 in December 2015 and Rs.65.5875 in September 2015. The net debt decreased by $52 million quarter-on-quarter to $610 million as on 31st December 2015 compared to $652 million on 30th September 2015. Majority of the company's debt is denominated in foreign currency. The cash and bank balance is at $124 million. CAPEX for the quarter is around $40 million. The effective tax rate for the current quarter is 25.8% of PBT.

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

**Moderator**: Thank you very much. We will now begin the Question-and-Answer Session. The first question is from the line of Saurabh Kumar from Motilal Oswal. Please go ahead.

**Saurabh Kumar:** I had a question on US business. We had received handful of approvals during the quarter and our sales have moved to 240 million from 228 million last quarter. Now, does that mean that we have seen a considerable decline in base business?

**Robert Cunard**: This is Bob Cunard from US business. On the Oral Solid side we have not seen an overall erosion on our base business in the US, we did see a few key items where we had some competitive pressures over the past quarter. Clearly we have seen a lot of approvals on the new products. The biggest factor we have seen on that is the timing of the introductions of those and some were related to the prior quarter as we talked in past calls, we are prioritizing as there are new products we are trying to identify the best opportunities and then some of the other ones will be rolling in over the next few quarters. So look at one

of the key product launches Aripiprazole. Our market share and our pricing expectations were pretty much in line of what we planned for the year. That is one and we were entering an existing Generic market so that does take some time before it rolls in. A very similar situation is with Raloxifine, which was actually a second fiscal quarter approval and we started to see first revenues from that here in the third quarter through our partner, but again, that was replacing an existing supplier so, really do not have the large pipeline fill or anything, it just begins to roll in through the period. So, I think new products will continue to drive more as we get a full quarter effect in Q4 as well as additional introductions that we have. But in overall base business we witnessed some softening on some key products but not overall.

**Saurabh Kumar:** On Suprax, is it because of the supply constraints or is there any other factors playing out that we have not been able to gain decent market share in that product?

**Robert Cunard:** I think the supply is not an issue in that market and if you look at the split of the Generic market as we talked before, Lupin did introduce and authorized generic into that space and the generic share has been kind of broken out in terms of market share as expected. What we have seen is a little bit slower than typical conversion from the branded product to the generic product. As we look at it there were some incentives put in place and some different plants around the country where the brands were incentivized over generics, we see that trend changing and I think we expect to see that product continue to grow. We do not see immediate generic competition on that but we certainly can see that as we get into next fiscal year. But I think we will see that a little bit more typical as we move forward over the next couple of quarters.

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

**Chirag Dagli:** Of the 30 approvals that we have sort of got in the nine months' period, how many have we launched in the US markets sir?

**Robert Cunard:** I do not have an exact number here, but we are probably about 18-20 that are launched.

**Chirag Dagli:** Of these sir, how many would have still not seen the full optimal impact in the third quarter?

**Robert Cunard:** Those are largely on the recent introductions. Obviously, you take any given generic launch into an existing generic market, it is an ongoing process, and we go through bid cycles with our customers and everything else. So, I think the most notable when you look at Q3 are Aripiprazole, Raloxifene and Methodone a new Aurolife product is one that we have some orders cued up under the 'A' products, that is in place now, so we will continue to grow. But these are the most notable of the group.

**Ronald Quadrel:** On the Injectables side, over the first three quarters, we have had in terms of product families 10 approvals plus 2 tentative approvals. Of those 10 approvals we launched 5 of those until the last week of the quarter and then we launched eptifibatide**.** From our perspective, as we look moving forward here, we will be launching more in the fourth quarter and going into first quarter next year.

**Chirag Dagli:** So the other four you launch in the fourth quarter?

**Ronald Quadrel:** Yes.

**Chirag Dagli:** Can you give us some sense of the 483 that we received at Unit-7 and what is your assessment of the seriousness or otherwise of the observations?

**N. Govindarajan:** Chirag, in our assessment, we do not see this as an issue, in fact, we had clarified earlier also that there are certain observations and we are appropriately responding and we do not expect an impact on operations. That is one. Second, after the inspection and the Form 483 issue we have received

3 approvals, out of which 1 is a final approval and 2 are tentative approvals. The unfortunate thing is that there are some reports circulated, had mentioned discarded instead of disregarded in terms of certain aspects of the observations. Having said that our people are working on the response and we will be responding within the stipulated time frame.

**Chirag Dagli:** In your opening remarks, did you say that we would file some Microsphere-based products in FY17?

**N. Govindarajan:** I did not say a specific time, I said in the next few quarters. Ron, would you like to comment on when the filing would happen on Microsphere?

**Ronald Quadrel:** I believe we will file our first Microsphere product about 4-5-quarters out from now. One of the reasons is taking longer to do that is, it is a much more complex development, and as well, we require some initial pilot bioequivalent studies followed by full bioequivalence. Itwill take that much time to get to that point, but so far everything looks good.

**Moderator**: Thank you. The next question is from the line of Jigar Valia from OHM Group. Please go ahead.

**Jigar Valia:** If you can just give some more color on the performance in the Europe market and explain the increase in the staff cost?

**Sanjeev Dani**: I will talk about the Europe business first and then maybe Govind can answer on staff cost. So during the quarter we saw quarter-on-quarter increase in the top line of about 2% and we have seen the second consecutive quarter where we had a positive EBITDA margin for Europe business. I think that is a good turn around and I think we will maintain this in positive territory going forward.

**N. Govindarajan:** On the staff cost, I think there are certain R&D recruitments happened in US as well as certain other recruitments, which has happened for the new capacities which are running up.

**Jigar Valia:** If I can follow up on the 483, in terms of root cause analysis and some of the other issues, if you can indicate in terms of timeframe, of how much would it take for us to address issues in our side before we await any further updates from FDA side?

**N. Govindarajan:** I think I am going to take 2 minutes to explain the issue. Typically, whenever we have an out of specification, we initate the lab investigation. In the lab investigation there are two parts; one is in terms of the equipment error, other is in terms of the human error. If one of these two happens, then the investigation focus is on that in terms of the root cause rather than progressing with any further investigation in any other aspects including the manufacturing process. So in this case it was found out clearly that there was a human error because of which we have concluded the lab investigation and we have analyzed the root cause. We are working towards clearly responding on what further improvement can be done. On the timeline, typically we get 15-days to respond to all these observations and our team are already working towards the same. Whatever responses we had given if it is satisfactory then they will come to the EIR part, in between if they have any queries, they would raise those queries and we have to respond to that. That is how the procedure would go. Our response would go within the 15-days from the date of closure of the audit.

**Jigar Valia:** Any inspections for any of our key units expected in the next couple of quarters?

**N. Govindarajan:** I would put it this way, In any given quarter, we will have at least one or two inspections which can happen, in fact, this particular inspection is for a pre-approval audit, it is not a regular GMP inspection and these inspections have happened even in less than a year frequency.

**Moderator**: Thank you. The next question is from the line of Surya Patra from PhillipCapital. Please go ahead.

**Surya Patra:** In fact, on the Injectable front, what is the number that you have mentioned for the quarter and same can you share for the Aurolife, AuroMedics and Aurohealth separately?

Ron Quadrel: AuroMedics number for the quarter was $23 million.

**Surya Patra:** So are we on track to achieve what was the guidance that we had given in the starting of the year on the Injectables front?

**Ronald Quadrel:** Yes, we are.

**Surya Patra:** The kind of markets what we are seeing for the launched Injectables, though there is around 10 approvals that we have received, but whichever Injectable launch happened, for that the market is not that impressive. Is that you are saying it is taking some time to really get some kind of base there in those markets or what is the case there?

**Ronald Quadrel:** As I mentioned in the past earning calls, a number of our approvals we received this year to date have been on products that are very small markets. For instance, some of these have been $4 million markets, some of them have been $15-16 million markets and as well there is a ramp up time period for gaining sales; however, as we have moved forward towards the end of the year, Eptifibatide was probably the biggest launch that we have done so far. We have done quite well on that one. We are lucky to an extent because the innovator Merck was on back orders and only one other generic was approved and they are on limited launch. So we are doing quite well of that. I expect over the next quarter we will have a significant ramp in our sales due to some other launches of larger products and then moving forward into next year there are a number of our products we are expecting approval to our larger markets. So, to answer your question more specifically, we have different market shares projected for different products depending on a number of competitors in place. We are very happy where we are right now. Our sales progress is more of a hockey stick mode where towards the last quarter and beginning next year our sales will ramp quarter-on-quarter .

**Surya Patra:** Any update on the Penem approval and the launch?

**Ronald Quadrel:** Our first approval will be Meropenem. On this product, we are actually waiting some comments from FDA on that ANDA. On Doripenem, we probably will have tentative approval next year but we have a Paragraph-IV there. That market has dwindled quite a bit. I believe latest IMS money on Doripenem is $7 million only. We have in fact also filed Imipenem Cilastatin last month and we are expecting that we are going to file Ertapenem, which is the largest market of the four penem products, probably within the next month or two.

**Surya Patra:** Meropenem, is that what we are expecting this quarter or sometime very soon?

**Ronald Quadrel**: It is taking a little bit longer than we expected. Even though this is an expedited review, this particular review team at FDA has been slower than some of the others. In fact we have called and asked them why we have not received a response. They have told us that there is nothing untoward happening, but they did tell us we should be expecting a response from them within the next month. That will probably be in the form of an information request on either chemistry or micro then we will take it from there.

**N. Govindarajan**: On the Aurolife, we do not segregate the numbers, because partially the controlled substance are going through Aurobindo USA, hence we do not segregate that number. As far as Aurohealth is concerned, at this juncture it is not significant. So when that becomes significant, we will segregate that numbers.

**Surya Patra:** So in that case, is it possible to say that what is the kind of base business price erosion or what is the kind of base business quantum that you can say for the quarter and what is the incremental revenue that you have received from the new launches for the quarter?

**N. Govindarajan:** I would request Bob to comment on this, but before that one of the key aspects is we do not segregate product wise revenues at all. Let me ask Bob to explain you on the erosion part of it on the base business.

**Robert Cunard**: As indicated earlier, on the base business we did see some erosion on some key products and we saw some other impacts that were more related to order timing and that was more closely tied to our third-party contractors and some of the private label programs we do there. So, that was a little bit softer in the third quarter than what we have seen in previous, but we do not see that as a recurring trend. So base business we are seeing some modest erosion. The new products will continue to be the drivers, they were about 12-13% of AP USA sales which is a kind of traditional generic business here in the US for the third quarter and once again we did not get full quarter effect on a lot of those items. We talked before as we look at base business going forward, clearly, we are in a situation where customer consolidation continues and they continue to pursue the synergies from that and we are seeing an acceleration of FDA approvals. So we anticipate that we will be in kind of a deflationary environment with that base business but again we think that is more than offset by new product introductions and also expansion of share on that base business. So when you look over the past year December '14 to December '15 more than 50% of our inline portfolio we saw market share growth in the space. So we think that continues to offset some price erosion as well.

**Surya Patra:** So are you happy with the kind of market that what you gather for Aripiprazole so far?

**Robert Cunard**: I think we always look for more and finding that right balance between volume and price, but Aripiprazole in terms of a share and a pricing perspective it really lined up with our expectations.

**N. Govindarajan:** Just to add to Bob whatever had said, one of the aspects is that even though this quarter there could be some softness in terms of the third parties which we believe could be more cyclical or could be for this specific quarter and we

still believe that momentum would be maintained as in the previous quarters as we move forward.

**Surya Patra:** Can you just give me some sense on the ROW growth, what has really led to this kind of momentum there?

**Sanjeev Dani:** Our normal growth pattern is expected to be 20% because the base is very small just 6% of business, but in this quarter there was some kind of lumping of the orders. So do not read too much into that but of course normal 20% growth will continue.

**Surya Patra:** This is despite the adverse currency effects that we might have seen during the quarter in the RoW market?

**Sanjeev Dani:** That is right but the country mix is such that there was both ways movement. So the overall net impact has not been significant during the quarter.

**Surya Patra:** In the RoW market, whether our billing is on the dollar terms?

**Sanjeev Dani:** Yes, if it is a direct billing, it is in dollar terms, but we also have subsidiaries. So there the adverse impact will come.

**N. Govindarajan:** But what Sanjeev said is overall the impact has not been significant in terms of this currency changes in the RoW or the emerging markets.

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

**Neha Manpuria:** First on Europe. With us seeing positive EBITDA for the second consecutive quarter, should we expect that the improvement on quarter-on-quarter had been linear or you are seeing flat and given our expectation of two years EBITDA target that we had given for Europe, is there upside to this number given we are doing must faster turnaround of the business that we had acquired?

**Sanjeev Dani:** Quarter is a very small period for the kind of the strategy that we have placed into the market. As you can see that in FY15 the first strategy was to integrate and streamline the operations so that we can stop making losses and then in this particular year in the second and the third quarter we have seen positive EBITDA. It is very wafer thin margin. I would not actually say that linear two dots make any difference, but we will stay in positive territory. That is very important. Going forward during the year end this particular 2016, we will do slightly better than may be originally we thought about may be $3-4 million positive EBITDA will be there, and then another one or two years we should be seeing high single-digit positive margins.

**Neha Manpuria:** So we are still saying high single digits positive margin by FY18?

**Sanjeev Dani:** Yes, that is what it will be because by that time our India transfer will be quite significant of the products and also we will be launching ex-India new products. So overall there will be gross margin improvement plus there will be ramp up of the top line and better integration thereby the operating cost will be minimized or optimized.

**Neha Manpuria:** Sir, on the transfer of products to India, is it fair to assume that this would be more a multi-quarter process rather than it is happening in one year given there are a large number of products and there could be cost associated with that or is it as simple we can make it all in let us say a couple of months?

**Sanjeev Dani:** You are right, it will be a phased out process and actually we have already moved in 28 products cumulatively. What we are doing is we are prioritizing those products movement. It does not mean that we have to move all the products. It is neither desirable nor feasible because there are some old Marketing Authorizations but ultimately net-net we will gain and this is a multi-quarter process, as you said, there are multi countries also involved even though it is approved in EU, we have to move out the inventory of the previous stocks and thereafter keep on launching those products.

**Neha Manpuria:** Next is a book-keeping question on the other operating income. The increase that we have seen year-to-date is that all because of the export incentive number or is there any other one-off number in that line?

**N. Govindarajan:** Before Subbu answers that I would like to clarify that as far as the export incentive is concerned I believe that it should not be more than 3% for any of the pharmaceutical companies, that is our belief. It will be around Rs.50-60 crores. Subbu, over to you on the remaining aspects of this.

**Santhanam Subramanian:** Around Rs.50-60 crores quarter-on-quarter we have been getting it. It is around 3%.

**Neha Manpuria:** But this is an increase over the last year, sir that is the bulk of it, there is no one off item in that?

**Santhanam Subramanian:** There is no one-off item in that.

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

**Girish Bakhru:** On US side, can you give some color on final approvals for Nexium and Angiomax?

**Ronald Quadrel:** On Angiomax right now we are waiting for the court to rule on the appeal that The Medicines Company filed for after Hospira went ahead and won the case back in June. What happened is that post that case, The Medicines Company went in and requested all 11 appellate judges to rule on their appeal. What we are expecting is that sometime in June or July, there should be a decision based on what Hospira filed plus in addition to what The Medicines Company has filed. It should be noted that we already have tentative approval on that product. Dependent upon what happens with that case in the appeal, if the appeal is denied, we will be ready to launch within a month of that decison. If it is not approved, then it will go back to the 2019 patent. So we are all awaiting to see what happens on that.

**Robert Cunard:** Regarding the Esomeprazole (Nexium) we did receive tentative approval on that. We have a targeted action date. We would anticipate would be final approval in April of this year. There is litigation outstanding on that. So there is a hurdle that we would need to clear in that regard prior to launch after approval, but we think that is a fiscal '17 event.

**Girish Bakhru:** Second question was a general question on the capacity utilization particularly in Injectables and Oral Solids. Given the pace of approvals have been really healthy. What sort of utilization levels are we running at right now and is there any significant constraint going to come from that end?

**Robert Cunard:** In regard to the Oral Solid, we talked about this in the past is that in certain areas we do have some constraints that we need to be sensitive to and we have been addressing those through numerous CAPEX activities and expansion across a number of existing and new sites. That is something that as we sat here a year ago we did not see this acceleration of approvals that has been a reality this year. So we have been accelerating a lot of those activities to bring that on line and that is the reason we are going some rationalization on the new product introductions and making sure we are capitalizing on the best opportunities, but we do not want to do anything to compromise existing business and placement that we already have in the marketplace. There are some outliers in regard to API with some specific products, but all the plans are in place and we do not see any significant capacity constraints over the next three to six months.

**Girish Bakhru:** So just on the rationalizing bid, when you say like eptifibatide a good opportunity, there are only Teva in the market. Is there a peak market share number that you work with like what kind of market share can you target with the existing capacity in that product?

**Ronald Quadrel:** We are talking now about the Injectable part of the business. Depending upon the number of generic competitors that enter and we are expecting that there will probably be three more competitors in maybe by June and July of this

year. That will govern how much we will have as a final market share. Right now, obviously with Merck on backorder and Teva with limited launch, we have the majority of the market. I would expect when this all settles out given the longer-term contracts that we have in place we should be still the number one majority shareholder in that market.

**Robert Cunard:** Just to go back to Oral Solid when I talk about rationalization, a great example is Omeprazole. That is one we got approval. It is a very large volume item, it is very competitive, very low price. So that is one we really chose not to introduce at this time. We do not see that as a good way to deploy the resources and there are much better alternatives. At a point in the future it is more than likely that will be part of our portfolio and we will build that in, but at the current time it is not a priority.

**Ronald Quadrel:** Back on the Injectables capacity issue, sometime back, we did a preliminary five-year plan, taking into account the number of filings we are expecting to file and approvals over the five years. Based on this, we have gone ahead and we are completing a capacity expansion of our Penicillin Injectable manufacturing. In fact, that expansion project has been completed, and it is currently being commissioned. Hopefully later this calendar year this will be up and running with FDA approval. We added on to Unit-4 and have tripled our lyophilization capacity. That expansion is still in process. When both of these projects are completed, we should have no capacity constraints over the next five years.

**Moderator:** Thank you. The next question is from the line of Prakash Agarwal from Axis Capital. Please go ahead.

**Prakash Agarwal:** First question is on the USFDA 483 that has come up. Just trying and understanding this better, in terms of a specific comment that there is a trend of Out of specification related to Assay failures from July to December, impacting commercial batches. So if you could highlight or make us

understand for a period of 6-months these issues have cropped up and the timeframe that we would require to assess and correct these measures?

**N. Govindarajan:** Out of this particular six, what are we talking about we have two tranches of analysis which we have done -- One is in terms of six batche; other is in terms of three batches out of which these OOS has been reported. As I had explained to you earlier that typically any OOS when we start getting deeper into it the first and foremost we will be looking at is the lab investigation. In the lab we will be looking at two large aspects of it -- One Is there any issue with the equipment or in terms of the manual error. In case if we find one of these two that is where we will focus in terms of the root cause. In this case we have found that the issue was more of a human error and that is the reason we had focussed on that. We are preparing our response, will explore even strengthening the further system in terms of the OOS investigation before the response goes to the FDA. The point what I was trying to make earlier was we don't see this impacting our continuing operations and also subsequent to this particular Form 483 we had received three approvals from the unit, out of which one is final approval and two are tentative approvals. That is our belief, Prakash.

**Prakash Agarwal:** We understand that sir, but in the past we have seen issues of giving approval and then canceling like what we saw for Sun Pharma and SPARC, so just trying to understand this better?

**N. Govindarajan:** First of all let me explain one thing, Prakash. It is not all comparable from one Form 483 to another Form 483. That is one aspect of it. The second aspect of it is every Form 483 has its own implication in terms of what has to be looked at. We have gone through it and we are responding for this particular issue which has been raised.

**Prakash Agarwal:** From the timeframe required in terms of any remediation or you do not think so that is even required?

**N. Govindarajan:** First of all remediation would come in picture for a different purpose, not for this OOS, Prakash, let me clarify that. First of all remediation word itself is a wrong connotation here is what I believe, Prakash. Any comments from you Bob and Ron in terms of the remediation?

**Ronald Quadrel:** I think you summarized it quite well. I believe it was a laboratory issue, and the investigation determined it was human error. I think we did an excellent CAPA investigation and I do not believe there will be any long-term FDA repercussions.

**Prakash Agarwal:** Just a double clarifying**;** there is no communication as voluntary action indication or official action indication VOI or?

**N. Govindarajan:** First of all let me explain you, when Form 483 is initiated, there has to be an action that has been initiated which is in terms of our response which has to go within 15-days, beyond this whenever a Form 483 is issued with any observations which could be as minimal as a minor observation to anything, it would be coming under the company's voluntary action.

**Prakash Agarwal:** Secondly, just one more clarification; there is a comment made by your US team on Raloxifene. Did he mentioned it has been launched through a partner?

**Robert Cunard:** That is correct. We have a partner that we ended up marketing it through, it is not in Aurobindo label right now.

**Prakash Agarwal:** Any specific reason given that we have such a strong basket and strong relationship?

**Robert Cunard:** This is one in particular that they had an existing presence in the marketplace and we thought it was the best way to capitalize on their existing share and maximize the opportunity.

**Prakash Agarwal:** Secondly, looking little longer-term since we are on a good growth trajectory given our strong approvals and handful of approvals waited, we had last time

talked about TADs. If you could help us understand the TAD especially the Injectables?

**Ronald Quadrel:** As of yesterday actually we have 27 TADs under injectable dated between now and August this year 2016. The FDA has accelerated quite a bit on their reviews and we have gotten quite a few approvals. In fact we have received three more approvals this quarter already. As for FDA information requests, we are responding within the prescribed response time from the FDA. FDA ANDA review activity over the last 5-6 months has picked up considerably and we are quite bullish on the approvals that we will be getting for the remainder of this year and next year.

**Prakash Agarwal:** A specific comment on Injectables which you made last quarter, are you expecting more approvals?

**Ronald Quadrel:** Yes, we are expecting probably five more approvals before the end of this fiscal year and we probably will be seeing an equal number of approvals that we have gotten this year to next year also. We have quite a few things in the pipeline. Some of these have been filed 2.5 years ago, 3 years ago and all the FDA reviews are really starting to pick up.

**Prakash Agarwal:** So which eventually would lead to a much better growth despite the high base is what we can conclude like 20-25% growth that we have been doing should be achievable?

**Ronald Quadrel:** I would say we will have some fairly significant growth next year. I do not want to give any numbers at this point but I feel quite comfortable that our growth next year would be as equal to or better than this year.

**Prakash Agarwal:** On Cephalosporin business, third quarter and fourth quarter are normally very strong seasons, we have shared number in the past. Any number you can share and did we see a strong season like Lupin did?

**Robert Cunard:** We did see a mix, now we had some changes as far as the break out on the Cephalosporin business were. We mentioned the third party sales. We had some business migrating to that specifically under the current program. So we did not break those up specifically but we did see growth overall similar to what we have seen in the market.

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

**Ranjit Kapadia:** First thing is regarding Peptide and Hormones. If you can give update on that? Are we in the process of entering Depot Injection space? Second question relates to debt reduction program. Currently, you stated debt is about $610 million. So how are we going ahead for this FY17, what is the expectation of debt reduction?

**N. Govindarajan:** On the Hormones and Depot Injection before Ron comments on that, as far as Peptide is concerned two DMFs were already filed and the third DMF would be filed in the current quarter. Already three more product validation batches are going on and further few more products are in the pipeline. So they would continue filing DMF as you might have seen in the last few quarters, at least every quarter or second quarter you will see one or two DMF getting filed. So that trend would continue for the next few quarters is what I would say as far as Peptides are concerned. Over to you, Ron in terms of Hormones and Depot Injections before Subbu can comment on the debt reduction.

**Ronald Quadrel:** On the Hormones and Oncology products, which are both on the same Eugia site, we are presently looking at 15 Injectable Oncology Drugs and several more Hormonal Drugs. As I mentioned earlier, we would expect filing our first group of those in about 4 to 5 quarters. In terms of the Depot Injections which are the Liposomal and the Microspheres products I had mentioned earlier, I am expecting that we will be filing at least three of our four products in 2017. So things are progressing very well on that front.

**Santhanam Subramanian:** In terms of the debt, we have achieved from $662 million to $610 million with the new launches, etc., taking place. We do not see any significant increase taking place. It will be in and around this number only.

**Ranjit Kapadia:** So any debt reduction program for coming year?

**Santhanam Subramanian:** Between now and March '16 there will not be any major debt reduction program. FY17 we will be working on that and we will get back in the next call.

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

**Nitin Agarwal:** My question is around the other expenses. If we have seen them pretty much flat lining out for the last 3-4-quarters now despite a healthy increase in the revenues and I presume of our R&D cost would also be included in these SG&A expenses which I presume would have been going up. So can you help us explain in terms of how we are managing to control these other expenses?

**Santhanam Subramanian:** That other expenses if you really see it is not only flat at the overall level, it is flat at most of the regional clusters also. There may be a slight increase on account of the inflation but we do not see any significant increase taking place at this stage apart from any R&D program which we are planning to do.

**Nitin Agarwal:** I was just trying to understand, this is quite unusual given the scale and the growth in the business. What are the kind of measures that we are taking, is there anything specific we are doing which is working so well for us? Other cost in the international business, it has been quite flat and it has been managed and I am sure you have been doing some restructuring.

**Sanjeev Dani:** Basically, we have integrated the management. That was the first point which helped us to control some of the cost. Second thing of course streamlining the operations in terms of the forecasting, in terms of better market information, etc. and the supply chain management. Any inventory overstocking or write-

off or any other debt provision, those things are better controlled and that has led to good control of the expense.

**Nitin Agarwal:** On the ARV in the presentation we mentioned about opportunity coming through with a new molecule tie-up that we have with Gilead. If you can give us some handle on when do you see this business scaling up for you?

**N. Govindarajan:** Dolutegravir currently the registration part is going on. So we expect the sale to start by calendar year 2017 and as per the last report of Clinton Foundation in the next 2-3 years they expect it to peak to around $2 billion across those PEPFAR markets as an addressable market. We believe that since we are one of the first licensees and this also has been backward integrated, we believe that we should be able to grow starting from FY'17-18.

**Nitin Agarwal:** How many players do you see being competitive sort of competing aggressively in this market?

**N. Govindarajan:** As far as ARV is concerned, we always have those four players would be relevant in terms of the markets, we expect those four players to be here, but we still believe since we have the advantage of almost a year or more in terms of having signed earlier and having gone through the trials and all, we believe that we would be able to take advantage in terms of that period apart from typically the first mover also has some good level of market share they can maintain over a period of few years.

**Moderator:** Thank you. The next question is from the line of Nimish Mehta from Research Delta Advisors. Please go ahead.

**Nimish Mehta:** Two questions; one, of late with the approvals like Angiomax that is Bivalirudin and that of integrellin, what we have noticed is that we have not been filing DMF for those products. So, just wanted to know because our philosophy is to have fully integrated launch portfolio so that we can compete effectively so?

**N. Govindarajan:** First of all please understand the fact that we already have partners in existing products and we are happy with the partnership to continue and there is no need for us to prioritize at the bulk When we started the bulk when there are certain products which are prioritized in terms of opportunity for NCE-1. Even though in the past our philosophy is to backward integrate every product possible. Nowadays, we are also looking at if we can run better products than existing products where we have good partnership, we would like to continue with that.

**Nimish Mehta:** Just partnerships would be a kind of on profit sharing basis or how will it be?

**N. Govindarajan:** Not necessarily. When I say partnership is they have supported us in terms of going through the entire filing program and approval. So that itself is a partnership not necessarily profit sharing.

**Nimish Mehta:** If you can just share us the CAPEX that we have incurred in this quarter and what is that we are likely to incur in Q4?

**N. Govindarajan:** As mentioned $40 million is what I remember in the initial comment in terms of the current quarter and annualized basis we expect it to be around Rs.1100 crores. Since we have raised the CAPEX I would also like to clarify that our fixed assets turnover ratio is around 2.5 to 2.7x and we along with our key investor had done analysis in terms of our peer group and we clearly believe that we are in fact equal or better than the industry average. So we believe that our CAPEX is pretty normal and this year it will be around Rs.1100 crores is what we expect.

**Nimish Mehta:** You mentioned $40 million we have incurred this quarter, right?

**N. Govindarajan:** Yes, sir.

**Nimish Mehta:** If you can just let us know the number of 483s that we have received that will be great?

**N. Govindarajan:** It is 4 observations.

**Moderator:** Thank you. The next question is from the line of Sameer Baisiwala from Morgan Stanley. Please go ahead.

**Sameer Baisiwala:** If my understanding is correct, I thought that Aurobindo was in the queue for Valganocyclovir is it something that you are expecting an approval anytime soon?

**Robert Cunard:** We do anticipate approval at some point. This is another product where we have a targeted action date of April. There are some labeling changes that need to happen that are at the FDA right now and that involves the overall market. We do anticipate being there immediately upon approval and that is likely in early fiscal 2016-17, so in the April-May timeframe.

**N. Govindarajan:** Just to clarify, Bob, we are ready with the product for launch expect for the label whatever changes which is needed, I think we can make it and quickly go ahead with the launch. Is that right Bob?

**Robert Cunard:** That is correct, we are ready to launch immediately.

**Sameer Baisiwala:** You said the target action date is April, did you not for this?

**Robert Cunard:** Correct.

**Sameer Baisiwala:** If I remember your earlier comment, did you say that for Suprax you are expecting more generic competition in a quarter or two?

**Robert Cunard:** Actually we do not see anything right now. It certainly could be something that happens in the next fiscal year, but at this point we do not see any additional competition.

**Sameer Baisiwala:** But do you see it next fiscal year is that what you are saying or?

**Robert Cunard:** I would be surprised if we did not have another player but once again that is ….

**Sameer Baisiwala:** Govind, on the 483, one part I did not get in respect to NAI or VAI, do you think FDA necessarily classifies them and then is it under any obligation to then let the company know?

**N. Govindarajan:** Ron or Bob you can even help me. Whatever I understand is whenever a Form 483 is issued with any observations which could be as minimal as a minor observation to anything, it would be coming under the company's voluntary action.

**Ronald Quadrel:** If we do not get 483 you have no action required. If you get 483 normally always get a voluntary action required.

**N. Govindarajan:** In case there is a serious violation, then it would get into official action initiated

**Ronald Quadrel:** Typically if it gets more serious you get an action letter and then a warning letter behind that

**Sameer Baisiwala:** So FDA has not indicated anything to you but you are assuming that you are VAI, is that what you are saying?

**N. Govindarajan:** Yes, any Form 483 will always qualify as voluntary action initiated by the company which is in terms of the responses followed by the EIR. I will give an example. Silicon which is our non-sterile API facility for Penem was inspected, there were four observations which has been issued and Form 483 it is considered as voluntary action which has to be initiated by the company in terms of the responses and once that is accepted then there will be an issue of EIR which we had received.

**Moderator:** Thank you. The next question is from the line of Surjit Pal from Prabhudas Lilladher. Please go ahead.

**Surjit Pal:** Could you please give us an idea because earlier you were expecting some 3, 4 niche generic injectable approval, which could drive your growth in Q4, given that already one-and one-and-a-half months has gone by and there is

no such approval, do you still believe that kind of opportunity last in Q4 or you shift that into Q1?

**Ronald Quadrel:** We have had three approvals in Q4 already. Tranexamic Acid, Levetiracetam, and Isosulfan Blue as well as the ones we had in Q3. Most of our Q3 approvals came in the last month. As I indicated earlier we are still sticking with our guidance and I expect a very large fourth quarter and then from there we move up next year.

**Surjit Pal:** So a product like Vancomycin or a product like Pantoprazole do you still believe that you can get this approval in Q4?

**Ronald Quadrel:** Vancomycin we probably will not get approval in Q4, but we are expecting Pantoprazole to be approved.

**Surjit Pal:** Another thing is that your FOREX gain in your interest, could you please help me because generally when dollar goes up, it is generally a loss?

**Santhanam Subramanian:** What has happened this quarter the volatility of the dollar against rupee was very less compared to current scenario and also we were able to borrow at better rates for the working capital purposes against the closing price. That is the way we are able to generate some income on the FOREX.

**Moderator:** Thank you. The next question is from the line of Isabel from Putnam. Please go ahead.

**Isabel:** I just had two questions; first of all, looking at the margin production so far you have done probably better than most people showed. I was just wondering if you think this trend can hold up if you think that the sales are accelerating or stronger in the fourth quarter and next year or do you think we should think about you have had a bit less sales but you focus on the very high margin products and therefore maybe the margin cannot hold up as the sales come through stronger? Question two is on the HIV opportunity. Is that an above or below margin opportunity because I always saw that HIV is a bit

lower than group margin, but if you are the only one or it is less competition in the TVK family, how should we think about the margin opportunity for this?

**N. Govindarajan:** I will answer both the questions. As far as the margin is concerned in terms of the next couple of quarters we clearly believe that the margins are not only sustainable, it could be even better. That is as far as the short to medium term I am saying. I am not commenting for the long-term basis. On the second question which you have asked about HIV, we believe that as far as Dolutegravir is concerned since it is a new product which is getting into the market the margin should be better than the typical ARV margins is what we believe. Would that be the same for the long term? I am not saying that, but at least for the foreseeable future of two years or so at least definitely the margin should be sustainable, should be better than any ARV portfolio.

**Moderator:** Thank you the next question is from the line of Nishit Shah from Ambika Fincorp. Please go ahead.

**Nishit Shah:** Govind, we have seen in many other companies' cases that in the emerging markets they have lost significant amount of money, on cross currency, etc., So do we have any such hit during this quarter on account of emerging markets?

**N. Govindarajan:** Sanjeev had already clarified, there is no significant impact due to the currency issues in terms of the emerging markets.

**Nishit Shah:** When you say not significant, you are saying that it is not even worth mentioning about it?

**N. Govindarajan:** Could be a million dollar plus or minus is what we are talking about. I do not see that making a major impact in either way. Probably I would request Sanjeev to explain.

**Sanjeev Dani:** That is right, we invoice in dollar in many countries and then there are subsidiaries in some market where there is an adverse impact in terms of local

currency translation to even Indian Rupee. Overall, it is insignificant impact. In any case emerging markets is just about 6-7% of our business.

**Nishit Shah:** Second question is Govind, on the color on new technology, the complex product that you are giving a thrust on. If you could give some color on various areas on which we are working on?

**N. Govindarajan:** Ron has already explained in terms of Hormones and Oncology over the six to nine months and Microsphere would be following after that and clearly there is a thrust on that. Our belief is as we progress the differentiated portfolio would be significant as we move forward compared to the current scenario both in finished dosage as well as in terms of even API. At one level even in API our so-called Beta-lactam used to be around 90%, it is at 65%. Our objective is even to bring that down close to 50%. Overall, clearly there is a shift which is happening and the thrust is on that only.

**Nishit Shah:** On the focus on free cash flow generation, Govind, I think there was some question asked on this, but it was not elaborated. You have reduced debt which is commendable that $52 million in an expanding mode. But going forward, how do you see this trend?

**N. Govindarajan:** The free cash flow should improve starting from next financial year. What Subbu said is that he does not have a specific number at that juncture because he is working out, but definitely from next year onwards the free cash flow should be better than where we stand today and that will keep improving as we progress.

**Nishit Shah:** Lastly on that which keeps hounding every time is on the fund raising program on the QIP especially, would you roll out a QIP at any point in time in the near future?

**N. Govindarajan:** We will not go ahead with QIP.

**Moderator:** Thank you. We have time for one last question from the line of Kaushik Pal from Manulife Asset Management. Please go ahead.

**Kaushik Pal:** On 483, that happens to be the one that has caused the most nervousness is the one relating to customer complaint because one of your competitors recently have mentioned in their warning letter, I think a lot of people asked about the root cause analysis but if I am not wrong, this was not discussed. Can you just briefly elaborate on this?

**N. Govindarajan:** It was discussed and I would like to clarify that whenever out of specification happens you start with the lab investigation and in the lab investigation there are two possibilities -- one is the equipment error, other is the human error. So that is also part of the root cause analysis when we do in the lab investigation. If this gets addressed in the lab itself, then you do not progress further in terms of any other investigation on manufacturing or other aspects of it. We believe that we have done that and we found that human error is there. In the response, our team will also be looking at whatever further strengthening has to be done in terms of this particular OOS investigation. Having said that we have been issued a Form 483 and our team is working on the same wrt the response.

**Kaushik Pal:** The customer complaint that is mentioned, can you let us know where are we on this?

**N. Govindarajan:** The customer complaint what we are talking about is for a specific product where there are around 12 complaints over a period of two years. We have done enough work in terms of looking at each of the specific customer complaint and finding out what is related to any of our unit or any of our manufacturing aspect of it. We have deep dwelled on to it to the extent of doing even certain aspects like LC, LCMS and all of which absolutely will give us clarity on the issue. Suppose, let us say there is a latex where it has come from and whether we could relate it to our facility in terms of the correlation.

So there is enough work which is going on and we have done somewhere around 1100 to 1200 batches, out of which this is better than even six-sigma.

**Kaushik Pal:** What you are saying related to the customer complaints, your investigations have already completed or there are already going on?

**N. Govindarajan:** It is under progress, we will do whatever work we need to do before we respond, and we will be completing that which will also happen in the next few days. Typically within 15 days we would be responding. The inspection has happened 5-7 days back. We have another week to respond is what I remember. We would be completing that and be responding.

**Kaushik Pal:** There were some newspaper reports about API for government business being sourced from US. Now, can you maybe quantify what kind of sales or what percentage of EBITDA might be coming from the government supplies in US right now and whether do you think this has a significant risk?

**N. Govindarajan:** Instead of getting into the quantification at this juncture, first of all, I am sure you might have read the clarification from the same newspaper as well as from others in terms of this not being reality in terms of what is being construed. So I would like to conclude that way rather than looking at that as a risk at this juncture.

**Moderator:** Thank you. I would now like to hand the conference over to Ms. Deepika for closing comments.

**Deepika Gupta Padhi:** Thank you all for joining us on the call. If you have any questions unanswered, please feel free to get in touch with Investor Relations. The transcript of this call will be uploaded on our website www.aurobindo.com Thank you.

**Moderator:** Thank you very much, members of the management. On behalf of Aurobindo Pharma Limited that concludes this conference call. Thank you for joining us and you may now disconnect your lines.