



“Aurobindo Pharma Limited Q1FY16 Earnings Conference Call”

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MANAGEMENT:

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Moderator: Ladies and Gentlemen, Good Day and Welcome to the Aurobindo Pharma's First Quarter of Fiscal 2016 Unaudited 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 Mr. Roychoudhury. Thank you and over to you, sir.

Tathagato Roychoudhury: Hello and Welcome Everyone to Aurobindo Pharma's Earnings Call to discuss the Unaudited Results for the First Quarter ended 30th June 2015. We released our Q1FY16 results on 1st of August and the same is available on our web site for your reference. I am Roy, handling the Investor Relations of Aurobindo Pharma, and with me we have the senior management of the company, represented by Mr. N. Govindarajan — Managing Director; Mr. Robert Cunard — CEO Aurobindo USA; Mr. Ronald Quadrel — CEO AuroMedics Pharma USA; Mr. Santhanam Subramanian — CFO; and Mr. Sanjeev Dani — COO and Head, Formulations.

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 we will discuss today are forward-looking including 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 developments of our business, a number of risk, 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. We expect this call to last about an hour.

And with that please let me turn the call over to Mr. Govindarajan for his opening remarks. Over to you, sir.

N. Govindarajan: Thank you, Roy. We are here to discuss the unaudited numbers for first quarter of fiscal 2015-16 along with the corresponding periods in previous year. As far as our revenues are concerned, our consolidated net operating income in Q1 FY16 grew by 14% to Rs.3,320 crores over Q1FY15. Gross sales from Formulations has been at Rs.2,637 crores, recording a growth of 16% over Q1FY15. The US Formulations sales which is at Rs.1,430 crores has grown by 28% against corresponding quarter last year amidst pricing dynamics due to customer consolidation. The approval and corresponding launch of Cefalexin Oral Solution during the quarter is an interesting development being the first approved generic on the market. Looking ahead, we have seen a notable change in the review process from FDA with the growing list of products with target action dates that offers better predictability on our new product launches.

AuroLife, our US manufacturing base has seen significant increase in volume of production during this quarter, which is mainly due to surge in government deliveries. The anticipated introduction of some of the recent FDA approved products and increased volumes for government is expected to keep the momentum going over the next few quarters.

AuroMedics, the company marketing Injectable products in USA is experiencing a significant increase in communication and activity from FDA including receiving approvals for four new injectable ANDAs.

We have several products under development including Oncology and Hormonal products which we plan to file over the next 18 to 24-months. We expect the sales uptick from our general injectable facility that is Unit-4 increasing with the launch of the new approvals and improved economics of the commercialized products.

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 with additional business under contract and plan for distribution in late second quarter. The current portfolio consists of 71 products and 111 SKUs developed to-date which are expected to be commercialized. Natrol, the acquired branded nutraceutical entity is also performing as expected.

In terms of our US Filings, we have 381 ANDAs filed as on 31st July 2015, of which we have received 177 final approvals, 28 tentative approvals including 21 ANDAs approved under PEPFAR program and not for commercializing in the US market and the balance 176 ANDAs are under review.

The Unit wise filing and approvals are as follows: From Unit-3 116 filed, 111 approved; Unit-7 141 filed, 42 approved; AuroLife USA 26 filed, 9 approved; Unit-4 66 filed, 13 approved; Unit-12 and Unit-6 19 and 11 filed respectively, all of which have been approved and from 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, Units-6 and 12 manufacture Cephalosporin and SSP respectively and AuroNext has its facility in Bhiwadi in Rajasthan for manufacturing Penem Injectable products.

Europe sales declined by 7% at Rs.741 crores in Q1FY16 over corresponding period of last year which was Rs.798 crores. Currently, the synergies between our acquired businesses from Actavis and Western Europe with our existing ground presence in several markets is translating into improving profitability which has been in line with our estimates and expectations for the year. The RoW Formulations sales grew by 25% to Rs.171 crores in Q1FY16 over Rs.137 crores in Q1FY15, led predominantly by Brazil and South Africa. There has been a growth in ARV Formulations sales by 32% to Rs.295 crores during the quarter as we have started executing certain notable tenders.

In terms of Segmental Classification, US Formulations contributed 54% to the overall Formulations revenue in Q1FY16 against 49% last year. The share of Europe decreased to 28% from 35% in the corresponding period last year while share of rest of the world remain the same at 6%, and ARV increased to 12% against 10% in the first quarter of FY16 against FY15.

Gross sales from API have been at Rs.723 crores in Q1FY16 which is higher by 8% over Q1FY15. The growth has mainly been led by the high value non-betalactam APIs during first quarter FY16 over first quarter FY15. We continue our debottlenecking efforts by expanding the API capacities.

Our EBITDA for the quarter is at Rs.725 crores which is at 21.8% of net operating income and has gone up by 10% over Q1FY15. As far as FOREX is concerned, the closing rupee versus US dollar rate was Rs.63.645 in June 2015 and Rs.62.5 in March 2015. The rupee depreciated by 2% and accordingly resulted in a net FOREX loss of Rs.(-26) crores during the quarter as against the gain of Rs.1.4 crores for the first quarter last year. The majority of the company's debt is denominated in foreign currency. The net debt is US\$682 million as on June 2015 as compared to net debt of US\$638 million in March 2015 thereby increasing by \$44 million. The increase in debt is mainly due to CAPEX payments and increase in working capital. The cash and bank balance is about \$77 million. CAPEX for the quarter is around \$42 million. The effective tax rate for the current quarter is around 30% compared to 27.5% of the previous year. This is mainly due to cessation of 100% tax exemption in the current year for our SEZ Unit-7. Effective 1st April 2015 the exemption benefitted 50% for the next five years.

I also take this opportunity to introduce Sanjeev Dani, who is an industry veteran with professional experienced of over three decades and has taken up the role of Chief Operating Officer and Head Formulations of the company effective 9th July this year and you will have the opportunity to interact with him during this call. This is all from our end and we will be happy to take the questions now.

Moderator: Thank you. Ladies and Gentlemen, we will now begin the question-and-answer session. The first question is from the line of Neha Manpuria from JP Morgan. Please go ahead.

Neha Manpuria: My first question is on Actavis, the acquired asset. You mentioned that we have started seeing improved profitability with the integration. Can you give some more color on what exactly has driven this improvement in profitability?

Sanjeev Dani: One factor that has contributed to improved profitability is, better cost control in terms of the inventory management. The product mix has also contributed to the improvement, but overall profitability is still below the breakeven point.

Neha Manpuria: What is the progress on us being able to shift production which will drive the larger part of the margin improvement?

Sanjeev Dani: In the last quarter we have shifted 3 products and some more products are expected to be shifted during this quarter.

Neha Manpuria: Sir, next, we have highlighted a lot of our initiatives in our annual report especially we will see some of them starting to contribute to revenue in the second half of this year. How should we look at margins especially after the improvement that we have seen in this quarter in the next year?

- N. Govindarajan:** Generally, Neha, we do not give any forward-looking projections at all.
- Neha Manpuria:** No, sir, I understand that R&D would increase but should we expect margin to improve from what we have seen in this quarter, was there any one-off that is there in this quarter?
- N. Govindarajan:** As you would appreciate that we have been having the strategy of filing for more differentiated products and it depends on when the approvals accrue and as the approvals happen the expansion should happen. That is something which we are clear about. But, is it going to be next quarter or subsequent quarter, is not something which we are specifically commenting about, Neha.**Neha Manpuria:** For Injectable, if you could give me the number of sales for this quarter?
- Ronald Quadrel:** The number of sales for the past quarter were about a little bit more than \$17 million.
- Neha Manpuria:** So we have not really seen the benefit from the approvals come through, that should start coming through from the second quarter?
- Ronald Quadrel:** Our approvals for our launches for the new products started at the very end of this past quarter. We had launched three products now and we will continue to as we get more approvals.
- Moderator:** Thank you. The next question is from the line of Ranjit Kapadia from Centrum Broking. Please go ahead.
- Ranjit Kapadia:** My question relates to Natrol sales if you can quantify. My second question relates to European-based business. What was the growth rate?
- N. Govindarajan:** As far as Natrol is concerned we do not break up the numbers I can only say that whatever plans we had is getting executed as planned.
- Sanjeev Dani:** During the quarter in Euro terms, we had about (+4%) growth rate in all for the consolidated operation.
- Ranjit Kapadia:** Sir, can you just give a latest update on Peptide business?
- N. Govindarajan:** We have filed one DMF last quarter . We have developed already almost 7-10 products. As and when the validation along with stability is completed we will start filing those products. And in all fairness the inspection should trigger once the ANDA is also filed by the customer.
- Ranjit Kapadia:** What is the addressable market for this Peptide range of products?
- N. Govindarajan:** I have said the DMF has been filed. So what happens is from an addressable market at this juncture it is difficult to predict in terms of all those specific products. We can have this chat later.
- Moderator:** Thank you. The next question is from the line of Prakash Agarwal from Axis Capital. Please go ahead.
- Prakash Agarwal:** Sir, if you could just help us break the sales into Injectables, Ceph and Aurolife for the last quarter?

- N. Govindarajan:** Ron has already talked about, it is \$17 million. On Aurolife if you can give that break up, Bob, in terms of what has happened.
- Robert Cunard:** The most significant one there is the Aurolife breakout of our government contracts business which is about \$14.3 million for the quarter and then the balance of their business obviously for Aurobindo and our own label products.
- Robert Cunard:** Regarding Cephs we did not break out specifics as Govind indicated in his general comments. We had the introduction of Cefixime OS this quarter which was a nice addition to the portfolio. The balance of the line was on par or slightly better to what we have seen in the past and obviously this is kind of the down quarter on Cephalosporin seasonality and we think that has another strong period next and through the course of the year.
- Prakash Agarwal:** On this Generic Suprax which we got approval, market share data is showing about 11%, but I am sure given Aurobindo's channel, we would have got fair share which is about 30, 40% or more?
- Robert Cunard:** The data is a little bit of a lagging indicator there based on the IMS and the prescription information as you are probably seeing that Lupin had introduced and authorized Generic of their own brand as well. So there are two generic products in the marketplace, Aurobindo being the only AB-rated ANDA approved and the share is split out as you would expect with two players in the market.
- Prakash Agarwal:** Understanding the good ramp up that we have seen in the 8 product approvals, like Entacapone, as you mentioned just now that the bigger products have probably come in the lead fag end. So, how many of these 8 products we have actually launched and how many are still pending?
- Robert Cunard:** Of our new introductions, we have a couple that have not introduced yet. Entacapone will be introduced this quarter. Extended Phenytoin will be introduced this quarter. As you can image with that product it is a little bit more complex as far as the substitutions that we did not prepare a product in advance for that and we are doing that now and securing our share. For the period it is really Cefixime was our new products and also the Olanzapine ODT, others will be commercialized subsequently.
- Prakash Agarwal:** So, we are yet to see the momentum from the approvals that we have seen?
- Robert Cunard:** Yes, but not all.
- Prakash Agarwal:** On the Europe piece is you talked about a few of the products being shifted. My understanding was that next 12-18-months you already putting up a big facility for Europe itself. So, is that on track and what are the new timelines and between now and then how many products you actually would be shifting already to India? You are filing fresh DMFs, dossiers for your Europe business to have a really cost effective and much more secured supply chain versus what you are shifting of products from Actavis portfolio
- Sanjeev Dani:** I divide the response to your question, into three parts — First , Aurobindo continues to develop products for Europe and in the last 15 months we have launched upwards of 70 products in Europe. As

far as Actavis portfolio is concerned, I mentioned earlier that, 3 products were transferred back to India for manufacturing in the last quarter and some more are expected in this quarter., As was mentioned in last investor call , we are expecting the inspection of manufacturing facility by October-November. Thereafter, early next year we will commence filing of products and then, await the approvals

Prakash Agarwal: In the meantime you would continue to transfer some of the products to your India-based facilities to take the cost advantage?

Sanjeev Dani: Absolutely, that is right.

Prakash Agarwal: That would be substantial, sir?

Sanjeev Dani: I think in the last investor call we had mentioned that roughly about 50% of our sales revenue will be shifted back to India.

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

Surya Patra: Just continuing with the same European business aspects. We had acquired some large chunk of the dossiers like 1200 odd. So, what portion of that are currently active? And what per cent of those dossiers have been already transferred to Indian manufacturing base?

Sanjeev Dani: All of them are active, but actually as I mentioned the last quarter we have transferred three products.

Surya Patra: So that means only three products have been shifted to India as of now?

Sanjeev Dani: Some more are expected this quarter.

Surya Patra: Regards the OTC US business, you possibly talked about around 70-odd products that has been developed and a few has already been marketed. So, what is the kind of progress that we have so far seen in the OTC front, if you can share the numbers, that would be great?

Robert Cunard: As far as the approvals, we have three ANDA approved products now that are under the OTC marketplace; Fexofenadine, Cetirizine Syrup and then we just recently received approval in Cetirizine Tablets. So they have not been commercialized yet. The balance of the current portfolio are Monograph products. So, those do not have a specific approval process per se but more guidelines that are directed from the FDA. So the balance of our existing revenues are really coming from our liquid manufacture here in the US on the OTC side. So, as indicated, for the past fiscal year and the first quarter it is very much Fexofenadine is a key driver of it and we see that but continuing to ramp through the balance of the year.

Surya Patra: Is it possible to share the number what is that we have so far achieved on the OTC front?

- Robert Cunard:** As far as product family, I want to say we are up to 8 in the marketplace currently.
- Surya Patra:** Actually, I wanted to know what is the kind of revenue number that you have achieved so far in this...?
- N. Govindarajan:** It is not significant. We are not giving a specific number for Auro Health is what I would say.
- Surya Patra:** Regards the Peptides business, is it the segment that we are targeting for API business or it is for the Formulations that we are ...?
- N. Govindarajan:** So, it is both. Basically, we started developing the APIs and we started filing the DMF, as we have mentioned our first DMF has been filed last quarter but prior to our initiation of API development, our injectable portfolio has already started filing certain Peptides as Injectable finished products. So, obviously, as we progress, our own portfolio will include both our own API, our own finished dosage in the future going forward, so it is both.
- Moderator:** Thank you. The next question is from the line of Manoj Garg from Bank of America. Please go ahead.
- Manoj Garg:** Just wanted to understand Mr. Govind, you alluded in your opening comments that we have started receiving a lot of activities from the FDA with regard to target action dates, particularly on the Injectable side. So, what is the visibility right now and how many approvals we are anticipating over the next 6-12-months?
- N. Govindarajan:** Just wanted to clarify, Manoj, it is both oral as well as on Injectable and Bob and Ron can throw some light in terms of what activity is going on. So that will give you clarity, Manoj.
- Ronald Quadrel:** We have seen an awful lot of activity from the FDA. As I had mentioned in the last call, there has been a very significant increase in back and forth communications. The FDA has been taking two paths at least with the Injectable products – one, in several of the products, they are giving targeted action dates and another, they have almost reverted back to the old ways where we are seeing questions specifically related to the chemistry, micro, labeling and as a matter of fact, the four products that we have gotten approved this fiscal year, three of those we did not get targeted action date, we just received approvals. So, as we are looking forward here, I have 16 products right now with significant interaction with the FDA. When that will be approved? I cannot say exactly but we are expecting approval probably this fiscal year on many of those. So, a very-very exciting. As I mentioned in the past calls, a number of these products moving forward especially out of the 16 are the larger products where right now the one that we received so far has been the smaller market products. So, we will see a ramp in sales once we get these products approved.
- Robert Cunard:** Just a little bit more color in addition to the Injectable side and more traditional kind of Oral Solid side.. There is not complete clarity but it appears the (clouds are parting) 26:21 a little bit and we are getting some better direction from the FDA. We have received to date 18 targeted action dates from the FDA. We are not anticipating that is necessarily an approval, it could be a complete response letter, something

else from the agency but clearly the dialogue continued and we think through this year, and next year we should have a lot better transparency on what is happening with the pipeline.

Manoj Garg: Another question basically if you look at three or five years down the line, obviously you are taking a lot of initiatives in terms of Microsphere technology, Peptide-based kind of products. How do you see Aurobindo's pipeline evolving over the next 5-years?

N. Govindarajan: We clearly believe that it would be highly differentiated compared to where we stand, Manoj. In terms of filing, it is easy to predict, in terms of approval, it is difficult to predict. As you talked about Microsphere technology, we had mentioned in the earlier call as well we are planning to file our first product by around 2017. Ron had also mentioned around four products having a market size of around 3 billion. So instead of looking at quantitatively in terms of the number of products, qualitatively I think even one or two product approvals can clearly change the shape of what we look at in terms of the differentiation. So, clearly, we see that the degree of differentiation would be much better than where we stand today. So, are we putting any specifics? It is very difficult at this juncture, Manoj.

Manoj Garg: Looking at the way the rupee is behaving now, just want to understand from now a personal perspective, how 1% movement in terms of currency will have a positive impact in terms of our EBITDA margins?

Santhanam Subramanian: I guess it should be something like Rs.7-8 crores in a qtr on the current product mix which translates to around 0.2%

Moderator: Thank you. The next question is from the line of Prashant Nair from Citigroup. Please go ahead.

Prashant Nair: I needed a clarification on one of the things you mentioned on the European side. So, you mentioned you would like to shift manufacturing for about 50% of revenues to India. Is this the target for say this year or the near future or is this the overall target?

Sanjeev Dani: This is the overall target over 24-months.

Prashant Nair: How would you source the rest of the products – would that continue to be from Actavis or would you look for other sources in Europe?

Sanjeev Dani: Most of the products are coming from third-party in Europe. I think it may not be immediately feasible to transfer to India. That was the assessment when we acquired this portfolio.

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

Nitin Agarwal: Bob, my question specifically on the impact that you have seen on the consolidation of the distribution channel on our portfolio. We have done a pretty good in terms of the way the business has grown over the last couple of quarters. But what has helped us to stave off in your experience the pressure which would have come with the consolidation?

- Robert Cunard:** We definitely saw some margin compression in the first quarter as a result of the consolidation primarily on the Mckesson and Econdisc business which was two bids that were out. So, as you look overall we are still seeing volume gains on a base business in the 2-3% range what we saw in the last quarter, we saw contraction in some of the pricing. So, how we do it? I do not know if there is a magic recipe or it is more, we are still aligned with some good customers, some of those are historic decisions that we made on strategic partnerships have been fairing pretty well as far as the way the business is consolidating. It is certainly a challenge, but again, Aurobindo, we have a solid value proposition and what we are bringing to our customers as far as the breadth of portfolio and again the industry as a whole has some new clarity on what that pipeline looks like, and the timing of it and that plays well for us. And just the value that we can drive through our infrastructure and our supply chain. So, it has been working well. We hope that continues and I think we put some things in place on the customer side they will continue to drive the growth for us.
- Nitin Agarwal:** In the Aurolife business, you mentioned something about the government tenders picking up. So, can you just throw some more light on specifically what really changed in this quarter or it seems like a change on a sustainable basis, so any major contracts got in or what is really the change out there?
- Robert Cunard:** As far as this quarter, we did not have anything new. There was some cyclical nature to that and just how they do their procurement and how their business grows and fluctuates with their demand. So, there are some additional products later we expect to come on line. So, I do not know if it is a huge growth, but it is a good stable platform for us right now, I think we can continue to introduce some products there. The other thing obviously with that business, although it is a lower margin, it is predictable, we do not have the ongoing price variation with those national contract awards.
- Nitin Agarwal:** What is the typical duration of this contract that you get from the government agencies?
- Bob Cunard:** They vary, but they are typical 2-years.
- Nitin Agarwal:** Govindan, one question on the financials. You mentioned about \$42 million increase in the net debt QoQ and we also had about \$45 million sort of CAPEX during the quarter. We had almost like \$100 million plus EBITDA generation during the quarter. So, where all cash would have got absorbed for us?
- Santhanam Subramanian:** It is not \$100 million, the cash that has been generated is around \$83 million and what we had incurred in the CAPEX is around \$42 million. So the balance \$83 million has gone for the working capital as well as the other liabilities reduction, etc., Overall, there is an increase in the debt to the tune of \$44 million.
- Nitin Agarwal:** How do you see this thing playing out during the year?
- Santhanam Subramanian:** One of the reasons why it has increased- is mainly on account of the inventory only. this is basically the increase is for the future growth of the businesses to improve the service levels, etc.
- Nitin Agarwal:** A lot of the working capital increase is on account of inventory?

- Santhanam Subramanian:** Mainly inventory.
- Moderator:** Thank you. The next question is from the line of Neha Manpuria from JP Morgan. Please go ahead.
- Neha Manpuria:** Just an extension on the debt question. We have been acquisitive in the last year. Given how the US manufacturing industry itself is consolidating, what is our strategy in terms of acquisitions or inorganic growth in context of our current net debt? Does it give us capacity to look at more inorganic opportunities and where would these be?
- N. Govindarajan:** I have given the answer, Neha, in the past as well. We do not have a separate M&A team which keeps continuously looking at opportunities, we do not do that. And if any appropriate opportunity comes up, the management would get involved including the specific leader who is handling that business and then we will evaluate it. That is how it is.
- Neha Manpuria:** A lot of Indian companies have also started acquiring to accelerate some of the complex generics opportunities. While we are investing in Injectable, you might be ahead of our peers, do you think there is a need for us to probably look at smaller deals to accelerate certain opportunities in the Complex side or are you comfortable with your pipeline at this point of time?
- N. Govindarajan:** We keep evaluating, Neha. We are not against that. I think there are opportunities which comes across like Injectable and Ron keeps evaluating it. So, we are not averse of any such opportunities. If a differentiated product comes across, it is not that we would not do that, we will be happy to do that if we have the right value proposition is what I would say. But having said that, you will also appreciate the fact that we have our own creation of portfolios like a Peptide portfolio or a biocatalysts portfolio or having our own Oncology development or a steroid development or even getting into vaccine. So we have a combination of both internal creation as well as in licensing.
- Moderator:** Thank you. The next question is from the line of Paurav Lakhani from Prime Securities. Please go ahead.
- Paurav Lakhani:** Sir, this is slightly a book-keeping question. This is with regards to tax rate. I believe there is a one-off SEZ thing that is included by which the tax is slightly bruted. So, if you remove the effect, what could be the PAT?
- Santhanam Subramanian:** No, we are not specifically giving the tax rate for the various units. So, overall because of the SEZ, earlier we were entitled for a five-year 100% exemption, we are entering second phase 50% exemption and that is the reason why the tax rate has gone up.
- Paurav Lakhani:** But, is it possible to give us the entire tax figure and normalize PAT for the entire company? I understand you cannot give it unit wise.
- Santhanam Subramanian:** Typically, our tax rate if you really look at the previous year was 27.5%, now it has reached 30% and predominantly that is because of the change.

- Paurav Lakhani:** So building in 27-27.5% going ahead, will be the right way to do it sir?
- Santhanam Subramanian:** No, going forward, at this juncture we will maintain what we have achieved because the reason is if you have heard the initial comment we clearly said that the tax exemption has come down to 50% from 1st April for the SEZ unit..
- Moderator:** Thank you. The next question is from the line of Jigar Walia from OHM Group. Please go ahead.
- Jigar Walia:** My only question pertains to the QIP and any plans to reduce debt or any utilization of funds?
- N. Govindarajan:** Obviously, we have got an enabling resolution approved across all the stakeholders including the clearance from the government as well. So at an appropriate time it will happen.
- 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, can you just let us know the status on Generic Angiomax we have filed?
- Ronald Quadrel:** Angiomax-- we have filed the ANDA, we have had discussions with the FDA back and forth in terms of the review of the filing. Right now the courts have declared that the latest patent from the Medicines Company is invalid, Hospira was the plaintiff. Right now, we are awaiting the courts to discuss whether they are going to allow the appeal by the Medicines Company. We are not sure how that is going to go but there could be a position where there is an opening without the patent over the next 60-days. Our entry to the market depends wholly on whether FDA completes review of our ANDA. So, we are hopeful all that will clear and we will be able to launch. We are in significant discussions with the FDA on reviewing now the ANDA.
- Nimish Mehta:** So any timeline for the approval? I understand the litigation will take whatever time it would take, but ...
- Ronald Quadrel:** The litigation is basically over and it is just a question of whether the appeal would be granted to the Medicines Company or not. I cannot tell you specifically when we will have approval but as soon as that litigation is completed, way will be open for us to have approval from the FDA. We are hopeful it will be coming sooner rather than later. It is a big market. There will be multiple players. So the order of which we get approval as compared to the other competitors will determine what our share can be and what our entry price would be.
- Nimish Mehta:** Second question, can you just confirm or reject what it is, whether any of our facilities are undergoing any USFDA inspection as of now?
- N. Govindarajan:** As of now, there are no inspections ongoing but I think I can give a standard disclaimer that since we have several facilities, at any given quarter, we will have inspection at one or two of our facilities.
- Nimish Mehta:** Last quarter, have we seen any inspection going through? Any update as in...

- N. Govindarajan:** Of course, we had some inspection last quarter also. There is no update as such is what I would say.
- Nimish Mehta:** Which unit if you can classify that will be helpful?
- N. Govindarajan:** Unit-12 got completed.
- Ronald Quadrel:** Inspection was completed in July.
- Robert Cunard:** We also had a completed inspection at Aurolife.
- N. Govindarajan:** At any given time, as I told you, one or two inspections would happen during any quarter is what I would say.
- Nimish Mehta:** On the cost related to shifting the products from Europe to our India facility, any ballpark you can give us and have we incurred this quarter or how would you look at it?
- Sanjeev Dani:** Actually, many of these particular products are being filed individually, hence they are in individual country P&L and we have about 9 countries. So, it will be very difficult to aggregate but in the filing costs for generics are already known and the aggregate depends upon how many countries we want to file.
- Nimish Mehta:** But any ballpark let us say per a product roughly on an average whatever that would be helpful if you can give that?
- Sanjeev Dani:** This would be an industry general question, but we can get the data, it is not specific to Aurobindo.
- Nimish Mehta:** I am just trying to understand what could the implication because we are looking at fairly large number of products to be done, that is the only reason for our modeling purposes?
- Sanjeev Dani:** We will have to aggregate across the country. We can get that.
- Moderator:** Thank you. The next question is from the line of Ashish Rathi from Spark Capital. Please go ahead.
- Ashish Rathi:** Just on the QIP, we have not had a discussion on QIP after the announcement. I was just wondering if you could help us understand why the funds are needed in the first phase? We have a debt level which is pretty comfortable, less than 1x debt-to-equity, almost 1x to EBITDA, rate of interest is extremely low compared to the cost of equity which we get the money for. We are not looking at acquisitions as you said anything in the near term.
- N. Govindarajan:** I do not want to take up this topic here but I will just still answer to clear the air. So, as far as QIP is concerned, we had explained in the past also and we had discussed individually that our debt has gone up due to Natrol acquisition by around \$104 million and apart from that like we have certain other CAPEX which we have been explaining about like the need for our capacity expansion in Brownfield and Greenfield projects which we are going ahead well. So, there is a need based on that. When we had

calculated, we found that there is a gap in terms of the need and that is how we have gone ahead with this particular need.

Ashish Rathi: But if you just do the math, we are getting around \$300 million sort of cash flow being generated by the company over the next 2-years which is probably lower than the CAPEX requirement, and also, the cost of debt is much lower but we need to pay the debt?

N. Govindarajan: That is true, but please understand the debt level is a perception in terms of what is the right debt. So, as I had mentioned there is a gap which we had seen in terms of the need vs generation which we found and also it is better to keep that headroom.

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

Prakash Agarwal: Just trying to understand this Injectable business better. Today, we are still \$17 million and we continue to see in the FDA website that your key products Bupivacaine, Lidocaine, all these are still under shortages even Tazo-Pip. Are these your peak sales from the current portfolio that we have?

Ronald Quadrel: From the perspective of Bupivacaine and Lidocaine, when the FDA put shortages out, they are putting shortages out on some specific presentations of the product. Both our Lidocaine and Bupivacaine we do not have every single presentation. So, we are gaining share on those. We have gained significant share in our Bupivacaine and Tazobactam where we are is basically level maybe a little bit ahead of where we were this quarter before and as we look moving forward, one of the things is very hard to predict is the exact timing of FDA approvals for our other ANDAs. As you are looking at launching new products you want to be a little careful of what you make in terms of large quantities and when you make those large quantities. You are not making them too early and running out your expiry period. So, as we looked at these four first products that have gotten approved over the last say 3 months or so we actually waited until we had approval, until we started making launch materials. So, our first launch for the new material and that being at the very last week of that first quarter. As we are moving forward here now we will get more impact from the new products. Wherever we can in terms of our Penicillin products, we are making inroads there in terms of getting more market share, but of course, given the amount of shortage out in the market, we cannot supply the entire market. So, we are supplying what we can at this point in time and again, as the year goes on, we will be increasing our sales from broadest perspective, not just the Penicillin products. So, hopefully that answers your question.

Prakash Agarwal: Yes, just if my understanding is correct, we are expecting some good products to ramp up our run rate of the \$17-18 million because last year we saw a huge growth of 80% and what we were looking for is \$100 million kind of sale this year in Injectables. So, are we on track to achieve that?

Ronald Quadrel: As I had mentioned in the last earnings call, it is going to be more of a ramp towards the end of this year. The first quarter as I said we had a small product injectable approval. I also told you that we have significant interactions with the FDA, on quite a number of ANDAs and I do expect those approvals as we move through this fiscal year, and they are some of the bigger products. So, as they get approved, our

sales will ramp significantly. So, to answer your question, yes, we are on target to what we told you earlier.

Prakash Agarwal: Second question, just trying to understand, US has a full segment better, so understand 1Q Fiscal '15 was a high base but if we exclude Natrol we are getting a 7% kind of growth for the quarter in the US business YoY. So, in the past we have talked about 15-20% kind of growth. So, you are saying second half will be much better... product approval ramp up and that should cover it up, right?

Robert Cunard: Just like as Ron indicated on the Injectable side. Such a key part of our business is the cycling of the portfolio and those approvals. Fiscal year ended March 31 we had a very dismal year as the rest of the generic industry as far as approvals, we were still able to grow and as we talked about in the past we drove that through expanding the base and driving some price opportunities where they existed and capitalizing on the new products we had. The customer consolidation was out there and we clearly saw that in our first quarter of this year, the effects of that in that bid process and we did not see a significant number of approvals outside of Cefixime. So, we always had the expectation that it is going to be quiet through this period and hopefully the latter part of the year and into the next year we get more of the benefits of the FDA approvals and the benefit of the GDUFA and all the expansions that the FDA has done. So, with this point, we definitely saw some softening on the Generics business from a price standpoint, the base business continues to grow from volume. I think there will continue to be opportunities as now we start to see perhaps the balancing of consolidation on the manufacturer side as well as the customer side and the thought is that potentially it creates opportunities for us as well.

Prakash Agarwal: Just wanted to check, Para-IV filings for Abilify and Namenda, so are we on the second wave of Generic launches and when would that be sir?

Robert Cunard: That is the anticipation that happens in the second half of this year.

Prakash Agarwal: Both these products sir?

Robert Cunard: Yes.

Moderator: Thank you. The next question is from the line of Praful Vora from Religare. Please go ahead.

Praful Vora: What has led to the sequential decline in the other expenses?

Santhanam Subramanian: Across the board everywhere there is a reduction, that is the reason why it is coming down, it is no specific single item which got reduced. We have reduced in US, we have reduced in Europe, as Sanjeev was mentioning there is a cost reduction.

Praful Vora: So, can we take this as a base

- Santhanam Subramanian:** It is quarter-on-quarter depending on the sales mix and other things because the expenses pertain all these are mainly carriage outwards, power and fuel. It also is a function of the sales being achieved in the next quarter.
- Praful Vora:** Secondly, if you can also highlight on the material cost, QoQ, there has been almost 200 bps decline there. What led to this?
- Santhanam Subramanian:** Between last year to this quarter, the ratios have remained more or less the same. Plus or minus 1% depending on the sales mix varies quarter on quarter
- Moderator:** Thank you. The next question is from the line of Nishit Shah from Ambika Fincap. Please go ahead.
- Nishit Shah:** Given the fact that you did not had Cymbalta which was there in the last year's first quarter. You have so many things going for you like you have Penems where you have already filed to and you are also trying to do nanosphere, you have peptides, you have oncology and hormones products where you mention in your annual report that you are going in for 15-products for which you are starting the batch testings, you have complex filings of products in ophthalmology, inhalers and you have consumer health, you have OTC and in branded space also and also the biocatalyst. So, where do you see the company moving in next 2-years, 3-years? I am not asking a guidance, but what I am asking is that you are actually going into so many different product areas where obviously, these are high margin, high value added products, niche segments, difficult to manufacture and you are working on several things at the same time.
- N. Govindarajan:** If you really look at, there are certain reports which are available in terms of mapping and where they clearly see that the quality of differentiation which keeps improving rather I would say year-on-year, compared to what we were three years back. In terms of the differentiation today Injectable has already taken off, the next wave already you have mentioned about few initiatives which we are already working on. So, as they keep progressing and as they keep expanding each of these verticals the differentiation would be much better or rather head level of differentiation would happen which is good for the margins is what clearly I would say.
- Nishit Shah:** You guys are doing a lot of things. Can you give a color on Penems that nanosphere you talked about an opportunity of \$3 billion. What do you need to do and what is the timeline for getting into Penems and nanosphere?
- Ronald Quadrel:** As was mentioned in response to one of the other questions, we have already filed two of our products. There are Four Penem Injectable products in the US. Right now, we are working on the remaining two penems. We are very close to filing one of them and we are actually running exhibit batches for the fourth. So, depending on the timing of the FDA approvals, within several years, we will have all four products on the market. I believe right now the addressable market is about \$450 million for the four products in the US. Some of that shifting because Doripenem sales are decreasing and Meropenem a little bit, but Ertapenem sales are growing, picking up the slack in sales from the other two products. So Ertapenem is the biggest product, followed by Meropenem followed, by Imipenem+Cilastatin and then

fourth Doropenem. The products that we have filed so far are Doripenem and Meropenem. In the near future, it will be an all four will be with FDA, it will just take a little time until the FDA approves them on.

- Nishit Shah:** Is the plant inspected or Bhiwadi plant is still to be inspected by the FDA?
- Ronald Quadrel:** Not yet, but I am expecting sometime between this fall and say maybe the first couple of months of 2016. Product FDA will be in for Meropenem.
- N. Govindarajan:** But meanwhile the facility has been already inspected by the European authorities and also we have started exporting to Brazil and Mexico.
- Nishit Shah:** So you started commercializing and encasing on that?
- N. Govindarajan:** Yes.
- Nishit Shah:** But my question was on Nanosphere which is where the \$3 billion market is. How will that take post the approval of the plant by the FDA and when that market opportunity opening up for Auro?
- Ronald Quadrel:** What I can tell you is as I mentioned this earlier obviously, Nanosphere's liposomes and microsphere specifically are much-much harder to develop than straight liquids of suspensions. Also, every single product requires a bioequivalence study plus some additional chemistry testing which we call a physical chemical characterization. That whole program takes probably an extra year and a half more than a normal development time. So, as Govind answered earlier, we are expecting the first filing to be in 2017 and the others will follow shortly behind that. I would expect especially with PDUFA now in place, that we should have approvals, if the FDA keeps its current timing or even approves a little bit, within around 24-months or so after we file. So, we are still a ways off yet, but very encouraging. Not every company can do these, but we have some very good experts working on these development projects and we are making significant progress.
- N. Govindarajan:** Just to clarify, Ron, these products would be run in our Unit-IV only?
- Ronald Quadrel:** Not sure yet, because some of them are oncology, we are going to have to determine where we do run them. we have about 12-months to determine where these will be manufactured.
- Moderator:** Thank you. The next question is from the line of Damayanti Kerai from HSBC. Please go ahead.
- Damayanti Kerai:** This is regarding the 15-odd pipeline products which you mentioned that are in active discussion with FDA. So, can you indicate how many of these products are Injectables?
- Ronald Quadrel:** When I mentioned that before I was talking about all of those being Injectable products.
- Moderator:** Thank you. The next question is from the line of Ranjit Kapadia from Centrum Broking. Please go ahead.

- Ranjit Kapadia:** My question relates to increase in other income and other operating income if you can throw some light on this?
- Santhanam Subramanian:** On the other income, basically, we got the power incentive pertaining to the past period. based on the virtual certainty we book the income. Since we got the sanction from the Government of Telangana on the power subsidy which we have paid in the past, we have booked it in the other income. That amounts to around Rs.21 crores. There is some more pending also. In future as and when the sanction happens only we will account it.
- Ranjit Kapadia:** Higher other operating income which has gone up by almost 200%?
- Santhanam Subramanian:** The other operating income is only the export incentives. This is based on the actual sales which is as per the export benefit rules .
- Ranjit Kapadia:** This will be sustainable?
- Santhanam Subramanian:** As on date based on the government rules only we have been accruing the entire tamount
- Moderator:** Thank you. Due to time constraints, we take up the last question that is from the line of Rakesh Jhunjhunwala from Rare Enterprises. Please go ahead.
- Rakesh Jhunjhunwala:** Now that means your main Injectable profitability is going to come from this quarter because you have only reserved \$18 million sales in the first quarter? What was the sale of Injectable last time in America?
- Ronald Quadrel:** Last year in America, our sales of Injectables was about \$69 million.
- Rakesh Jhunjhunwala:** You expect a substantial increase in the current year?
- Ronald Quadrel:** Yes...
- Rakesh Jhunjhunwala:** But in the first quarter sales has been if you analyze it was only about \$68 million which is what you did on an average last year also?
- Ronald Quadrel:** Yes, but one of the things that we have, last year probably about 85% of our products were coming from sales from Unit-12 with the rest of sales coming from Unit-4. As we are looking this year, we are going to get a much higher percentage of sales from Unit-4 from new products.
- Rakesh Jhunjhunwala:** That is the same thing I am saying. That means the real increase in the Injectable products is going to come in the second, third and the fourth quarters?
- Ronald Quadrel:** Probably from the end of the second quarter through the end of the year.
- Rakesh Jhunjhunwala:** That means the best part of the Injectable is still ahead of us?

- Ronald Quadrel:** Yes, definitely.
- Moderator:** Thank you. With this I now hand the conference over to Mr. Roychoudhury for his closing comments. Over to you, sir.
- Tathagato Roychoudhury:** For further information, please visit our website, www.aurobindo.com or feel free to get in touch with me with any additional queries that you may have. Thank you, everyone for joining us in the call today and wish you a very good evening.
- Moderator:** Thank you very much, sir. Ladies and Gentlemen, on behalf of Aurobindo Pharma Limited that concludes this conference call. Thank you for joining us and you may now disconnect your lines.