“Cadila Healthcare Limited Q4 FY17 Post-Results Conference Call”

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Moderator: Ladies and Gentlemen, Good Day and Welcome to Q4FY'17 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 telephone. Please note that this conference is being recorded. I now hand the conference over to Mr. Ganesh Nayak – COO and Executive Director of Cadila Healthcare Limited. Thank you and over to you Mr. Nayak.

Ganesh Nayak: Good Evening and Welcome to our Post Result Teleconference for FY'17. We have with us Mr. Pankaj Patel – Chairman and Managing Director; Dr. Sharvil Patel – Joint Managing Director; Mr. Nitin Parikh – Chief Financial Officer; Mr. Tushar Shroff – Senior Vice President and Mr. Vishal Gor – Senior General Manager, Corporate Finance.

The year gone by, though a challenging one on the business front, turned out to be quite an encouraging one on the regulatory front. Two of the largest businesses, namely, the US Formulations and India Formulations, continue to face different challenges.

Our US business got impacted due to the lack of significant new product approvals and a difficult pricing environment. Our Moraiya Formulations facility, the largest manufacturing facility, remained under warning letter resulting in non-receipt of new product approvals from that site during the year, though we continue to receive new product approvals from other sites. However, in the last quarter of the year, we completed the USFDA inspection at our Moraiya Formulations facility with zero 483 observations. Apart from Moraiya, our Oral Solids manufacturing facilities in Ahmedabad SEZ and Baddi and the topical manufacturing facility in Ahmedabad also completed USFDA inspections.

The year marks our foray into the specialty pain market in the US with the acquisition of Sentynl Therapeutics Inc., a US-based Specialty Pharmaceutical company. We have gained access to specialty distribution network and a large prescriber base through this acquisition.

Recently, we successfully defended the claim of non-infringement in the US Court of Appeals for the Federal Circuit in the case of Lialda. Our India Formulations business, the second largest contributor to our top line, got impacted primarily on account of reduction in prices of more drugs announced by the NPPA during the year and the government's decision to ban fixed dosege combination drugs. Overall, our consolidated top line was flat at Rs.96.3 billion; however, with the successful completion of regulatory inspections at our major formulations manufacturing sites, we are hopeful of getting back to the growth trajectory. As is known, we have made sizeable investments in new technologies such as Transdermals, Biosimilars, Vaccines and New Chemical Entities which are expected to contribute to our future aspirations.

With that, first of all, let me take you through the broad Financial Numbers: During the year on a consolidated basis, our total income from operations was flat at Rs.96.3 billion. Earnings

before interest, depreciation and tax was down by 18% YoY to Rs.19 billion. The EBITDA margin for the year declined by 440 basis points to 19.8% as against 24.2% registered last year. Excluding the impact of income earned on the sale and transfer of ownership in certain ANDAs for generic products during FY'16 and exchange rate fluctuations gain on operating transactions, the EBITDA was down 13%. Profit before tax was down 23% to Rs.16.2 billion. Excluding the impact of income earned on the sale and transfer of ownership in certain ANDAs for generic products during FY'16, exchange rate fluctuations both on operating transactions and debt and exceptional items, PBT was down 19%. Net profit was down 23% YoY to Rs.14.9 billion. Net profit margin for the year declined by 460 basis points to 15.5% as against 20.1% registered last year. Our consolidated debt at a gross level stood at Rs.52.1 billion and debt net of cash stood at Rs.36.1 billion. Net debt-equity ratio was 0.52 as on 31st of March 2017. Our consolidated CAPEX for the year was Rs. 29 billion. This includes the CAPEX incurred towards the acquisition of Sentynl therapeutics Inc., and the acquisition of trademarks in India from Organon India Limited, a subsidiary of MSD B.V., AstraZeneca, and ISSAR Pharma.

With that, let me share some of the Highlights of the Operations for the Year. In the US Generic market, we launched 15 new products during the year. New launches include the launch of the authorized generic version of Asacol HD. We filed over 45 ANDAs with the US FDA taking our cumulative ANDA filings to over 305 and received approvals of over 10 ANDAs during the year taking our cumulative approvals to over 110. This includes our first topical product approval which was filed from the Formulations facility located in Changodar, Ahmedabad. In addition to our own filings, we acquired two ANDAs including one Transdermal Patch from Teva. Overall, our US business posted sales of Rs.37.1 billion, down by 8% during the year.

On the India Formulations front, we launched over 75 new products including line extensions in India during the year, of which 17 were for the first time in India. We acquired six trademarks from Organon India Limited, a subsidiary of MSD B.V., to strengthen our presence in the Men's Health, Women's Health, Wound Management and Cardiovascular Therapy Areas. We acquired a few trademarks from AstraZeneca to strengthen our presence in the anesthesia, gynecology and anti-infective therapy areas. Overall, our India Formulations business posted sales of Rs.32.4 billion, up by 9%. Growth excluding the impact of the price reduction on NLEM products and discontinued fixed dose combination drugs was 13%.

In the emerging markets of Asia Pacific, Africa and Middle East, we retained our number 1 position in Sri Lanka with eight brands, featuring amongst the country's top 50 brands. We launched nine new products in the focused markets of Asia Pacific, Africa and Middle East during the year. This includes the launch of Zyrop in Myanmar, the second biosimilar launched in the emerging markets. Overall, our emerging markets business posted sales of Rs.5 billion during the year, up by 8%.

Now, coming to Latin America, we launched two new products in Brazil during the year. We filed three new products dossiers with ANVISA and received approvals for seven new products during the year. In Mexico, we launched five new products during the year, taking our cumulative number of launches to 21. We filed one new product dossier with COFEPRIS taking the cumulative filings in Mexico to over 40 and received approvals for two new products, taking the cumulative number of approvals to over 35. Overall, our business in Latin America posted sales of Rs.2.4 billion during the year, up 12%.

Among the other businesses, we launched three new products in France, including one from India and five new products in Spain which include four from India. We filed four new product dossiers taking our cumulative filings to over 205 and received approvals for nine new products taking our cumulative approvals to over 170 for the European market during the year. Overall, our European business posted sales of Rs.2.6 billion during the year, down by 11%.

Zydus Wellness posted sales of Rs.4.6 billion, up by 8% and net profit of Rs.1.1 billion, up by 5%. It has maintained its leadership position in the Sugar Free, Everyuth Scrub and Peel Off categories.

On the Animal Health front, we received the "Animal Pharm Award for the Best Company in India, Africa, Middle East 2016" from the World's Leading Pharma News Publication, Animal Pharma, UK.

We also received "The Best Animal Pharma Award 2016" from the Indian Poultry Journalist Association.

Overall, our Animal Health business launched five new products in India during the year and posted sales of Rs.4.5 billion, up by 42%. Growth excluding the Zydus portfolio was 10%.

On the APIs front, we filed 7 DMFs with the US FDA during the year, taking the cumulative number of DMF filings to over 125.

Coming to our JVs and Alliances: The Zydus Hospira JV successfully completed the inspection by MHRA, the Regulatory Authority of UK. We entered into a strategic collaboration with Eczacibasi, a Turkish healthcare company to market Biosimilars in Turkey. On the Biosimilars front, we completed Phase-III clinical trials for one more mAb and initiated Phase-III clinical trials for one more product. We continue to file dossiers of First Generation Biosimilars and monoclonal antibodies in the emerging markets.

On the Novel Biologics front, we received the regulatory permission to initiate Phase-III clinical trials for Rabimabs.

During the year, we receive the WHO GMP Certificate from the regulatory authorities of Columbia, Philippines and Uganda for the newly commissioned finished product manufacturing facility.

On the Vaccines front, we received the marketing authorization from the DCGI for seven vaccines out of which one has been launched in India. We also completed clinical trials for one more vaccine during the year.

We entered into a partnership with Takeda Pharmaceuticals Co. Ltd. for developing the vaccine for chikungunya.

On the NCE front, we initiated Phase-2 clinical trials of Saroglitazar magnesium for two indications viz. NASH and Severe Hypertriglyceridemia (TG>500) in the US and received approval from the USFDA to initiate Phase-2 clinical trials for one more indication, namely primary biliary cholangitis.

We signed a collaboration agreement with the Medicines for Malaria Venture (MMV) to develop the investigational anti-malarial compound.

On the Manufacturing and Operations front, our Baddi Formulations facility, Sikkim Formulations facility and Vatva Formulations facility successfully completed the WHO GMP audit. We successfully completed site transfers of two products from Moraiya to Baddi for the US market during the year, taking the cumulative number of such site transferred products to 14.

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

Moderator: Thank you very much, sir. 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: On the US business, I understand some of the benefit from Sentynl is reflected in the quarter. But if I were to strip that out, could you highlight a little bit on how our US Generic business has performed in the quarter please?

Pankaj Patel: Neha, we do not share the specific numbers from Sentynl at this moment. So I would not be able to give you the number. But, I believe that minus Sentynl numbers, we still have reasonably good growth because Sentynl growth has not been big.

Neha Manpuria: How much would be the base business erosion in the Generic business?

Pankaj Patel: Base business erosion is high single digit, approximately maybe $8-10 million.

Neha Manpuria: Have we seen benefit from new launches probably because there would not that many approvals that came through in the quarter?

Pankaj Patel: We got the benefit of new launches.

Neha Manpuria: My second question is on the India business. Now that we have started going back to the 9-10% growth, this quarter probably reflected some of the acquisition, but how do you see steady state growth going into next year particularly given we also have the GST headwind?

Pankaj Patel: At the most, GST could be a quarter effect which is the current quarter , we are trying everything possible to revise, but otherwise we are confident that we would grow at around 13-14%.

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

Anubhav Agarwal: Pankaj bhai, can you give some commentary on this warning letter close out possibility at Moraiya facility, in a sense that what is the typical timeframe, our understanding was three months but it has already been more than three months since the facility was inspected?

Pankaj Patel: Usually, the warning letter close out takes about six months, that is what generally we have seen in other cases, so we can only say that it could be six months. But I cannot provide on it because we do not hear from FDA where it will be closed out.

Anubhav Agarwal: But sir, what is the process – you would have already intimated that?

Pankaj Patel: When they do the audit, the auditors will give a report to FDA, FDA will review the report, and based on that they will take a decision and intimate us. There is nothing like we have to apply for it. The process is done automatically.

Anubhav Agarwal: In the price erosion number that you mentioned $8-10 million that you would be mentioning year-on-year, right, if you can just help with there were as you mentioned Sentynl was… ?

Pankaj Patel: This is sequential, not year-on-year.

Anubhav Agarwal: Likewise in the India business growth if we exclude MSD portfolio, what would have been growth this quarter for the India business?

Pankaj Patel: I think I do not have a detail in front of me, but Vishal, please provide the information.

Anubhav Agarwal: On Transdermal, when do you expect your first approval of course, assuming Moraiya gets cleared in next quarter or two?

Pankaj Patel: We are expecting approval for maybe two products, we are waiting for it. All the formalities were completed, we have visibility on two-three products but they have not given us the target action date yet.

Anubhav Agarwal: But would you say that approval stuck only because of Moraiya clearance?

Pankaj Patel: For one or two products because it is out of Moraiya, the third product of course is coming from SEZ, new facility which is under review at this moment.

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

Sameer Baisiwala: Pankaj bhai, just your thoughts on Lialda, having won district court and federal court, when do you expect to launch?

Pankaj Patel: From legal side, we have settled, we have won the case both at the district and federal court level. So now we are waiting for approval.

Sameer Baisiwala: What is the timeline do you think that you will be in the market?

Pankaj Patel: I think it should happen along with the warning letter lifting.

Sameer Baisiwala: Sir, just broadly speaking hypothetically Moraiya comes clear, EIR comes through in say three months or whatever time it takes, what is the outlook for approvals which have been stuck at Moraiya and overall approvals from US for Cadila in fiscal '18?

Pankaj Patel: So we expect that this year, after the warning letter is over, we have several of the products for which everything is done except the site clearance, so looking at that Moraiya itself could be about 30 approvals plus there is going to be approval coming from SEZ and Baddi, so we could expect maybe 40 approvals.

Sameer Baisiwala: Counting Lialda out, how many do you think would be substantive approvals like $30-40 million sort of potential drugs?

Pankaj Patel: I think six of them.

Sameer Baisiwala: Just on the US market, there is so much that is going on. So what is the outlook for price erosion for a base business in fiscal '18, '19 as we go forward?

Pankaj Patel: I think the price erosion was getting stabilized but we all hear that there is going to be one merger happening. So we will wait and watch what happens at the outcome of this merger. So price pressure will continue according to my estimates; however, this will be like high single

digit. Estimate I cannot say more than that but based on my judgment, I am just saying that it could be high single digit price erosion continuing.

Sameer Baisiwala: As far as site switch is concerned, you mentioned I think 14 have been done from Moraiya. Now, is this now relevant any longer, one? Second, I understand these are all for the products already in the market? Three, the site transfer means that that is an option that you have or does it mean that you have to stop manufacturing from Moraiya and have to switch it to the new one?

Pankaj Patel: No, it is basically risk mitigation strategy. So that is the way it would be. We can produce in either site.

Sameer Baisiwala: This is for all the products already in the market, not the…?

Pankaj Patel: Yes.

Sameer Baisiwala: Is it relevant any more sir because …?

Pankaj Patel: I do not think it is relevant any more now but ultimately the warning letter is still not over. Till the warning letter is over, it is relevant. But we expect that warning letter will be over because of the good inspection.

Moderator: Thank you. The next question is from the line of Nimesh Mehta from Research Zenar Advisor. Please go ahead.

Nimesh Mehta: Sir, just wanted your views on the impact of this preference given to generic-generic in the Indian market, have you seen any impact on sales for in general, do you see any kind of …?

Pankaj Patel: Nimesh bhai, it is too early to comment on it because it just happened recently, we are not seeing at this moment any impact. Coupled with that there is also GST things, destocking issues. So if you look at that, we do not know what is happening. Today, it is very difficult for me to say. But when I look at prescription, there are still prescription and also, you might have read that there is a clarification given by IMA and other bodies that they can write brand along with generic name**.**

Nimesh Mehta: There has been also some new norms set for quality assurance in the Indian market, like do you need trials for the all the products to be launched and stuff like that. Will that have any impact on the overall competitive intensity in the …?

Pankaj Patel: It will definitely have impact on the competitiveness for a company like us. Our products are all bioequivalent and there has not been much in India. So looking at those products which are coming in the market, without any bioequivalence or anything else, would a lot come in the

market and that is the reason why there will be a possibility. The only thing is currently what is being talked about is only for the new products, not for the existing products. So it is going to be a limited impact, but as far as new launches is concerned, of course there is going to be some sort of less competition happening, also there is a woo that one company may not get more than one brand name, and in that case currently some companies make product into 10 or 20 brand name and give it to everybody, it would also happen. So over a period, I think you will see a fair competition happening in the marketplace.

Nimesh Mehta: These new launches when you are taking, so what would be the reach of the new launches, those are new for the market as a whole or a new for the company?

Pankaj Patel: They are the first-time new products in the market.

Nimesh Mehta: So that will be limited products?

Pankaj Patel: Certainly, that is going to be limited number of products basically.

Nimesh Mehta: But I was under the impression that was anyway us like BAb trials for all the new products anyway there in the past?

Pankaj Patel: Past thing they have not yet decided.

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

Karthik Mehta: Pankaj bhai, is there a date until which we have to launch Lialda or is there in any scenario that we can lose the exclusivity to the next guy?

Pankaj Patel: At this moment, nobody has any approval, so I do not think we have a date commitment at this moment.

Karthik Mehta: So would you mean you may need something similar to pre-MMA where your exclusivity under scenarios is completely safe?

Pankaj Patel: Yes.

Moderator: Thank you. The next question is from the line of Nitin Gosar from Invesco Mutual Fund. Please go ahead.

Nitin Gosar: I just wanted to check on Asacol HD. Does the agreement allow Cadila to launch a generic version at a later date?

Pankaj Patel: Yes.

Nitin Gosar: This would be like post the Moraiya clearance couple of quarters down the line?

Pankaj Patel: I cannot give you timeline because we have a confidentiality on that, so we cannot talk about it.

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

Surya Patra: Just wanted to have a sense, this pre-GST destocking what is the level of destocking is anticipated sir, why because the channel checks is something like 30-40% kind of destocking is …?

Pankaj Patel: Let me just give you, Surya, a little bit color on this. I think the GST law which was enacted in the parliament was talking about that if there is no excise gate pass available, the credit will be available up to 40%. That is what basically has created this confusion in the marketplace because of that people felt that "Oh, they will lose 60% of the excise amount." That is why they are looking at reducing the stock. The transition rules of the GST yet not announced. I think the meeting is happening next week and that GST Council meeting will finalize the transition rules. Whatever I hear and I believe is that the 40% will be significantly increased. So the kind of challenge which we are seeing today because people feeling that there will not be any credit available, will be neutralized in the process. If that happens, then there will be limited impact. If that does not happen, companies like us have already been issuing now excise gate pass to the stockists. So as a result, stockists can take full credit. So that should not be also challenge for them. So I would say there will be some impact but there is going to be limited because things are becoming more clearer now. But since this is a new thing, there is always going to be confusion, people will have some kind of apprehensions and things like that. So in fact in this sort of environment, one can expect some kind of disruption in sales.

Surya Patra: Regards the tax guidance, what would be your guidance for FY'18 sir?

Nitin Parikh: Overall current tax rate would be between 12-15% and overall tax including deferred tax would be less than 20%.

Surya Patra: The CAPEX for the full year, how much it would be for FY'18 and what all projects that we are targeting?

Nitin Parikh: It will be about Rs.1,000 crores.

Surya Patra: Any specific kind of investment for Rs.1,000 crores? Almost we are maintaining the run rate though.

Pankaj Patel: There are no specific big projects happening but we are moving into automation, so there is going to be some investment happening in the automation of all the facilities, that would call for investment. Also, there is going to be balancing equipment because we are seeing in so many approvals, we will require kind of a line balancing for additional capacity, some additional equipment purchase, etc., will be there.

Surya Patra: On the R&D front, things are rising. So there on that front, still it would be moving on like this beyond 9% levels?

Pankaj Patel: No-no-no, this is only for the quarter, it is a one-off. We cannot just spend exact amount every quarter because it depends upon some studies will come in this quarter or next quarter and all that. But I think overall R&D spend would be around 7% to 8%.

Moderator: Thank you. The next is a follow-on question from the line of Anubhav Agarwal from Credit Suisse. Please go ahead.

Anubhav Agarwal: Pankaj bhai, Sentynl acquisition is one part of the piece, but what are the areas that you are looking to build portfolio here and what will be the big steps here, so would you go largely inorganic initiative to build the portfolio, how are you thinking about it?

Pankaj Patel: Our strategy for Specialty business is that there are some mid-term and short-term products opportunities we are seeing here and short-term opportunities going to be a kind of line extension in the current products and maybe some small acquisition of some small brands. The mid-term would be more about acquiring and getting into other than Pain area and the long-term will be our own product. So that is the kind of thing we are doing in and our focus is going to remain mainly into three-four therapeutic areas, at this moment we are going to remain focus on Pain, when we will do significant business in Pain and we will move it to the other therapeutic areas which we have identified and we will do that. There are three areas other than Pain we have identified. I would not be able to give you the other areas, but that is where we are going to move in course of time. That is the way our whole strategy for Specialty business has been worked out.

Anubhav Agarwal: Diabetes would be one part of the area because you already have NCE over there?

Pankaj Patel: Obviously that is going to be a very long-term but of course we have NCE, we are already doing clinical studies in US and we are very confident that diabetes related indications or diabetes either of that will happen in the US market as well.

Anubhav Agarwal: Sir, when you say line extension in current products, you are basically meaning NDDS here?

Pankaj Patel: Yes.

Anubhav Agarwal: So in the pipeline that you have, do you already have some of the ANDAs filed here?

Pankaj Patel: We are going to be filing now… of course, we have already filed some 505(b)(2) applications, but in the Pain area we are filing it now.

Anubhav Agarwal: Just about the selection of Pain area is the key focus area. Let us say most of the other companies focusing on derma inhalation or eye drugs. Just curious that why we have zeroed onto Pain area?

Pankaj Patel: Very limited competition. Specialty means if you get niche opportunity any therapeutic area would have been set. So you have to understand that Specialty would have been niche. If you get into niche products then you are in the Specialty business because anything what you do in Specialty is going to be with a limited number of sales force, and if you were to work with a limited number of sales force, the only way you can get there is to basically getting into niche.

Anubhav Agarwal: On Phase-2 of Lipaglyn, approximately when will you have the results with you, let us say two…?

Pankaj Patel: The clinical trial to be completed by end of this April.

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

Neha Manpuria: Sir, just on the extension, the Specialty business question, could you give us your initial thoughts on Sentynl now that we have seen one quarter, how do you see that ramping up and other than line extension, would that require more investment in terms of promotion, field force addition, etc.,?

Pankaj Patel: We do not expect any additional investment in Sentynl.

Neha Manpuria: What has been your initial observations on this product, I mean, in terms of…

Pankaj Patel: We are meeting the targets.

Neha Manpuria: If I were to look at our debt with the recent acquisition, it has crept up. How do we look at that versus inorganic growth that we might be looking at?

Pankaj Patel: Our policy of debt will remain the same as I have always said that we would generally like to have debt-equity ratio of 0.5 which can never exceed 1 and we will follow that discipline going forward as well.

Neha Manpuria: Inorganic sir, priority areas would be?

Pankaj Patel: Anything which is not having technology or any new geography.

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

Sameer Baisiwala: Just a quick follow-up. Pankaj bhai, do you plan to exercise your option to launch own Asacol HD at some of point in future?

Pankaj Patel: Yes.

Moderator: Thank you. The next is a follow on question from the line of Nitin Gosar from Invesco Mutual Fund. Please go ahead.

Nitin Gosar: A follow-up on Asacol again. Sir, what happens to the AG status, then once we launch the generic version. Do we have to give it away?

Pankaj Patel: I cannot discuss this more as I told you, we are in the confidentiality, I can only just say yes or no answer which I have given.

Moderator: Thank you. The next question is from the line of Bharat Celly from Equirus Securities. Please go ahead.

Bharat Celly: Sir, there were two products, Climara as well as Catapres which were filed from Moraiya. So just wanted a clarity, whether it is stuck only because of the facility or there is some product related issues also?

Pankaj Patel: No-no, it is facility thing.

Bharat Celly: Actually, we got to know that Moraiya status has been updated to NAI but still we are not seeing any approvals till date. So how should we look at it – is it like once warning letter will be lifted, then only you will see approvals or even NAI status change also fetch new approvals from the facility?

Pankaj Patel: Bharat, both can happen, but I cannot say.

Moderator: Thank you. As there are no further questions, I would now like to hand the conference over to Mr. Ganesh Nayak for closing comments. Over to you, sir.

Ganesh Nayak: Thank you very much and look forward to seeing you in the month of August for our Q1 FY'18 Results. Good night.

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