



# “Aurobindo Pharma Q4 / FY2014-15 Earnings Conference Call”

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**MANAGEMENT:**

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**Moderator:** Ladies and Gentlemen, Good Day and Welcome to the Aurobindo Pharma Q4 FY15 Earnings Conference Call. As a reminder, all participant lines will be in the listen-only mode and there will be an opportunity for you to ask questions at the end of today's presentation concludes. Should you need assistance during the conference call, please signal an operator by pressing '\*' then '0' on your touchtone telephone. Please note that this conference is being recorded. I now hand the conference over to Mr. Subramanian. Thank you and over to you, sir.

**Santhanam Subramanian:** Thank you. Hello and Welcome everyone to Aurobindo Pharma's Earning Call to discuss the Unaudited Results for the Fourth Quarter and the Audited Result for the Full Year. We released our Q4 FY Results yesterday and the same is available on our website for your reference. I am Subramanian and with me we have the senior management of the company represented by Mr. N. Govindarajan – Managing Director, Mr. Arvind Vasudeva – CEO, Formulations; Mr. Robert Cunard – CEO, Aurobindo Pharma USA, Mr. Ronald Quadrel – CEO, AuroMedics Pharma USA. We will begin this call with the opening remarks from the company's management followed by an interactive Q&A session.

Please note that some of the matters which we will discuss today are forward-looking and without limitation, statements relating to the implementation of strategic initiatives and other affirmations on our future 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 obligations to publicly revise any forward-looking statement to reflect future events or circumstances. We expect this call to last about an hour. And with this, please let me turn the call over to Mr. Govindarajan for his opening remarks. Over to you, Govind.

**N. Govindarajan:** Thank you, Subu. We are here to discuss unaudited numbers for 4<sup>th</sup> Quarter of fiscal 2014-15 along with corresponding periods of the previous year. As far as our revenues are concerned, our consolidated net operating income in Q4 FY15 grew by 36% to Rs.3,162 crores over Q4 FY14. Gross sales from Formulations have been at Rs.2,517 crores recording a growth of 56% over Q4 FY14. The US Formulations sales was at Rs.1,341 crores, have grown by 20% against corresponding quarter last year, which was at Rs.1,116 crores. Cephalosporin represented \$12.4 million of sales for the quarter. Aurobindo Pharma USA continues to deliver strong revenue growth despite on it's its customer consolidation, competitive pressure and in the absence of any significant new launches during the quarter through increased market penetration of existing products. In Aurolife, the manufacturing arm of Aurobindo USA, the growth has been due to the penetration of controlled substance. AuroMedics, the company marketing Injectable products in USA continued to outperform and generated 17 million revenue in Q4 FY15 and cumulative USD68 million for the year, growing by 84% year-on-year as a whole.

During the quarter, we have integrated the operations of nutritional supplement maker Natrol which we had acquired during the month of December 14 and manufactures and sells nutritional supplements in

USA. The financials of the acquired entity have been integrated effective 4<sup>th</sup> December 2014. Natrol achieved a turnover of \$31 million during the year which affectively is from December 4<sup>th</sup> till March 31<sup>st</sup> of 2015.

In terms of our US filings, we have 376 ANDAs filed as on March 2015. We have received 166 final approvals, 27 tentative approvals and the balance 183 ANDAs are under review. The unit wise filing and approvals are as follows: From Unit-3, 115 filed, 111 approved; Unit-7, 135 filed, 35 approved; Aurolife, 26 filed, 9 approved; Unit-4, 66 filed 8 approved; Unit-12, 19 filed, all of which has been approved; Unit-6, 11 filed and 10 approved and Auronext, 2 products have been filed so far. Unit-3 and Unit-7 manufactures oral non-betactam products and Unit-4 manufactures general Injectables and ophthalmic products and Unit-6 and Unit-12 manufactures Cephalosporin and SSP products respectively. And Auronext which has its facility at Bhiwadi, Rajasthan is manufacturing Penem Injectable products.

Europe recorded a sale of Rs.769 crores in Q4 FY15, thereby growing by almost 4.3 times over corresponding period of last year which was at Rs.177 crores, this has been largely on account of our acquisition of the Western European Commercial Operations of Actavis to help enhance our European presence. France has been our biggest market in Europe, followed by Germany, Netherlands, UK, Spain, and Portugal. The profit numbers for integrated European operations has been in line with our expectations for the year, however, the revenues numbers are low due to depreciating exchange rate of Euro during the year. The Rest of the World Formulations sales has been at Rs.134 crores in Q4 FY15 against the previous year of 126 crores in Q4 last year, the focus market being Brazil, Canada and South Africa. ARV Formulations sales increased by 52% to Rs.267 crores against 195 crores during the quarter as we have started executing some notable tenders and surpassing some of the combination products which has helped growing this segment.

The US Formulations contributed 53% to the overall Formulations revenues in Q4 FY15 against 69% last year, and the share of Europe has increased to 31% from 11% in the corresponding period last year. Share of Rest of the World has come down from 7% to 5% while ARV marginally declined to 11% against 12% in the 4<sup>th</sup> quarter of FY15 against FY14. Gross sales from API have been at Rs.676 crores in Q4 FY15 which is lower by 10% over Q4 FY14 which was at Rs.755 crores. The additional sales which had happened in API were moved towards internal consumption in line with the exponential growth in the Formulations business. We started expanding the capacity across various units in API, while certain capacity would kick in by current quarter that is the first quarter of 2015-16, the commissioning of the large block that is the validation has been already initiated at Vizag. The capacity would be streamlined by the second quarter of FY16. Our EBITDA for the quarter is at Rs.656 crores which is 20.7% of net operating income against 32% of Q4 FY14. The Actavis EBITDA margin of acquired entity is in line with our expectation. During the quarter staff cost has gone up by 38 crores and other expenses by 26 crores mainly due to Natrol acquisition. As far as FOREX is concerned, the closing rupee versus US dollar rate was 62.50 in March 2015 and 63.04 in December 2014. The rupee appreciated by less than 1% and accordingly resulted in a net consolidated FOREX gain of Rs.1 crores during the quarter as against the gain of Rs36 crores in Q4 last year. The company's net CAPEX including maintenance CAPEX has been in line and is around Rs.700 crores for full year of '14-15. The majority of the company's debt is

denominated in foreign currency. The net debt is at USD639 million as on March 2015 compared to the net debt of \$599 million in March 2014. Cash and bank balance is about USD75 million. The company has reduced USD64 million of debt as on date but our investment in Natrol has resulted in additional borrowing of USD104 million to fund the acquisition. Growing export revenue offers hedge against repayment of foreign currency terms loans which is payable over the next 4-years. So this is all from our end, and we will be happy to take your questions now.

**Moderator:** Thank you very much sir. Participants, we will now begin with the question-and-answer session. We have the first question from the line of Prakash Agarwal from Axis Capital. Please go ahead.

**Prakash Agarwal:** On the sir numbers if I look at, the margins have come better than expectations. So this is despite Natrol which is a low margin acquisition for us. I understand there has been a Euro depreciation which has resulted in lower loss in Europe, but what could be the other reasons for this, I mean is the US really generating lot of profits specially the Injectable and Control substance?

**N. Govindarajan:** It is a combination of various aspects of the business Prakash, obviously the largest being the US which is both the orals as well as Injectable which are improving. As you might have seen the growth in both orals as well as from Aurolife apart from that Injectable also if you had seen they have grown by almost 84% in terms of the sales and obviously the bottom line would be far better than the previous period. So it is a combination of various aspects like this has really improved the margin.

**Prakash Agarwal:** So you would say Injectables as well as orals in the US have led to better margins?

**N. Govindarajan:** Yes.

**Prakash Agarwal:** Okay. And sir secondly on the outlook, so we had a very good year with some acquisitions first half with free cash flow, second half with acquisitions. So how do you see the fiscal '16?

**N. Govindarajan:** So we do not give any projections or forward-looking statements Prakash but we are fairly confident because of the fact that we still have enough headroom left in terms of the continuing growth of both oral and Injectable in the US and Natrol also contributing in the current year in terms of the bottom line. Over and above that the turnaround of Europe wherein we will breakeven at the PAT level.. And the growth which can happen both in terms of Rest of the World, API as well as ARV we will definitely further improve is our belief but we do not make any specific forward-looking statements or any projection.

**Prakash Agarwal:** Okay. And last question sir, on Natrol, if you could also help us explain the synergy benefits, because what I understand it is about \$100 million top line with about mid-teens margins. So what is the synergy benefit especially to our OTC ramp up that we are planning?

**N. Govindarajan:** So we do not necessarily look at thy synergy benefit with OTC division, What we are doing is, the advantage of Aurobindo USA in terms of bringing in more customers who were already customers of Aurobindo which in fact Bob has been already facilitating that, that is one aspect of it. Over and above that, Aurobindo USA facilitates certain benefits in logistics or insurance. Aurobindo as such is also helping

in terms of improving the sourcing capability and also collaboratively working in terms of R&D so that we can enhance the product pipeline. So these are the various resources which are being invested in term of our efforts to improve both the top and bottom line in Natrol.

**Prakash Agarwal:** Okay. And like you had earlier discussed on Actavis acquisition to turn it PAT neutral second year, any guidance for Natrol?

**N. Govindarajan:** We are maintaining that in terms of Activis. As far as Natrol is concerned, again, we are not getting into specific projection but definitely our numbers would improve. So if you look at last year they closed somewhere around 96 million, 97 million net revenues and around 14% adjusted EBITDA because of the various cost which they had incurred during the legal process. So current year EBITDA we would like to bring it up close to the company averages which is what we are working towards.

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

**Nimish Mehta:** Just if you can explain us to why has there been Gross margin phenomenally high QoQ basis and that is it sustainable going forward, how do we look at it?

**N. Govindarajan:** So we believe our margins are sustainable Nimish, as I had explained earlier, the question as well in terms of the various opportunities which are available, so we believe the margins are definitely sustainable Nimish.

**Nimish Mehta:** And the increase is because of the change in business mix?

**N. Govindarajan:** Yes. The more high value products which are getting penetrated would definitely have improved the margin.

**Nimish Mehta:** Okay, understood. And did you talk about one-off expenses in the commentary, if I missed, just wanted to know about it.

**N. Govindarajan:** I do not think that we have mentioned about any one-off expenses in the commentary. Subu?

**Santhanam Subramanian:** No, there are no one-off expenses we have mentioned.

**Nimish Mehta:** Okay, fine. And just last one question on the balance sheet side, I see the other liability increasing drastically, so any particular reason, I mean it has been almost 1365 crores versus some 300 crores earlier.

**N. Govindarajan:** Subbu?

**Santhanam Subramanian:** Yes. It is mainly - because compared to last year it has increased we have the Natrol as well as Actavis impact has come this year, hence it is not comparable between last year to this year

- Nimish Mehta:** I was actually comparing with the second quarter results, in that it was actually more than 300 crores in which Actavis acquisition was already built in.
- Santhanam Subramanian:** Actually, it is mainly the creditors coming effectively from Actavis, otherwise last year we had closed around 1800 crores, this year around 3000 crores, it is a mainly of acquisition both in Actavis and Natrol.
- Nimish Mehta:** I see, okay. So that is, I am talking about the other current liability...
- Santhanam Subramanian:** The other current liability-, it is mainly because of we have ECB to the tune of around 60 million going to be repaid within the month of December, so that will be regrouped under the other current liability
- Moderator:** Thank you. Our next question is from the line of Dheeresh Pathak from Goldman Sachs. Please go ahead.
- Dheeresh Pathak:** Sir first question is on Natrol, the products sold under Natrol are all made in US?
- N. Govindarajan:** Yes sir.
- Dheeresh Pathak:** And other expenses you said were higher because of Natrol, so is there a marketing field force for Natrol or is it just supplying to large distributors?
- N. Govindarajan:** No, we do not have a marketing sales force like the similar to the MR, so what we have is a sales team which is regionally based and they are selling, so they are not going store to store. So the predominant sale is to the mass marketing retail, so hence we do not have a field force as such.
- Dheeresh Pathak:** Sir how many employees have you taken as part of Natrol?
- N. Govindarajan:** 215 people.
- Dheeresh Pathak:** 215 people?
- N. Govindarajan:** Yes, 2-1-5.
- Dheeresh Pathak:** Okay. How many are in sales and marketing out of that?
- N. Govindarajan:** Approximately 24 people.
- Dheeresh Pathak:** So this is high compared to the, so it would involve some element of detailing?
- N. Govindarajan:** No, the 24 people includes sales team, marketing team, brand team including the sales & marketing admin team so it would include everybody sir.
- Dheeresh Pathak:** Is there scope for rationalization of that over time?

**N. Govindarajan:** So at this juncture we would like to ensure that we are able to penetrate using this team rather than optimizing that, I mean our objective is to grow by better penetration as well as introducing new product which will definitely improve sales and margins rather than looking the other way around sir.

**Dheeresh Pathak:** Okay, that is helpful. On Actavis portfolio can you give the actual sales in Euro terms for this year?

**N. Govindarajan:** Arvind or Subu, who is going to take it?

**Arvind Vasudeva:** Yes, I can take that. I think we have done in dollar terms about \$ 400 million - \$410 million for Actavis.

**Dheeresh Pathak:** Okay. And our expectation should be that you can grow this by high single-digit, double-digits?

**Arvind Vasudeva:** I will say mid single-digit.

**N. Govindarajan:** No, I think one of the input I can give you just to add to whatever Arvind said, I mean our focus is more in terms of improving the bottom line at this juncture rather than aggressively growing the top line.

**Dheeresh Pathak:** Okay. I think at that time of the acquisition you had said the three phases, one is to add Aurobindo's products with the portfolio and then second was I think to bring manufacturing to India. So you are still in Phase-I?

**N. Govindarajan:** Yes, Arvind will explain that.

**Arvind Vasudeva:** Yes. Phase-I was to integrate Aurobindo Pharma as well as Actavis teams, that phase has been completed, so we have one country, one leader, one team now. Second phase has just begun in the end of last quarter of bringing products into India which will last for next 18 to 24 months which will be this year and 12 months of next year. And with that, it could be closer to 50% portfolio coming out of India.

**N. Govindarajan:** Just to add to Arvind, the facility is getting ready and we expect the inspection to happen somewhere between October-November time line, is that a fair time line Arvind?

**Arvind Vasudeva:** Yes, right.

**N. Govindarajan:** So obviously I think we are in line with whatever Arvind was mentioning.

**Dheeresh Pathak:** Alright. And you have whole bunch of units manufacturing assets, so anything from an FDA compliance point of view that is worth highlighting?

**N. Govindarajan:** So we got our Unit-9 which is an AP intermediate unit and Unit-7 which is our largest oral solid unit, as well as Unit-11 our largest AP unit, all of them have been inspected by FDA.

**Dheeresh Pathak:** Okay. I am assuming everything is okay?

**N. Govindarajan:** Yes sir.

- Dheeresh Pathak:** Okay. And last question if I may, on US sales can you give the sales of AuroMedics and Aurolife for the year?
- N. Govindarajan:** So as far as AuroMedics is concerned, I think it is \$67 million
- Robert Cunard:** Do you want me to take the Aurolife question?
- N. Govindarajan:** Go ahead Bob, go ahead.
- Robert Cunard:** On Aurolife what we have typically done is, the revenue source for that is the VA National contract business or the Federal Government contracts. So for the year it was about \$35 million in that business. Then another large chunk of Aurolife production and products are commercialized through our Aurobindo unit which we do not breakup separately.
- Dheeresh Pathak:** No, the Aurobindo USA would be how much Bob, overall sale for the full year?
- Robert Cunard:** We were just shy of 500 million.
- Dheeresh Pathak:** So in order to break the US sale into four buckets, one would be Auro US, second would Aurolife, third would be AuroMedics and fourth would be Natrol?
- N. Govindarajan:** No, four would be AuroHealth and the fifth would be Natrol, AuroHealth is our Pharma OTC one.
- Dheeresh Pathak:** Okay. How much is Aurohealth for the year?
- N. Govindarajan:** That is right now insignificant because they have started just now in terms of launch, they have launched the product only last quarter so that would be insignificant at this juncture.
- Moderator:** Thank you. We have the next question from the line of Ranbir Singh from Sharekhan. Please go ahead.
- Ranbir Singh:** Sir, just if you could give some organic growth during this quarter excluding Natrol and Actavis business?
- N. Govindarajan:** Subbu?
- Santhanam Subramanian:** Yes, out of the total turnover, this quarter Actavis is 613 crores and Natrol is Rs. 130 crores.
- Ranbir Singh:** Sir in Natrol, what I heard was 31 million has been booked in this quarter or part of it has been in Q3 also?
- Santhanam Subramanian:** Natrol we have done around 21 million and Actavis around 100 million in US dollars.
- Ranbir Singh:** 100 million, okay. And on Margin front we are currently breaking even at Actavis business in this quarter?
- N. Govindarajan:** No, no at the end of the year we are going to PAT neutral in 2015-16.

- Ranbir Singh:** So what has been the loss during this quarter on EBITDA level?
- N. Govindarajan:** This would be below 10 million, so it has been far below 10 million.
- Ranbir Singh:** Dollar?
- Santhanam Subramanian:** Yes.
- N. Govindarajan:** Now Euro and dollar is almost same, I would say yes.
- Ranbir Singh:** Okay. And effective tax rate, can you give any guidance for FY16 in this year has been higher than last year so...
- N. Govindarajan:** Subbu, effective tax rate?
- Santhanam Subramanian:** Effective tax rate for the year i is around 27.5%.
- Ranbir Singh:** Okay. And can you reconfirm the gross debt?
- Santhanam Subramanian:** Gross debt was actually 714 million and cash is around 75 million, that effectively comes to around 639 million is the net debt.
- Ranbir Singh:** Okay. So how was the FOREX debt?
- Santhanam Subramanian:** I think FOREX debt as a whole we are having more than 97%.
- Moderator:** Thank you. Next question is from the line of Ranjit Kapadia from Centrum Broking. Please go ahead.
- Ranjit Kapadia:** Sir my question relates to the Injectable business in the US and the control substances in the US. So if you can give some color how it is going to shape up in the current year, both these businesses?
- N. Govindarajan:** Yes, Ron would take it up in terms of Injectable and probably Bob will follow up.
- Ronald Quadrel:** I believe on the Injectable part of the business we will see some growth on our existing products as well as the products we expect approval for this year. We have currently 43 product family filings under review with FDA. With FDA it is a little difficult to predict exactly how many will be approved during the year but we expect a significant amount to be approved so I am expecting some significant growth year-on-year from this past year probably in the range of 40%, 50% and that is wholly dependent on timing with the FDA.
- Robert Cunard:** This is Bob, regarding the control substances, as Ron said the FDA timing is one of the big questions. If we look at what we did this year with controlled substances, we have six products in the market currently and they generate about 10% of our traditional generic revenue in the US. As we look forward we have seven products that are pending with the agency in the controlled substance space, so we think that

generates significant opportunity for us and the existing portfolio still has some run way as well and we think we can continue to grow on that base line. So this past year we made some penetration into the Dexamphetamine and the Dexamphetamine Combo markets that were nice drivers for the business as well as the Hydrocodone with APAP. So we are pleased with our growth, we think there is opportunity to continue and there will be additional when we get some of these approvals out of the FDA.

**Ranjit Kapadia:** And any more acquisitions are we looking in the US market?

**N. Govindarajan:** So we do not strategically keep stating that, we want to acquire something. So if something comes up interesting we evaluate but we are not looking at any big ticket at this juncture sir.

**Moderator:** Thank you. Our next question is from the line of Surya Patra from Phillip Capital. Please go ahead.

**Surya Patra:** Regards this Auro USA, see that is the oral OTV business which is like annually \$500 million kind of base it has attained, so on this high base effect what is the kind of growth or visibility that you are currently having for future?

**Robert Cunard:** As far as the growth rates, again this is Bob, I think clearly what we understand right now, we have seen some significant customer consolidation and the lack of FDA approvals. They are few things that are kind of on the negative side and have created some margin compression for us. We still have been able to grow in that context through additional penetration of our existing portfolio and then also being opportunistic with new product launches as they do occur. Clearly we are not going to see the growth rates that we have seen over the past couple of years, greater than 40% growth year-over-year just as our base line has grown larger. But we do think we are still an engine of growth, the big question will be how the timing of the customer consolidation and what we have seen in bids and the expected price version from that and how that is all set by some of the timing of FDA approvals. So this has been shared publicly that the FDA is said from now through end of September we will see targeted action dates for the backlog products, being products that were filed prior to October 2014. We have seen a few of those to this point but not a significant number of the 130 plus Oral Solids that we have pending with the Agency. So as we get some more color around that and can estimate timing better, I think we will have a much better idea of what we can do on the growth front.

**Surya Patra:** Out of this 130 odd pending products with FDA, how many are prior to 2014 kind of a filings?

**Robert Cunard:** The vast majority, we just have a few that have been filed subsequent to that.

**Surya Patra:** Okay. And what was the kind of price correction that we have seen because of this channel consolidation for our portfolio?

**Robert Cunard:** We have not really seen the full effect, it has been specific customers so we have seen some compression and it varies product by product as we always have in the case with our business. So in some it was much more significant, others it was minor and then we have seen some opportunities over

the past year so we have seen some price appreciation in some areas. So I really cannot give a number on what we have seen overall as far as that compression.

**Surya Patra:** Okay. And regards this European operation, see if we remove the possibly the estimated number of this acquired business then the base business seems to be like kind of a decline YoY, is that true?

**Arvind Vasudeva:** No, the base business has grown again like I said in the single-digit, so then their European business has now crossed half billion mark.

**Surya Patra:** Okay. And this year your new facility that is the integrated one what you have talked about, by when you are saying it would attain a kind of meaningful portion of your European business can be catered from this particular facility? Some time line if you can provide.

**Arvind Vasudeva:** It is indicative that it will, out of the transfer has happened to current facility, the new facility which will take larger volume will be on stream by end of this year or early next year and like I said transfer will happen or supply will happen from there 18- 24 months from now.

**Surya Patra:** Okay. So that means you are factoring this sight transfer approval of around 12 months' kind of a timeline?

**Arvind Vasudeva:** Yes, because once facility comes up you have to start filing and then wait for inspection and approval.

**Surya Patra:** Okay. And just last one question on Natrol again, possibly we have in the initial comment indicated that a moderated odd kind of steady growth in Natrol business, on the other hand we are talking about the penetration of the business as of now it is very low. And third aspect also with regards to Natrol, we are saying possibly we would be looking for some in license product of something like that. So all these three aspects gives me an indication that possibly the growth should be much stronger growth for Natrol in the subsequent period.

**N. Govindarajan:** So we are not talking about in licensing the products, what I meant about is collaborating on the R&D between Aurobindo and Natrol to enhance the product portfolio is what we said. So we would like to introduce new products which can get into the market. So what is more important is three fronts what we talked about, one is increase the sale, improve the cost and increase the product portfolio as a pipeline. So these are the three areas we are working on it and we believe like definitely the growth would start happening starting from the second half of this year and it will grow further is what we are expecting as we progress.

**Surya Patra:** Okay. Sir currently what is the business opportunity of this Natrol business, the number of products whatever is there with you and what visibility that you are having for the existing basket and what is the kind of new product additions that you are looking for that business?

**N. Govindarajan:** So to give an example that we have started getting into probiotics, we have launched a certain products and we are looking at that portfolio very clearly. So if you really look at probiotics as a portfolio like I think

the leading companies, the products would be in the range of 70 million, 80 million for the particular portfolio. So there are enough opportunities in the market for such product portfolio and we are fairly confident that having started late, it will take some time for us to reach some significant level but definitely I think we will grow in those portfolio as well.

- Moderator:** Thank you. Our next question is from the line of Neha Manpuria from JP Morgan. Please go ahead.
- Neha Manpuria:** Sir first on our debt, given this year obviously we saw the increase because of Natrol, assuming status quo from current level, meaning no acquisition, should we expect debt reduction going into next year?
- Santhanam Subramanian:** Yes, there will be a reduction in the debt going forward, no doubt about it, but we cannot put up a number right now.
- Neha Manpuria:** Okay. Let me ask this way, is there a comfort level or a target leverage that we are looking at and what was like to stable off?
- Santhanam Subramanian:** Currently we are around , 0.7 to one and we will be certainly looking to reduce it but there is no threshold or anything fixed internally.
- Neha Manpuria:** Fair enough. And the second question is, obviously a large part of our US growth now depends on US FDA approvals picking up. What is the sense that you are getting, do we expect an improvement at all going into second half of 2015? And how much of our Injectable filing is in the year one and year two cohort of the GDUFA plan?
- Ronald Quadrel:** This is Ron. From the Injectable perspective, right now we have 43 product Injectable filings in with FDA, all of which were filed prior to this last fiscal 2015 with FDA, with almost no activity from FDA in Fiscal Year 2015.. Last fiscal year we did not have any approvals whatsoever and as a matter of fact, as with most of the Injectable companies in the US, I have seen there was really very little activity. However, end of February, beginning of March things start picking up, we are starting to get some targeted action dates, we are getting questions from the FDA. So we are confident that the approvals will start coming fairly soon, the number of which is hard to predict as Bob said earlier, but it definitely the activity has picked up tremendously from where it was last year.
- Neha Manpuria:** Okay, that's helpful. And my last question is on CAPEX, do we have a CAPEX guidance in mind for FY16?
- N. Govindarajan:** Yes, so we expect it to be in the range of 800 crores to 900 crores Neha, and as we had mentioned we had expended 700 crores last year so with additional capacities coming in this year we are expecting to be around 800 crores to 900 crores.
- Moderator:** Thank you. We have the next question from the line of Mithul M from Lucky Investments. Please go ahead.

- Mithul M:** Sir I could not hear you before, what is the gross debt number including short-term maturities which are sitting in current --?
- Santhanam Subramanian:** It is \$714 million.
- Mithul M:** And how much of that is sitting in current liability sir?
- Santhanam Subramanian:** I think what is sitting in the current liability is to the tune of around INR596 crores it is around \$95 million i sitting in the current liability. .
- Moderator:** Thank you. Next question is from the line of Girish Bakhru from HSBC Securities. Please go ahead.
- Girish Bakhru:** Actually just following on the Injectables a bit, would we have received any target extend date on Injecatble products?
- Ronald Quadrel:** We are and we have and we have approximately I believe 12 product filings which we are currently working with answering questions from the FDA. What they are doing is they are giving us targeted actions dates on some of the filings that there is short amount of questions, where we are getting complete response letters, they are not giving this targeted action dates, basically they want us to answer and then they come back right away. But as I said before, we have 43 active product filings with FDA, about a dozen of those we have some action with the FDA. We are expecting more as we go forward based on what we have seen. And so overall it is a lot more positive than we thought from the previous nine or 10 months.
- Girish Bakhru:** Right. And when you say 12 products which you are discussing with FDA, are these products largely where there is shortage or there are very few players or how is FDA looking at collecting products?
- Ronald Quadrel:** Some of them are, some of them not. I think part of it has to do with a particular reviewer, we have seen some products that we did not expect to have action on, move forward based on the shortages, and some of the products that we expect to hear from the FDA where there are no shortages, we have not heard from yet. So it is quite a mix right now, I really could not say there are because of shortage but it is very dependent on the particular reviewer and the reviewing team for the particular ANDA. But it is looking up.
- Girish Bakhru:** Okay. Second one was on actually control substance. I know you gave a color that that business is also gaining momentum but if you look at the market share data, it is still fairly weak. Like in Natrol we still have like 4%, 5% market share whereas Teva is holding large part of the markets. So what exactly will take the share away from Teva is it pricing or is it the quota which is preventing market share gain?
- Robert Cunard:** We have not had any issues regarding quota and I think one thing is important when you look at market shares is how voluminous these markets are. So we currently are expanding capacity at our US location, we have about 100,000 square feet of manufacturing today, we are going to be doubling that over the next year so that will give us some more opportunity to grow. And once again, we look at the right

opportunities from a margin standpoint as well. So just like any portfolio when we look at the controlled substances, there are some that are very large but very little price and that is not our ideal target so we are looking for the right mix and we will continue to grow in that and I think to reach our goals we do not need to be 20% or 25% in those markets and can still provide a lot of growth opportunity for us.

**Girish Bakhru:** And just lastly on the OTC side, I do know if I missed this part before, how is the launch of Allegra been and if you could comment on whether the earlier guidance of about \$40 million business from pharma OTC is achievable in FY16?

**Robert Cunard:** Yes, as far as OTC, as Govind indicated, that is a very early launch that is a little bit different than our traditional prescription business and you do not have that immediate jump out of the gate upon approval. So with the Fexofenadine that we got late last calendar year, we do have penetration in that and I think that will be a nice driver for us for this year coming as well as the products that we continue to build around that in the monograph space. This year that is probably somewhere between a \$5 million and \$10 million business and then growing from there as we continue to expand the portfolio and a big part of that is developing those customer relationships and get some pilot projects going and then build from there. And that is all in place, so the foundation looks good and we should be able to continue to add additional products to those agreements.

**Girish Bakhru:** How many customers would you have in this business?

**Robert Cunard:** Overall I would say we are probably in the 8 to 10 range right now. Now again when we look at that business it is very different than the prescription business as far as some of the key customers and one of the most notable is Wal-Mart which can represent up to 50% of the total OTC markets in some areas. And we do have a presence with them right now, we think that is an opportunity to grow as well and some of the other customers are in place and will be further additions over the next weeks and quarters.

**Girish Bakhru:** And just correct me if I am wrong, would a 12 month be say an adequate time to prepare an RX-to-OTC switch filing?

**Robert Cunard:** Yes, I think that is plenty of time as far as the filing but with those things, the FDA approvals is the larger question, it is not getting that in so easy as getting that out.

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

**Jigar Valia:** Couple of questions, one is on the Actavis, for the Actavis phase two was it always planned at there would be a separate dedicated facility for the Actavis manufacturing in India or would it actually be across the plants?

**Arvind Vasudeva:** It is across the plant, we have supplies to Europe from Unit-3, Unit-7 and the new plant which is coming up will have product which are getting transferred but whatever molecule commonality we had like we said earlier we have supply coming from Unit-3 and Unit-7. And the newer ones which had come from Actavis acquisition will come from both these units as well as the new units.

- Jigar Valia:** Got it, perfect. My second question pertains to the Injectable business, of the overall Injectable portfolio that we are addressing if you can split how much is the general Injectable and complex how many products out of the 40 and maybe a market size potential?
- Ronald Quadrel:** The 43 products, two products are Penems, the remainder of the products right now are the general handling products that would go into the Unit-4 facility. I would say the majority of our sales of new products over the next two years will be from what we will consider the general handling Injectable products, within that general handling there are cardiovascular products, there are neuromuscular blockers, and there are general antibiotics. But most of the newer products with the exception of the Penem products are all from Unit-4.
- Moderator:** Thank you. Next question is from the line of Rakesh Jhunjhunwala from Rare Enterprises. Please go ahead.
- Rakesh Jhunjhunwala:** I wanted to know I read that we have filed an HIV drug in association with the innovator and the Clinton Foundation which allows us to sell that drug outside America, so how significant is that business?
- N. Govindarajan:** Sir the products name is Dolutegravir sir and this is launched by the innovator in fact last year and what is significant is it typically this is something where people would have waited to go through medicines patent pool. Whereas Aurobindo was considered as a preferred partner in terms of transferring the technology to Aurobindo to speed up the access as a generalization to the various markets. So the product is pretty early but it is a pretty good product from a dosage angle because it is a very low dose compared to the existing product which have higher dosage and we are pretty optimistic about the opportunity for this product sir. The only challenge for us is we have to work with all these tender market to ensure that this is being introduced in this tender, now that we have applied for the product and we will parallelly work in terms of introducing this in terms of this tender markets and then we will accrue the benefit out of it.
- Rakesh Jhunjhunwala:** No, but what is the kind of volumes will that have?
- N. Govindarajan:** Sir it is too early at this juncture to come and tell volumes sir but this can replace one of the existing products which has pretty high volume sir.
- Rakesh Jhunjhunwala:** Right. So there is a product, it is a good product with good potential?
- N. Govindarajan:** Absolutely sir.
- Rakesh Jhunjhunwala:** Because if we are chosen there won't be any generic competition in it?
- N. Govindarajan:** No, there will be, see there will be a gap but definitely there will be generic competition because it also has been brought into medicines patent pool later but we have headroom compared to others for a period of year or so. The others have to now start developing and then they have to file whereas we are the first one to file.

- Rakesh Jhunjunwala:** Right. Another thing which I wanted, this Suprax we already launched?
- N. Govindarajan:** Yes sir.
- Rakesh Jhunjunwala:** Is it a good product for us, is it something substantial?
- N. Govindarajan:** Bob will be able to answer that sir. Bob?
- Robert Cunard:** Yes, that was outside the 4<sup>th</sup> quarter, we launched it in April shortly after approval and at this point it is still early but the market is kind of shaped up as we anticipated, Lupin did introduce their own generic label as well but the market has been somewhat proportionately split and price assumptions and everything are in line with what we estimated. So right now it is strong product for us and hopefully we have as much limited competition on that as we can get.
- Rakesh Jhunjunwala:** And how is the, I read some notes and we are going to make big investment into pesticides and derma and ophthalmology, all kind of nodes going around. I mean what is the reality, what are the other areas which we are looking at?
- N. Govindarajan:** I believe it should be peptide, sir as far as peptide is concerned our first DMF is going to be filed by this quarter, by the end of this quarter, the second product would be by next quarter. So we expect every quarter one product to be filed as we continue in terms of the API level, the DMF. What is more significant which Ron can throw more light is like apart from forward integrating in terms of microsphere and Ron you can throw some light in terms of the microsphere products?
- Ronald Quadrel:** Sure. This past year we formed a group in the US here, specifically to develop some microsphere and liposomal injectable I products. This year by the end of this fiscal year we will have invested about \$6 million in to the four projects that we are currently working on. The addressable market of those four products is about \$3 billion. We are expecting that we will start filing these products probably end of calendar 2016 beginning 2017 because there are some lengthy BE studies that have to be conducted and also physical chemical characterization studies. I am expecting that our first approval will probably be sometime in calendar year 2018 with the first product followed closely by the other three products.
- N. Govindarajan:** But what is more important is sir these products would have limited competition unlike the typical products.
- Rakesh Jhunjunwala:** And they are on the peptide area?
- N. Govindarajan:** Yes sir. This is on the microsphere which is a forward integration of the peptide.
- Rakesh Jhunjunwala:** And the pardon my ignorance I don't understand microsphere and what is peptide there?
- N. Govindarajan:** It is a peptide sir basically, sir chain of amino acid sir.

**Rakesh Jhunjunwala:** Okay. So it a \$3 billion products?

**N. Govindarajan:** Yes sir.

**Rakesh Jhunjunwala:** A limited composition and we are trying to file for this?

**N. Govindarajan:** Yes sir.

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

**Nishit Shah:** My question is on Penems, Govind if you can throw some light on the time lines that you see in terms of when the new Penems that you are going to file and ones which you have filed I believe more than a year has gone through, so any time the FDA inspection should be triggered. And then on the peptides, while Rakesh asked you on this question but you have six peptides on development and when do you expect those to be filed and when do you expect that to be approved by the US-FDA? And the third is on the oncology and hormone side, when do you expect your first filing in the US?

**N. Govindarajan:** I think Ron would take up both the oncology, hormone as well as the Penem and then I will come back on the peptides please. Ron?

**Ronald Quadrel:** Okay. On the Penems we have filed Meropenem, Doripenem, I would be expecting the meropenem most probably to be approved sometime before the end of this particular fiscal year. We do have to have the FDA Inspection at the facility because it is a brand new facility. And what I am hoping is that as we get closer towards the fall, hopefully the FDA would come in. Doripenem, we have a Para-IV, it is a very small product, sales wise. Doripenem has been declining with time, it is probably down in the \$10 million to \$15 million range for the total market. However, Ertapenem which is probably the biggest of the four penems that we are working on which comes off in November 2017 is now probably in the \$240 million range. We are developing that as we speak, we are hoping to file that sometime before the end of this calendar year, maybe the beginning of next calendar year with the hope that we are there when the patent expires. The last product that we are working on which we are intending to file within the next two months is Imipenem Cilastatin that market is already genericized; probably about \$70 million market. So within the four products it will probably about \$400 million addressable market which I believe will do very well for the competition there and particularly since we are in a position where we are vertically integrated I think we should do well.

In terms of the hormones and oncology products, our two facilities are completed. We have just done our first exhibit batches for the hormones for several of the products so I would expect that the filing for the first hormone products will be sometime in the next seven to eight months. The oncology facility, the tablet part of the oncology facility is completed and commissioned, we are starting to run our exhibit batches now. The Injectable portion of that oncology facility should be commissioned within the next three, four months. We are developing in parallel our products there and we expect to start running our exhibit batches sometime I would say probably somewhere in the November range. Based on having six months requirements by the FDA and looking out I do not believe we are going to have any approvals in

the next calendar year, we will probably start having approvals two years out, depending on FDA review time for the hormonal products and shortly afterwards with that on the oncology products.

**N. Govindarajan:** And just to add on the penem apart from whatever Ron has said, we have already filed in EU for Meropenem in October 2014, the inspection is already over subsequently we have filed the product and also filed in South Africa and we already got the approval in Brazil. And in fact Imipenem is also filed in Brazil in 2012 so the experts have already started for Meropenem in Brazil and some quantities are also going to Mexico. So next year could be the commercialization as Ron was explaining about the approvals accruing.

**Nishit Shah:** Okay. So you already started selling in other countries apart from US, is that correct?

**N. Govindarajan:** Not a major way I would say, like I think the capacities would be like more optimal when we get the EU and the USA as such.

**Nishit Shah:** Okay. And when do you expect the EU approval, your inspection is already through, right?

**N. Govindarajan:** No, our filing happened after the inspection only that is how the procedure is. In fact our approval we would expect towards the end of the year or beginning of next year is what I would say in terms of the calendar year. And the peptide, yes, six products development has been completed right now, three products validations are running, one is in stability which would be filed by the end of this quarter let's say June end. So next quarter one product would be filed because that is also stability studies has started, and the third product would be filed by at the end of next quarter or the subsequent quarter. So every quarter we expect at least to file a product is what I would say as we progress.

**Nishit Shah:** And would you like to give some color on the market side on the peptide and at some conference call you had said that you will be able to have the capability to manufacture all the 33 peptide, right?

**N. Govindarajan:** Yes, we have the capability to manufacture those commercially available products, except for one which is a large volume fermented product, other than that we have a capability of manufacturing most of the other peptides.

**Nishit Shah:** Okay. And one more thing, you have acquired 60% stake in one of the biotech companies, would you like to throw some color on that?

**N. Govindarajan:** Last call we had clarified it is Tergene Biotech where they are developing a pneumococcal vaccine, so our objective was in terms of there is a need for the product in the tender market and we clearly believe that I think we can collaborate with Tergene to take that product into commercialization. So that is the JV which we had announced and we had given more details on that as well.

**Moderator:** Thank you. We have the next follow-up question from the line of Ranjit Kapadia from Centrum Broking. Please go ahead.

- Ranjit Kapadia:** Sir my question relates to Australian market, you have divested our Australian business to the partner and can you sir give some details that why this has been done and we have given as I understood the ANDAs back to them.
- N. Govindarajan:** Arvind?
- Arvind Vasudeva:** Beyond US and Europe we will focus on only specific market which are larger in number and Australia was not fitting into that, it has a very high regulatory cost and it was not scaling up, so we have divested that business. However, we are supplying the products to this company two more customer whom we supply this product for Australian market. This customer supply business will be profitable.
- Moderator:** Thank you. We have the next follow-up question from the line of Nimish Mehta from Research Delta Advisors. Please go ahead.
- Nimish Mehta:** Sir you mentioned that we are likely to shift our products of the Actavis acquisition to the India facility, can you just let us know what would be the rough cut cost of filing one product, shifting one product and how many products we are targeting in the first year?
- Arvind Vasudeva:** See, like I said earlier we will be shifting some of the products into our site which will be less than 50% of the acquired portfolio. And regulatory cost varies from country-to-country and varies from the type of variation, so I won't be able to give you one number, it varies from country and also varies from type of variation that we file.
- Nimish Mehta:** So we would be targeting at shifting one product to Indian facility for all the markets, right, that would be the objective?
- Arvind Vasudeva:** We are doing market by market, prioritizing the larger market and then the profitable products and following wherever the benefit is more, we are prioritizing countries and we are prioritizing the product.
- Nimish Mehta:** Okay. So how many products we are expecting to transfer this year in FY16?
- Arvind Vasudeva:** I think we should be looking at about 20 product which may multiply in terms of SKUs. But the numbers are in that range like I said in 18 to 24 months we should be moving about half of the product portfolio.
- Nimish Mehta:** Half would be what, about 200? That is including SKUs, right?
- Arvind Vasudeva:** Yes, next 24 month.
- Nimish Mehta:** That would be including SKUs, right?
- Arvind Vasudeva:** Only products, SKU will be much more.
- Nimish Mehta:** Okay. So without SKU how many over 18 to 24 months?

- Arvind Vasudeva:** It will be close to 200.
- Moderator:** Thank you. We have the next follow-up question from the line of Prakash Agarwal from Axis Capital. Please go ahead.
- Prakash Agarwal:** I just have one question on the proposed fund raising that we have taken and enabling resolution for. So the thought process is behind buying something in terms of the growth asset or it would be for repaying the debt?
- N. Govindarajan:** No, I think see it is a combination, because if you remember I think we had to raise the debt again for Natrol which was not budgeted for in terms of on the overall plan, so that is one aspect of it as well as I was mentioning in the call we have a CAPEX in terms of 800 to 900 and further cost which would happen in terms of the filing transfer plus certain BE cost which would happen, clinical trial costs which would happen in to microsphere. So it is a combination of various aspects of it, we looked at the gap and then we thought about going for it. So that is the background.
- Prakash Agarwal:** So the 800-900 crores of CAPEX if you could give broad split how you want to spend it.
- N. Govindarajan:** So we have continuing CAPEX in terms of both the API capacity as well as the finished dosage capacity because whatever spending we have done is only partial in terms of the last year, so for us to complete those expenses plus our filing expenses plus our clinical trial expenses or the various bullet points I can say in terms of the need.
- Prakash Agarwal:** Okay. And lastly on the R&D side, what is the absolute in rupee terms or dollar terms we have spent?
- Santhanam Subramanian:** R&D we have spent around 3%.
- Prakash Agarwal:** 3% of the total sales?
- Santhanam Subramanian:** And in terms of the absolute number it will be of around INR 350 crores.
- Prakash Agarwal:** And last if I can add one more, what is the debt level we are comfortable at, I mean I know the business is growing rapidly and you need lot of working capital and fund through some debt. But what is the level of debt we are comfortable at?
- Santhanam Subramanian:** There is no specific number we are comfortable at, but certainly we have been able to reduce it, today we are around 639 million, we are making every effort to reduce it immediately in the short-term below 600. we work on the target in a phased manner, but there is no specific target for a medium-term to long-term.
- Moderator:** Thank you. We have the next follow-up question from the line of Jigar Valia from OHM Group. Please go ahead.

- Jigar Valia:** Sir, first is the follow-up on the R&D question, how do you expect this 350 crores to increase over the years, and if you can give a summary cost of 200 products have to be transferred over the next 24 months to India for Actavis, what would be the overall regulatory cost? Individually it may differ but approximate cost on regulatory transfers.
- N. Govindarajan:** As far as filing is concerned, Arvind can throw some more light but actually it would happen from the individual country perspective rather than being consolidated as an R&D cost. Arvind?
- Arvind Vasudeva:** Yes, see all products may not need R&D work, it will be more taking validation batches in case that is required. But it is more filing and having variation filed which could be a company name change, address name change, those sort of variations will be done and it will be within the P&L of the local country.
- Jigar Valia:** Cumulatively, any ballpark number in terms of the cost on normal?
- Arvind Vasudeva:** I think we have not looked at that way, we can come back on that please.
- Jigar Valia:** Okay. And overall the 350 crores over the next two, three years given the investments that we are making into peptides and onco and the more complex filings, how do you see this 350 crores increasing?
- N. Govindarajan:** Instead of looking at absolute number we can keep it as like our R&D cost will not be more than 3.5 give or take 0.5% here, let's say 3% to 4% should be the range of R&D expenses.
- Jigar Valia:** And last question, for Tazo-Pip our run rate would be at what about \$30 million to \$40mi approx? And if you can comment on the pricing environment right now.
- N. Govindarajan:** This is on Pip-Taz, Ron.
- Jigar Valia:** Yes, on Tazo-Pip.
- Ronald Quadrel:** Can you repeat the question please.
- Jigar Valia:** On Zosyn – Tazo-Pip generic. Would we be doing run rate of \$30 million, \$40 million plus right now and if you can comment on the pricing environment for the quarter?
- Ronald Quadrel:** The pricing environment is fairly stable, what I mean by that is that we are not able to increase prices where we have contracts. We have raised prices a bit where we do not have contracts. We are probably in the high \$20s millions of sales right now, Sandoz is in the market also, Hospira is now, Pfizer has continued to sell more bags, not **vials**, but more bags. So although we have been able to increase some sales, there is still basically a limit on how high we can go based on the other competitors without getting into the situation where prices starts coming down again.
- Moderator:** Thank you. Participants, that was the last question. I now hand the floor back to Mr. Subramanian for any closing comments. Thank you and over to you, sir.

**Santhanam Subramanian:** Yes. For further information, please visit our website our website, [www.aurobindo.com](http://www.aurobindo.com) or feel free to get in touch with me or our investor relations team with any additional queries that you may have. Thank you everyone for joining us for the call today and wish you a good evening. Thank you.

**Moderator:** Thank you, sir. Ladies and Gentlemen with that we conclude this conference call. Thank you for joining us and you may now disconnect your lines. Thank you.