“Cadila Healthcare Limited Q1 FY17 Post-Results Conference Call”

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Anant Gupta: Ladies and Gentlemen, Good Day and Welcome to the Q1 FY17 Post-Results Conference Call for Cadila Healthcare Limited. As a reminder, all participant lines will be in the listen-only mode, and there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal for 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. Ganesh Nayak – COO and Executive Director for Cadila Healthcare Limited. Thank you, and over to you, sir.

Dr. Ganesh Nayak: Good evening, and welcome to our post-result teleconference for the first quarter of FY17. We have with us Mr. Pankaj Patel – Chairman and Managing Director, Dr. Sharvil Patel – Deputy Managing Director, Mr. Nitin Parekh – CFO; and Mr. Vishal Gor – Senior General Manager, Investor Relations.

Effective 1st April, 2016, we have started reporting financial numbers as per the new Indian Accounting Standards which are commonly known as IndAS. Accordingly, the results for the first quarter of FY17 and comparative numbers of the first quarter of FY16 have been published as per IndAS. A reconciliation of the net profit reported under previous GAAP to the total comprehensive income reported under IndAS has been furnished along with the results, which should enable you to understand the impact of IndAS on our financial numbers.

Coming to the key financial numbers. during the quarter gone by, on a consolidated basis, our total income from operations was down 4% year-on-year to Rs. 22.9 billion. Excluding the impact of income earned on the sale and transfer of ownership in certain ANDAs for generic products during Q1 FY16, the total income from operations was down by 1%. Earnings before Interest Depreciation and Tax was down by 9% year-on-year to Rs. 5.24 billion. Our EBITDA margin declined to 22.9% in Q1 FY17 from 24.3% in Q1 FY16. Excluding the impact of income earned on the sale and transfer of ownership in certain ANDAs for generic drug products during Q1 FY16, the EBITDA grew by 3%.

Profit before tax was down by 15% to Rs. 4.41 billion. Excluding the impact of the income earned on the sale and transfer of ownership in certain ANDAs during Q1 FY16 and exceptional items, PBT de-grew by 3%. Our net profit was down by 23% to Rs. 3.56 billion. Net profit margins declined to 15.6% in Q1 FY17 from 19.3% in Q1 FY16. Excluding the impact of the income earned on the sale and transfer of ownership in certain ANDAs during Q1 FY16 and exceptional items, our net profit de-grew by 15%.

Now, let me share some of the highlights of the operations for the quarter. Our business in the US posted sales of Rs. 8.5 billion, down by 14%. We launched two new products during the quarter in the US market. We acquired two ANDAs, including one transdermal patch from Teva, which were divested by Teva as a precondition to its acquisition of Allergan's generic business. We filed six additional ANDAs with the US FDA, and received approval for three new products. Our India formulations business posted sales of Rs. 7.9 billion, up by 6.2%.

Growth excluding the impact of price reduction on NLEM products and discontinued fixed dosage combination drugs, was 8.6%.

We launched 20 new products, including line extensions in India, of which four were for the first time. This includes the launch of Vactyph, the Vi Typhoid Polysaccharide Vaccine, the second vaccine launched by the company.

In Brazil, we received approval for four new products and launched one new product during the quarter. In Mexico, we received approval for one new product and launched one new product during the quarter.

Exports to the emerging markets grew by 7%, and posted sales of Rs. 1.3 billion during the quarter. We signed a strategic collaboration agreement with Eczacıbaşı, a leading healthcare company of Turkey to market biotech products in the Turkish market. We launched five new products in the focused markets of Asia Pacific, Africa, and Middle East during the quarter. This includes the launch of Zyrop 4000 IU injection in Myanmar, the second biosimilar launch in the emerging markets.

Our Animal Health Business grew by 45% and posted sales of Rs. 1.1 billion. Growth excluding the Zoetis portfolio was 14%. Zydus Wellness Limited posted sales of Rs. 1.2 billion, up by 12%. Net profit of Zydus Wellness Limited was up by 20% to Rs. 234 million. On the biosimilars front, we received regulatory approval to launch two products in Philippines.

We continue to expand our vaccines portfolio as we received marketing authorization in India for three vaccines during the quarter. Clinical trials for three more vaccines were also completed during the quarter.

On the NCE front, we received approval from the US FDA to initiate Phase-II clinical trials of Saroglitazar in patients with Non-alcoholic Steatohepatitis, which is NASH.

On the manufacturing front, our Moraiya formulations facility received the EIR from the US FDA against the inspectional points 483s, raised upon the completion of inspection, which was carried out between the 28th of August, 2014, to 5th of September, 2014. We received site transfer approval for one product from Moraiya to Baddi for the US market during the quarter, taking the cumulative number of site transfer approvals to 13.

Thank you. And we shall now start the Q&A session.

Moderator: Thank you very much, sir. Ladies and Gentlemen, we will now begin with the question-and-answer session. Our next question is from the line of Saion Mukherjee from Nomura. Please go ahead.

Saion Mukherjee: Is it possible to share the JV revenue number for the quarter?

Dr. Ganesh Nayak: I think Vishal will provide, Saion, the numbers.

Saion Mukherjee: Okay. As far as the India growth is concerned, you mentioned that excluding the impact of NLEM and fixed dose combination, it is 8.6%. Isn't it slower than let's say what you were indicating earlier of double-digit growth and what is the expectation going forward?

Dr. Ganesh Nayak: So, Saion, there are two points. One is, what we have shown here is excluding the impact of price reduction and the fixed dose combination related products etc. But question is there were lot of confusion with respect to this new price tinkering and all that. So there was kind of a hesitance at the trade level to buy the product, so to some extent that was impacted. However, we cannot exactly calculate and give you the number. In fact, some of the old stocks were returned in the process because the new price are announced and all those. So a lot of confusion occurred also, so to some extent that might have impacted. I would not be able to give you exact quantity of that, but my rough estimate is this could be anything between 2% to 3% impact on the growth because of that. That's roughly I can say.

Saion Mukherjee: Just one last question, if I can. On the US revenues, the decline that we have seen sequentially, is it primarily on account of price correction in HCQS and where do you see HCQS, I mean, how much more correction we can expect going forward?

Dr. Ganesh Nayak: Yes, you are right, it is mainly because of price correction of HCQS. Going forward, I think we have reached the bottom and at this moment we do not see further price erosion happening in HCQS. You must be aware that we have just launched the authorized generic of Asacol and the sale would start appearing in our numbers from August onwards.

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

Prakash Agarwal: Sir, question again on the US business, just trying to understand this better. Despite this fall in the US business, our gross margins are still very healthy. Now there could be a scenario where we have lost some market share and the price erosion impact is yet to be felt, is that a fair assessment or you feel that the price erosion has already been felt in this current quarter and this is the base gross margins for us?

Pankaj Patel: So Prakash, basically, during this quarter we also had some impact of favorable exchange rate fluctuations, so if you exclude that, then during the first quarter of FY17 our gross margins have been about 1% lower than Q1 of FY16, and about 2% lower than what we had in the last quarter.

Prakash Agarwal: But as sir pointed out that price erosion has been felt in this quarter, I mean, so the HCQS impact is totally baked into this 1% decline in gross margin overall?

Dr. Ganesh Nayak: Yes.

Prakash Agarwal: And sir, secondly on the employee cost, if you see, I mean, last quarter also there was a bump up, thought it to be a one-off, but if I see YoY, 13% going to 16% of sales. Is there a clarity there? What exactly we are ramping up? Why is that happening?

Pankaj Patel: So, a couple of things we have commissioned, some additional facilities, the new injectable facility, now it is ready and it is under a validation process, the full employees have been taken there, also our new SEZ facility is coming up straight, so we have employed people for that. So there is a higher employment happening in the process. There is also some beef up in quality and regulatory function done during the last, maybe one year period as a part of overall future strategy. And I think all of these have impact of some growth….. Yes, of course on top it, you know, that the market is such that, there is also a normal increment, etc., involved in that.

Management: Plus, Prakash, you also need to consider the fact that we have removed the sales and employee cost of JVs as per IndAS and JVs typically have lower employee cost as percentage to sales. So that is why you see increase in the percentage of sales for employee cost.

Prakash Agarwal: Sorry sir, can you explain that again JV please?

Management: See, as per IndAS, we had removed the sales and all the other operating cost of joint ventures. So now, as per IndAS, the net profit of JVs is taken as single line item in the financial. So employee cost as well as sales does not include the portion of JV, and JV typically has lower employee cost as percentage to sales. So as a result, you see some increase in the employee cost as percentage to sales.

Prakash Agarwal: So there is no one-off in this numbers and this is the base one should go forward?

Pankaj Patel: For IndAS, yes.

Prakash Agarwal: And similarly, one more comparison if I do for other expenditure, in the past you have mentioned that there has been some US FDA related costs, and that seems to have come down reasonably by 250 basis points. So is our US FDA remediation largely done and cost wise we do not see this piece escalating, if you could help us understand. Thank you.

Pankaj Patel: Yes, I think we have already completed all that what is required to be done. So we do not expect significant expenditure going forward.

Dr. Ganesh Nayak: Plus, Prakash, if you are comparing the other expenses of last quarter versus this quarter, then you also need to consider the R&D spend and R&D costs compared to last quarter have gone

down by about Rs. 17 crores - Rs. 18 crores. So excluding that, other expenses are largely in line with what they were in Q4.

Prakash Agarwal: No sir, Q1 2016 versus Q1 2017?

Dr. Ganesh Nayak: Yes, there it would have some impact of remediation things and other costs also.

Pankaj Patel: Yes, that is because of rationalization of admin cost and some saving in expenses also in this quarter compared to same quarter last year.

Prakash Agarwal: And is your meeting done, sir, FDA meeting that we were expecting?

Dr. Ganesh Nayak: We have not done yet the FDA meeting. We are in contact with the FDA and as and when they call us for meeting, we expect maybe in September, we might have a meeting then.

Moderator: Thank you. Our next question is from the line of Kumar Saurabh from Motilal Oswal Securities. Please proceed.

Kumar Saurabh: Sir, just a follow-up question on margins. As you have said sir, the pricing of HCQS, the way it has kind of plateaued at these levels, sir is it something that the improvement in margin or actually the margins did not decline to that extent, the way we were expecting? Is it also because of the JV, because the JV margins I am assuming would be lower than the company level margins, and now it is…

Pankaj Patel: See, JV margins were comparable, so I do not think it is because of JV. See, HCQS was a major product as far as US is concerned, but we also had other products. So net-net if you see, the US sales has gone up in some products, some products it has gone down. So net-net, US margin, there is not a significant erosion and that is why we see overall margins almost in line.

Kumar Saurabh: So net-net sir, the pricing pressure would be how much sir, on our US sales during the quarter?

Pankaj Patel: I do not have –the number of the quarter.

Pankaj Patel: Yes, so we can provide you these numbers offline, because there are too many details for each product.

Kumar Saurabh: So that is what, I wanted to have it at a consol level basically, the whole US sales level rather than product level would have…

Pankaj Patel: Yes, I think, I do not have specific data to share at this moment. But, Vishal will be happy to give you more information.

Kumar Saurabh: So sir, should we expect that this should be our base margins at EBITDA level and from here on, ramp up in US sales should actually help improve margins from current levels?

Pankaj Patel: Yes.

Moderator: Thank you. Our next question is from the line of Anubhav Agarwal from Credit Suisse. Please proceed.

Anubhav Agarwal: Pankaj bhai, one question on the EIR. Just a clarity, I actually am not clear what does EIR for us mean? Does this imply that the 483 issues which were there in the Form 483, those are resolved now, but only the warning letter needs to be taken care of from now, is that a very clear indication from the EIR?

Pankaj Patel: Yes, that is what exactly they have written. They have closed the inspection, they have sent back the EIR and they have said we have closed the inspection related matter and they will address the warning letter separately.

Anubhav Agarwal: And second on the Asacol AG, now a simple question is that in your determination to go for the launch as an AG, is there any possibility for us to launch our own product later on and when could that be? Like I mean, is that there are riders that when other generic comes in we can launch it or the moment we get the approval we can come to the market?

Pankaj Patel: So these are the confidential information, so I cannot give you more detail. Only I can say that as far as Asacol HD is concerned, we have currently launched the authorized generic. In future we could consider doing that, but we cannot give you any timeline.

Anubhav Agarwal: No, I am just trying to understand sir, yes I completely appreciate that, but just trying to understand your thought process. When you finally decided to launch it as an AG, is this like considering that site transfer may not have happened fully and Moraiya is not yet out, was this the net-net…?

Pankaj Patel: So it is a purely commercial decision based on different scenarios we worked on and based on that, we took this decision, so it is purely a commercial consideration. Because I cannot share more information at this moment, because we have confidentiality in our agreement, and that is why I cannot say more about it.

Anubhav Agarwal: I respect that, sir. Just one more question on the biosimilars work that you are doing for the developed market now. The 2015 annual report mentioned that you have almost actually done Phase-III trials of one MAB and now you have initiated Phase-III trial on other MAB. Can you just little talk about it that the trials that you already completed now, when do you expect to file that product?

Pankaj Patel: So these trials are for India, this Phase-III trial what we have mentioned about is for India and not for USA.

Anubhav Agarwal: So, for the developed market where does our, let's say the most progressed molecules for us, where does it stand right now for the developed market?

Pankaj Patel: So we have made application, BLA application with the FDA, we had our meeting with the FDA, FDA has given us a guidance and we are currently working on as per that guidance. More details, once we have a final plan we can share with you.

Moderator: Thank you very much. Our next question is from the line of Purvi Shah, Sharekhan. Please proceed.

Purvi Shah: Since most of the things have been answered, I just need clarification on two things, one is the increase in depreciation cost, so where do we see this going forward? And the other is the tax rate, it has been 22% for this quarter. So, if you could just guide us, sir.

Management: So, depreciation is little higher because of the new practices that we have not capitalized during the period, also because of certain brands that we acquired, depreciation on the brands. So at present we expect the current tax rate between 20% to 22%, in that range.

Purvi Shah: And depreciation we expect this Rs. 85 crores run rate going forward as well, right?

Management: Yes.

Moderator: Thank you very much. Our next question is from the line of Surjit Pal, Prabhudas Lilladher. Please proceed.

Surjit Pal: I need to understand your Asacol HD, because I found that you said Asacol HD in the exclusion list of both Express Scripts as well as CVS Caremark and very recently the exclusion list of Express Scripts released yesterday day before, and that also has Asacol HD be continued to bar it for their client. And they are suggesting seems to be a Lialda and another Mesalamine product. Do you think this will, I mean, if you see the market share for that, Lialda has increased quite a lot vis-a-vis Asacol, Asacol has come down almost 8% to 9% in Mesalamine segment. So, do you think this will impact the AG off take?

Dr. Ganesh Nayak: We are in a discussion with CVS and ESI. I cannot discuss more with you because of the nature of the discussions. Bottom line is it is not going to affect our AG.

Surjit Pal: Yes, because there is no generic so they are mentioning only the other brands rather than any generic.

Dr. Ganesh Nayak: Yes. See, we have fully seized up the situation and our team has already got into a discussion with them. With that said, I cannot give you more details. Bottom-line is, our plants are not affected.

Surjit Pal: So even if it removed, how much time will it take, six months, five months, any idea?

Pankaj Patel: I think Mr. Nayak clarified that we are not expecting our business getting affected because of this negative listing.

Surjit Pal: The second point is that, how many key product launches you were expecting in US and how many key product site transfer approval you are expecting in FY17?

Pankaj Patel: So, we are expecting around 12 to 15 products to be launched in US by December 2016. And that would be coming out from Baddi and SEZ facility and also Nesher facility.

Surjit Pal: And how many of them are quite a bit meaningful?

Pankaj Patel: Few of them, I cannot exactly give you the number, but at least the three of them are meaningful.

Surjit Pal: And last one is, if you can tell me what is your revised growth rate expectation for domestic market?

Pankaj Patel: We believe that this impact of NLEM and all that is going to wane after some time, and we should be able to move to about double-digit growth for the balance part of the year.

Moderator: Thank you very much. Our next question is from the line of Surya Patra, Phillip Capital. Please proceed.

Surya Patra: Again on the Asacol HD that we have launched. So what is the kind of margin profile one should consider for this kind of AG opportunity, sir? Whether it would be…

Dr. Ganesh Nayak: Sorry Surya, I cannot give you more information, for the reasons that we have a confidentiality agreement and we cannot share the margin details with you.

Surya Patra: Fine sir. So, it would be in line with our company margin level, is that kind of fair understanding or how?

Dr. Ganesh Nayak: You are asking me the same question again.

Surya Patra: Okay, fine. And this quarter, though JV income which we believe is slightly better margins profile revenue stream, and which is not there in the top-line, so possibly to some extent, some impact on the margin front we might have witnessed from that. But the R&D spend also

sequentially is lower, and now we are talking about doing clinical development and all in the advanced market for the biosimilar and all that. So considering that, what is the kind of R&D spend outlook that we are giving and what would be the likely impact on the margin?

Management: So we expect 7% to 8% R&D spend, and I think quarter-to-quarter that could be always kind of a plus/minus. So I do not think we can take one quarter and extrapolate it, but we expect the R&D expenditure to be in the range of 7% to 8%.

Surya Patra: So, which is already 7%, so there may not be significant spike from the current level?

Dr. Ganesh Nayak: Yes.

Surya Patra: And is it possible to quantify what is the JV revenue that we have removed out of the top line?

Dr. Ganesh Nayak: I think Vishal can provide you those information, there is no problem. We can provide the information because of IndAS we had to remove it, but we can definitely provide you all those information.

Surya Patra: And just one last question on the domestic Indian formulation business. Sir, the FDC ban impact that we have not yet witnessed, so how was that we are factoring and what is the risk to our top-line?

Dr. Ganesh Nayak: So currently we do not have significant FDC ban issue, number one. So that is the first point we would like to point to you, we do not have on the FDC front a significant product coming into that. So mostly it is NLEM impact which we have.

Surya Patra: And you said that it is 2% kind of impact, right?

Dr. Ganesh Nayak: Yes.

Moderator: Thank you very much. Our next question is from the line of Manoj Garg, Bank of America. Please proceed.

Manoj Garg: Pankaj bhai, I am still confused about this Moraiya issue, whether the warning letter had any fresh observations which were not there in the 483 or they are more or less the same kind of observation?

Pankaj Patel: So there are no additional observations in the warning letter in fact they are less than what was there in 483. So that is exactly, I think you have copy of 483 and also a copy of warning letter, it is exact line-to-line. So there is nothing additional. However, what we received from FDA is what we conveyed to the market that we have received the EIR and there FDA said that the inspection is closed. And they said that they will communicate separately for warning letter.

Manoj Garg: So the question is, on the very premises on which this warning letter was being issued, if that issue itself got resolved by the way of EIR, then why the warning letter is still there sir?

Pankaj Patel: To that question I have no answer, I have no answer to that question, unless I hear specifically. I think they might do an inspection before they clear the warning letter.

Manoj Garg: And so where is the timeline now, when do we see, like earlier you were talking about may be a third-party validation and after that you will invite FDA for inspections. Any timeline, any update you can give here?

Pankaj Patel: I think, as far as all that process we have to do we have completed. Now I cannot give you specific timeline because that depends upon when the schedule and inspection and then clearance.

Manoj Garg: So, the third-party validation and everything has been done from our end sir?

Pankaj Patel: Yes.

Manoj Garg: And sir, another thing just wanted check for the emerging market including Brazil and all, if you look both YoY and even sequential, YoY I can understand because of currency, but even sequentially also I think the growth is more or less muted kind of thing. So, any update here sir, like how do you see business going forward in these markets?

Dr. Ganesh Nayak: See, Brazil what happened was from 1st of April, this time they have given a very, with the highest ever price increase of something like 12.5%. This was known earlier. So in the month of March, there was a heavy purchasing by all the distributors and that's why it impacted our April and May. The other is, now coming to the positive side going forward, which I think is part of your question, we have in my opening talk I did mention that we have four approvals of which we have launched one. And other three we are going to launch. So, going forward the picture is definitely going to better in the coming quarters.

Pankaj Patel: Manoj, I would just like to add here because this is a question everybody ask me, so I thought maybe is better that I clarify. Some of the numbers what you see here is basically have lot of impact of IndAS and then there is a comparison to IndAS. Suppose IndAS would not have come, I mean, the India GAAP which we were following would have continued, then the number would have looked much differently, in fact PAT growth would have been almost 16%. However, because of IndAS, the whole numbers have become a different way representation and that is why you see a decline in that. However, I cannot hide behind this and talk about that, so that is the reality because now that is the way accounting will be reported going forward. But this is what I wanted to stress upon is that a lot of these numbers what you see here also have impact of IndAS that tax is significantly higher and that has impacted the bottom-line.

Manoj Garg: And sir, last question from my end. The two ANDAs which we have acquired from Teva, if you can give some color on that in terms of potential, the timeline of launch, etc.

Pankaj Patel: I think we can provide you that information, but at this moment I do not have the data. They are not very big, but they are good, I would say they are not very big but they are good.

Moderator: Thank you. Our next question is from the line of Nithin Agarwal from IDFC Securities. Please proceed.

Nitin Agarwal: Sir two things, one is on the Nesher facility, what kind of pipeline do we have there in terms of potential approvals that can come through there? And how are we looking at R&D from that setup?

Dr. Ganesh Nayak: So, Nesher we already have one product approval from a new filing happen and we have seven filings from Nesher which we expect the approval to happen over the next maybe 12 months' time.

Nitin Agarwal: All seven of them?

Dr. Ganesh Nayak: Yes, hopefully all the seven.

Nitin Agarwal: And all of them would be the controlled product category?

Dr. Ganesh Nayak: Yes. Barring two, except two, others are controlled category.

Nitin Agarwal: And second sir, on the other expenses, we have had a number of around Rs. 630-odd crores for the quarter, which means around these levels barring the distortion that we have because of the remediation measures of last three or four, two or three quarters, I mean, so we have done a pretty good job of capping these other expenses over the last almost two years now, I mean, if you adjust for the remediation cost maybe as an exception. So can you just throw us some light on the kind of measures you have taken to keep these costs under control despite the inflationary situation that all of us, I mean, most of the industry seems to be facing.

Pankaj Patel: As an organization we continuously run a program, they are codenamed in the organization as PRISM and SLIM and both are talking about basically non-labor spend expenditure to be controlled through basically doing lot of creative projects, etc. So that continuously helps us to basically bring down the bills down, and of course there are inflationary cost goes up, but because we continuously keep on doing the other activity, it helps us to basically maintain the low cost level, number one. The second is also we have generally a culture across organization that, the Company, the businesses and the managers are focused on removing wastages wherever it is possible. And all these are helping us to control the expenditure, I would say broadly.

Nitin Agarwal: Sir, do you have still scope to squeeze these costs further more or it is probably done, largely done?

Pankaj Patel: It is a continuous process, I can never say that I have fully squeezed because this is like a continuous process, you have to keep on continuously doing, it is the culture of the organization which ultimately will develop which basically continuously work for optimizing cost. And that is a continuous running program in the organization, so it doesn't run for one day or two and then stop the other day, it is a continuous process every year organization and every function would take targets to optimize the cost and work towards that and they hopefully achieve all the targets. That's what the track record up till now. So they are encouraged to do this on a continuous basis.

Nitin Agarwal: I mean, it will be a fair comment that Rs. 630 crores, if we adjust for the increased R&D, more or less that should be the base we should go with in terms of modeling for the SG&A expenses.

Pankaj Patel: We will discuss offline, because there can be a several different models to work on this and there is nothing like a standard to work here.

Moderator: Thank you. Our next question is from the line of Atul Khemka from DSP BlackRock. Please proceed.

Atul Khemka: So sir, if I request you for your R&D guidance in terms of an absolute number, I know you said 7% to 8% of sales, but sales seems to be sort of highly volatile in terms of how many approvals you can get and all that. So, what would be your budget for R&D in the absolute number for this year, for FY17?

Pankaj Patel: I think we can provide you an exact number, but it is difficult to be an absolute number. But I think the philosophy, when we said 7% to 8%, that itself means that we are not talking about some particular number. But we monitor this on an annual basis, quarter-to-quarter depending on the products which are developing in a particular quarter, the number can be different. So you should not read in a particular quarter and generalize based on that, but within the range of 7% to 8% on annual basis, we will be in a position to ensure.

Atul Khemka: And in terms of this other expenses line item, I am talking about YoY where your other expense is down 10%. Can you help us with what was your remediation cost incurred in the first quarter of FY16?

Pankaj Patel: If you see, if you have studied our warning letter, there is not significant remediation cost, except these are third-party costs involved in terms of collecting some data and also doing some inspection. So it is not a significant cost, because if you study our warning letter, we did not need to really engage consultant on a full time basis or put some organization.

Atul Khemka: So sir, would you say that last year it was like, same quarter last year it was like less than $5 million in terms of remediation cost?

Pankaj Patel: Yes, I think we did that.

Atul Khemka: So sir if it is little less than $5 million and actually your other expenses on an absolute basis, excluding remediation cost, has actually come down by more than 5% year-over-year. So I know we are running these efficiency programs, but there is some inflationary pressure as well, which I do not think can be sort of done with, I mean, you have to take inflation and some costs. So which means, if I adjust for inflation as well then efficiency has improved like 10% - 15% to result in this, would that be a fair assessment and is that in your mind sustainable?

Pankaj Patel: Are you comparing Indian GAAP with IndAS numbers or the two IndAS numbers?

Atul Khemka: No sir, I am comparing what you reported in this press release on the front page, consolidated. So I am presuming both of those are IndAS numbers.

Management: So excluding the remediation cost, which we had incurred last year, what we are saying is the result of the rationalization of expenses which would have initiated because we knew that sales are going to go down in the US. As a result of that other operating expenses have been kept under control.

Atul Khemka: So, if I were to ask this question the other way around, if I take this Rs. 630 crores, can I take this Rs. 630 crores as the quarterly run rate for other expenses for this year? So this year full year other expenses will be about Rs.2,500 crores.

Management: Yes, roughly you can say that.

Moderator: Thank you. Our next question is from the line of Sameer Baisiwala from Morgan Stanley. Please proceed.

Sameer Baisiwala: Pankaj bhai, most of the products that you talk about 13 cumulative sites, which is done. These are all the existing products if I am not wrong.

Pankaj Patel: Yes, they are all existing products.

Sameer Baisiwala: So if you can update us on the unapproved ANDAs which are the pending ANDAs, what is the update on for the site switch for these?

Pankaj Patel: They are all going to be filed maybe over the next three months or so. So couple of products, which we identified to be filed are being filed, seven of them are there and they are being filed now. So they should be filed over the next three months or so, once we finish all the stability and other related work.

Sameer Baisiwala: And how much time will this take for the approvals to come by?

Pankaj Patel: Difficult to say because they have bio also involved, so bio data also will be included. So how much time FDA will take to review and give a site transfer approval. So if it is simple, it takes about 60 days, but if it is not simple, we have no experience how much time it will take, but maybe six months maybe.

Sameer Baisiwala: And then sir, you mentioned that you expect 12 to 15 launches over next five months or so up till December 2016. So these are the products which have been originally filed in those respective sites only, Baddi…

Pankaj Patel: Yes, correct. They have been filed from Baddi and SEZ sites.

Sameer Baisiwala: And sir, if you can confirm that Metoprolol Xl was filed from Neshar, right?

Pankaj Patel: No, it was filed from our SEZ site. No, sorry, Moraiya site.

Sameer Baisiwala: And sir the other question is related to, and I didn't get that, for Saroglitazar you said something about the NASH indication, can you just repeat that in your opening comments?

Pankaj Patel: Yes. So Saroglitazar we applied to US FDA for NASH clinical studies, which has been approved and we are going to start very soon the Phase-II clinical study for NASH in the US.

Sameer Baisiwala: And how are the Phase-III studies in India for the same initiated?

Pankaj Patel: The Phase-III study in India is going on, along with that we also initiated Phase-III study in two other markets in Asia and Europe to expedite the Phase-III data from India and nearby markets. Plus, we are doing a Phase-II study in the USA for US approval.

Sameer Baisiwala: And one final question, regards to your lead biosimilar compound if I am not wrong, last time you mentioned that you have submitted pre-submission file to US FDA. I think, you mentioned earlier in this call that you have submitted BLA. So just wanted to know what exactly have you filed and what is the update over there?

Pankaj Patel: So I think we filed a pre-submission file to FDA on which the FDA gives you a meeting to discuss. So then after the filing, we have the meeting. The FDA has given us guidance how to proceed further and accordingly we are now working on it. And as I mentioned earlier, that we will be then able to come out with timelines for filing with FDA.

Moderator: Thank you very much. Our next question is from the line of Kartik Mehta from Deutsche Bank. Please proceed.

Kartik Mehta: Yes, all my questions are answered. Thanks.

Moderator: Thank you. Our next question is a follow-up question from the line of Saion Mukherjee from Nomura. Please proceed.

Saion Mukherjee: Just on Peg G-CSF for the US market, I mean, based on the feedback, when do you expect this can be potentially filed?

Sharvil Patel: Hi, this is Sharvil. So I will give you a brief update. So we have had a pre-meeting with the FDA regarding our data for both CMC and Clinical. And the FDA has found the CMC work to be appropriate, and what they have requested is that, we will have to do the Pk again and so that is why we are working on the protocol in terms of how we will do that. So I do not see us being able to file this product before early 2018.

Pankaj Patel: Calendar 2018?

Sharvil Patel: Yes, early part, first part of first quarter of 2018.

Saion Mukherjee: This other question I had was on Nesher, I think in one of the responses you mentioned seven approvals over the next 12 months or so. I remember you had filed Focalin XR from there, do you expect that approval in that timeframe?

Pankaj Patel: I cannot talk about a specific product, but I do not expect the Focalin approval by that time.

Saion Mukherjee: And sir in general for the US market, you mentioned two or three big approvals, large size approvals, opportunities that can come this year. So, I mean how would you define a large size opportunity?

Pankaj Patel: Anything which is more than $30 million to $50 million.

Saion Mukherjee: Annualized sales?

Pankaj Patel: In terms of our sales, yes.

Saion Mukherjee: Sir, on the alliance revenues that you have disclosed, there has been a decline and there are some 20 or 25 ANDAs which are pending there. So how should we think about that piece over the next one or two years?

Pankaj Patel: Yes, see what happened is that subsequent to our warning letter for a period they were continuously auditing and basically had stopped the business, now they have cleared everything and they started lifting the stock, so we will see that the sales are going to happen now.

Saion Mukherjee: Sir, but this is, a large part of this is your partnership with this Sagent, right?

Pankaj Patel: With Sagent, yes.

Saion Mukherjee: And finally one more question on transdermal, so again this is an area where we have been working for quite some time. Two of your filings are from Moraiya, but rest from the other facilities, which I do not think has an FDA issue. From an approvability standpoint, has there been any major change because there has been some guidance which FDA has issued on transdermal. Does that mean that the approval is substantially delayed for these products?

Pankaj Patel: No, we are in compliance with our guidelines which FDA has issued, so we do not see any delay in the approval, and in fact, we should be looking at approvals next year.

Saion Mukherjee: Calendar 2017?

Pankaj Patel: Yes.

Saion Mukherjee: From Zydus Technologies?

Pankaj Patel: Yes.

Moderator: Our next question is from the line of Chirag Dagli from HDFC Mutual Funds. Please proceed.

Chirag Dagli: Sir, can you provide a rough breakup of the Rs. 800 crores R&D spend across the several buckets, vaccines, biosimilars, generics, NCE just ballpark numbers?

Pankaj Patel: So Chirag, we can provide this, but since this information I do not have in front of me, I request Vishal to give you this information.

Chirag Dagli: And sir, you seem to transferring a lot of products out of Moraiya. So this is just a risk mitigation or is it also to sort of capacity enhancement, I mean, while the FDA seems to be addressing Moraiya and the development seems to be going in a positive way, you are actually transferring a lot of products to other sites. So I am just trying to sort of…?

Pankaj Patel: So that strategy has two components. One is, of course the risk mitigation, but also speeding up Moraiya capacity, because there is significant filings and when those approvals come, we will have capacity available at Moraiya to manufacture and launch. So it is a mixture of both.

Chirag Dagli: And sir, last question, on this FDA communication on the 483 but not on the warning letter, obviously to us investors this seems like a change in the way FDA has been communicating in the past. So if you have any thoughts, do you think this is a change in the way they are communicating?

Pankaj Patel: I think so, but we do not have specific proof of that or we have not heard exactly whether they have changed it or not, but we believe that is so.

Chirag Dagli: So this is like probably on their part to just finish of the outstanding 483 just to show industry that there are not too many 483s pending, is that how we should think about this?

Pankaj Patel: I cannot comment on that in particular. Only thing is I can only say what they have said to us that they have closed our inspection, so we do not expect any further activity or action by FDA on that. And now they are going to address the warning letter. That's what they are saying.

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

Girish Bakhru: Just on the US side, how many ANDAs we will file this year?

Pankaj Patel: So we expect maybe 35 plus filings this year.

Girish Bakhru: And are you still filing from Moraiya or mainly from Baddi?

Pankaj Patel: No, we are filing from all other sites, currently there are no filings from Moraiya happening. May be one or two, but not much.

Girish Bakhru: And sir, from previous remark, when you said three critical launches of 12 to 15, it seems to be these three launches, are these some new filings because we have not site transferred the material products from Moraiya yet. So, what...

Pankaj Patel: These are the filings which we've done either for SEZ or Baddi facility.

Girish Bakhru: And then when you say meaningful, there could be at least $25 million, $30 million plus opportunity?

Pankaj Patel: Right.

Girish Bakhru: What is the update on the launches from Alidac facility, have you launched any product from there so far.

Pankaj Patel: So currently that facility is basically manufacturing products for partners and the production will be launched by our partner.

Girish Bakhru: Okay, in the overall scheme of things, just trying to understand, when do you see some of these injectables, topical launches to start from the US?

Pankaj Patel: Injectables, our filings has happened from Moraiya. So those will happen after Moraiya's cleared. As far as topical is concerned, we expect approvals and this year we should be able to launch topical products from our topical site.

Girish Bakhru: And sir lastly on doxorubicin, any update on that project filing?

Pankaj Patel: Still maybe next year we should be filing it

Moderator: Thank you. Ladies and Gentlemen, that was our last question. Due to time constraints, I now hand the conference over to Mr. Nayak for closing comments. Over to you, sir.

Dr. Ganesh Nayak: Thank you very much. And look forward to seeing you again in the October.

Moderator: Thank you very much. Ladies and Gentlemen, on behalf of Cadila Healthcare, that concludes today's conference call. Thank you all for joining us. And you may now disconnect your lines.