



“Cadila Healthcare Limited Q1FY15 Post Results Conference Call”

July 30, 2014



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Moderator: Ladies and Gentlemen, Good Day and Welcome to the Cadila Healthcare Limited Post Results Conference Call. As a reminder, all participant 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 the conference, please signal an operator by pressing ‘*’ and then ‘0’ on your touchtone telephone. 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. Ganesh N. Nayak: Good evening and welcome to our post Result teleconference for the first quarter of FY15. We have with us Mr. Pankaj Patel – Chairman and Managing Director; Dr Sharvil Patel – Deputy Managing Director; Mr. Nitin Parekh – CFO, and Mr. Vishal Gor – Senior General Manager, Investor Relations.

During the quarter gone by on a consolidated basis, our total income from operations was up by 25% year-on-year to Rs.20.5 billion. Earnings before depreciation, interest, and tax excluding the impact of exchange rate fluctuations was up by 42% year-on-year to Rs.3,714 million. The EBITDA margin stood at 18.1%. Profit before tax excluding the impact of exchange rate fluctuations and exceptional items was up by 50% to Rs.2,948 million. Excluding the impact of increase in depreciation charge due to revision in useful lives of the assets, growth in PBT was 56% year-on-year. Net profit, excluding the impact of exchange rate fluctuations, exceptional items, and income tax refund received in Q1 of FY13-14 was up by 39% to Rs.2,364 million. Excluding the impact of increase in depreciation charge due to revision in useful lives of the assets, growth in net profit was 45% year-on-year.

Now, let me share some of the highlights of the operations for the quarter:

Our India formulations business posted sales of Rs.6,749 million, up by 8%. Growth excluding the impact of NLEM and the discontinuance of BI products was actually 16.6%. We launched 19 new products, including line extensions, during the quarter, of which six were for the first time in India. Our business in the US posted sales of Rs.7,165 million, up by 88%. We launched four new products in the US market during this quarter. We filed 26 additional ANDAs with the US FDA during this quarter. In Mexico, we launched 2 new products during the quarter taking the cumulative number of launches to 9. During the quarter we received the approval for 5 products taking the cumulative number of approvals to 15. Our business in Europe grew by 9% and posted sales of Rs.1,012 million with the launch of 2 products in France and 3 products in Spain. We received approvals for 4 new product dossiers for the European market. Exports to emerging markets grew by 19% and registered sales of Rs.1,050 million on the back of 12 new product launches in different markets during the quarter.

Zydus Wellness Limited posted sales of Rs.1,075 million. Net profit of Zydus Wellness Limited declined by 25% to Rs.171 million. However, excluding the impact of income tax

refund received during Q1 FY13-14 and higher depreciation provision during the current quarter, net profit is up by 5.5%. Our API business grew by 17% and posted sales of Rs.1,007 million during the quarter. Our animal health business posted sales of Rs.737 million, up by 24%, backed by 3 new product launches in India. On the R&D front, we completed phase III clinical trials for one of the mAbs. Phase III clinical trials were initiated for one more mAb. We initiated global clinical trials for one of the first generation biosimilars, which is currently being marketed in India. Thank you and we will now start the Q&A session. Over to the coordinator for the question-and-answer session.

Moderator: Thank you very much, sir. Ladies and gentlemen, we will now begin the question-and-answer session. The first question is from Jiten Doshi of Enam Asset Management, please go ahead.

Jiten Doshi: A couple of questions. How sustainable is this 18% margin going forward, and we had our own sight set at 20% plus margins, how fast now do you think we can reach there? My second question is that given where the momentum is now, how do you see the whole US business panning out this year and next year and what sort of visibility do you have for that business? And last question is how do the entire Consumer Products business picking up, because it has been lagging market performance in the last couple of quarters, what are our plans now that Sharvil bhai has come on board, etc., to take on, what are we seeing in that business going forward?

Pankaj Patel: Thank you Jiten bhai for the questions. I think first of all the current quarter margins of 18% and our expectations to move towards 20%. I think we are on track in moving towards that. It will all be dependent on another two quarters to really see the markets panning out, particularly in the US, which will tell us exactly when we can get, but it will not be too late for getting us to the 20% margin and going forward. I cannot specifically give you a timeline when we can get there, but I expect that the margins will continue improving. There are a lot of one-time impact in the past and also now from the JV side which ultimately will get neutralized and then margin improvements will be seen going forward. As far as US business is concerned, it is on growth trajectory and we expect it to remain on growth trajectory. We have a number of products launched and we expect more products to be launched in future which should help us continuously grow the US business. Last question was on consumer products business, I generally do not take questions on consumer products business at the beginning, I will take this from you Jiten bhai, but I would request every participant to restrict questions on Cadila Healthcare because we are not able to give justification to Cadila Healthcare questions. As far as Zydus Wellness is concerned, the company has moved to a distributor led field force model, that requires significant reduction of the number of stockists in the market by almost one-third from the earlier numbers, and almost doubling the field strength from the current field strength through this mechanism, while making sure that the costs do not go up. That whole roll out happened in the last two quarters and full roll out has been completed. We also launched some products and we believe that these all will help us to see growth coming back as far Zydus

Wellness is concerned, and you will see from this quarter onwards that positive change moving, and then we will see that we are back into the momentum.

Jiten Doshi: Pankaj Bhai, you think worst is over and we are on a good track now?

Pankaj Patel: “Acche Din Anewale hai” if that not being said then its fine.

Moderator: Thank you. Our next question is from Anubhav Aggarwal of Credit Suisse, please go ahead.

Anubhav Aggarwal: One question on the R&D spend. If I look at your R&D spend last year, it was about 460 crores, what percentage of the spend would be going in Generics, I am just trying to exclude your entry in this space.

Pankaj Patel: About 80%.

Anubhav Aggarwal: Pankaj bhai, now you are doing almost 40-50 filings, we just divide this number and multiply it, Rs.460 crores into 80% and the filing spend for you let us say 40-50 filings, the amount comes to only \$1.4-1.5 million you are spending on each product, where you are doing litigations, you are doing complex generic filings, my question here is are you outsourcing part of your R&D or is this all you have been so efficient that you are able to file 6 transdermal products in this small budget?

Pankaj Patel: So we are basically doing everything in-house, we are not outsourcing. We have done a lot of things in terms of improving R&D productivity and some of the factors are responsible for our costs being lower. Last year, base was high, so I think that we will continue maintaining the same number. It is basically productivity improvement that has helped us.

Anubhav Aggarwal: The question I have here is tell me if my understanding is wrong, typically, transdermal filing you would at least spend about \$3-4 million on a minimum, including the trials, I appreciate it is spread over two years, but since you are doing 7 filings, I can easily assume that for two or three years you would have spent at least \$10-15 million annually in transdermal filing, would that be wrong?

Pankaj Patel: Your numbers are not wrong if you look at general industry. There are some ways to make sure that our cost elements are limited, so again I cannot share more specifics about it, but that is what we are spending.

Anubhav Aggarwal: In your previous quarter you mentioned that this absolute R&D spend for you is likely to be similar this year as well. So that statement still remains the same?

Pankaj Patel: Yeah.



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- Anubhav Aggarwal:** My second question is on the authorized generic products that you have in the US right now, Divalproex and Fenofibrate basically with Abbott. Is there a timeline till which you have this AG rights or is this indefinite right now?
- Pankaj Patel:** There is no specific timeline that is described in that agreement. So to my knowledge, I can give you more specific details once I refer the agreement.
- Moderator:** Thank you. We will take our next question from Girish Bakhru of HSBC Securities, please go ahead.
- Girish Bakhru:** Just again on the R&D side, given 50 filings in the last year and another big chunk of filings 26 this quarter, can you tell us how many are Para-IV filings or largely these are Para-III filings?
- Pankaj Patel:** I would request Vishal to provide you this information.
- Girish Bakhru:** But if you can give a color in terms of would these filings mean that there are significant launches in next one or two years or all these will be much later?
- Pankaj Patel:** FDA's average timeline for approval is close to 36 months. So if you expect anything in two years for which you file now, it is not possible.
- Girish Bakhru:** Then it would be fair to assume that a large chunk of benefit will come two-three years ahead?
- Pankaj Patel:** Whenever the product approval happens. Rate can improve also, we do not know, FDA has been promising a lot in GDUFA so maybe, there could be improvement in the rate, but we do not know today.
- Management:** At the same time there are a lot of pending product approvals also out of which we can get growth.
- Girish Bakhru:** But, I am just trying to assess, were there any ANDAs that you were not able to file earlier when you had the issue with the Moraiya facility that you are filing now?
- Pankaj Patel:** First of all, we never had any restrictions on filing ANDAs . So, we never stopped filing ANDA with FDA. The only thing was that the new approvals were not given, but filing was not an issue.
- Girish Bakhru:** Second question was on Niospan. Can you comment on the launch of Niospan and that would be an authorized generic?
- Pankaj Patel:** I cannot specifically comment on that particular product.

- Girish Bakhr:** On the launches from Neshar, how many launches can we see in this year?
- Pankaj Patel:** One more launch we are expecting in Q4.
- Girish Bakhr:** But the product that we launched in last year has that really picked up in US or is it still...?
- Pankaj Patel:** Yes, it has picked up in US.
- Girish Bakhr:** What I am trying to understand is, in that product how many other players are there apart from you?
- Pankaj Patel:** You are asking too many specific details, Girish. I would request you to contact Vishal, he can give you specific information. I do not have product wise number of competitors detail in front of me.
- Moderator:** Thank you. Our next question is from Prakash Aggarwal of CIMB, please go ahead.
- Prakash Aggarwal:** Question is on the India business. We have seen 8% growth YoY and we have commented that excluding the NLEM and BI impact, it has been 16.6%. When you see that excluding this impact we will see a mid-teen kind of growth which the other industry players have already started reporting, so what is our thought here?
- Management:** The fact that net of NLEM and these two products, the growth currently is 16%, and from this month onwards that thing gets neutralized. I am talking about NLEM impact, and of course some new products also have come under NLEM two months ago, but broadly we are aiming at the mid-teens in terms of our growth for the domestic business.
- Prakash Aggarwal:** So, for the next nine months you are expecting a higher growth to meet the target?
- Pankaj Patel:** Yes.
- Prakash Aggarwal:** On our own product side in the US, we have seen fairly good success in terms of getting the product approvals now, but the larger products still await approval. Have we been hearing from US FDA on the CRL front for the larger products which we are expecting like Toprol, Azelastine of the world, if you could give some broad level color?
- Pankaj Patel:** We do have received CRL for some of the products, so we believe that those products are under process of approval. We cannot give you a specific timeline for that because there is no timeline FDA gives, but we have received CRL, that means we have moved to the next step.
- Prakash Aggarwal:** And fair to assume that there are not too many complexities in the CRL which could take a long time?

- Pankaj Patel:** Yes.
- Prakash Aggarwal:** Tax rate if you look at in the past, we have been under 15%, we move towards higher tax rate of 17%, our guidance was around 15% for the next two years and 17% was higher tax. So we still stick to 15% guidance or we...?
- Pankaj Patel:** We continue with 15% as a guidance.
- Prakash Aggarwal:** On the FOREX hedges front, in the past we had hedges at lower rates which had restricted our gross margins. Now, I believe that FOREX hedges are at higher rates. If you could give color on the FOREX hedges and if it is fair to assume that with earlier FOREX hedges being largely over we could see some gross margin improvement also?
- Pankaj Patel:** There are no hedges currently, every situation is an open situation, all hedges which we entered into earlier are over by this time.
- Prakash Aggarwal:** And that would have restricted our gross margins in the past?
- Pankaj Patel:** Last year, yes.
- Prakash Aggarwal:** Those would have been at lower rates of 55?
- Pankaj Patel:** They were not at 55, they were at around 59, but then actual rate in the market was above 60, so in that context we lost.
- Moderator:** Thank you. We will take our next question from Anshuman Gupta of Edelweiss Securities, please go ahead.
- Anshuman Gupta:** Hi Sir, there was a news flow that you guys have taken price hikes in Warfarin. So, is this a big product for this quarter?
- Pankaj Patel:** We are not aware of any price hike on that product.
- Anshuman Gupta:** The other question was broader on the US, right, the warning letter clearance for Moraiya happened sometime in July 2012 and it has been two years almost, and we have got about 15-odd approvals so far. One of your Indian competitors actually if you see when their warning letters got lifted they got almost 50-60 odd approvals in a span of about two years. Is there anything specific that is stopping us from getting approvals?
- Pankaj Patel:** So I think, if you file PEPFAR products you can get approval. So PEPFAR products are priorities, so if you see the number of approvals and if you study that, then you will find a lot of PEPFAR products got approved during that period for that competitor. So from our point of view, our approvals are picking up and we are seeing that clearly, so again I cannot exactly

comment on that company, because I do not know about that. From our point of view, we are getting approvals and we will get approvals.

- Anshuman Gupta:** So this year should we assume that you will get at least 10 to 15 ANDA approvals?
- Pankaj Patel:** Yes.
- Moderator:** Thank you. Our next question is from Nimesh Mehta of Research Delta Advisors, please go ahead.
- Nimesh Mehta:** I wanted to know whether the India business reflects a higher trade margin that you allowed for the NLEM products?
- Management:** Yes.
- Nimesh Mehta:** We had increased the trade margin on the NLEM product side.
- Management:** Yes.
- Nimesh Mehta:** Full quarter impact or?
- Management:** Yes it takes into account the whole quarter.
- Nimesh Mehta:** Second, did we launch any other authorized generic in the US market other than the three that we had launched in the last quarter itself?
- Pankaj Patel:** Yes, we launched Paricalcitol.
- Nimesh Mehta:** Can you give us some color about that product – how big would that be in terms of branded business side?
- Pankaj Patel:** Sorry, I have no details. Since you asked me, I remembered that. Vishal can also share some information with you.
- Moderator:** Thank you. Our next question is from Saion Mukherjee of Nomura, please go ahead.
- Saion Mukherjee:** Sir, in your opening remarks, I just wanted to clarify, you mention about some global biosimilar trials. Is it for the regulated market and which product is that?
- Pankaj Patel:** It is for the regulated market. We are not disclosing currently the name of the product. We will let you know once we file.
- Saion Mukherjee:** Is this monoclonal antibody?

- Pankaj Patel:** No, it is a first generation, it is not a monoclonal.
- Saion Mukherjee:** And you are already marketing that product in India?
- Pankaj Patel:** Yes.
- Saion Mukherjee:** And the two MAb trials that you mentioned for Indian market?
- Pankaj Patel:** Right.
- Saion Mukherjee:** When do you expect in terms of timeline for these products to be launched in India?
- Pankaj Patel:** We expect next financial year.
- Saion Mukherjee:** On the US, in terms of the new launches, particularly, Cymbalta which I guess you had launched and authorized generic for Niospan, what is the pricing environment like at this point?
- Pankaj Patel:** There is a price competition as far as Cymbalta is concerned. It is very new. So we currently do not know exactly what kind of price erosion is going to happen. But there is a pricing competition happening in the US market as far as Cymbalta is concerned. For Niaspan, I do not have any data.
- Moderator:** Thank you. We will take our next question from Surjit Pal of Prabhudas Lilladher, please go ahead.
- Surjit Pal:** One Brazil regulation says that if you file your generic along with pairing up with a branded product you will get faster approval. Do you see any impact in your application? And what is that new regulation means, if you can...?
- Pankaj Patel:** Personally I have no idea about this and we have not seen any impact, though we have filed products where we have both branded and generic.
- Surjit Pal:** Similar thing also if you can see ANDA regulation, they have said that they will speed up. If your applications have some prior approval supplements, it will be cleared within six months and ANDA amendments within 10 months. Do you see any impact going forward in your application?
- Pankaj Patel:** No, that is for the existing approved products, what you are mentioning about, any addendum is always for the products which are already approved and you want to do some changes in that, that is what this timeline applies, but as far as new entity is concerned, currently average timeline is about 36 months. Going forward, under GDUFA, it has to come down to 18 months, but we do not know when.

- Surjit Pal:** They said it will take around three days step-by-step by FY17.
- Pankaj Patel:** Yes, that is what they say again. That is a public knowledge we all know, but today I can only give you it is 36 months average, and going forward they have promised to go to 18 months.
- Surjit Pal:** Going forward in your US business, your policy of launching AG more and more, will it remain the same or do you think that you will...?
- Pankaj Patel:** We have a relation with the partner, which is a strong relationship, I think if partner does AG, they will definitely give it to us. So we are not going to stop doing that, because of the fact that we have relationship and this relationship is helping both the companies. So we will continue doing that if there are opportunities. It depends upon if there are product opportunities again.
- Surjit Pal:** A few quarters back you were talking about some important product to be brought in your Hospira JV. Has there any development happened in ...?
- Pankaj Patel:** On our JV we did not talk about imported product, we have mentioned that we are expanding the JV with more products and that is already happening.
- Surjit Pal:** So any large product or any significant product that could change the?
- Pankaj Patel:** They are not going to be exclusive products as we had in the past, so that could not be a huge opportunity, but there will be an incremental opportunity. We will only see in the next financial year, once we have all the approvals in place.
- Surjit Pal:** The last question is on this latest price ceiling under DPCO, how far will be the impact for this year in cardiac and diabetology portfolio?
- Management:** The total impact on an annualized basis on top line is around Rs.25 crores, and on the bottomline it is about Rs.23 crores and for the current financial year, the impact could be something like Rs.18 crores or so on the bottomline.
- Moderator:** Thank you. The next question is from Tushar Manudhane of Quant Broking, please go ahead.
- Tushar Manudhane:** With respect to ANDAs which are pending approval, let us say 158 ANDAs, just would like to have a color in terms of classifying them into as Oral Solids, Nasal, Transdermal, could you give the numbers for that?
- Pankaj Patel:** We are currently not providing that information.
- Moderator:** Thank you. Our next question is from Chirag Dagli of HDFC Mutual Funds, please go ahead.

- Chirag Dagli:** What would be the MAT credit that we have taken in the quarter on tax? Till last quarter we were disclosing that number.
- Management:** Rs.23 crores.
- Chirag Dagli:** If I look at our numbers sequentially fourth quarter versus the first quarter both the US business as well as the India business is much higher, and despite that our margins gross or EBITDA have not improved. What is the takeaway of that, sir – is the US business growth much more inferior than what was the base, is that how we should take it?
- Management:** Earlier also we had mentioned that business mix affects the gross margin in weighted average terms. We have authorized generic business in US, obviously, it has lower margins compared to Zydus' own products.
- Chirag Dagli:** So even the EBITDA has...?
- Management:** At the EBITDA level there is an improvement, but at gross margin level, there is difference, so you can clearly see that if you sell AG, the cost of goods will be higher, so the GC will come down but at the same time, when you look at EBITDA, you will see the impact.
- Pankaj Patel:** So in the last call also, we had mentioned that you should look at EBITDA percentage.
- Chirag Dagli:** So the scale up in the US business over the last two quarters is predominantly due to AG products, is that the take away sir?
- Pankaj Patel:** Not totally right, but there is a contribution of AG also in the growth.
- Moderator:** Thank you. Our next question is from Prakash Aggarwal of CIMB, please go ahead.
- Prakash Aggarwal:** US business is showing growth. India, you are saying is expected to come back post the NLEM impact and stuff. JV you said is going to come back in '16. So any color you could give in other businesses like Mexico and other emerging markets?
- Pankaj Patel:** Mexico, we just began the journey, this is going to be a one full year of Mexico business happening first time. We have launched about 8 to 9 products already and we have 15 approvals already in Mexico, We believe that this market will rapidly develop for us. The other important market for us is Brazil, though we do not have significant growth in Brazil. It is mainly driven by the fact that we have no product approvals, but we expect that the product approvals should happen now based on the meetings we had with the regulatory agency. Again, I cannot give you when exactly the approval will happen, but we believe that approval will start happening and we will see, as and when we launch products, the growth will pick up again. So this is the key. And then, of course, the market for us is emerging markets where the markets are growing and we expect good growth also coming from those markets.

- Prakash Aggarwal:** And sir, animal health this quarter has grown 30%. Any color there?
- Pankaj Patel:** There are two reasons for that – one is, of course the business has grown, but there is some base effect for the last year as well, some of the vaccine products were not available last year, We also launched new products, and of course the business is continue growing. So, on a like-to-like basis also, business has grown, but because last year some products were not available, now they are available, the growth looks a little higher.
- Prakash Aggarwal:** Second question is on the Transdermals. One is we were expecting some approval this year based on the earlier filings. So, are we on track on the development of Transdermals?
- Pankaj Patel:** As of today, we believe that we should have approvals. Again, it depends on FDA.
- Prakash Aggarwal:** Just a follow-up here on in terms of the investments that we are doing both in terms of filing and the CAPEX for the facilities, so how are we accounting for it, are we waiting for the revenues to kick in then take into P&L or we have already started taking effect in the P&L?
- Pankaj Patel:** Plant investment, whenever the plants are commissioned, it is taken into account.
- Management:** Transdermals we are yet to start the commercial production.
- Prakash Aggarwal:** Sir, for filing?
- Pankaj Patel:** Filing also, we have not started commercial production yet.
- Prakash Aggarwal:** Just for the Transdermals, anything is not passing to the P&L currently?
- Pankaj Patel:** Yes.
- Moderator:** Thank you. Our next question is from Aditya Ahluwalia of Invesco. Please go ahead.
- Aditya Ahluwalia:** I had a couple of questions on the US business. First, how many more AG launches are expected in the US?
- Pankaj Patel:** Maybe one, but we are not sure.
- Aditya Ahluwalia:** And the AG EBITDA margins are lower than the company margins or they would be higher?
- Management:** EBITDA margins will be lower than the company margins.
- Aditya Ahluwalia:** Second question is on the approvals for the complex products. I know that we cannot put a timeline to when FDA does its work, but generally I wanted to get a sense that from our experience of dealing with FDA to what extent would you put the blame on us because our

filings may be in some way incomplete or some way not proper, and to what extent would you put the blame to FDA for not giving the approval, would you say that we did our work perfectly in most of the cases and it was just a procedural delay or do you think there was some lacunae from our side also in the previous filings?

Pankaj Patel: I think I would say 80%, I would blame on regulatory delays and 20% on our filings.

Aditya Ahluwalia: So, are you saying we corrected in our recent filings and now we are a little more careful when we are filing and we are doing more detailed work?

Pankaj Patel: What happens, we file so many, and there will be always some products where there could be issues, so I would say only a small number 20%. 20% of the total filing, Your question was really interesting, I answered you also correctly saying that 80% is regulatory delay and 20% is due to us, but it is across the board the regulatory delays are happening. So only thing is that since now we have CRL in hand, we believe that product approval should happen.

Aditya Ahluwalia: I did hear the number you said, but can you just share the guidance once again of the number of approvals you are expecting this year?

Pankaj Patel: Yes, 10 to 15 for this financial year.

Aditya Ahluwalia: How many have we got in the first quarter?

Pankaj Patel: So, for the first half of this year, because we follow the calendar year, we received seven approvals.

Aditya Ahluwalia: Another 7-8 is expected?

Pankaj Patel: Another 10 to 15 approvals we are expecting.

Aditya Ahluwalia: Any injectable approvals that we got sir amongst these seven?

Pankaj Patel: We have got one injectable approval.

Aditya Ahluwalia: Our product or with the partner?

Pankaj Patel: Of course our product.

Moderator: There is a question from Gagan Thareja of Comgest India, please go ahead.

Gagan Thareja: Could you possibly give the debt and cash positions?

Management: Our gross debt was Rs2624 crores, and cash balance was about Rs.564 crores.

- Gagan Thareja:** What would be the cash tax rate for the quarter?
- Management:** Cash tax rate would be around 20%.
- Gagan Thareja:** You indicated that there are no outstanding hedges, what is the thought process behind strategically keeping full open positions vis-à-vis having hedge positions last year?
- Nitin Parekh:** The idea is that we have a natural hedge with our US exports and we take PCFC limits against that. So we consider that as a natural hedge. Certain loans that we have taken in foreign currency have been given to some of our subsidiary companies, which operate in the same currency and therefore, at balance sheet level, we consider there is some natural hedge and because foreign markets are quite unpredictable, we have thought this time that rather than taking any call, let us keep the position open and wait and watch game. Also because of political situation, elections going in a particular way there were a lot of speculations in terms of what the exchange rate can be, and therefore, we thought that let us not take any particular stand, and continue with the open market position.
- Gagan Thareja:** What could be the effective tax rate for the full year?
- Pankaj Patel:** 15.
- Gagan Thareja:** You discontinued with your agreement with Microbix on KINLYTIC. What is the thought process behind that?
- Pankaj Patel:** We were not finding it interesting to make the further investment, it would not commensurate with the return we might expect, and that is why we discontinued that.
- Gagan Thareja:** The matter regarding Transdermals which was subjudice, this is versus Mylan, has that completely been settled or is it still outstanding?
- Pankaj Patel:** It is still outstanding.
- Gagan Thareja:** Does that in anyway become material to when you can launch the Transdermals?
- Pankaj Patel:** No.
- Gagan Thareja:** I know quite a few people and I have already asked you this but I would like to repeat it again, given the number of filings that you might have made two-three years ago, and the fact that in the last two years, you have not really had very strong rate of approvals coming through, and of late also the acceleration is by and large because of the Abbott AG. Could you maybe elaborate a little more on why the rate at which approvals are coming through for Zydus seem to be sort of slower than the peers in general in spite of...

- Pankaj Patel:** we reviewed the approvals of different companies and we do not find that our numbers are lower than others. In fact, we recently reviewed last six months approval of different companies and we do not see a significant difference in numbers.
- Gagan Thareja:** I missed out on the initial part, so if you could maybe give the total number of filings year-to-date and the composition if broadly in terms of how much are in Transdermals and Injectables and how much in Oral Solids?
- Pankaj Patel:** I think we can only give you overall number, our total filing as of today is 249.
- Gagan Thareja:** Out of which how many are approved?
- Pankaj Patel:** 91.
- Gagan Thareja:** How many do you market out of those 91?
- Pankaj Patel:** 64.
- Moderator:** Our next question is from Prakash Aggarwal of CIMB, please go ahead.
- Prakash Aggarwal:** Just a follow up on just a reiteration of what you said, 10-15 approvals we expect for this financial year which is fiscal '15?
- Pankaj Patel:** For the next nine months.
- Prakash Aggarwal:** We have got one approval so far in this financial year which was the injectable product.
- Pankaj Patel:** Okay.
- Prakash Aggarwal:** So 10 to 15 approval is what we are guiding for this year?
- Pankaj Patel:** Yes.
- Moderator:** Thank you. Our next question is from Ashish Thavkar of Asian Market Securities, please go ahead.
- Ashish Thavkar:** Excluding the filings that we have done during the last two quarters, could you let us know what could be the average age of filings in the US market?
- Pankaj Patel:** Age of filing, I do not have the data, I think we will work on it and give you.
- Ashish Thavkar:** Again, on the depreciation side, since we have done revision, so for the future quarters, shall we assume higher rate of depreciation?

Pankaj Patel: Yes.

Ashish Thavkar Can I have the average cost of debt?

Management The cost of debt for this quarter is about 2.8% without FOREX impact.

Ashish Thavkar Largely, entire debt is dollar denominated.

Management Out of the total gross debt of Rs.2600 crores, about 47% is denominated in foreign currency.

Ashish Thavkar And the rest is INR terms, right?

Management INR terms or local currency debt.

Moderator: Thank you. Our next question is from Anubhav Aggarwal of Credit Suisse, please go ahead.

Anubhav Aggarwal: One clarity on the Transdermal questions that you answered earlier. Sorry, I was not clear. So, the 6-7 filings that you have made so far, the R&D cost do you book that in the P&L or do you wait...?

Pankaj Patel: We have not booked in P&L.

Anubhav Aggarwal: So how will you go about it – as you get the approval immediately you will book it or you will amortize over 10-year period?

Pankaj Patel: Amortize.

Anubhav Aggarwal: Why a different approach for Transdermal?

Pankaj Patel: It is not Zydus alone. It is a joint venture company, under which the Transdermal is filed. So that is why for the partner it is capitalized because there is no commercial activity today.

Anubhav Aggarwal: Would your annual report give the disclosure how much cumulative you spend there?

Pankaj Patel: It should be there in the annual report and if you do not find it, Vishal can help you.

Anubhav Aggarwal: I just wanted to check that after recent management changes at Zydus Wellness, Pankaj bhai, is your involvement in Zydus Wellness reduced now or are you already spending lower time there?

Pankaj Patel: I was anyhow not spending much time there and going forward we wanted to basically bring in newer thoughts and newer leadership, so as a result I stepped down from the board and gave the opportunity to Dr. Sharvil Patel to lead it, and let us all hope that he will do well.

- Anubhav Aggarwal:** Let us hope that, but what about Cadila, your time ...?
- Pankaj Patel:** I am very much in Cadila full time. I am not running away from Cadila, my friend. I am Chairman and Managing Director of Cadila. As far as Zydus Wellness is concerned, I am still the shareholder of that company through Cadila Healthcare, and I will make sure that this company performs going forward.
- Anubhav Aggarwal:** Let us say the core part of the business R&D or which is the main business which is directly reporting to you today in the company?
- Pankaj Patel:** To me, I am responsible for finance, HR, innovation, and API.
- Anubhav Aggarwal:** And R&D will be held by...?
- Pankaj Patel:** Innovation is R&D.
- Anubhav Aggarwal:** So generic R&D will be part of that as well or...?
- Pankaj Patel:** Generic R&D is not my responsibility, it is Dr. Sharvil Patel's responsibility.
- Moderator:** We will take our next question from Chirag Dagli of HDFC Mutual Fund, please go ahead.
- Chirag Dagli:** I was just trying to understand the finance cost. On Rs.2200 crores debt we have less than Rs.100 crores of interest cost flowing through the P&L. If you can try and throw some color on how is it?
- Management:** We have a plain interest cost for the quarter which is 2.82%, but if I consider mark-to-market as well as gain or loss on settlement the rate comes to 3.12%. This is because of the mix of debt that we have in terms of rupee currency, local currency and dollar currency. We have been very aggressive in terms of our interest cost and that has allowed us with discipline in terms of utilization of limits as well as a particular mix, which has helped us in terms of bringing down the interest cost.
- Chirag Dagli:** There is no element of interest cost which is not passing through the P&L, right sir?
- Pankaj Patel:** No.
- Moderator:** Thank you. The next question is a follow-up from Gagan Thareja of Congest India, please go ahead.
- Gagan Thareja:** You are seeking shareholder approval to increase debt limits given that you already have the kind of a pipeline that can ensure you a good organic growth. Why would you want to increase the debt limits?

Management: It was an enabling resolution.

Gagan Thareja: Could you also indicate what is the degree of backward integration in terms of having your own API for the launches and for the products that you already have approval and marketing in US?

Pankaj Patel: Approximately 50%.

Gagan Thareja: Is that what will be for the future as well for...?

Pankaj Patel: By and large, yes.

Moderator: Thank you. Our next question is from Saion Mukherjee of Nomura, please go ahead.

Saion Mukherjee: Sir, just one question, you mentioned about capitalization of R&D spend at Zydus Technologies. So the addition in total assets that we are seeing almost Rs.80-90 crores every year, is that entirely due to R&D spend, will that be the kind of quantum of R&D spend that is happening at Zydus?

Pankaj Patel: It is R&D spend plus normal running cost, etc.

Saion Mukherjee: But, will it be fair to assume that R&D spend is the largest chunk of this increase?

Pankaj Patel: Yes.

Saion Mukherjee: There are some products like Prevacid ODT and Mesalamine, etc., which are high value products. So have you received CRL for these and how do you feel about approval this year?

Pankaj Patel: There are some product CRLs, I cannot tell you specific products. We believe that we are on the path for approval.

Saion Mukherjee: In this fiscal year?

Pankaj Patel: Sorry, I cannot say the timeline, I do not want to commit a timeline because I cannot predict what FDA timeline will be, but we have received CRL that is why we know we are on the path of approval now.

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

Bhavin Shah: Pankaj bhai, once the approvals start gathering pace in the subsequent quarters, would you want to consciously cut down on the low margin AG supplies or would you continue keeping them?



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- Pankaj Patel:** We will continue keeping them.
- Bhavin Shah:** So any qualitative view on the Bayer joint venture, how is it progressing, the ramp-up and all?
- Pankaj Patel:** The ramp up is happening well, the business is growing and doing well, and our relationship is becoming stronger every day. It is a very good joint venture. We are very happy with what is the performance of JV and going forward we have a lot of hope from this JV.
- Bhavin Shah:** In terms of launches and all is everything in place...?
- Pankaj Patel:** It is in place and we are also planning to launch more products in times to come.
- Moderator:** We will take the last question from Ashish Thavkar of Asian Market Securities, please go ahead.
- Ashish Thavkar:** Any timelines on the likely launch of Generic Toprol in US?
- Pankaj Patel:** I am sorry I cannot give you a timeline.
- Ashish Thavkar:** What is causing the delay because like...?
- Pankaj Patel:** There is no delay, but approval has to happen. I cannot say why the approval is not happening.
- Ashish Thavkar:** Is it that the FDA is asking for some additional studies from the generic companies?
- Pankaj Patel:** Not really, FDA is not asking additional studies on generics, but for critical products, they are increasing their scrutiny.
- Moderator:** Thank you. Ladies and Gentlemen, I will now like to hand the floor back to the management for closing comments.
- Dr. Ganesh N. Nayak:** Thank you very much and look forward to interacting with you again in the month of October for our second quarter results. Thank you and good night.
- Moderator:** Thank you. On behalf of Cadila Healthcare Limited that concludes this conference. Thank you for joining us, and you may now disconnect your lines.