“Cadila Healthcare Limited Q2 FY 17 Post-Results Conference Call”

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MANAGEMENT: **MR. PANKAJ PATEL -- CHAIRMAN & MANAGING DIRECTOR, CADILA HEALTHCARE LIMITED**
DR. SHARVIL PATEL -- DEPUTY MANAGING DIRECTOR, CADILA HEALTHCARE LIMITED
DR. GANESH NAYAK – CHIEF OPERATING OFFICER & EXECUTIVE DIRECTOR, CADILA HEALTHCARE LIMITED
MR. NITIN PAREKH – CHIEF FINANCIAL OFFICER, CADILA HEALTHCARE LIMITED
MR. VISHAL GOR -- SENIOR GENERAL MANAGER, INVESTOR RELATIONS, CADILA HEALTHCARE LIMITED

Moderator: Ladies and Gentlemen, Good Day and Welcome to the Q2 FY 2017 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 an operator by pressing "*' then '0' on your touchtone phone. Please note that this conference is being recorded. I now hand the conference over to Dr. Ganesh Nayak -- COO and Executive Director of Cadila Healthcare Limited. Thank you and over to you Dr. Nayak.

Dr. Ganesh Nayak: Good Afternoon and Welcome to our Post-Result Teleconference for the Second Quarter of FY'17. 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.

Coming to the Key Financial Numbers: During the quarter gone by, on a consolidated basis, our total income from operations was marginally up 0.4% year-on-year to Rs.24 billion. Excluding the impact of one-off income earned on the sale and transfer of ownership in certain ANDAs for generic drug products during Q2 FY'16 and exchange rate fluctuations included in the other operating income, the total income from operations was up by 2%. Earnings before interest, depreciation and tax was down by 16% year-on-year to Rs.5.16 billion. The EBITDA margin declined to 21.5% in Q2 FY'17 from 25.5% in Q2 FY'16. Excluding the impact of one-off income in Q2 FY'16 and the exchange rate fluctuations on trading transactions, our EBITDA was down 3%. Profit before tax was down 20% to Rs.4.35 billion. Excluding the impact of one-off income in Q2 FY'16, exceptional items and exchange rate fluctuations both on trading transactions and debt, PBT was down 7%. Our net profit was down 29% to Rs.3.38 billion, net profit margin declined to 14% in Q2 FY'17 from 19.8% in Q2 FY'16. Excluding the impact of one-off income in Q2 FY'16 exceptional items and exchange rate fluctuations both on the trading transactions and debt, net profit was down 19%.

Let me share some of the highlights of the operations for the quarter: Our business in the US posted sales of Rs.9.9 billion, down 2%. We launched four new products during the quarter in the US. New launches include the launch of authorized generic version of Asacol HD. We filed 4 additional ANDAs with the USFDA and received approval for 1 new product.

Our India formulations business posted sales of Rs.8.2 billion, up 8.8%; however, growth excluding the impact of price reduction on NLEM products and the discontinued fixed dosage combination drugs was 13.3%. We launched 15 new products including line extension in India, of which 4 were for the first time in India. New launches include the Melgain brand, which was acquired from Issar Pharma.

Our Latin American formulations business posted sales of Rs.656 million, up 25%. In Brazil, we filed 1 more dossier and received approval for 1 more product from ANVISA. In Mexico, we launched 3 new products during the quarter.

Our Animal Health business posted sales of Rs.1.2 billion, up 53%, growth excluding Zoetis portfolio was 16%. Zydus Wellness Limited posted sales of Rs.1.1 billion, up 8%. The net profit of Zydus Wellness Limited was up 9% to Rs.321 million.

On the Biosimilars front, we completed Phase-II clinical trials in India for one of the novel biologics. On the Vaccines front, we entered into a partnership with Takeda Pharmaceuticals Co. Ltd. for developing the vaccine for chikungunya.

On the Basic Research front, we signed a collaboration agreement with Medicines for Malaria Venture to develop the investigational antimalarial compound. Two of our formulations manufacturing facilities, namely, the Oral Solid Dosage facility in Ahmedabad SEZ and the topical formulations facility received the EIR from the USFDA pursuant to the inspections carried out in the months of January and March this year.

Thank you. We will now start the Q&A Session. Over to the coordinator for the Q&A.

Moderator: Thank you very much. We will now begin the Question-and-Answer Session. Prakash Agarwal of Axis Capital. Please go ahead.

Prakash Agarwal: If you see the US sales sequentially has moved. Just wanted some color on the base business ex of the AG sales of Asacol HD. Would you ascribe the entire thing to Asacol HD or more given the decline in the base business that one would expect given general consolidation?

Dr. Ganesh Nayak: First, I think our base business included HCQ and as you are aware that HCQ had a significant price reduction. So there is a reduction in the base business. The launch of Asacol HD helped for two months out of the three months in terms of sales, and that is why you see the sales at almost same level as what was there last year, so growth is almost not there. There is a significant price erosion on HCQ and that has significantly impacted the base business growth coupled with of course the normal price erosion which also has happened in other products.

Prakash Agarwal: So from last quarter Q1 to Q2 also HCQ would have gone down?

Dr. Ganesh Nayak: Yes, it has gone down.

Prakash Agarwal: So if one was to guess the Asacol sales, it would have been Q2 minus Q1 and some decline in the base business?

Dr. Ganesh Nayak: I have not done that calculation, so I would not be able to correctly answer you that question. But, of course, Asacol has contributed a good amount of sales in this quarter.

Prakash Agarwal: Are we sharing any details in terms of market share, price erosion?

Dr. Ganesh Nayak: No, we are not sharing any information on that.

Prakash Agarwal: On USFDA update, where do we stand in terms of Moraiya remediation. We have done that, we have asked FDA to come. So, has there been any update sent post which and have we received any information from FDA?

Pankaj Patel: We have invited FDA for audit and FDA has informed us that they are scheduling an audit; however, we do not know when they will come for audit.

Prakash Agarwal: Our remediation updates continue to go?

Pankaj Patel: So all commitments which were made under remediation has been completed.

Moderator Thank you. The next question is from the line of Anubhav Aggarwal from Credit Suisse. Please go ahead.

Anubhav Aggarwal: Pankaj bhai, one question on this gross margins. Now, excluding Asacol, I am surprised to see gross margins for Cadila has expanded from June '16 quarter to now the September '16 quarter. With your comment on HCQs further down, what would lead to gross margin expansion for our business sequentially?

Vishal Gor: This is Vishal. If we look at the Q1 and Q2 gross margin because of Asacol HD, there is a reduction. How much reduction is because of Asacol HD? We cannot share. Because of other products also there is some sequential impact, but not material, because a lot of it was already factored in Q1. More details I can share you offline, I would request you as well as the other participants to have questions on strategy and on the other things.

Anubhav Aggarwal: No, but this is very important question, Vishal, because you have mentioned reduction, in the reported numbers, we are seeing a significant expansion in the gross margin.

Vishal Gor: So you are excluding the foreign currency translation reserve impact only which we have shared as a separate number. But there are other events also which we have not shared. So if you see reported numbers, there is a sequential decline in the gross margin.

Anubhav Aggarwal: Anyways, I have to call you up and take this number. Pankaj bhai, secondly on the strategy question, our R&D absolute number is down 8% in this first half. I thought we are doing

Lipaglyn Phase-II trials as well. Are we working on lesser number of products now that our absolute R&D spend is declining each year?

Pankaj Patel: No, I think we have not reduced our effort on R&D, I think this quarter, what you see in number is we have not spent money, so it will not come in this quarter, but we will be spending going forward. As far as Lipaglyn, clinical studies have started, but the real expenditure we will see only after a couple of quarters when actual trial will start coming in. Initial cost would be minimal as you understand that initially you do not spend money as the preparation on recruitment starts, cost will go up.

Anubhav Aggarwal: So Pankaj bhai, if you can just help it, not as percentage sales guidance, but as an absolute R&D number for this year '17 and '18, are we looking for flattish R&D spend what we have done in '16 higher or lower?

Pankaj Patel: Yes, we are looking at the flattish absolute number for '17 versus '16.

Anubhav Aggarwal: What is your outlook for '18 -- will we see an increase because Lipaglyn trial will be on?

Pankaj Patel: Yes, some increase will happen in '18, because Lipaglyn trial invoices will start coming in then.

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

Surya Patra: Just wanted to take whether apart from the Asacol HD anything else that has surprised positively on the US revenue front this quarter, sir?

Pankaj Patel: No.

Surya Patra: That is the only incremental development we have seen so far as US is concerned during the quarter, right?

Pankaj Patel: Yes.

Surya Patra: Going ahead, considering the kind of a progress on the plant front, what is the kind of outlook that we are now sharing for the US business?

Pankaj Patel: We expect the number of approvals as we have said earlier will be happening, because they were not dependent on Moraiya facility approval. Additional approval will be only after FDA completes the inspection and then we would see significant number of products getting approved. This year we expect about seven more approvals by December 2016 and additional approval we will see in the last quarter of this financial year; however, once the Moraiya

warning letter issue is resolved, then only we can tell you about Moraiya number, we can only say that we have a significant number of ANDAs where FDA has concluded all the CRLs and awaiting for Moraiya site release.

Surya Patra: Post Moraiya, we can see a kind of blow up of this approvals coming for the…

Pankaj Patel: We expect a larger number of approvals post-Moraiya resolution.

Surya Patra: Just wanted to check, whether we have opportunity for Gleevec in the near-term once it is…?

Pankaj Patel: No.

Surya Patra: On the Lialda case, I think district court has given favorable verdict towards us. So any update on that and what is your expectation?

Pankaj Patel: As expected the appeal has been filed by them in higher court and we are in the process of litigating that.

Surya Patra: Overall what is the kind of a CAPEX number that we are targeting for this year and next year -- whether it would be similar to that of the last year around Rs.1,000-odd crores kind of number?

Pankaj Patel: Yes, this year we expect CAPEX of about Rs.1,000 crores.

Moderator: Thank you. The next question is from the line of Kunal Mehta of Valuum Capital. Please go ahead.

Kunal Mehta: Just wanted to know about the status of approvals regarding four of our products; so Toprol XL, Prevacid and Sirolimus where we have received a tentative approval. So, is it dependent on the resolution of Moraiya issue?

Pankaj Patel: Yes.

Kunal Mehta: So as per your understanding, when do you expect the Moraiya issue to be resolved in the next probably 8-10-months?

Pankaj Patel: That is what we expect, but we cannot give you exact timeline, once the FDA inspection happens, we should be able to tell you the timeline.

Kunal Mehta: Your comment on decline in standalone revenue so it has seen a sharp decrease this quarter if I see it on a year-on-year basis. So what was the factor that attributed to that decline?

Pankaj Patel: I think you should more focus on consolidated numbers, standalone number, Vishal can explain you in detail, I think standalone number would not have much value.

Vishal Gor: Standalone numbers would also depend upon how much sales we make from standalone entity to our global subsidiaries. So that has gone down and that is the main reason, but you should not be looking at standalone numbers really, you should be concentrating on consolidated numbers only.

Kunal Mehta: Just wanted to understand your views on channel consolidation in the US because now the four distributors are having around 80% market shares. What are your views on the pricing which they would impose on the generic players?

Vishal Gor: I think same view as you have Kunal "More stronger the buyer, more power he has."

Moderator: Thank you. The next question is from the line of Saion Mukherjee of Nomura Holdings. Please go ahead.

Saion Mukherjee: Sir, on Lialda, since the district court verdict is favorable, is it right to say that the regulatory hurdle is the one which is the key bottleneck now and given that Cadila is the first to file, I would assume that there is interaction with the FDA and how are you feeling about approvability of the product?

Pankaj Patel: So I think on Lialda, as we have won the first appeal and we are now litigating the second appeal. As far as regulatory front is concerned, we have addressed the CRL fully, so we are awaiting FDA feedback on that, and we have requested FDA for expedited approval.

Saion Mukherjee: Given that is an unique product and there are not any Oral -Mesalamine product approved so far, do you see a possibility of it getting approved in the next 12-months assuming Moraiya getting resolved?

Pankaj Patel: I think so.

Saion Mukherjee: The second point is on the US business, so we have a base now right. Do you expect further erosion in some of your assets that is there in the base, and how should we think about growth in the US going forward? Any specific product or product segment that you can talk about which would lead the growth over the next 12-months?

Pankaj Patel: Saion, I think what we see is that most of our portfolio is the old products, and I think we have touched the base, I think one of the major challenges was with respect to the HCQ which of course the whole price erosion whatever risk we have already happened now. So we do not expect significant price erosion pressure going forward. So only we will be at maybe the historical level of price erosion which we have had.

Saion Mukherjee: What about growth, what product segments, how do you think about traction in the US business going forward?

Pankaj Patel: I think first of all, new products approval is what is going to basically create the traction and growth for the US business and then as we have said, we are expecting many approvals both from SEZ site and the site at the Baddi. So both the sites we are expecting approvals and this approval should actually give us enough number of products to achieve growth going forward, #1. Of course, when the Moraiya get resolved, then we will have much more opportunity going forward. With respect to SEZ, the manufacturing facility, we are almost close to completing the facility expansion also now. So, we should be ready as and when the product approval comes to manufacture the product and supply to US market.

Saion Mukherjee: What about Transdermals and Nesher?

Pankaj Patel: Coming back to the Nesher, we expect three to four product approval in this financial year and that should actually help us to increase the sale further at Nesher. Transdermal, we have addressed all the CRLs. So, we are awaiting approval. Assuming that is the last CRL, then in that case, we would basically be expecting approval in maybe 6-8months time.

Saion Mukherjee: Sir, you mentioned in the last call that 2-3 products with like $30 million plus potential are possible in FY'17. So you still expect that is possible?

Pankaj Patel: It is still possible to get those product approvals.

Saion Mukherjee: Because we have seen significant price correction in some of your key products like HCQs, Tamsulosin, etc., So are there any risk of charge-backs etc., and are they already in the financials?

Pankaj Patel: No, they are all charge backed whatever could be there has been already factored in financial. So we do not expect any surprises.

Moderator: Thank you. The next question is from the line of Ritika Jalan of Narnolia Securities. Please go ahead.

Ritika Jalan: I just need clarification on two things -- one is the increase in the depreciation cost. So, where do we see the going forward depreciation?

Pankaj Patel: So, I think Vishal can give you, Ritika, information about depreciation. If you make investment, there is going to be increased depreciation.

Vishal Gor: It is mainly because of increased CAPEX.

Ritika Jalan: Where this CAPEX will go Rs.1,000 crores that you are planning?

Pankaj Patel: Spending on additional manufacturing capabilities.

Ritika Jalan: Tax rate?

Nitin Parekh: 20-25%.

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

Sameer Baisiwala: Pankaj bhai, on Moraiya facility, two parts -- one is, for the existing business, how much has been derisked? Second, for the pending ANDAs, you were planning the site switches and I guess submission around September or so. So what is the update over there?

Pankaj Patel: So first of all Moraiya, existing business some of the products have been derisked to move out, but it is not a part of the derisking strategy, but decongestion strategy that Moraiya existing products have been shifted to other sites, so that there is a less work load on Moraiya. #2 is, as far as the site transfers are concerned, important products like Lansoprazole and Metoprolol we have completed the site transfer process to SEZ site.

Sameer Baisiwala: You have submitted the data to FDA?

Pankaj Patel: We are expecting to submit the data very soon.

Sameer Baisiwala: In total I thought you were doing it for 7-products?

Pankaj Patel: Yes, we are doing for 7-products, so some of the other products have been filed before, these 2-products are going to be the last two we are going to be filing now.

Sameer Baisiwala: Your assessment that these get reviewed and approved what in 6-9-months?

Pankaj Patel: The review has also already happened and the hold is basically for the site. So, maybe 6-8-months to get approval.

Sameer Baisiwala: Pankaj bhai, on Asacol HD, I thought your original settlement had it 1st July launch, but then you finally did it in 1st August. So, what was driving this one month lag? Second is, what do you say given that it took you 2-3-weeks to ramp up the market share that this quarter really captures maybe 45-odd days of the upside?

Pankaj Patel: I think first of all we did it as per the agreement to inform them about launch of authorized generic by end of July and then there was 30-days lead time to get approval, product supply

and launch. So I think we took decision towards the end of July and that is the reason why we launched in August. Since we launched in August, obviously, our sale is reflecting at the most 60 days, because you can expect some orders would be also fill about the pipeline, so almost two months orders have been reflected in sales for the quarter which has just gone by and going forward, I think we will have same monthly average possible for the next foreseeable future. We are the only generic in Mesalamine in the market today, there are no other generic at all for any kind of Mesalamine.

Sameer Baisiwala: But Pankaj bhai, on the third part, are you still pursuing your own ANDA approval for Asacol HD?

Pankaj Patel: That is we already filed it. So we are expecting approvals once the Moraiya site gets cleared.

Sameer Baisiwala: You have the leeway to then discontinue authorized Generic and then get in with…?

Pankaj Patel: I would not make any comment on that because of the legal compulsion we have.

Moderator: Thank you. The next question is from the line of Ashish Kumar from Bank of America-Merrill Lynch. Please go ahead.

Ashish Kumar: Pankaj bhai, like just in continuity of the previous comment which you made on Asacol HD, is it fair to assume that since being the only generic player in Mesalamine, Asacol HD is being able to take the market share of some of other Mesalamine products as well?

Pankaj Patel: It is too early for me to say that, maybe after maybe 6-months we should be able to understand that more, it is just a short period of two months, we cannot give you exact idea at this moment, maybe yes, maybe no, I do not know.

Ashish Kumar: The second comment which you made on Asacol HD, that you have completed all the queries with regard to Asacol HD from the FDA and now it is only the Moraiya plant approval which is holding back the product approval from the FDA?

Pankaj Patel: Yes.

Ashish Kumar: So once the Moraiya gets clear, probably we may see the approval for both Lialda as well as Asacol HD?

Pankaj Patel: Yes.

Ashish Kumar: Like maybe a couple of years ago you had a strategy to have focus on the key markets like India, Mexico, and Brazil; however, all of these three markets if you look at in terms of growth prospects, I think still the growth are not up to the mark what probably we have anticipated in

the past. So how do you look at these markets and what do you feel the need to be done more in order to accelerate the growth momentum in these markets?

Pankaj Patel: First of all, I think India growth is coming to line, but because of kind of disruption happening in the marketplace which you are all aware of, that our growth gets impacted because of price erosion, price reduction, etc., So though we grew by 13%, but then our growth is 9%. So that is one thing which happens as far as India market is concerned. But 13% or more, I think it would be like a good growth for India market in my opinion. That is the market which will continue to be more predictable going forward as well. Then coming to the Brazil, we are now getting product approvals and in the process you can see that we are getting into growth phase now, the Brazilian market this quarter also you have seen that it has grown by about 25%. Of course, Mexico is a new market we enter and there the growth of course is very high but the base is bit low. I am not going to tell you that percentage is so exciting, because we are just beginning to really start seeing the benefit of launch in Mexican market. So we continue to focus on this market, because this market offers lot of opportunity. As you also aware that as a part of strategy, our third pillar of significant revenue we are looking at Mexico, Brazil and some of the other emerging markets put together should actually help us to make a strong player in emerging markets as well. So we would have three revenue streams helping us to really continue sustainable growth of the overall business.

Moderator: Thank you. The next question is from the line of Anubhav Aggarwal of Credit Suisse. Please go ahead.

Anubhav Aggarwal: Pankaj bhai, one clarification on this Moraiya facility. Last time you mentioned that you were seeking face-to-face meeting with the FDA. Has that already happened?

Pankaj Patel: FDA says that they are going to come and audit and then if they do there will be a face-to-face meeting. So currently we are not having any face-to-face meeting with FDA, they are going to come and audit us.

Anubhav Aggarwal: Pankaj bhai, just on this Transdermal case that we had with Mylan, is that case over now or what stage is that case right now?

Pankaj Patel: Case is over.

Anubhav Aggarwal: So the decision is already in our favor, there is no blockage in us to launch…?

Pankaj Patel: There is no blockage now.

Anubhav Aggarwal: Nitin sir, interest cost for us has been rising very sharply from the fourth quarter, debt is also up Rs.600 crores versus the March. When does this normalize for us and at what level will this get normalized and consequently interest cost normalize for us?

Nitin Parekh: So, interest cost has gone up when you compare on year-on-year basis because of the increase in the US business and especially in this quarter, as you know we started selling Asacol HD, and the way the terms are there in US, you receive payment letter from your parties, but you start making payment to or charge back to channel partners. So that has increased my working capital cycle in US and that is responsible. But going forward, we do not see this interest cost going up.

Anubhav Aggarwal: But, at the same time, so this is now Rs.19 crores almost what we have reported this quarter, which had Rs.2 crores of FOREX element, but Rs.17 crores is almost in the vicinity will sustain here?

Nitin Parekh: Yes.

Anubhav Aggarwal: Ganesh sir, on the India business, what is the total impact to Cadila from this recent Bombay High Court ruling where the writ petition from ITA was turned down… special narcotic portfolio -- I think the number which some of the other let us say databases suggest would highlight some Rs.30 crores to Rs.40 crores impact on the India business?

Pankaj Patel: Anubhav, Pankaj here, I think the judgment came very recently. We have not yet heard from NPPA. So, it is very difficult for us to actually give you the number at this moment. Once the things get more clearer, we should be able to tell you the number. The number could be what you said or nearby that. But I do not want to give you a number without a complete idea from NPPA exactly what they are going to do and etc., The second point is many of the products subsequently came into the NLEM list. So we already have in the process reduced the prices. So, only for limited period there may be some liability to pay if at all will come. We do not know the exact amount now. But once that is more clearer, we would inform you.

Moderator: Thank you. Next question is from the Kunal Mehta from Valuum Capital.

Kunal Mehta: Just wanted to understand about the approval received to your product Sirolimus. So have you received the final approval?

Dr. Ganesh Nayak: No.

Kunal Mehta: As per your understanding, what is the expected time when you shall receive it?

Dr. Ganesh Nayak: This is contingent to Moraiya site approval. So once the Moraiya warning letter things are resolved, we would have the approval.

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

Surjit Pal: Just two questions: Is that your exporting incentive came down quite drastically. Any particular reason for that? Asacol HD what I thought is that it is one of those seven products which you shortlisted for site transfer to de-risk your Moraiya uncertainty, which I believe you were supposed to complete by say Q4 and then file and expect 6-8-months that approval. As far as Asacol HD is concerned for your side, are you still in the schedule or if you can explain on that?

Dr. Ganesh Nayak: I will take the last question first and then Nitin bhai will take up the first question. So as far as Asacol HD is concerned, we are not doing site transfer because we are closer to Moraiya site resolution so that we would prefer to wait for that. So we are not doing any site transfer as far as Asacol HD is concerned.

Nitin Parekh: Reason export incentive income has come down in this quarter is because of lesser sales from Cadila Healthcare Limited largely to its US subsidiary. So this time US sales which you see is also consisting of the AG sales, to that extent sales from India is lower.

Moderator: Thank you. Next question is from the line of Abhishek Sharma from IIFL. Please go ahead.

Abhishek Sharma: Sir, in one of the comments you mentioned foreign currency translation reserve. Just wanted to understand broadly how does it get created and where would it reflect?

Pankaj Patel: I think Vishal will give you this information and give you more detailed explanation offline. I will ask Vishal to do that.

Abhishek Sharma: Secondly, so you said, Asacol you are not doing site transfer. Can you give us an update on Lialda.. are you attempting a site transfer there and what is the status if…?

Pankaj Patel: No, we are not doing site transfer on Lialda as well.

Abhishek Sharma: Third is more around the fact you would be working to that assumption that Moraiya now we are nearing resolution at least in your business case and in the meantime your ANDAs would have continued to get processed. So do we expect bunched up approvals once the resolution comes through for Moraiya site and any quantum based upon the CRL activity that has…?

Dr. Ganesh Nayak: Answer to that is 'yes'. But number is the good number, I do not want to say, but it is about more than 20.

Moderator: Thank you. The next question is from the line of Purvi Shah from Sharekhan. Please go ahead.

Purvi Shah: Sir, I just wanted two clarifications: One was on the tax rate, in the last call we had guided for 20-22%, and if I am not mistaken, in this call you said it is 22-25%. Is that right?

Pankaj Patel: Yes, 20-25%.

Nitin Parekh: So if you see our current tax has gone down compared to last year, but if you see our deferred tax liability or reversal of deferred tax asset has gone up and that is resulting into increase in the tax rate. Deferred tax liability creation of reversal of deferred tax assets have been done as per IND AS provision. The majority part of this is on the stock which we have for our intercompany transaction. So that is something which you cannot estimate for every quarter, range of 22-25%.

Purvi Shah: I understand that, because earlier it was 22% was the higher band, now it is 25% is the high band, so that is why I asked it. So is it the same rate for FY'18 as well?

Pankaj Patel: You can take this range which we mentioned.

Purvi Shah: One more clarification was on Lialda that did we just say that in case the approval comes in we will be the only generic launcher?

Pankaj Patel: We have exclusivity on Lialda as you might be aware. That is why we expect that we will be exclusive launcher.

Purvi Shah: No, no, apart from the exclusivity

Pankaj Patel: Other filers also for Lialda.

Purvi Shah: So only for the FDA situation we have seen?

Pankaj Patel: That is right.

Purvi Shah: On the India business front, I just wanted to know is that, if I am not mistaken, in our balance sheet we just stated that the contingent liability is of around Rs.13.5-14 crores for the DPCO thing, NPPA ruling method recently come in. So to the earlier participant you were answering that roughly around Rs.30-40 crores. So am I missing something?

Pankaj Patel: So, I think Purvi, first of all, I cannot give you a specific number with respect to the liability, we are still evaluating and once we have clarity on that we would be able to give you a specific number. So there is some estimate that, maybe correct or not correct, so I do not want to commit to a number at this moment.

Purvi Shah: If you could just tell us what is the percentage under DPCO currently?

Pankaj Patel: Little less than 30%.

Moderator: Thank you. The next question is from the line of Saion Mukherjee from Nomura Holdings. Please go ahead.

Saion Mukherjee: Sir, on the domestic business, we have seen a few quarters of good double-digit growth and it has again come down because of multiple issues. I am just wondering how should we think about growth from a slightly longer-term perspective and I know what measures are taken to ensure that double-digit growth sustain? Secondly, how do you see the profitability of the domestic business in terms of let us say EBITDA margin versus the rest of the company and how that has moved over the last many years since there has been lot of regulatory interventions?

Pankaj Patel: First of all, Saion, on a long-term we are still very confident that the market will continue growing and we should be able to grow the business at about 15%. This will be achieved of course through new product launch and through better focus on some of the key brands. These are the two strategies which is going to help us to achieve that kind of a growth. Your second question about how the profitability has behaved over the last three years… it is a good question, I do not have the numbers in front of me, but definitely it gives me a thought to really study it and maybe give you more color to it. So we will study that and give you specific details.

Saion Mukherjee: Is it right to assume that the EBITDA margin for the Domestic business would be more than 20%, which is the company level margin?

Nitin D. Parekh: Yes.

Saion Mukherjee: Sir, second question on R&D, because many of your peers have increased R&D spend quite substantially as they are investing in more complex products which require clinical trials and the whole thought process is that the market is getting very competitive in the US. What are your thoughts around that… two years down the line do you see the spend substantially going up for Cadila as well?

Pankaj Patel: My personal view is that we will maintain 7% to 8% R&D spend going forward as well. I cannot comment about the competition because I am not fully aware of their strategy. This would also include some clinical studies what we need to do from time-to-time.

Saion Mukherjee: On Biosimilars if you can share what is the size of the business currently and what are the key things that we should watch out for both for emerging markets and regulated market perspective over the next 3-years?

Pankaj Patel: Currently, our Biosimilar business is approximately Rs.300 crores. Going forward we expect good growth in that business. We are getting into several markets for registration process now. Once the registration happens, we would see the growth coming from those markets as well.

We are getting a lot of traction from emerging markets for the Biosimilars, and we clearly see there are good opportunity. The big numbers can occur in USA which is too early for us to really comment about it, because still it is very new for the US market and how the market will respond ultimately we will see. The way we have modeled our business both from India and emerging markets, we would generate significant revenue going forward and we believe that this business has the potential to touch 500 million in maybe next 5-7-years time and even go beyond that.

Saion Mukherjee: I just wanted to understand which are the business segments which are like materially lower than your company level EBITDA margin, it could be certain markets like Latin America or segments like Vaccines, if you can help us list down those businesses?

Pankaj Patel: I can provide you that information, but broadly I can say that Europe is the lower margin business, Latin America is still emerging. So that is why you see lower margin, but when the growth happens, then the margin can be in line. So that is what I can say. But Vishal can give you all the details offline, that which are the business which are going to remain always lower margin, which are the business which are going to be currently having lower margin but will go to the normal margin, and also business of course are in good margin.

Moderator: Thank you. The next question is from the line of Kartik Mehta from Deutsche Bank. Please go ahead.

Kartik Mehta: Just trying to understand on Lialda again. Pankaj bhai, do you believe that FDA's bioequivalence guideline are high for all the generic manufacturers to receive an approval on this product? If so, do you believe that we may need to reformulate it which in turn could also trigger further rounds of litigation?

Pankaj Patel: First of all, I think we do not expect any reformulation activity anymore because our bio has been completed and filed with the FDA long back and we have not received any CRL on that.

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

Neha Manpuria: On Lialda again, I know there are two other filers for this which are still under the 30-months stay for the IP challenge. But, do you see a situation where we get approval and we do not see a multi-source market for this even after exclusivity, which means Cadila gets an extended period of exclusivity?

Pankaj Patel: I think earlier question was in the same line, it is a tough bioequivalence guideline and we are part of that guideline and our products has met requirement, other companies may and might have challenges, I am not aware of that. Apart from that, they have litigation, and of course, we are first filer still and we have 180-day exclusivity as of today.

Neha Manpuria: But beyond that, do you think this could be an extended product, particularly given it is a tougher IP and regulatory barrier hurdle?

Pankaj Patel: Could be, but I am not aware fully, I do not know what exactly the challenges my competitor is facing.

Moderator: Thank you. Next we have a follow-up question from the line of Ritika Jalan of Narnolia Securities. Please go ahead.

Ritika Jalan: How many of the product launches are quite a bit meaningful?

Pankaj Patel: There are a number of ANDAs which are very meaningful and it depends upon the timing of approval, product could be meaningful today, it cannot be meaningful tomorrow, but there are a number of products which are meaningful as far as products which are going to get approved.

Ritika Jalan: Is there any plan to raise equity or debt moving forward?

Nitin Parekh: Currently, our debt-to-equity is 0.29:1 and we have told that we would not exceed 1:1 even if we go for inorganic growth. Our internal guideline for debt-equity is that we would usually like to maintain our debt-equity below 0.5, will never exceed 1.

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

Nitin Agarwal: On the Biologics, in the portfolio currently that we are selling which are our leading products that we are selling across different markets right now in our portfolio?

Pankaj Patel: Currently, our majority of the sale is coming out of India only. Other emerging markets, we are just getting approval and the sales will begin maybe next quarter onwards.

Nitin Agarwal: How many products are you looking to take it to the emerging markets right now that you see registration coming through?

Pankaj Patel: It is about 7-products.

Nitin Agarwal: You are filing for all 7 simultaneously?

Pankaj Patel: Yes.

Nitin Agarwal: From a global trial perspective, on the regulated markets, how many products are we working on right now from global getting approvals in the developed market?

Pankaj Patel: 2-products.

Nitin Agarwal: Have we name them?

Pankaj Patel: Yes, it is Pegylated G-CSF and Adalimumab.

Nitin Agarwal: Sir, secondly on the R&D front, there is obviously a reduction in the number of ANDAs that we are filing for the same R&D spends in the past. So qualitatively what has been the change in the R&D thought process in terms of kind of products that we are targeting over the years?

Pankaj Patel: So our portfolio consists of all kind of products, so I cannot specifically say that per product R&D spend has gone up or gone down, our R&D spend has, I just explained earlier that it is going to remain flat in terms of total amount of money we are going to spend this year. Number of filings has been given before will be close to 40. So we do not expect that R&D spend productivity will come down and even number of filing will also remain good.

Nitin Agarwal: On the SG&A front, I think we continue to do extremely good job in terms of controlling our cost. How much further can we stretch this cost optimization measures before the inflation on this…?

Nitin Parekh: Nitin, any organization has to do optimization on a continuous basis. So we will continue doing so. Now, it cannot be overnight I can reduce significantly, but over a period there is always emphasis to control the cost.

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

Prakash Agarwal: Just a couple of follow-ups: So just a clarity on Prevacid SoluTab. You mentioned about the site transfer which would take about 6-8-months?

Pankaj Patel: What we mentioned is that we have done this site transfer from Moraiya site to SEZ site. The submission for that data once the stability is completed will be done in next few weeks and then we would expect that, after that we should have an approval of the product in 6-8-months.

Prakash Agarwal: So practically fiscal '18 kind of launch or approvals?

Pankaj Patel: Prakash, just for the benefit of you and the other members, so far we have made filings of 13 site transfer applications. All of them are for existing products, none of them are for the pending approval products. Out of 13, all of them have been approved, 11 we have already clinically switched the time. For the products which are not yet approved, which include some of the key products, we have not yet made any site replication, we are in the process of generating the data and then we will decide whether we would switch or not.

Prakash Agarwal: The key ones which we are in the process which includes Prevacid and Toprol XL?

Pankaj Patel: Correct.

Prakash Agarwal: Any other products you are sharing?

Pankaj Patel: Other products we are working, but we are not sharing as an information.

Prakash Agarwal: On the JV business, we have seen a sharp decline. Is it due to the Bharat Serum Vaccine business or?

Pankaj Patel: Yes, it is mainly because we had some offtake of one of the contract products which we are supplying, and some of the customers of the Alidac Pharma which was earlier Zydus BSV because of these two, otherwise our other joint ventures are on track and this is a one-time impact on this quarter, next quarter the picture should be better.

Prakash Agarwal: On the filings front, you mentioned you still maintain your 40 plus filings. We have done 6 plus 4, 10 filings in 1H, so we expect this momentum to be very high in the second half?

Pankaj Patel: Yes.

Prakash Agarwal: Lastly on the Vaccine business, we said in the past that we are looking at India launch. If you could throw some light for the India and the emerging markets where this product is and when do we expect the launches?

Pankaj Patel: So, we have received the approval for three Vaccines from Indian regulatory authority and we are expecting more approvals to happen over the next two quarters. So we expect to launch Vaccine in the next financial year.

Prakash Agarwal: How large sir approximately these could be… could be sizable pieces like sub-Rs.100 crore kind of thing?

Pankaj Patel: Yes, some of these.

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

Sameer Baisiwala: Pankaj bhai on Moraiya, what is your current capacity utilization?

Pankaj Patel: On Moraiya, currently, our capacity utilization should be around 60%.

Sameer Baisiwala: Then it is a little surprising that you were talking of not derisking of the existing business but decongestion?

Pankaj Patel: I will tell you because we needed approval in Moraiya. When the approval will come I should have capacity to produce, no. I am getting ready for when the Moraiya get resolved and then my product approval happen I have to produce at Moraiya. I cannot then do the site transfer and do the capacity release. I am releasing the capacity so that when the product approval happen I can produce in Moraiya.

Sameer Baisiwala: But I thought 60% was low enough. So after you decongested, what would your capacity utilization fall to?

Pankaj Patel: So after decongestion it will be 60%.

Sameer Baisiwala: Pankaj bhai, then on the re-inspection of Moraiya, we are almost getting to the end of October, maybe you got another 4-6-weeks and then the Christmas time. Do you think the chance that this happens in 2017 calendar?

Pankaj Patel: We can say that it can happen now or if it happens, it happens before 15th December or otherwise in January.

Sameer Baisiwala: But there is nothing in your ongoing…

Pankaj Patel: Because we do not know when the inspection will be scheduled.

Sameer Baisiwala: Finally on Lialda, a couple of questions. Within 30 months you did not get the tentative. So would this not lead to forfeiture of your exclusivity as per MMA?

Pankaj Patel: Sameer, one thing FDA changed the guidelines and since the FDA changed guidelines that 30-months will not be applied. You understand the point? Because originally it was only clinical study, subsequently, they came out with a guideline to have a bioequivalence study. So after we filed, thereafter the guidelines were published. Our first filing was with the clinical study, subsequently, they came out with the bioequivalence guideline, so we have to do bioequivalence and resubmit the additional information. That is the reason why there is calls for delay in approval. It is not our fault but FDA changing the guideline.

Sameer Baisiwala: That was the guidelines if I remember was September 2012 and you have filed just before that?

Pankaj Patel: After the guideline was issued then we did the bioequivalence study and submitted to FDA.

Sameer Baisiwala: Then Pankaj bhai, what also happened was I think the latest revision to that happened in July 2016. So therefore…

Pankaj Patel: We have compliance to that as well.

Sameer Baisiwala: One final point on this, now assuming this regulatory thing is cleared at some point in time, would you then worry about the appeal litigation or would you take a chance that launch at risk?

Pankaj Patel: We have not made up our mind yet. So it is difficult to say, Sameer, at this moment whether we will launch at risk or not.

Moderator: Thank you. Next we have the last question from the line of Nimish Mehta from Research Delta Advisors. Please go ahead.

Nimish Mehta: Just to continue a little bit on Lialda. What would happen theoretically if the other Para-IV filer gets an approval because the court cases in favor of Generics, can they trigger the exclusivity, you do not have an approval, it can be triggered and post six month they can launch, is that a possibility?

Pankaj Patel: First of all, everybody is currently having a stay, they are under litigation. #2 is that, none of the player has got approval… not even a tentative approval. The third is that, we have exclusivity and we believe as per the advice we received that we have a strong case for our exclusivity and that is why we would have the exclusivity. So we believe that is so we would have first chance to launch. That is our belief.

Nimish Mehta: I was just trying to understand the hypothetically if they get the approval first and we get the approval later, so they can launch after waiting for 6-months? That was only thing I am trying to understand.

Pankaj Patel: That is the call FDA has to take. Whether they would give them approval to launch.

Moderator: Thank you very much. That was the last question, ladies and gentlemen. I would now like to hand the conference over to Dr. Ganesh Nayak for closing comments.

Dr. Ganesh Nayak: So Happy Diwali and Happy New Year and look forward to seeing you in February 2017 for our Q3 Results. Thank you and good night.

Moderator: Thank you very much. On behalf of Cadila Healthcare Limited, that concludes this conference. Thank you for joining us, ladies and gentlemen. You may now disconnect your lines.