# "Cadila Healthcare Limited Q4FY14 Earnings Conference Call"

## May 16, 2014

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**Moderator**: Ladies and gentlemen, good day and welcome to the Cadila Healthcare Ltd Post Results Conference Call. As a reminder, all participants' lines will be in the listen-only mode. There will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during this 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, Dr. Nayak.

**Dr. Ganesh Nayak:** Good Afternoon and Welcome to our Post Results Teleconference for FY14. We have with us Mr. Pankaj Patel – Chairman and Managing Director; Dr. Sharvil Patel – Deputy Managing Director; Mr. Nitin Parekh – Chief Financial Officer; and Mr. Vishal Gor – Sr. General Manager, Investor Relations.

The year gone by saw gradual revival in the performance of the company. After the quiet start with the sales growth of 6% in Q1, sales growth accelerated from the second quarter onwards and the company registered an overall sales growth of 15% for the year. Our US business was the key driver of growth especially from the second half onwards. Our India formulations business faced a challenge due to the new DPCO notified by the government which affected both price led growth and volume led growth. However, in such a challenging environment our moment of cheer was the launch of Lipaglyn™ Saroglitazar which is the first NCE discovered and developed indigenously by an Indian pharma organization. While our company objectives and strategies remain intact, challenges in some of the markets may take some time to get resolved. We are putting in our best efforts to ensure that we overcome these issues as early as possible. On the cost optimization front, the prism program is well on track and has achieved its targeted savings during the first year of its implementation phase. The scope of prism was further expanded during the year so as to address all indirect spends as well. New technologies like transdermal, Biosimilar and vaccines where we have already made sizable investments are also expected to contribute in our long 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 14% to Rs.72 billion. Earnings before interest, depreciation and tax was up by 7% to Rs.12,002 million, profit before tax excluding the impact of exceptional items was up by 19% to Rs.9,594 million. Net profit was up by 23% to Rs.8,036 million and in line, earnings per share also grew by 23% to Rs.39.25 . Our consolidated debt at a gross level stood at Rs.27,004 million and debt net of cash stood at Rs.21,516 million. Net debt equity ratio improved to 0.63 from 0.79 last year. Our consolidated CAPEX for the year was Rs.4,661 million. Our return on net worth increased to 25.6 % from 23.6 % last year.

With that let me share some of the highlights of operations for the year gone by. On the India formulations front, we performed better than the overall market during the year despite the challenge in the form of the new DPCO 2013, which affected both price led and volume led

growth. We maintained leadership positions in cardiology, gynecology, gastrointestinal and respiratory therapy area in our represented markets. In the dermatology space we improved our ranking by 2 positions - from 6th rank last year to 4th rank. We launched over 75 new products including line extensions in the country during the year of which 19 were for the first time in India. This included the launch of Lipaglyn™ being the first NCE discovered and developed indigenously by an Indian pharma company. Overall our India formulations business posted sales of Rs.24,644 million up by 6%. However, the growth excluding impact of NLEM on prices and the discontinuance of the in licensed products of BI was 11% during the year and during the last quarter, it was 16%.

In the US generics space, we launched 7 new products, of which, 3 products were launched in the last quarter. This includes Divalproex Sodium ER which helped bouy overall business growth. We are currently the 8th largest generic company in the US in terms of prescriptions, thus, implying a gain of 2 positions compared to the previous year. A large US wholesaler awarded us the 'Service Level Excellence' award during the year with an overall customer service level exceeding 99%, as quality and manufacturing remained key focus and strength areas for us. We filed a record of 50 ANDAs with the US FDA taking our cumulative ANDA filings to 227. This filings include the first filing made from Nesher facility during the year. We received approval of 15 ANDAs (including 6 injectables) during the year, taking our cumulative approvals to 91. Overall, our US business posted sales of Rs.21,704 million, up by 44% during the year.

Coming to Brazil, we continued our focus on brand building initiatives with an aspiration to be a leading player in key therapeutic areas. During the year, we took several initiatives focused on optimizing cost of operations, inventory management, and sales force effectiveness. We filed 13 new product dossiers with the regulatory authority ANVISA taking our cumulative filings to 113. However we received only one new product approval during the year. Overall, our Brazil business posted sales of Rs.2353 million. In Mexico we commenced commercial operations during the year with the launch of 7 products. We filed 16 new product dossiers with the regulatory authority COFEPRIS, taking our cumulative filings to 36. We received the approval for 7 products during the year, taking the cumulative number of approvals to 10.

Coming to Europe, we consolidated our business in France by exiting the less exciting opportunities both in terms of portfolio and customers while in Spain, we performed in line with the overall Spanish generic market. Our focus in Europe was more on the improvement in profitability than on the top line. We launched 8 new products in France including 2 Day-1 and 7 from India and 12 new products in Spain including one Day-1 and 8 from India. We filed 14 new products taking our cumulative filings to 175 and received approvals for 26 new products taking cumulative approvals to 138 for the European market during the year. Overall our Europe business grew by 6% and posted sales of Rs.3,902 million.

On the emerging markets front, exports to the emerging markets grew by 17% and reported sales of Rs.3,673 million. 35 new products (including several first in the market) were launched in the focused markets of Asia Pacific, Africa and Middle East during the year.

On the Zydus Wellness front, Sugar Free maintained its leadership position in the low calorie sugar substitute market with a commanding 93% market share. Despite slowdown, we maintained our leadership positions in EverYuth Scrub and peel off categories while the face wash category continued to witness stiff competition from larger brands. We continued our thrust on new product launches and launched Fairness Peel Off, 3-in-1 Neem Face Pack and Tulsi Turmeric Face Wash during the year. In the Nutralite category, we launched a low priced variant 'Nutralite Yummy' in North India.

Overall Zydus Wellness Ltd posted sales of Rs.4296 million up by 5% while the net profit was flattish at Rs.965 million.

Amongst other businesses, in the animal healthcare space, we launched a range of products for specialty companion animals under the new division Petz during the year to focus on the growing pets care needs in India. Overall, our animal health business posted sales of Rs.2,754 million up by 17%, backed by 11 new product launches in India. Our API business registered a growth of 13% and posted sales of Rs.3,497 million. We filed 10 DMFs with the US FDA, taking the cumulative number of DMF filings to 117.

Coming to our JVs and alliances, Zydus Hospira completed successful audits by the regulatory authorities of Japan and Korea. Zydus BSV successfully completed the audit by the German FDA. It also filed 4 ANDAs with the US FDA for its contract manufacturing business during the year, taking the cumulative number of such filings to 6 and supplied the first product to the partner for the US market. Under the out licensing deal with Abbott, we commenced the supply of 5 products for 4 different markets. We also commenced supply of 3 additional injectable products to our partner in the US taking the cumulative number of such supplied products to 6. Overall the JVs are progressing well in the Q4, sales being more than the Q3 sale by 10%.

Talking about new technologies, on the biosimilars front, we initiated Phase-III clinical trials for one of the mAbs and received the regulatory approval to conduct Phase-III clinical trials for one more mAb during the year. We received the regulatory approval to conduct clinical trials for global development for one of the first generation biosimilars, currently being marketed in India. On the novel biologics front, we completed phase 1 clinical trials for both PEGEPO and Rabimabs. During the year, we completed the commissioning and qualification of the large scale monoclonal antibody manufacturing plant.

Coming to the vaccines, development of different vaccines progressed well during the year with 10 vaccines in different stages of clinical trials at the end of the year. On the NCE research front, we completed the pre-clinical studies and filed an IND of ZYDPLA1 a novel,

next generation, orally active small molecule DPP-4 inhibitor to treat Type 2 Diabetes with the US FDA. Phase-I development of GPR119 Agonist ZYG19 for the treatment of diabetes continued during the year.

On the manufacturing and operations front, we received the approval from the regulatory authority of Mexico, COFEPRIS, for our Moraiya and topical formulation facilities. Our Moraiya facility received 'Gold Award - Pharma Sector, Mega Large Business' from The Economic Times and Frost & Sullivan for achieving the operational excellence.

Thank you and we will now start the Q&A session. Over to the coordinator.

**Vishal Gor:** One request for the participants. We shall first take questions related to Cadila Healthcare only and at the end, we will take questions regarding Zydus Wellness Ltd. So I request all participants to first raise questions only on Cadila Healthcare Ltd.

**Moderator**: Thank you. Ladies and gentlemen, we will now begin with the question-and-answer session. The first question is from the line of Jiten Doshi from Enam Asset Management. Please go ahead.

**Jiten Doshi:** I would say today is a very historic day because it is a comeback for Cadila and it is a comeback for BJP. I think you have timed your meeting very well. I am very happy that 2 people have really comeback, Mr. Pankaj Patel and Mr. Narendra Modi. So it is a good day to celebrate today for all of Gujarat. Pankajbhai, just give us a little flavor. The US business is surprising us. Can you tell us how many ANDAs you plan to file in the current year? What is the filings you have done last year? What is our pipeline looking like? If you could just give us some kind of a visibility there, I think that will be good for us to have an idea.

**Pankaj Patel:** As far as US business is concerned, I think we said that we filed 50 ANDAs during the last year and we continue to put our efforts to file more in this year. We have a total of 227 ANDAs filed till today. We have got 91 approvals up till now and we are expecting more approvals to come in during the year. We expect that we should have at least 15 to 20 approvals during the year which would be launched also and from a pipeline perspective, we have a very healthy pipeline that would help us to grow the business. On top of it, you also know that we have a strong relationship with Abbot Laboratories and we are selling authorized generic products as well in US which also actually helped us boost the sale in US further. So, on an overall basis, we have an opportunity to really look at US becoming the largest business for the group in times to come. Our target for this year is to file 40 product filings.

**Jiten Doshi:** Now that we have hit a run rate of about 110 million I think it is not too far away for us to be at about half a billion annually.

**Pankaj Patel:** That is the first milestone we have to achieve.

**Jiten Doshi:** I can see that every quarter that I have been speaking to you for the last 3-4 quarters, one I think your commitment is very high, situations getting better. I think team has done some amount of reengineering to come back in a big way. So if you have to today come back and talk to us about next 3 years and we had a $3 billion goal. It is always good to have a goal. Sometimes we achieve them couple of years down the line. It may not be as per our target but if we do not have a goal there is no sense in doing things. I am very happy that Cadila had a goal. It pushes the team. But if you were to tell us today and give us some visibility where do you think we will be in 3 years from today?

**Pankaj Patel:** Our first milestone will be 2015 and it is difficult to give target in dollar terms now because of the fact that rupee is continuously changing valuation. What we expect in 2015 is to cross the Rs.10000 crore sales mark.

**Jiten Doshi:** 10000 crores sales in 2015. This is March 2014. And you are always giving us this target in billions. I am assuming with stable government and better flows even if we take at Rs.60 I do not think 2 billion is too much of a stretch by 2016. Can I say if we get some good approvals and things kick start everywhere ….

**Pankaj Patel:** If everything goes well then yes, we can achieve that number but we cannot give you that commitment at this moment because it is still very volatile. We do not know what is going to be really. That is why we are now saying we are going to talk about rupees and meet a 10000 crores in 2015-16.

**Jiten Doshi:** I think the team is pushing towards that goal.

**Moderator**: Next question from the line of Manoj Garg from Merrill Lynch Bank of America. Please go ahead.

**Manoj Garg:** Just would like to understand from an Indian perspective since we have seen some recovery in this quarter with 9 to 10% kind of growth if we have to attribute this growth between volume value and new introduction how would you divide that growth?

**Pankaj Patel:** We were hit right from the month of April because the trade started expecting the DPCO and then they started destocking but the ramp up has been good and you would have heard me saying that, in this quarter gone by, on an apple-to-apple basis, our growth has been 16% for the quarter.

**Ganesh Nayak:** So, your question relates to what, the next quarter or the next year?

**Manoj Garg:** I just want to understand like out of this 9% growth or 16% apple to apple growth, is this growth largely been driven by volume expansion?

**Ganesh Nayak:** Yes, it is mainly by volume, except for two products, the names I would not like to mention, by and large it has been volume driven, the main volume growth has come from those products which were affected by the NLEM.

**Manoj Garg:** Second is now, you know, going by this run rate, do we expect mid-teens kind of growth in the years to come?

**Ganesh Nayak:** Well, let us first talk about the year to come, then the years to come. In the year to come, in the next 12 months, looking at our last quarter apple to apple growth of 16% we definitely expect a growth in the teens.

**Manoj Garg:** Pankaj Bhai, like you have given the topline target of this 10,000 crores by FY16, any aspirations on the margin front, like when do we look back to go back to the historical number of 21 to 22% kind of margin?

**Pankaj Patel:** Margins will continue improving, you will see, this quarter, the margins are going up, if you look at the EBITDA level, and I think by 2015, 2016, we definitely see the margins going up by at least 3% or so, from the current level, so that is what we expect from the current level, so the margins would hit earlier margin level by 2015-2016.

**Manoj Garg:** If I can assess, like we are talking about 3% improvement from the whole of FY14.

**Pankaj Patel:** Quarter's numbers.

**Manoj Garg:** From quarter numbers. I see that is great. The last question from my side before I get into the queue, any visibility on the transdermals?

**Pankaj Patel:** I am sorry to interrupt, but let us understand very clearly, margin, when I say margin, margin is EBITDA, not gross margins. I think we should all understand that clearly, because please understand one thing, we sell our manufactured products and we also sell authorized generics. When we sell authorized generics, we don't have any manufacturing cost and any other costs. So, as a result our gross margins on those products will be lower, so you will not see the margins improvement directly at the gross margin level but you will see margin improvement at the EBIDTA level, so I think that is where I am focusing. All of you have to understand that this 3% what I am talking about is at EBITDA level.

**Manoj Garg:** Right Sir, and the last question from my side, Sir, like just want to understand like we have been investing in new technology areas like transdermals and nasal spray and all those things, so when do we start seeing the up side from some of these initiatives?

**Pankaj Patel:** It depends on the approval and I cannot give you timeline for approval, because it is very difficult to say. But we expect that approvals should come now and once the approval is there we should be able to get benefit.

**Moderator:** Thank you, the next question is from the line of Kartik Mehta from ICICI Securities, please go ahead.

**Kartik Mehta:** Hi, just wanted to understand on the R&D cost in this quarter, it is actually low in absolute terms and also lower in terms of as a percentage of the revenue. We have quite a lot of filings that we have done in this year, expect almost similar number next year, how should we build this cost Sir.

**Pankaj Patel:** Let me explain to you. Last year, there was some one-off expenditure because we had done specific studies which were having very high cost in the last quarter of the last financial year, so, on an apple to apple basis,it may not be comparable, the second thing is you will see that, on a year-to-year basis, our R&D expenditure is almost flat, or a little lower, the reason is that, I think we conducted some very major exercises two years back about improving R&D productivity and introduce new systems and processes in R&D, which actually helped us to improve the productivity while bringing down the cost, so going forward, we will continue to invest 6 to 7% of our sales on R&D, because as we move forward, we will also be doing some clinical development as you heard in biological, in vaccines. Also in some ANDAs we are also doing filing with clinical development, etc. Going forward, we would continue to spend about 6 to 7% on R&D.

**Kartik Mehta:** Sir, will the split on this be the same as you have shared historically. Will it be 35% on NC or actually longer yielding R&D and the rest would for the generic one?

**Pankaj Patel:** Yes.

**Kartik Mehta:** My second question is on the gross margins. I am just unable to add up the numbers, and if you can help me here. The US business has increased by about 75% on a YOY basis, I am not just seeing any increase in the overall gross margins on a sequential basis.

**Pankaj Patel:** Let me explain to you, we sell authorized generics, when we sell the authorized generics, the gross margins are lower in that but we do not have any additional cost on that, because we just distribute the product. So, what you will see as a result, that gross margins may not be comparable because we are selling authorized generics in US market, and if you see in IMS data, we have already seen some reflection in our IMS report as well. So, also as a result, it is very difficult for you to find out exact gross margins calculation based on that and very difficult for us to also give you a reconciliation of that, but if you look at EBITDA level then, you will realize that these gross margins, because there are no additional costs, actually helps in improving the EBITDA.

**Kartik Mehta:** But if you look at it and so the EBITDA margin is, maybe one of the reason is actually R&D cost of a sequential basis, which you said were actually very bulky in nature for the previous quarters, so all maybe I want to understand is that how do we build in improvement in gross margins when there is such a high increase in the US sales for the future quarters?

**Pankaj Patel:** First of all, you understand that gross margins are not likely to go down below this, so don't expect that, because I think there is a mix between our own product and our authorized generics, there is a limitation to which the sale of an authorized generics will happen. Also you know, there is an impact of NLEM price reductions on these gross margins, there is an impact of we losing marketing right of a few products from our license partners, so all that has a negative impact on the margin . Also if you see our joint venture with Hospira, we had the exclusivity margins and now, we have done away with that also, so all these things are now factored into this number and going forward, we should see improvement in gross margins.

**Kartik Mehta:** Yes Sir, and the last one what is the CAPEX that one should assume over the next two years and also the income tax rate, thank you.

**Vishal Gor:** CAPEX you should assume around 450 crores, and tax rate you can assume 15%.

**Kartik Mehta:** Actually this 450 will be for each of the years FY15 and FY16.

**Vishal Gor:** No. it may be, but currently we are talking for one year only.

**Moderator:** Thank you, the next question is from the line of Prakash Agarwal from CIMB, please go ahead.

**Prakash Agarwal:** Yes, congratulations and thanks for the opportunity, on this strong relationship of AG that you talk about, clearly seen from the scale up in the Divalproex, earlier your market share was 3 to 4%, now it is touching 18 to 20%, so when you talk about ongoing strong relationship, what kind of products do we already have and what kind of scale up you see in this business?

**Pankaj Patel:** What I can suggest is, I would give you the exact product names off line, currently I don't have it in front of me, but there are a couple of more products which we have launched recently and we would provide you the information on that.

**Prakash Agarwal:** And would it be fair to assume that you know, Niacin, which is already into semi-exclusive mode, since it is an Abbott product, this would be one of the products in the near term?

**Pankaj Patel:** Could be, I cannot give you specific names now, but if we decide then, we will let you know.

**Prakash Agarwal:** Sure, and again as the question was highlighted on the gross margin side, because we have seen this scale up in the US business as you said, this is an AG business, but I mean, if you see the product approval that we have seen in the last quarter, there are seven to eight product approvals plus we expect 15 to 20 more product approvals, so from a directionally perspective would it be fair to assume 100, 200 bps improvement or would you say it would be flattish.

**Pankaj Patel:** We would expect margins to improve because there are three to four reasons, one is that the base effect of NLEM will go away, second is, there is opportunity to basically have some advantage because of price increase which we can get into Indian market, third is that we are

actually to launch some important products in the US market, which should help us improve the margins further. So going forward, we should see margins to be going up from the level we have, at the gross level, but I think I would strongly want all of you to focus on EBITDA, because EBITDA is what is going to see the improvement because if there is going to be sale of authorized generics we will still have improvement in EBITDA, because the margins are such that are no additional costs involved in distributing, so all that margin goes into the EBITDA directly, so EBITDA will keep on improving. I think that is where we should basically focus on, but as the product mix is changing, we would also have improvement in gross margins as well.

**Prakash Agarwal:** Okay, but I look at R&D also, I mean, there were 49 ANDA filings for the last nine months, and you have 50 for the full year, so we have filed one product during the quarter.

**Pankaj Patel:** Yes.

**Prakash Agarwal:** Okay, and lastly some color on your launches, if you could give some color where we are in terms of launches of our products of Toprol, transdermals, and Alastin?

**Pankaj Patel:** I think it is very difficult for us to give you anything because we have been awaiting approvals. We may be able to tell you more about all this once we are closer to approvals or once we have approval in place. Currently, we don't have approvals and I think I don't want to give you any color on that unless I have approval in hand.

**Prakash Agarwal:** Okay, but would it be fair to assume that as per last discussions we were expecting approval cycle to resume in fiscal 15, so would it be fair to assume that this should come this year?

**Pankaj Patel:** Yes, I believe so.

**Prakash Agarwal:** Okay, perfect, and lastly on the other operating income, could you just give us a small breakup?

**Vishal Gor:** Breakup, we can provide offline, if you can restrict yourself to strategic questions that would be better.

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

**Anubhav Agarwal:** Thank you Sir, just one clarification, was there any contribution of Tricor or Trilipix in this quarter or will it start only from the next quarter?

**Pankaj Patel:** There is a small contribution from those products, but we will see more in the next quarter.

**Anubhav Agarwal:** Okay, just on the continuation of the previous participant, about transdermals, nasal toppers, have you got any complete response letter from the FDA so far in any of these?

**Pankaj Patel:** We have received some.

**Anubhav Agarwal:** You have indeed, okay, but to be specific, on transdermal, have you received anything?

**Pankaj Patel:** Yes.

**Anubhav Agarwal:** Okay, and just on the nature of this Zydus International Private Limited, you almost are investing now 120 crores last year, and another report says you are investing another 14 crores there, I was a little confused with the nature of the entity, what business does this entity do, because the annual report says that the sales of this entity is only 9 to 10 crores.

**Pankaj Patel:** Are you talking about Zydus International?

**Anubhav Agarwal:** Private Limited, where in this accounts, you have mentioned that you are going to invest further 120 crores over there.

**Pankaj Patel:** That is investment vehicle.

**Pankaj Patel:** All our international holdings are through Zydus International.

**Anubhav Agarwal:** Okay, this is just a holding company there.

**Pankaj Patel:** Holding company.

**Anubhav Agarwal:** Okay and just on Lipaglyn™, one question, when doctors prescribe Lipaglyn™, what exactly are the substituting? I understand it is an add on therapy to diabetes, for triglycerides, so is it like just substituting statins, or what exactly is it substituting?

**Pankaj Patel:** It does not substitute anything. It actually creates an add-on therapy for people who are suffering with diabetes and high triglycerides level. Typically, for a limited number of patients they were using Fenofibrate, but Fenofibrate has its own side effects so they were not using on all, with this they are able to use on more patients, the drug.

**Anubhav Agarwal:** So it was basically, so I probably did not word that question properly, so it was basically Fenofibrate is what Lipaglyn™ initially will be taking market share from.

**Pankaj Patel:** Yes.

**Anubhav Agarwal:** And last question on the European market, so this quarter was one of the weakest quarters ever, at least let us say, in the last two years for European market, so, when you talk about steps you have taken in the French market, is this a new base that we should take from here, what exactly happened in French market, have you discontinued some of the products?

**Dr. Ganesh Nayak:** Let me answer that, see the French market, one is the market is de-growing, for this quarter, to be very specific, the de-growth has been 6%, whereas our de-growth is higher. Now we have two components in our French business, one is the generic business which we do on our own, and the other is we have some third party sales. On the generic front, we have been affected more than what the market de-growth has been and on the third party sales, as compared to the last year, because we are referring to the growth, has been less than half of what it was in the corresponding quarter and that is because the market is down and the stocking by these third parties has been drastically reduced, so we have a kind of double effect on our sales, so that is how you see in this quarter, the degrowth is quite high. The other is, our concentration now is to improve the profitability of our French business and that is why as I mentioned in my opening talk, we have been exiting certain molecules where the margins are very low. So it is a combination, we are looking at it from a strategic profitability point of view, and also some of the environmental factors have affected which I just mentioned.

**Anubhav Agarwal:** As things stand today, are you profitable in both the markets, French and Spain markets. These are EBITDA positive.

**Pankaj Patel:** In France we are profitable, we are closer to break even in Spain.

**Moderator:** Thank you. The next question is from the line of Girish Bhakru from HSBC Securities. Please go ahead.

**Girish Bhakru:** Hi, back on the authorized generic launches, is there a change in strategy from previous, I am asking this because you have a healthy pipeline in the US and yet there is a focus on authorized generic launches.

**Pankaj Patel:** There is no focus on launching of authorized generics. you have to understand that, a couple of years back, we had issues with product approvals and at that time we basically took this route and now we have strong relationship with Abbvie and wherever there is an opportunity, we are going to launch authorized generics, which actually increases our overall business size, so it is not going to be our focus, but it is an existing relationship which is also giving us a nice margin to move forward.

**Girish Bhakru:** So would it be fair to assume there would be authorized generic in Niaspan as well?

**Pankaj Patel:** It is difficult to give you a specific product information but whenever we have an opportunity we are going to launch authorized generics and I cannot give you product specific information.

**Girish Bhakru:** Right, the second question was on the case with Mylan on transdermals where would that have been moving?

**Pankaj Patel:** The litigation is going on. It is difficult for us to comment on the litigation further at this moment.

**Girish Bhakru:** But any particular timeline that we can look at, when the outcome would come out?

**Pankaj Patel:** We don't know that exactly.

**Girish Bhakru:** Right, on the product development side, where would be the status on the liposomal or doxorubicin product.

**Pankaj Patel:** It is currently undergoing Phase-II study in India, and we are awaiting the results before we can move forward.

**Girish Bhakru:** But if I am not mistaken, you are selling the doxorubicin in Europe, the plain doxorubicin right with …

**Pankaj Patel:** We are selling plain doxorubicin in the US.

**Girish Bhakru:** In US as well, okay, and liposomal, that means would take at least two to three years to file that.

**Pankaj Patel:** Yes.

**Girish Bhakru:** Right, just lastly on the approvals, I mean, given that you had pretty interesting start on approvals this year, but since then we have not seen any material approval. I mean your 15, 20 number, does it includes some spray launches or aerosol launches as well, or would it be more ….

**Pankaj Patel:** We expect that, we don't know exactly what approvals will come, but we expect that based on the stage that we are.

**Girish Bhakru:** But should not this number go on higher, because of the pace of filing is higher, all these filings are on the patented products?

**Pankaj Patel:** I would love to have all the approvals tomorrow, but I cannot comment on that, today we say that we can expect approvals, whatever I say 15 to 20.

**Moderator:** The next question is from the line of Chirag Dagli from HDFC Mutual Funds. Please go ahead.

**Chirag Dagli:** Yes sir, I had a question on the US business, Divalproex Sodium is our product or is it also an AG from Abbott?

**Pankaj Patel:** We are selling both.

**Chirag Dagli:** We are selling both, so how do you split this 20 to 22% market?

**Pankaj Patel:** We cannot explain you that,.

**Chirag Dagli:** If you have seen the US business, the scale up from $70-75 million a quarter to about 100 to 110 now, would you see a substantial part of this from authorized generics, this growth?

**Pankaj Patel:** For the quarter yes, overall no.

**Chirag Dagli:** No Sir, I am looking at it from the last six months' standpoint, what was $70-75 million of quarter run rate, has become $100 odd million, so that is what I wanted to understand, this incremental 25, has it substantially come from authorized generic products?

**Pankaj Patel:** No, not substantially, but some part of that has come from authorized generics.

**Chirag Dagli:** Okay Sir, and a question on the India business, what is the level of generic-generic business that we have in this total sale of domestic formulations of almost 2400 crores?

**Dr. Ganesh Nayak:** This is a small percentage, it is not a substantial percentage of our total business.

**Chirag Dagli:** I wanted the exact number.

**Dr. Ganesh Nayak:** I don't think we can give that now.

**Chirag Dagli:** But does it vary between the quarters, dramatically?

**Dr. Ganesh Nayak:** No.

**Chirag Dagli:** Remains stable between quarters.

**Dr. Ganesh Nayak:** Yes.

**Chirag Dagli:** The proportion remains stable.

**Pankaj Patel:** Yes.

**Moderator:** The next question is from the line of Sonal Gupta from UBS Securities. Please go ahead.

**Sonal Gupta:** On India business how much sales force do you have now and how many people have you added this year?

**Dr. Ganesh Nayak:** We have not added any number this year. Our total number is around 5000.

**Sonal Gupta:** Right, and just from the US, I mean you filed 50 ANDAs, so I just want to, and while the productivity of R&D is clearly very strong, but just want to understand in terms of strategy, I mean how many products would you be backward integrated on.

**Pankaj Patel:** Almost half of them.

**Sonal Gupta:** Okay, and how many of these are Para-IV filings, if you could.

**Pankaj Patel:** Vishal can give you this information, right but if I remember correctly, about 19.

**Sonal Gupta:** Of the 50.

**Pankaj Patel:** Yes.

**Sonal Gupta:** Okay, but I just want to understand, in terms of your strategy, because you seem to be doing backward integration is more limited and more of filing what is the strategy and we are also not seeing a very big increase in CAPEX. So you are not really aggressively investing heavily in CAPEX also, what is the strategy with filing these products? Do you see these as niche opportunities or a lot of these are commoditized products?

**Pankaj Patel:** Please understand one thing, we have invested and our sales was not growing, everybody was asking the question, you are investing but there is no growth. Now that we have completed the investment phase, we have got filing happening, we will have approval, but we already have invested into assets before. So I do not see there is a relation between these filings and investment and all that, so that is the way I would put it. So first point is that I think we have basket of products which is good opportunity that is the way I would put it. It could be in different classes, but we have basket of the products which is in different classes, but as I mentioned to you already that we have got 19 Para-IV filings. We are making First-to-File opportunity, we are doing some very difficult product filing, and we are also looking at niche opportunities. So it is basket of everything, and then different dosage forms.

**Sonal Gupta:** Right, and just one question on Lialda, I mean, do you still retain the First to-File status?

**Pankaj Patel:** We retain the First to-File status.

**Sonal Gupta:** So you retain that?

**Pankaj Patel:** Yes, we retain that.

**Moderator:** Thank you, the next question is from the line of Balaji Prasad from Barclays. Please go ahead.

**Balaji Prasad:** Firstly on Lialda itself, can you help us understand why the court case was reopened again. If I remember, this had been closed administratively.

**Pankaj Patel:** Sorry, I cannot comment too much on the legal aspect of that because it is very difficult for me to specifically tell you but whenever we shall meet, I can ask our legal people to explain, but I cannot explain more detail.

**Balaji Prasad:** Do you have any partners to produce this, or is the technology completely yours?

**Pankaj Patel:** It is all ours.

**Balaji Prasad:** Okay great. On the same lines, Pentasa when do you expect to see it coming to the market?

**Pankaj Patel:** Whenever we have the approval. As per the agreement, you know that, we are free to launch as per the agreement, but once we have approval, we should be able to launch as per the agreement.

**Balaji Prasad:** Right, when did you file this exactly?

**Pankaj Patel:** You are asking me questions for which I don't have the data to tell you, so maybe you can take it off line, because I don't have the data.

**Balaji Prasad:** Just lastly one quick question on biosimilars you are doing a lot of progress on this, what kind of expenditure are doing on this annually, both OPEX and CAPEX?

**Pankaj Patel:** For what.

**Balaji Prasad:** On biosimilars.

**Pankaj Patel:** Again, all this information we can give you offline. You can ask Vishal, he will be able to help you on that.

**Moderator:** Thank you, the next question is from the line of Minesh Mehta from Research Delta Advisory. Please go ahead.

**Minesh Mehta:** I just wanted to know, we have got an approval on Wellbutrin XL, and first of all I wanted to know whether we have launched it, and if no, then when are we expecting and what is stopping the launch?

**Pankaj Patel:** Yes, we have launched it.

**Minesh Mehta:** You have launched it, this is the part of the current year, current quarter, right?

**Pankaj Patel:** Yes.

**Minesh Mehta:** Okay, any color that you would like to provide on the Prevacid ODT case which is a kind of now in favor of the generics and I think we are awaiting approval so what do you think, when can we launch this?

**Pankaj Patel:** It will go down again to the court, so we don't know exactly when does the final things will happen? So it is difficult to say, at this moment it is only referred to the lower court , to get the direction.

**Minesh Mehta:** Right, in terms of approval, when are we expecting it? The court will take its own time, but

**Pankaj Patel:** Approval time line is difficult to comment because it is not possible for us to predict when exactly the approval will come. That is very difficult for us to comment.

**Minesh Mehta:** Okay, but this year, next year, nothing of that sort.

**Pankaj Patel:** Well, yes, you can take that way. Actually we don't know, so I am not able to give you anything. It is very difficult to predict exact approval time.

**Minesh Mehta:** Okay, fine. The other question is actually about the domestic business – does this number include the trade margin impact or we are yet to see that because we have increased the trade margins.

**Dr. Ganesh Nayak:** Yes, it includes the trade margins, which we effected from April.

**Minesh Mehta:** Okay, this is basically taking into account all the DPCO as well as trade margin pressure.

**Dr. Ganesh Nayak:** Yes, because that started impacting from June, last year.

**Minesh Mehta:** Okay, fine, just on the transdermal, I mean, if you can just reiterate as to when are we likely to launch or expect any approval or …

**Pankaj Patel:** We would not be able to give you any specific answer on this question.

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

**Surya Patra:** You talked about price increase in certain products in the domestic market. So can you tell us what is the kind of price increase and what is the kind of volume increase that you have seen for the domestic business in the quarter?

**Pankaj Patel:** Exact breakup you can take it offline.

**Vishal Gor:** Offline we can give you that information.

**Surya Patra:** Okay, so is there any chance that you would be playing some price gain in the subsequent year also in the domestic business, that 10% kind of price hike is allowed.

**Pankaj Patel:** Yes, your question is understood, on the NLEM products they have already announced that from April onwards 6.32% price increase is allowed as per NPPA, And also on the the products outside the scope of NLEM, depending upon the product mix, one can increase the price up to 10%.

**Surya Patra:** So, you are considering to take some price hikes for certain baskets of products.

**Pankaj Patel:** Yes, some product mix, definitely we will have price increase.

**Surya Patra:** Okay, and regarding the JV you had in your opening remarks indicated some new products, some new initiatives for all of your JVs, can you please repeat on that?

**Pankaj Patel:** No, we had not mentioned.

**Surya Patra:** Like, a few new products that you filed for that you are anticipating launches from this.

**Pankaj Patel:** This is from our joint venture with BSV we have filed some ANDAs with USFDA for our partner.

**Surya Patra:** Okay, and just lastly one clarification, you talked about 40 filings in FY15 for US market, is that correct Sir?

**Pankaj Patel:** Yes.

**Surya Patra:** So, it seems Sir, you are sounding very optimistic about US initiatives. You are talking about 15 to 20 product launches during FY15 and also you are stepping up your filing efforts for the US market. So is there something which is giving you confidence with regards to the US business or what is that which is giving you that confidence to you for the US business?

**Pankaj Patel:** US is the largest market in the world, so obviously every pharma company will focus on the US market.

**Surya Patra:** So, that means we will see a substantial increase in the R&D, though you have indicated 6 to 7% kind of R&D.

**Pankaj Patel:** We do not expect beyond that.

**Surya Patra:** Okay, so for some time this is the trend, or it will be just for one-off year, where you will file this 40 number.

**Pankaj Patel:** Our objective will be to keep a trend like that but it is difficult for me to predict what we will do next year, we will tell you when we talk next year, when we finalize the plan.

**Moderator:** Thank you, the next question is from the line of Rashmi Sancheti from Sunidhi Securities. Please go ahead.

**Rashmi Sancheti:** Yes, thanks for the opportunity, I just want to know the breakup of your 50 ANDA filings in terms of injectables, nasal spray, transdermals, and your Nesher products and your topicals?

**Pankaj Patel:** Sorry we are unable to provide you the exact breakup of that at this moment. You can talk to Vishal for further information on that.

**Rashmi Sancheti:** Okay, and Sir, in India business this year it has just shown a single digit growth, was it only because of the trade related issues and NLEM impact or also because of the termination of your marketing contract of two in-licensed products.

**Pankaj Patel:** I think first of all, our growth for India formulation business is 11% and not single digits, but yes, there is an impact of NLEM and the licensed product going off which has impacted the growth. So, if you remove the impact of those things and neutralize then, the growth is higher.

**Rashmi Sancheti:** How much is the growth then, if you just exclude that part.

**Dr. Ganesh Nayak:** As we mentioned, in the last quarter our growth is 16%, now I am giving you an apple-to-apple in light of what you said. Excluding the impact of NLEM as well as those discontinued two products, our growth for the quarter is 16% and for the year is 11%.

**Moderator:** Thank you. The next question is from the line Alok Dalal form Motilal Oswal. Please go ahead.

**Alok Dalal:** Pankaj Bhai you mentioned consolidation as one focus area for the company over the next few years, like you exited Japan last year, are there any other businesses that you think are not working and you may want to revisit them in FY15?

**Pankaj Patel:** Currently, we have revisited the whole portfolio and based on that, we decided to exit the Japan market and we have completed that process. We do not have plan at this moment to exit any other area. All the businesses look very promising from a long term and short term perspective, so we are not planning to exit any other business as this moment.

**Alok Dalal:** Pankaj Bhai, some of the businesses that we have like Animal Health and APIs they seem to be a little bit lacking on scale, how do you see those unfolding over the next two years?

**Pankaj Patel:** If you look at Animal Health, we are among the top players in India, so I fail to understand why we are not at scale. We are one of the top players, we are first, second, or I don't know, exact number, because there are no IMS available. But we have the scale and we have the wherewithal to really do it and it is growing at good rate and also highly profitable business. Coming to API, substantial portion of the API business is captive, which is not reflected in the numbers. So API size and scale is still big, but what you see is only what we sell to third parties.

**Alok Dalal:** Sure, and Nitin Bhai, any reason why our tax rate continues to be at 15% lower than the peer group.

**Nitin Parekh:** As we mentioned in the earlier conference call, we have partnership form in Sikkim which pays alternate minimum tax but we avail credit entitlement for that and therefore, in

accounting terms, there is no outflow though cash flow wise there is outflow. Keeping that credit in mind overall rate comes down.

**Alok Dalal:** Okay, so that continues for FY15 and FY16 should we think about higher tax rate.

**Pankaj Patel:** The benefit of that backward area benefit in Sikkim will continue till March 2017.

**Moderator:** Thank you, the next question is from the line of Amit Dalal from Tata Investments. Please go ahead.

**Amit Dalal:** Pankaj Bhai, you mentioned earlier that we should concentrate on EBITDA because of some of your purchases made of finished products itself, and not on the growth in PBT. I was not clear what numbers you were addressing?

**Pankaj Patel:** We talked about gross margins. Okay, so this was comparison, don't focus on gross margins, focus on EBITDA. And whatever we are saying is improvement in EBITDA, gross margin does not give a correct picture because on some of the finished product purchases, the gross margins will be lower. Because there is no additional cost of sales and marketing, etc., that directly impacted the bottom-line.

**Amit Dalal:** And in the next two years you expect to have any major CAPEX.

**Pankaj Patel:** CAPEX would be around 450 crores.

**Amit Dalal:** Per year.

**Pankaj Patel:** For this year 2014-15.

**Amit Dalal:** And the same perhaps 2015-16.

**Pankaj Patel:** The same number may continue next year also.

**Amit Dalal:** And increase in revenue would be approximately about, you said in two years you will reach about 10,000 crores, so approximately a 15 to 16% annual increase in revenue, right.

**Pankaj Patel:** For financial year 2015-16, we have said 10,000 crores as our sales.

**Amit Dalal:** Correct, and that would exclude non-pharma business, this is only for pharma revenue, would that be correct?

**Pankaj Patel:** It is a consolidated revenue.

**Moderator:** Thank you, the next question is from the line of Dhiresh Pathak from Goldman Sachs. Please go ahead.

**Dhiresh Pathak:** Hi, thank you Sir, can you share the cash flow hedges we have.

**Pankaj Patel:** We will provide you offline, we have no hedges right now.

**Vishal Gor:** We don't have any hedges.

**Dhiresh Pathak:** Of the 15 products that were approved this year, how many were launched?

**Vishal Gor:** We launched 7 products during the year in the US market.

**Dhiresh Pathak:** Okay, in US 91 approvals we have, how many products are actively marketed?.

**Pankaj Patel:** 61.

**Moderator:** Ladies and gentlemen, due to paucity of time that was the last question. I now hand the conference over to the management for their closing comments.

**Dr. Ganesh Nayak:** Thank you very much and we look forward to seeing you again at the end of the next quarter at the time of result announcement. Thank you and good night.

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