“Cadila Healthcare Limited Q4 FY15 Post-Results Conference Call”

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

Moderator Ladies and Gentlemen, Good Day and Welcome to the Cadila Healthcare Limited Q4 FY15 Post-Results Conference Call. As a reminder, all participant lines will be in the listen-only mode, and there will be an opportunity for you to ask questions 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. Thank you, and over to you sir.

Dr. Ganesh Nayak Good afternoon and welcome to our post-result teleconference for FY15. We have with us Mr. Pankaj Patel – Chairman & Managing Director; Dr. Sharvil Patel – Deputy Managing Director; Mr. Nitin Parekh -- Chief Financial Officer and Mr. Vishal Gor – Senior General Manager, Investor Relations.

The Year 2014-15 was a year of resurge for us as our collective efforts aimed at accelerating our drive for value creation, optimizing market strategies, sharpening focus on innovation and exploring newer avenues of cost optimization, catapulted us to the next phase of strategic growth. The results of all these initiatives taken under the aegis of Resurge are clearly reflected in our operating and financial performance for the year gone by. The year saw healthy growth on the top line and bottom line, improvement in operating and net margins and increase in net worth. The top line of the company grew by 20% during the year. Once again, our US business was the key driver of growth in the top line. During the year, the US business crossed the $500 million mark in sales for the first time and became the largest contributor to the consolidated top line. India Formulations business, the second largest contributor to the revenue, faced a few challenges on account of lower sales growth of a few pillar brands, discontinuance of a business of a few in-license products and the NPPA's order to reduce prices of cardiology and diabetology drugs, there by impacting the primary sales. Amidst these challenges, the business had its moments of pride and prestige when Exemptia, the world's first biosimilar of Adalimumab was launched. Though our business in some of the other markets faced challenges, our long-term objectives and strategies remain intact. As you are aware, we have made sizeable investments in new technologies, such as transdermals, biosimilars and vaccines which are also expected to contribute in our mid-term 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 up 20% year-on-year to Rs.86.5 billion. Earnings before interest depreciation and tax was up by 46% year-on-year to Rs.17.6 billion rupees. EBITDA margin for the year improved by 370 basis points to 20.3% as against 16.6% registered last year, which is in line with our committed endeavors at improving operating margins. Profit before tax was up by 53% to Rs.14.5 billion. PBT margin for the year improved by 370 basis points to 16.7% as against 13% registered last year. Net profit crossed Rs.10 billion mark for the first time and stood at Rs.11.5 billion, up by 43%. Net profit

margin improved by 220 basis points to 13.3% as against 11.1% registered in last year. In line, earnings per share also grew by 43% to Rs.56.2. Our consolidated debt at the gross level stood at Rs.26.5 billion and debt net of cash stood at Rs.19.8 billion. Our net debt-equity ratio improved to 0.47 from 0.63 last year. Our consolidated CAPEX for the year was Rs.3.8 billion. Our return on net worth increased to 30.1% from 25.6% last year while the return on capital employed increased to 18.3% from 14.6% last year.

With that let me share some of the highlights of the operations for the year: In the US Generics market, based on IMS data, we are currently the eighth largest generic company in terms of prescription, thus maintaining our position of the previous year. On account of stronger focus on customer service, we continued to receive awards for superior service levels from our large wholesale customers. We launched 9 new products in the US during the year. We filed 38 ANDAs with the USFDA taking our cumulative ANDA filings to 260 and received approval of 8 ANDAs during the year taking our cumulative approvals to 99. Overall, our US business posted sales of Rs.33.9 billion, up by 56% during the year.

On the India Formulations front, we launched a new strategic business unit -- Zydus Biologics -- to maximize the market share in the emerging and high potential business area of biologics. We maintained our leadership positions in the Cardiology, Gynecology, and Respiratory therapy, while in the Gastrointestinal and Dermaceutical space, we continued to remain amongst the top five players in the market. We launched over 55 new products including line extensions in India during the year, of which 19 were for the first time in India. These included the launch of Exemptia, the first Biosimilar of Adalimumab, to be approved anywhere in the world.

Overall, our India formulations business posted sales of Rs.26.8 billion, up by 9%; however, growth excluding the impact of discontinuance of the business of in-license products and price reduction by NPPA in a few products was approx. 12% during the year which was mostly in line with the market growth.

In Latin America, we filed 10 new products dossiers with the Brazilian regulatory authority ANVISA during the year. In Mexico, we launched two new divisions to focus on the segments of Cardiology and CNS. In terms of new launches in Mexico, we launched 7 new products during the year taking the cumulative number of branches to 15. We filed 7 new products dossiers with the Mexican Regulatory Authority COFEPRIS, taking the cumulative filings to 43 and received approval for 14 products, taking the cumulative number of approvals to 24. Overall, our business in Latin America posted sales of Rs.2.3 billion, which, on a like-to-like basis excluding the currently fluctuation impact, grew by approximately 3%.

Coming to Europe, we rationalized our product portfolio in France by expanding the business of profitable in-house portfolio so as to improve the profitability, while in Spain, we performed mostly in line with the market with focus on increasing customer base and share of in-house products. We launched 5 new products in France, including 2 Day-1 and 4 from India and 12 new products in Spain, including 1 Day-1 and 9 from India. We filed 16 new products dossiers, taking our cumulative filings to 191 and received approvals for 13 new products, taking our cumulative approvals to 151 for the European market during the year. Overall, our European business posted sales of Rs.3.4 billion during the year, with a 15% growth registered in the last quarter on a like-to-like basis.

On the Emerging Markets front, we continued to focus on brand building initiatives and strengthening the branded generics portfolio in the emerging markets of Asia-Pacific, Africa and Middle East to ensure sustainable growth both on the top line and bottom line. 20 new products were launched in the focused emerging markets during the year. Overall, our emerging markets business grew by 14% and posted sales of Rs.4 billion.

Amongst other businesses, Zydus Wellness Ltd. posted sales of Rs.4.4 billion, up by 3% and net profit of Rs.1.1 billion, up by 13%. It maintained its leadership positions in Sugar Free, Everyuth Scrub and Peel-Off and Nutralite categories. Our animal health Business in India received "The Best Poultry Company Of India - Fortune Award 2014". The manufacturing facility of our subsidiary company, Bremer Pharma, GmbH in Germany successfully completed the GMP audit. Overall, our animal health business posted sales of Rs.3.1 billion, up by 12% with healthy margins, backed by 8 new products launches in India.

Our two major API manufacturing sites at Ankleshwar and Dabhasa successfully completed the USFDA audit during the year. Our API business registered a growth of 6% and posted sales of Rs.3.7 billion. We filed 10 DMFs with the USFDA, taking the cumulative number of DMF filings to 116.

Now, coming to our JVs and Alliances: Zydus Hospira JV successfully completed audits by several regulatory authorities including the USFDA and ANVISA. The JV also completed the ISO/OHSAS inspections successfully during the year. Zydus Takeda JV was awarded the Best Energy Efficient Unit by the Confederation of Indian industry at the national level. Overall, our JVs and Alliances posted sales of Rs.4.7 billion, up by 3%. Zydus BSV which has become our 100% subsidiary w.e.f. 26th March 2015, after we acquired the remaining 50% stake from our joint venture partner, filed two more ANDAs with the USFDA during the year.

Talking about the new technologies, on the biosimilars front, we completed Phase-III clinical trials for one of the mAbs. Our global biosimilar development program progressed well and we completed global clinical trials for one of the products for launching the same in developed

markets. We continue to file dossiers of first-generation biosimilars in the emerging markets. On the novel biologics front, we received the regulatory approval to initiate the next phase of clinical trials for both PEGEPO and Rabimabs. During the year, we completed commissioning and qualification of a dedicated drug product manufacturing unit for our biological products.

On the vaccines front, developments of 10 Vaccines which are in clinical trials have reached the last stage of testing before the marketing authorization. 2 new vaccines entered clinical testing phase during the year while 3 vaccines are under various phases of pre-clinical study and efficacy evaluations.

Coming to the New Chemical or NCE Research front, we Completed the first year of post-marketing patient registry program for Lipaglyn successfully. Results confirmed Lipaglyn's efficacy in managing dyslipidemia and improving glycemic parameters in diabetics. We initiated development of Lipaglyn for additional indications viz. Non-alcoholic Steatohepatitis (NASH), Lipodystrophy and Type-2 Diabetes. We initiated Phase-1 clinical trials in the US for ZYDPLA1, a novel, next-generation, orally active, small molecule DPP-4 inhibitor to treat Type-2 Diabetes. We developed an IND dossier and initiated Phase-1 clinical trials in Australia for ZYAN1, HIF-PH for treating Anemia.

On the manufacturing and operationals front, our Moraiya facility received the Green Manufacturing Award - 'Gold Category' by International Research Institute for Manufacturing. Our Baddi facility achieved the 'Gold Certificate Merit' in IMEA India Manufacturing Excellence Awards 2014 by the Economic Times in partnership with Frost & Sullivan.

We firmly believe that the goals that we have set for ourselves for the times to come are within our reach and with our proven capabilities, we are in a stronger position to leverage our strengths, optimize costs successfully compete in the global marketplace and efficiently target leadership.

Thank you and 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. We have our first question from the line of Aditya Khemka from Ambit Capital. Please go ahead.

Aditya Khemka: Firstly, how much our authorized Generics contributing to your US sales in this financial year?

Nitin Parekh: We do not share those numbers separately.

Aditya Khemka: In the delta that you got in the US business from your fourth quarter compared to your third quarter, was the delta entirely coming from one product – Hydroxychloroquine Sulphate?

Pankaj Patel: No.

Aditya Khemka: On the emerging markets sales, we have seen some muted growth although we are at a low base in these markets. What would you attribute this low growth to?

Pankaj Patel: We have had a 14% growth. Now I do not understand what exactly you mean by lower base, anyway, to give you some explanation in Sudan and Philippines, we had some set back because of which our growth was lesser than the 20s which we have targeted. Otherwise, rest of the markets are in place, and for the Latin American area, Brazil still continues to be an area of concern in terms of approvals, but that is changing, because we have just got the first approval after long time around two weeks back. So, hopefully, in the next three quarters of this calendar year, we should be expecting some more approvals in Brazil.

Aditya Khemka: If you look at peers who have credible respiratory portfolio in India, they have also started filing or developing Respiratory products especially Inhalers for regulated markets, would Zydus be on a similar path?

Pankaj Patel: Yes.

Aditya Khemka: Any timelines that you would like to share where are we at this moment?

Pankaj Patel: At this moment, we are in early stage, but I think next year onwards our filing should begin.

Aditya Khemka: And the filing will be in the US or in Europe to begin with?

Pankaj Patel: To begin with, in US.

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

Anubhav Agarwal: Just one question on this HCQS market. What is approximately the market size of this molecule now?

Pankaj Patel: I do not have that information, we only know the IMS data, other than that it is very difficult for us to give you any information.

Anubhav Agarwal: Last time you indicated that this market is less than $150 million?

Pankaj Patel: We, as a company have not indicated any, I think whatever is coming is basically IMS data, which cannot be the actual number, because these are like gross numbers and there are discounts on that and so IMS numbers do not give indicator except maybe it gives you some idea about the market share but not actually the overall size of the market.

Anubhav Agarwal: But the sale that you guys have done this quarter, is it a normalized sales or is there some component of high inventory of this molecule in the channel in this quarter?

Pankaj Patel: No, this is normalized sales.

Anubhav Agarwal: Second question is on the 483 on the Moraiya facility. Have you heard anything from FDA at all on that so far?

Pankaj Patel: Not yet.

Anubhav Agarwal: Is there any sort of de-risking that you guys carrying out on some of the key filings there or you are very confident and you wait for clearance from FDA?

Pankaj Patel: We believe that we should able to get clearance from FDA.

Anubhav Agarwal: So you have not carried out any de-risking activities for some of the key filings so far?

Pankaj Patel: No, we have not done any.

Anubhav Agarwal: On the India sales growth, with the launch of Exemptia and SoviHep would they have contributed in some manner because this quarter growth was 9% with the launch of these two drugs. Was there a meaningful contribution from these drugs in this quarter?

Dr. Ganesh Nayak: SoviHep, we launched not even at the end of March, it was launched somewhere in the April, SoviHep has absolutely no role to play in that, and we launched Exemptia almost in the month of January by the time the stock appeared in the market. So, the answer to your question is 'no,' it has not made any perceptible impact on the 9% growth that you saw.

Moderator: Thank you very much. Our next question is from the line of Manoj Garg from DSP Merrill Lynch. Please go ahead.

Manoj Garg: First question is primarily on the domestic market. I do understand that there is impact of BI portfolio as well as pricing policies. But when we will start seeing the normal growth from the domestic market because we are seeing momentum now, overall peaking up in the domestic market for the rest of the companies.

Pankaj Patel: Yeah, your point is valid; we discontinued from the month of January last year, these two products which contributed quite heavily, then we also had this impact of NLEM, and as I mentioned though the growth shows 9%, actually the growth is 12%, and the market also has grown by that. So we feel that we have overcome all those hurdles, and from this quarter onwards, we should be having a good double-digit growth on the Domestic business.

Manoj Garg: My second question is for the US market. Sir, like base of $155-157 million, can we take this as a base for the US market going forward?

Pankaj Patel: Yes.

Manoj Garg: Any impact you have seen of one of your competitors coming back in the HCQ market so far?

Pankaj Patel: As of date. we have not seen yet.

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

Girish Bakhru: First question was on the 38 filings in US last year. What is the guidance for this year?

Pankaj Patel: We would be doing 40 plus filings this year.

Girish Bakhru: On the filings front, just wanted some clarification, when you file say 38 or 40 products, are these ANDAs basically like different products or could there be a scenario where 1 product may have 2 ANDAs or 3 ANDAs?

Pankaj Patel: They are all new products.

Girish Bakhru: Many are like patented products not Generic products, right?

Pankaj Patel: Yeah, there are mix of that, most of them are patented products and not Generic products, some of them are products for which there is not enough competition in the market or where there are only one or two competitors.

Girish Bakhru: You had indicated R&D would stay around 6-7% of sales. Just wanted color of where it would be and how much of that is going into Generics vis-à-vis Novel initiatives?

Pankaj Patel: About three-fourths goes to Generic and the balance goes to Novel initiatives, and the R&D spend will remain in this range only.

Girish Bakhru: So the mix also will not drastically change given you have so many new products going to clinical trials as well?

Pankaj Patel: No, it should not change, because our base is also increasing.

Girish Bakhru: An update on Liposomal, Doxo, what are the plans , now that the JV is dissolved, how will you take the product?

Pankaj Patel: Yeah, we are working on filing now and we expect to file, that is under progress, so we believe that next year we should be filing for US approval.

Moderator: Thank you. Next question is from the line of the Mitul Mehta from Lucky Investments. Please go ahead.

Mitul Mehta: Sir, my question is pertaining to the regulatory status of each of our plants. Can you just take us through that in terms of 483s that we have and what is the progress on each of those?

Pankaj Patel: Our plants have been inspected, almost each of our facility has been inspected by various regulatory agency time and again, and currently, we do not have any regulatory action on any of the plants. Only thing is conclusion of last inspection at Moraiya is still pending and we expect that this should happen in the next couple of months.

Mitul Mehta: Of course, though it will be small for us, but just to get some sense on Sovaldi which we have with Gilead, what is the progress and how do you see the market, assuming that it is going to be a crowded market and margins are not going to be healthy, so what is the arrangement that we have?

Pankaj Patel: So yes, there is competition on this market but we have been among the first companies to launch this product, and we have already taken a leadership position in the process, we believe that we would continue to remain aggressive in marketing of this product, we have sufficient capability to compete pricing pressure going forward also, and should be able to not only protect our market share but also develop the market further.

Mitul Mehta: Are we manufacturing at our own site or we are sourcing from a third-party?

Pankaj Patel: Currently, we are sourcing from a third-party where we have a long-term arrangement.

Mitul Mehta: Is it possible for you to divulge what kind of margin this product have?

Pankaj Patel: It is not possible to share the information.

Mitul Mehta: What would be the potential market size?

Pankaj Patel: Market size would depend upon the ultimate price, but we believe the prices will go down and we expect that this product would have a size of about Rs.20 crores for us.

Moderator: Thank you. Our next question is from the line of Ranvir Singh from Sharekhan Limited. Please go ahead.

Ranvir Singh: This time reporting format has changed. Just wanted a few numbers: Animal Healthcare business in India what we have generated from this segment?

Pankaj Patel: Can I suggest one thing? If you want some number clarification you can speak to Vishal Gor and Vishal will be happy to do that.

Ranvir Singh: Okay, I will do that.

Moderator: Thank you. Our next question is from the line of from Bharat Seth from Research Delta. Please go ahead.

Nimish Mehta: This is Nimish Mehta. Sir, if you can just tell us we had this tentative approval on Aripiprazole which is Generic Abilify. What is the reason why we did not get a final approval although some of the other companies have got?

Pankaj Patel: We are still expecting approval but we have not heard from FDA why the approval has not yet come in.

Nimish Mehta: On the tentative approval part, what can stop you because…?

Pankaj Patel: It is possible that when the plant inspection is not closed FDA may withhold the approvals. But, we do not know exactly why it is not given. So I am just guessing.

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

Anubhav Agarwal: Sir, on Vaccine business, you have 10 under development right now. When do you see that you launch a first Vaccine out of the subset of 10?

Pankaj Patel: We expect to launch next year.

Anubhav Agarwal: Next year in which market?

Pankaj Patel: India.

Anubhav Agarwal: How large you think this business can become in 3-years once you launch it ?

Pankaj Patel: It depends upon which Vaccines are coming to market. Vaccine market is divided into two parts -- One is the private market and second is the government market. So initially first we will be launching in the private market and the market will be like slowly growing and then there is going to be a kicker when we start getting into tenders with the Government in India and also the global tenders. In three to five years from this market, we can expect sales of approximately Rs.250 crores or so.

Anubhav Agarwal: That is a very decent size of the market. If I am not wrong, the total market size is about Rs.1500 crores or so about?

Pankaj Patel: That is Indian market today but I think there is also a good opportunity to get into the global market, there the number can be much-much larger but I am just giving you conservatively we can touch to Rs.250 crores.

Anubhav Agarwal: Which is the Vaccine you are talking about launch in the next year?

Pankaj Patel: We cannot share that information because of competition.

Anubhav Agarwal: So essentially on the Vaccine… just to get it right, India and the other emerging markets, that is the game plan here?

Pankaj Patel: Also the international agencies.

Anubhav Agarwal: Just a couple of more clarification on the balance sheet: CAPEX this year was less than Rs.400 crores. What is the expectation next year?

Nitin Parekh: About Rs.550 crores.

Anubhav Agarwal: I just notice that this year receivable days have increased by 10-days, gone from almost 60-days to 70-days, that is why there were a lot of increase in the working capital, so we ultimately did not generate much cash after paying dividend, of course, one is US contribution has gone up. But, any particular reason why receivable days increased?

Nitin Parekh: That is because of larger sales in US market.

Anubhav Agarwal: So US proportion increasing, that is the key reason?

Nitin Parekh: That is right.

Moderator: Thank you. The next question is from the line of Abhishek Sharma from India Infoline. Please go ahead.

Abhishek Sharma: Sir, if you could just give us some color on the 40 expected filings during this year, how many of them are in the complex space vis-à-vis the plain vanilla space and what kind of filings are you planning?

Pankaj Patel: Around (+50%) are in the complex space.

Abhishek Sharma: Would these be Injectables or Modified Release sort of…?

Pankaj Patel: Both.

Abhishek Sharma: One broad industry question: We have been hearing a lot about customer consolidation and its impact on pharma players. Apart from HCQS have you in your base business seen any impact of the customer consolidation?

Pankaj Patel: Yes, we have seen it.

Abhishek Sharma: Is it significant enough?

Pankaj Patel: It is not significant but there is an impact of customer consolidation because of the fact that they have become larger customers and in the process they also expect some kind of benefit of consolidation.

Abhishek Sharma: And the price erosion that you are seeing would be in what range typically across the board – 5%, 10%?

Pankaj Patel: Average would be around 5%.

Moderator: Thank you. The next question is from the line of Manoj Garg from DSP Merrill Lynch. Please go ahead.

Manoj Garg: Basically, looking at the US, out of this 160 pending approvals which we have, can we get a sense how many of them are pending from Moraiya and from the other facilities?

Pankaj Patel: I do not have the numbers, but Vishal can provide you that number.

Manoj Garg: In terms of approvals, what is your outlook – have you started seeing a bit of improvement in terms of target extended delivery by the FDA and you are getting a fair sense that which are the products probably which can come in this year and the next year?

Pankaj Patel: I think we are getting some sense because we are receiving this target action, we are receiving CRLs and all that. That clearly indicates that there is a positive movement happening; however, if you see number of products approved by FDA across the industry we still have a smaller number.

Manoj Garg: But we have to get a sense for the next two-years, how do you see this ramping up – whether you see approval happening starting from second half of this year onwards or maybe the next year, what could be the key critical products which you are anticipating or building in your projection for the next two-years?

Pankaj Patel: First of all, approval numbers should definitely go up the way the FDA is coming out with response quickly, etc., like previously when I file an ANDA, it used to take two months, three months, four months to get acceptance, but now the acceptance is within a week. That clearly sees a kind of thing. Second thing from our company perspective if you see, we have a site at Moraiya and we have a site at Baddi and we have created a new site at our Special Economic Zone and recently the site has been inspected, the inspection was okay and we expect that in the process, this site should also get the approval . So we have three sites now from where we could expect approvals coming in.

Manoj Garg: Is it fair to expect some good high value kind of approvals over the next 12 to 18-months?

Pankaj Patel: Yes.

Moderator: Thank you. The next question is from the line of Gagan Thareja from Comgest India. Please go ahead.

Gagan Thareja: You had eight approvals in the last financial year. Any tentative numbers we can work with in terms of what is the possible number of approvals for FY16?

Pankaj Patel: Based on whatever progress we see, we should have almost 20 approvals in the next financial year.

Gagan Thareja: On Abilify is your filing only for ODT or is it for the other versions as well?

Pankaj Patel: Yeah, we filed for everything.

Gagan Thareja: So the tentative approval is on the ODT part?

Pankaj Patel: Yeah, tentative approval came for ODT and then subsequently the immediate release were filed.

Gagan Thareja: It would seem that the USFDA is expediting approvals for ANDAs filed specifically post-October 2014 to start with and for those which have been filed before they are sort of picking and choosing based on their own priorities. If I recall correctly whole host of your filings in the last year were in the first half prior to October 2014, do you see that sort of a thing impacting the approval rate, what impact or what is your opinion on how could this play out for the market as a whole?

Pankaj Patel: If you see the filings , we have good number of filings after October '14 and we continue to do so.

Moderator: Thank you. The next question is from the line of Dheeresh Pathak from Goldman Sachs. Please go ahead.

Dheeresh Pathak: Sir, if you can give some guidance on Transdermals approvals in the US?

Pankaj Patel: We have received the three CRLs. So let us see what happens.

Dheeresh Pathak: And these three all from Moraiya there are two facilities for Transdermals?

Pankaj Patel: Yeah, Moraiya and one from our Zydus technology new site which is also inspected by FDA recently without any 483.

Dheeresh Pathak: On Moraiya on the 483 there were 2 483s – one was in July I think which were some product-specific and then there was something in August last year which was a GMP related. So both are open or …?

Pankaj Patel: No, the first one is closed, second one is open.

Dheeresh Pathak: Has there been any tentative approval also post the…?

Pankaj Patel: We are getting approval for the amendments which we are doing , but we have not received any new approval, one tentative approval we have received during the period.

Dheeresh Pathak: Is this facility also an API facility or this is just …?

Pankaj Patel: No, it is only a Formulation facility.

Moderator: Thank you. The next question is from the line of Bhavin Shah from Geecee Investments. Please go ahead.

Bhavin Shah: On Nasals and Topicals again, would we expect something coming in FY16-17?

Pankaj Patel: For Topical, we have a new facility which is not yet inspected by FDA. So it is very difficult for us to say whether we will have an approval coming in, because the inspection has not yet happened. Nasal… we do not know when we will get the approval.

Bhavin Shah: Best case scenario in Transdermals, would it be second half or FY17, what is your guess on it?

Pankaj Patel: I think second half should be possible, but it is very difficult for us to tell exact timeline, sorry, but I am hoping that we should get in second half.

Bhavin Shah: A little bit on your CAPEX plan: You mention Rs.550 crores. Anything meaningful or it is spread across the APIs?

Pankaj Patel: It is mostly in the area of API and Formulations,a new Injectable facility plus additional manufacturing capabilities.

Moderator: Thank you. The next question is from the line of Rahul Baijal from Bharti Axa Life Insurance. Please go ahead.

Rahul Baijal: On the Moraiya facility, are you expecting a re-inspection from the FDA post submission from your side?

Pankaj Patel: We do not know.

Rahul Baijal: Which month of this year the submission you have done from your side to the FDA?

Pankaj Patel: Last month.

Moderator: Thank you. The next question is from the line of Lalit Kumar form Nomura Securities. Please go ahead.

Lalit Kumar: Sir, do you feel confident of receiving approval for Asacol and Prevacid in FY16?

Pankaj Patel: Yeah.

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

Neha Manpuria: My first question was on Europe: That has been quite weak over the last year. How do we see that region emerging going forward?

Dr. Ganesh Nayak: Europe market has also started looking up. If you got my statement when I read out, in the quarter gone by, we have grown at 15% which is the highest growth in the last several years and we see a similar kind of trend coming up in the next quarters too.

Neha Manpuria: This would be driven by essentially because all are restructuring the organization, portfolio, etc., it is all done there and we are launching new products?

Dr. Ganesh Nayak: It is a mix; it is launching of new products, you heard me say we had Day-1 launches, the MA is looking up and also we have kind of tweaked our portfolio there to make it more profitable.

Neha Manpuria: The second question is more Generic on the US market. We are seeing consolidation not only among the customers but also among the manufacturers there. What is your sense on how the industry would shape up and how do you view Cadila's inorganic growth strategy at all if there is any?

Pankaj Patel: First of all, this consolidation process is a part of the game which will continue, but I think there are also new players keep on coming in. So market will still remain fragmented. So, from our perspective, just for scale consolidation does not make sense, we will be always open to do inorganic growth where we can get additional product portfolio or an additional capability with some of the organizations. That is what overall we will be open to look at inorganic growth; however, for the current business plan, we do not factor any M&A for the current year.

Moderator: Thank you. The next question is from the line of Abhishek Sharma from India Infoline. Please go ahead.

Abhishek Sharma: Just had a question on Transdermals. The three CRLs that you have received, have you submitted your response and what is the status on that?

Pankaj Patel: We have already replied for two of them, one of them is under process.

Moderator: Thank you. The next question is from the line of Farhana Lambe from NVS Brokerage. Please go ahead.

Farhana Lambe: Overall, was there any price rise in the Q4? And also if there are going to be any price rise in FY16?

Pankaj Patel: Overall, there was no price rise in the last quarter, in India market there is a 3.8% price increase which was given on control product which has been implemented. We do not expect a price rise because generally, it is very difficult to hike prices in Generic industry. Very rarely you see price rise.

Farhana Lambe: Because if there is any lower competition, like last quarter, you had the price of antimalarial drug, hydroxychloroquine so by 3.5x. So I just wanted to know if there is any other drug which…?

Pankaj Patel: First of all, we did not increase the price of that drug, we were always selling at that price, we got a market share.

Moderator: Thank you. The next question is from the line of Bharat Seth from Research Delta. Please go ahead.

Nimish Mehta: Again, Nimish Mehta. First, on the fund raising, the enabling resolution that we have passed, if you can just elaborate on the purpose of utilization of the funds?

Pankaj Patel: In an enabling resolution, we have no immediate plans to raise the money at this moment, It is only an enabling resolution which we have passed.

Nimish Mehta: But this was keeping in view the potential acquisitions that you might do at a late stage or the normal CAPEX also…?

Pankaj Patel: For CAPEX, no, but if we look at good opportunity in times to come and if we have enabling resolution that becomes handy.

Nimish Mehta: It is largely for M&A is what I understand, right, whenever you do it?

Pankaj Patel: Yeah.

Nimish Mehta: Just to understand better, we have filed for a product Asacol. I know practically it is not relevant any more, but since we have filed, we should be receiving the approval as well, it should serve as a precursor to the Asacol HD approval as well, is that a fair understanding?

Pankaj Patel: No, we did not file for Asacol, we filed for Asacol HD only.

Nimish Mehta: Because that was also a product that we target earlier because it got shifted?

Pankaj Patel: There are two Asacols in the market; the Asacol plain was a lower strength which was then converted into a new product called Delzicol or something and the other is Asacol HD which continues in the market.

Nimish Mehta: So we never targeted the plain Asacol?

Pankaj Patel: Asacol plain was a tablet, the originator put that into capsule and changed the product to Delzicol. HD is a much larger tablet, so it cannot fit into a capsule, so they have not yet done it. So the same strategy they could not use for HD.

Nimish Mehta: Did we file for Asacol or we never filed for plain Asacol?

Pankaj Patel: We filed for only HD.

Nimish Mehta: Some of the approvals that we are expecting this year especially in the Nasals, can you name some of the products which can be meaningful and which might …?

Pankaj Patel: We cannot.

Nimish Mehta: But any ballpark… the potential size branded size that they target?

Pankaj Patel: Sorry, we will not be able to give you such specific information.

Nimish Mehta: For all these products we are conducting clinical trials in India or outside India? I guess you need to do clinical trials.

Pankaj Patel: Yeah, we are doing both in India and outside India.

Moderator: Thank you. The next question is from the line of Chirag Talati from Kotak Securities. Please go ahead.

Chirag Talati: Just a couple of clarifications on Asacol HD agreement that you have. In case you are not able to get an approval, do you have a time defined authorized generic duration, in other words, like it is only for three months or six months and by that time you do not get or it just continues for life long?

Pankaj Patel: It continues for life long.

Moderator: Thank you. The next question is from the line of Aditya Khemka from Ambit Capital. Please go ahead.

Aditya Khemka: Did I hear you correct you said the last submission from the Moraiya facility was done last month, so is this a product submission or is this data submission to satisfy the FDA on these?

Pankaj Patel: Product submission. We are also giving FDA a monthly update. That is a separate thing. What was asked was did you file any dossier and we said we filed last month only.

Aditya Khemka: So when did you last file a monthly update with the FDA, are you filing it on a continuous basis to-date?

Pankaj Patel: Yeah, every month we are filing update.

Aditya Khemka: Sir, given that we have not heard back from the FDA for a long time, what information are you filing every month because you…?

Pankaj Patel: There are some things for which some equipments to be purchased and installed. For all equipments, they come in and then we inform FDA that equippments have arrived and we are installing. Suppose, a thing which you are doing for a long-term, just to keep FDA inform about what else we are doing, other than what we have committed , we give them monthly update just to keep them aware of what we are doing. It is a practice industry does to keep FDA aware of what we are doing.

Aditya Khemka: Sir, my check with the FDA sort of indicated that the reason why the 483 could not be resolved possibly be due to the inspectors being backlog with other inspections, the specific inspectors who investigated your facility. Would you share a similar view?

Pankaj Patel: Frankly, I do not know. Had I known it I would have definitely shared with you.

Aditya Khemka: Because you are developing Biosimilars and you are conducting global clinical trials, so in your assessment what would be say the cost of developing a Biosimilar and doing a global clinical trial, what is the average ticket size of R&D spend on such a product…?

Pankaj Patel: It will vary from product-to-product, so it can start from as low as $10 million to as high as $50 million depending upon what product you are doing, because most of the cost is involved in innovator sample purchase.

Aditya Khemka: But many other companies have indicated that sometimes the global clinical trials could also cost as much as $100 to $150 million. What would…?

Pankaj Patel: It depends on what kind of trial people are doing. I cannot say trial cannot cost 100 million or 200 million, it can cost even a billion dollar, depending on what trial you are doing. But, our product what we are talking about the range is between $10 to $50 million depending upon which product you are going to file.

Aditya Khemka: In Europe, are you seeing any improvement in terms of pricing given the way the euro has behaved against the rupee and the already weak sort of ROC your margins in that geography, is there improvement in the pricing environment at least in Spain and France or does the pricing sort of remain flattish?

Management: There is no increase in price.

Moderator: Thank you. The next question is from the line of Krishna Prasad from Franklin Templeton. Please go ahead.

Krishna Prasad: Given the kind of momentum you are seeing now on the margin front, would you want to revise your guidance now for the next few years both your sales and margins if you could just talk about that?

Pankaj Patel: Sales…we are maintaining the same guidance which is we are going to cross Rs.10,000 crores as per our plan. We are looking for 21% EBITDA.

Krishna Prasad: If we look at least the last few quarters now, clearly, there is an opportunity to do much higher numbers for the next year, do you think you are being a bit conservative here?

Pankaj Patel: We would not like to revise it.

Moderator: Thank you. The next question is from the line of Gagan Thareja from Comgest India. Please go ahead.

Gagan Thareja: Recently, in the end of April, there was a Standing Committee on Chemicals and Fertilizers which submitted a report regarding the affordability in pricing of drugs and it would seem that some sort of a case is again being made to increase the ambit of price control in the domestic market. I do not know what the subsequent follow up in terms of action, but what is your opinion, do you feel that there is a possibility of this sort of a thing happening?

Pankaj Patel: You asked me such a difficult question for which I cannot comment, but I think the policy is there and unless the policy change, nothing can change except new NLEM list can come which is expected.

Gagan Thareja: So the new NLEM list will have possibly a larger number of products?

Pankaj Patel: I cannot say anything about it because I have no idea.

Gagan Thareja: If I recall correctly, something of the same sort happened last year, but were subsequently rolled back and it is a matter under litigation if I understand it correctly. What is your position on that issue?

Pankaj Patel: It is still under litigation and the government has said that they are not going to do any further on that basis now.

Gagan Thareja: Coming on to the Liposomal product, Doxyrubicin product that you expect to file, this is a non-pegylated version or this is a pegylated version?

Pankaj Patel: Yeah, pegylated version.

Gagan Thareja: Did you also indicate that in Biosimilars you have completed Phase-III global trials for one product, if I heard it correctly?

Pankaj Patel: Yes.

Gagan Thareja: Is it possible to know which product this is?

Pankaj Patel: We will not be sharing the information at this moment. Once we file maybe then, we will inform you.

Gagan Thareja: You indicated that you expect that in two months' time the issue on the open 483 will be resolved and also you indicated that 20 approvals is what you expect for the year. So this 20 approval is after taking into consideration the open 483 which will take 2-months to resolve?

Pankaj Patel: I think we have filed not only from one site, we have filed from other sites as well which is the Baddi site and the SEZ site, from those sites also we have filed, so we will have approvals from those sites also, plus we have a site in US Nesher there also we just completed FDA inspection. So we expect approval from Nesher site also.

Gagan Thareja: In Nesher, the consent decree is complete and over or …?

Pankaj Patel: Not yet, we are in the process.

Gagan Thareja: Because if I remember correctly in the last few quarters, you did indicate that …?

Pankaj Patel: Our FDA inspections was to happen, which just got concluded recently and it will move to the next level.

Gagan Thareja: One book-keeping question; going ahead, what should we expect in terms of tax rates?

Nitin Parekh: Around 17%.

Gagan Thareja: The cash tax rate would also be similar to the accounting tax rate?

Nitin Parekh: Yeah, more or less.

Moderator: Thank you. Ladies and Gentlemen, due to time constraints, that was the last question. I now hand the call back to Dr. Ganesh Nayak for closing comments. Thank you. And over to you, sir.

Dr. Ganesh Nayak: Thank you very much and look forward to interacting with you again during our next teleconference. Have a nice evening.

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