Dr. Reddy's Laboratories Limited
Q4 FY 2014
Earnings Call Transcript

Kedar Upadhye:

Good morning and good evening to all of you and thank you for joining us today for Dr. Reddy's Earnings Call for the Fourth Quarter and Full Year-Ended 31st March 2014. Earlier during the day we have released our results and the same are also posted on our website. We are conducting a live webcast of this call and a transcript shall be available on our website soon. As a reminder, the discussion and analysis in this call will be based on IFRS consolidated financial statements.

To discuss the business performance and outlook, we have the leadership team of Dr. Reddy's comprising Satish Reddy – our Chairman; GV Prasad – Chief Executive Officer and Managing Director; Saumen Chakraborty – Chief Financial Officer; Abhijit Mukherjee – Chief Operating Officer and the Investor Relations team.

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Before we proceed with the call I would like to remind everyone that the Safe Harbor language contained in today's press release also pertains to this conference call and the webcast. After the end of the call, in case any additional clarifications are required, please feel free to get in touch with the Investor Relations team.

Now, I would like to turn the call over to Saumen Chakraborty, our CFO.

Saumen Chakraborty

Thank you, Kedar. Greetings to everyone.

You would have noticed the press release that we have made earlier during the day on the senior management organization changes. These changes are in line with our endeavor to adhere to the best-in-class governance practice of segregating the roles for Chairman and CEO. Accordingly, Satish Reddy is designated as Chairman with Abhijit Mukherjee taking up the mantle of the Chief Operating Officer. GV Prasad continues to lead us in the role of Chief Executive Officer with an additional designation of Managing Director and Co-Chairman.

Let me begin with the key financial highlights. For this section all the amounts are translated to US dollars at a convenient translation rate of Rs.60 which is the rate as on 31st March 2014.

Consolidated revenues for the year FY 14 were Rs.13,217 crores or $2.2 billion. We registered year-on-year growth of 14%. Revenues for the fourth quarter were $580 million and grew by 4.2% year-on-year. Revenues from our Global Generic segment were $455 million and grew by 21% year-on-year. This growth was driven largely by the performance of this year's new launches in the US market, sustained scale up in our Emerging Market Territories and India Formulations. Revenues from our PSAI segment were $111 million and declined by 35% year-on-year, primarily due to a high base effect and lack of any notable new launches. However on a sequential basis, PSAI revenues grew by 31% on the back of revival of orders from some of our key customers.

Consolidated gross profit margin for the year was healthy at 57.4% vs 52.1% in the previous year. Consolidated gross profit margin for the quarter was 57.2% vs 50.4% in the same quarter of the previous year. Corresponding values for Global Generics and PSAI were at 65.8% and 20.5% respectively. As we have highlighted earlier, the significant margin expansion is due to improved product portfolio, business mix and favorable currency situation.

SG&A expenses for the year were at $646 million and increased by 13% year-on-year. Corresponding values of the quarter stands at $172 million and increased by 18% year-on-year. The cost increase in absolute terms is largely due to depreciation of the rupee against multiple currencies, annual increment, additional manpower deployment in select areas and sales and marketing expenses for events specific to this quarter.

R&D expenses for the year were at $207 million representing 9.4% to revenue vs 6.6% in the previous year. For the quarter R&D expenses were at $66 million, representing 11.4% to revenues vs 7% in the corresponding quarter of the previous year. The increase in R&D spend during the quarter and year is in line with our planned scale up in activity.

EBITDA for the year stands at $553 million which is 25% to revenue and grew by 19% over the previous year. EBITDA for the quarter stands at $132 million which is 23% of the revenue.

The effective tax rate for the year is 19%.

Key balance sheet highlights are as follows: Our working capital balance decreased by $45 million over the previous quarter, and is largely in line with expectation. Capital expenditure for the quarter was $32 million. Our net debt-to-equity ratio now stands at 0.12.

Foreign currency cash flow hedges for the next 18 months in the form of derivatives and loans are approximately at $335 million, largely hedged around Rs.58 to Rs.62 to a dollar. In addition, we have balance sheet hedges of $660 million.

With this I now request Satish to take us through the key business highlights.

Satish Reddy

Thank you, Saumen. Greetings to everybody and I extend a warm welcome to you on this earnings call.

We ended the fiscal year 2014 on a good note with strong sales growth in our key markets accompanied by a healthy margin expansion. In several ways we demonstrated steady progress towards our strategic goals. Notable accomplishments during the year include the strong injectable product franchise in the US, first wave of differentiated product launches in India and continued scale up on our presence in the emerging markets. Our development engine continues to prioritize on complex generic assets across identified dosage forms and therapies. We are also investing aggressively to build best-in-class manufacturing infrastructure to service future demand across the markets. While the US generics influenced the current quarter's performance and the annual performance to a great extent, our key emerging market geographies and India also contributed despite challenging macroeconomic environment. PSAI business had a tough year, though the fourth quarter performance improved in the back of better offtake from our key customers.

Now, let me take you through some of the business highlights for each of the key markets for the quarter. Please note that in this section, all references to the numbers are in respective local currencies.

Revenues from North America Generics for the quarter were $244 million. As you would recollect we had alluded to a possible sequential decline in Q4 due to bunching up of some customer orders and initial billings for a couple of new accounts. This played out as expected resulting in the Q4 year-on-year growth of 14% and the second half year-on-year growth of 30%. Our key launches for the year namely zoledronic acid, azacitidine, decitabine, donepezil 23mg and divalproex ER consolidated the market shares on the back of seamless supplies coupled with lack of significant competitive activity. As you are aware, we launched sumatriptan auto-injector, amlodipine-atorvastatin combination and moxifloxacin during the quarter, for which we are working towards garnering a fair market share in the coming period.

Revenues from India were Rs.410 crores and recorded 18% year-on-year growth. This was on account of strong volume expansion in our NLEM portfolio, revival of some of the key therapeutic lines and also a lower base effect. We continue to introduce new differentiated products to enrich the portfolio mix and address existing unmet medical needs for the market. We believe that with better field force

execution, enhanced portfolio and presence in the growing institutional business, India can consistently grow faster than the market.

On the emerging market front Russia revenues were at $60 million for the quarter and grew by 4% in Ruble terms. While January and February saw healthy in line double-digit growth the market was quite volatile in March due to the currency headwind and the resultant liquidity issues. This financial year we have been the fastest growing company among the top 20 Russian pharma companies. OTC sales are at 37% of the total sales in Russia and as per IMS we grew by 10% during the year compared to the market growth of 1.4%. We gained five ranks during the year over the previous year.

In spite of the ongoing geopolitical issues and currency devaluation, our emerging market territories witnessed faster than market growth. Our thrust on these territories continues and we believe that there is enough head room to grow our market shares.

Our PSAI business declined 42% on a year-on-year basis, mainly due to the higher base, though sequentially it grew by 31%. Past few quarters have been challenging for the business. However, we continue to identify improvement opportunities. In addition, PSAI continues to provide strong support to our global generic new product launches.

On the Biologics front we continue to commercialize our products in emerging markets as we progress our pipeline towards approval in the US and Europe. This strategy allows us three distinct advantages – First, ability to provide improved access to life saving medications for patients in significantly underserved emerging markets. Second, real world experience and data on our products. And the third it allows us to capitalize on early revenue opportunities while we make progress on developing our assets for approval in mature markets. We filed US IND for the proposed Biosimilar of Rituximab in July 2013 and permission to proceed with the Phase-I trial under this IND was received during the year. We also filed a US IND for the proposed Biosimilar of pegylated filgrastim (peg G-CSF) in December 2013 and the permission to proceed with the Phase-I trial in normal healthy volunteers under this IND was received in January 2014. At this time we are in the midst of planning, designing and executing the studies under these INDs.

Against this backdrop of Financial Year 2014, the year 2015 presents us with its own set of opportunities and challenges. We have made significant progress in our journey towards operational excellence during the last four years. There is also a strong focus on enhancing the portfolio of complex products and targeting a greater share of limited competition opportunities. As you are

aware, it is not our practice to provide any forward-looking quantitative guidance. However, we are quite optimistic on opportunities across the board in branded and unbranded generic markets, as well as our ability to execute on operational agenda. We expect the growth momentum to continue. We believe the journey in fiscal 2015 and beyond will be quite interesting and rewarding to our stakeholders.

With this I would now like to open the session for Q&A.

Balaji Prasad: My first question is on your US growth this quarter. When I analyze your US sales data it seems that decitabine and azacitidine contributed around 70% of incremental growth this quarter. Is that a fair estimate?

Abhijit Mukherjee: Both assets are doing well. We had messaged in the last call that there were some additional sales in Q3. Considering this Q4 may not be as good. But in terms of competition, both assets have been doing well.

Balaji Prasad: It is good to note that both the products are doing well. Is it a concern that incremental growth was largely dependent on these drugs especially considering that launches in FY15 do not seem to be comparative to FY14?

Abhijit Mukherjee: Launches of FY15 is a different topic. In Q4, we did not have any big launch. Caduet and sumatriptan-auotinjector were launched. Although both are reasonably good products they are not in the league of Dacogen or Vidaza. FY15 has just started. Let us see how this plays out. There are a few product launches. As we launch we will know as to how many players get into the market etc.

Balaji Prasad: Do you see any possibility of an earlier than day-181 launch in any of the scenarios which can play out on Nexium?

Abhijit Mukherjee: I do not think FDA's principle of honoring first-to-file is still valid. In the case of Diovan its more than two years. We also saw in Rapamune, it is now six months almost and we are not able to launch because the first-to-file has not launched. It may not be very different in Nexium unless there is some change in legislation or specific decision making by the FDA.

Balaji Prasad: You think the probably is high that the launch would only be a day-181 launch for you?

Abhijit Mukherjee: I guess so.

Prakash Agarwal: From a year basis, we did 9.4% in R&D and fourth quarter particularly was a heavy quarter where the number of filings also went up. Could you give a) the

guidance in terms of what you are looking at for next year and hereafter and b) which broad buckets are we having incremental filing into?

Satish Reddy: This year we ended at 9.4% of sales and we expect that to be double-digits next year. The spend could be anywhere between 10% to 11% of sales. If you see there are three parts on which the spend is classified at this point of time a) Global Generics and PSAI b)Biologics and c)Proprietary Products. Roughly you can take 65% spend on Global Generics and PSAI and the balance on Biologics and Proprietary Products. In terms of the incremental spending it's on the clinical trials for the two Biosimilar products that I just talked about. There is also progress on some of the Proprietary Products. However the biggest increase will come from the Global Generics pipeline because there is a mix of complex generics products, as well as some external partnerships. All put together we see quite a substantial increase.

Prakash Agarwal: The filing has been in the range of 12-13 products, would you be able to give what portion would be the complex side or which broad buckets (oncology, injectables) or what kind of buckets should we look at?

Satish Reddy: I do not think we can go into that level of classification at this point of time.

Prakash Agarwal: On the US side we saw nine product approvals. Would you say FY15 and FY16 have similar kind of product approvals? With GDUFA increasing their action, would you expect better approval run rate going forward?

Abhijit Mukherjee: Going forward it is difficult to say. It is pretty much in the same rate of receiving deficiency and approvals. So far we have not seen great deal of increase in the speed of approval or the files going ahead.

Prakash Agarwal: In terms of your number and quality of products versus launched last year?

Abhijit Mukherjee: Last year was a little skewed with some great products. Beginning of the last year if you had asked the same question we would not have been able to answer that. It played out much better than we thought. It may happen in one or two products this year as well, difficult to say that how it will play out, but

we have launches. We already launched a few. We have few launches in Q1 and Q2 as well. Let us see how these play out.

Prakash Agarwal: On the Russia piece you talked about the March month seeing some disturbance, have you seen any structural change because we saw Teva also talking about warm winter and political disturbances which has hit the OTC market. Could you be a little more elaborate on what happened and do you expect fast growth to come back?

Abhijit Mukherjee: As a result of all these effects the pharmaceutical market has slowed down. Yearly basis it declined by 2% as per the IMS reports. All this is playing out in the results of all pharmaceutical companies who are in Russia. How long this is likely to continue is difficult to say. The year has started on a good note. We are doing very well. We are actually in the top 20 companies in IMS and we are growing the fastest. The improvement in rank in OTC is by five counts. We are doing well even in this somewhat adverse situation. Let us see how the market plays out.

Chirag Dagli: Any thought on how sustainable these 57% kind of gross margins are especially given that FY 14 has been driven by some niche launches? Any thoughts on how we should think about the future?

Saumen Chakraborty: The way we always put our business model is to ensure that we are having north of 50% gross margin and is something that we definitely would like to protect. If we do not get a very favorable currency kind of thing keeping the same gross margin would be challenging. At the same time with the new product launches and better price realizations in some of the products that we have seen in US Generics last year, it would be favorable to us.

Chirag Dagli: On the tax rate with higher R&D, how should we think about tax rate?

Saumen Chakraborty: For modeling purpose you can have anywhere between 21% and 23%.

Neha Manpuria: On the R&D spends when we talked about Proprietary Products and Biologics could we mention the sort of investment that we are looking in both of these businesses? For Proprietary Products specifically, Could you give us an update

on the pipeline we are looking at, what areas we are focusing on and when we should expect any launches from the investment that we are making?

Saumen Chakraborty: As Satish mentioned earlier on Biologics that there are two INDs which have been filed during FY14 and both have been accepted by US FDA where more development will start. We are at the design phase and we have an alliance with Merck Serono for that. The investment that we have been making in Proprietary Products has shown some early proof of success and we expect some good progress. At some point of time during the financial year we will disclose all the Proprietary Products portfolio in greater detail, then you will have complete idea.

Neha Manpuria: Are we looking at like upper limit to investment in these areas specifically in Biologics?

Saumen Chakraborty: We have an upper limit in terms of total cumulative cash that gets consumed by the business. In Biologics we get some earnings out of the revenue from emerging markets. For Biologics we have set an upper limit of $150 million. Within that we expect that business to breakeven and start contributing to the profitability of the company. Proprietary Products definitely in higher development areas, it will be around $300 million kind of investment that we will be willing to put.

Neha Manpuria: An update on Cymbalta, when are we expected to launch it?

Abhijit Mukherjee: In six to eight weeks maybe.

Girish Bakhru: You said $150 million for Biologics containing how much portfolio, how many assets are there in that?

Saumen Chakraborty: We have four currently and of course there are more in the pipeline in terms of development which is going on.

Girish Bakhru: This would be your share apart from the Merck Serono share, right?

Saumen Chakraborty: Yeah.

Girish Bakhru: Comparing you to what bigger guys like Celltrion are spending, $200 million per product, you do not see that kind of investment necessary for these products in the regulated markets?

Saumen Chakraborty: I talked about cumulative cash which is getting consumed because we have already launched some of the biologic products in emerging markets from where we get revenue and profit.

GV Prasad: The scale of investments will be similar but we are developing this through partnership and we will limit our cumulative additional cash flow to $150 million over the horizon of the next three to four years. After that we expect the business to be self-sustaining.

Girish Bakhru: On the US side wanted to get a sense of OTC business in US and specifically on Cloderm there seems to a generic launch there by Dr. Reddy's itself. What has happened there exactly?

GV Prasad: We are trying to maximize the penetration of the molecule and being in both the generic and the brand gives us an advantage. We have seen this experience in our other products also which is Isotretinoin, where we have a brand as well as a generic. We have figured out how to maximize penetration through a combined approach.

Girish Bakhru: How much would be OTC in the US?

Abhijit Mukherjee: The store brand OTC is somewhere in the range of $140 million.

Girish Bakhru: On the R&D side, wanted to get clarification, there is no spend going on the sit up in a better molecule, is there any NCE spend happening right now?

GV Prasad: There is a small spend for the early stage pipeline but it is quite small.

Anubhav Aggarwal: Does the Merck partnership include PEG G-CSF as well? I had the impression that Merck partnership is mainly for MAbs.

GV Prasad: We are not disclosing the full portfolio. There are multiple products.

Anubhav Aggarwal: No, the clarity here is you have got two INDs, one is Rituximab and second PEG G-CSF. What is the future of PEG GCSF? Is this what you will spend alone or with Merck?

GV Prasad: We are not disclosing that.

Anubhav Aggarwal: You have been saying that your R&D expense will increase. Earlier you were at least indicating about 9% to 10% with more expectation of reaching towards 10%. What has changed in one or two quarters that you are thinking about 10% to 11%? Is it more spend towards the Generic side or more spend towards the Biologics side. Has getting two INDs approved bought about this change towards higher R&D?

GV Prasad: It is not easy to predict at a very accurate number what the spend will be. This depends on the timing of the clinical trials and the ability to accelerate the pipeline, at times. A combination of factors including expansion on the generic side where we are getting into more products which have a component of clinical trial to the development and changes in how the clinical development happens in our Biologics and Proprietary Products with raising the R&D intensity. As you can see our margins are also expanding. We believe that we can finance this additional R&D spend and we believe it is wise to do so today.

Anubhav Aggarwal: Sequentially your R&D expense increased by almost Rs.100 crores, and given the state of your molecules which are in Biosimilar side now, will you be still recruiting the patients?

GV Prasad: We are not going to give you a break up of where that went. All of it did not go into Biologics, some did.

Anubhav Aggarwal: Markman's hearing is right now on Reclast status. There are about four players in the market today and five have not got the approval. Do you expect that as and when the competition gets approval, they will be there in the market?

Abhijit Mukherjee: No messaging heard so far in the market, but certainly if they get approval they will come in.

Anubhav Aggarwal: What about the hearing status for your Markman going on? Is there a timeline for the final hearing of the case?

Abhijit Mukherjee: We have not tracked that so closely.

Anubhav Aggarwal: Last clarity about Vidaza and Dacogen. Have you heard any chatter in the market that at least for this quarter you are safe without any more incremental competition?

Abhijit Mukherjee: That we would not be able to comment on. So far it's been good.

Sonal Gupta: What is your field force in India right now? Did you add anything and how much was the addition during the year?

Kedar Upadhye: It is around 4,000.

Sonal Gupta: In terms of Russia what was your local currency growth for the full year?

Kedar Upadhye: It is 11%

Sonal Gupta: In primary?

Kedar Upadhye: In Ruble terms, yes.

Sonal Gupta; How many products do you plan to launch in Russia in FY15-FY16? What is the pipeline like?

Abhijit Mukherjee: Roughly five or six products.

Sonal Gupta: Over two years or every year?

Abhijit Mukherjee: No, probably over a year, four or five or six products. We are in various therapies, so one or two products per therapy.

Sonal Gupta: Coming to the R&D side, you are saying $150 million of cumulative investment in Biologics whereas right now your Biologics portfolio is pretty small. So I do not think there are a lot of net revenues or net profits coming from there to support the rest of it. In that sense it does not look like you are going to spend more than $50 million a year on the Biologics side. So if you are looking at R&D spend which is now touching almost closer to $250 million to $300 million that is a lot .Is it all going to generics? Can you give some more clarity? How much of your R&D spend is really being driven by outsourced R&D? Is there a split that you can give?

Abhijit Mukherjee: There is no split but as we have said overall generics R&D is also increasing year-on-year. Every year, it is going up and we have said that the product complexities are increasing. There are products needing clinical trials and we are funding those.

Sonal Gupta: Roughly what looks like $50 million, you are saying you are spending $150-200 million in Generic R&D, is that how to look at it?

Abhijit Mukherjee: Slightly lower than that but yes.

Sonal Gupta: In terms of number of filings 13 seems a bit low for the full year. How do you see this going forward? Do you see this run rate to continue or do you think there is some step-up which is going to be there?

GV Prasad: Tracking number is not a game we are playing. We have a pipeline in development, costs of developments vary and complexities of development vary so one is not equal to other. The number 13 does not mean much to us. The value is what we track.

Sonal Gupta: Would this include any partnered products or partners would be filing on their own and then you will help them commercialize?

Abhijit Mukherjee: There are quite a few partnered products. The principle which we follow is we will file. It is sometimes developed in-house, sometimes some of the aspects of development are done outside, but eventually we would own and file every product.

Surya Patra: On the IND filings that you have made for the Rituximab and Filgrastim, what is the route that you are following for US market? Is it the 505(b)(2) route or the biosimilar, can you give us some clarity?

GV Prasad: It is not by 505(b)(2). It is the biosimilar route most likely but it is too early for us to comment on it.

Surya Patra: Have you initiated a similar approach. What is the progress with regard to the filing of the products for the European market? Have you already done that or what is your thought process for the European market?

GV Prasad: The European market and the US will go in parallel.

Surya Patra: That means you have already filed your file for starting the clinical trials there?

GV Prasad: Yes.

Surya Patra: Amortization for the full year has declined Y-o-Y. Would we be seeing a reduced amortization amount hereon or have we revalued the timeline of the asset?

Kedar Upadhye: We have a schedule of amortization asset-by-asset. P&L charge goes in line with that schedule.

Surya Patra: Can you give some idea for your US based business in terms of what is the kind of momentum of price and volume that you are seeing for your generics business?

Abhijit Mukherjee: There is a lot of consolidation on the customer side and hence it is having an impact on the price of product in terms of erosion. Also there it is counterbalanced to an extent by new share gain in certain products which we are aiming to and sometimes by price increases. So I think on both sides there is downside but partially compensated by the two things I mentioned.

Surya Patra: On the margin front since you are saying that there could be chances that the gross margin cannot be maintained at this level and also on the other end R&D is increasing gradually. Is it a difficult task for us to maintain the kind of margin what we have reported for the last financial year?

Satish Reddy: No, the margin was talked about was on the basis of the currency benefit that we got. It is with that particular currency effect. It really depends on how the situation is going to be.

Abhijit Mukherjee: Yeah, out of the currency fluctuation we are optimistic but it depends. Also you asked the question on how quickly we will see competition in some of the products. Those things will matter a lot. Overall, the business is still quite healthy.

Surjit Pal: How long can we see the pain in PSAI scenario to continue? Can you throw some light to understand how you are planning to evolve this business considering FY2015-FY16?

Satish Reddy: Reason why the business did not pick up is something we had discussed earlier. If you see the order book and kind of lock-ins that we have with the customers is now on the positive side. We track that very closely. Even sequentially that is why you see there has been an improvement. Yet, a lot more needs to get done before we see the full effect of the turnaround which we expect may be in a quarter or two from now.

Surjit Pal: Do you think this turnaround is sustainable given the basket of products is dwindling every quarter or every year?

Satish Reddy: If you look at the overall PSAI business, there is API and there is the CPS. In terms of the traction, we see that on both the fronts and if everything falls into place we should see the sustainable business to ensure from now on. Some of the things that we slipped up on the last year, that correction will take us a little bit more time than what we anticipated.

Surjit Pal: I have observed in the PSAI business typically it is in Q4 that there is quite a bit of bulk. If you compare rather Q1, Q2 and Q3, in both the years you got

the highest average per quarter sales always in Q4. Is there any kind of seasonality in PSAI?

Satish Reddy: That is not to be taken as a trend. Could have just been a bunched up of orders but it is not a trend that you should track.

Surjit Pal: In your presentation you said for Heparin-based drugs you put up a plant. Could you throw some light on that whether the plant is now operational and how many product filings were you targeting? Out of them how many of them are patent challenged?

Kedar Upadhye: There will be some investments but not a dedicated plant.

Surjit Pal: In biosimilar you have already started clinical trials in the US. By the end of 2015 when the clinical trials on biosimilar might be concrete and finalize, would you need additional investment in terms of matching those parameters or requirements? Is there anything different t you have done currently or you have been doing?

GV Prasad: We are in close touch with the regulator, taking their guidance at every step and we do not see any deviation from how we are planning the trials and what the requirements will be. We are in early clinicals now which means to go to the large Phase-III trials it is still some way off.

Surjit Pal: How much time does it require – two to three years?

GV Prasad: Yes.

Surjit Pal: On biosimilars wanted to understand your understanding about that. Do they not allow any R&D unlike in generics, do you believe that there will be a similar kind of interest from the generic companies to enter into biosimilars in US?

GV Prasad: R&Ds are available.

Surjit Pal: No, there is a strong debate over there whether they will be allowing them or not, R&D to the branded drugs like the way you do in generics. Do you think will it be interesting for the generic company to put such a kind of huge investment to get into that market?

GV Prasad: I am little confused by your question but if I understand it you are asking me whether it is worth a biosimilar at all? Is that the question you are asking?

Surjit Pal: Yeah.

GV Prasad: We obviously believe it is a very high value proposition and that is why we are investing in that. It is not going to be a game that everybody can play because it is a very large investment and it is also a lot of complexity in matching biosimilarity. We believe that the companies which navigate these challenges will make a lot of money in this portfolio.

Sameer Baisiwala: Just to understand the US base business progression, Abhijit, roughly $900 million sales base that you had for FY14. We are assuming that there is no a supply disruption or additional competition, just the base business as it stands. What would be your guess? Would there be a price deflation for this business and has the full impact of customer consolidation been felt by the company or is there more to come?

Abhijit Mukherjee: As we speak large part of it is true, they are downsized on account of customer consolidation yet partly being made up through share gains and some price increases. There is a last bit, some more to come I guess the last public domain consolidation that is not yet through, but 75% of it is through.

Sameer Baisiwala: What would be your expectation for the base business as it stands right now going into FY15?

Abhijit Mukherjee: Figures specifics will be difficult to get into, but as I said erosion is being handled through share increase and some price increases.

Sameer Baisiwala: Could you update us on how many products from proprietary filing which I reckon as 505(b)(2) based products are in clinical trials right now and when

do you expect the first filing to happen? Last call you mentioned there were two in clinical trials.

GV Prasad: Yes, there are two. We expect the first NDA to be filed in 18 to 24 months from now.

Sameer Baisiwala Satish, is the understanding correct that with your elevation now to being a Chairman, it would be a far less executive if at all any executive role that you will be playing?

Satish Reddy: That is correct. It will be much lesser, yes.

Sameer Baisiwala: What is driving this? It is quite unusual in the context of Indian promoter at such a young age.

Satish Reddy: No, Sameer, the main thing like we explained in the note is clearly in terms of separation of the role of Chairman and CEO. It was something that we have been studying for quite some time to see when we can do it. The timing is right at this point of time especially when we look at it from the point of governance on one side and also providing internal growth. That is how we see it as.

Sameer Baisiwala: Is it not a reflection of lesser commitment by the promoters in the business?

Satish Reddy: Not at all. In case you are assuming that my involvement in the company is going to be little, actually it is going to be different but not less. That is the change.

Alok Dalal: On US now that you have crossed $900 million in sales and you have about 62 ANDAs pending approval, do you think this 62 ANDAs is kind of enough or are you satisfied with this number to drive growth over the next 2-3 years?

Abhijit Mukherjee: Numbers do not drive growth. It is the quality of the assets that would drive growth. What we have in those 62 and how we get those approvals are going to be important. The overall numbers, I do not know whether that would mean anything.

GV Prasad: Just to add to what Abhijit is saying, if you correlate the way we are spending on R&D, the acquisitions we are making and the overall focus of the company is clearly on complex products with sustainable revenue and you have seen the first few launches from them in the last fiscal year. That is the choice that we have made and we are going to continue to deepen our commitment to that choice.

Alok Dalal: The reason for asking that question was that some of your peers with a similar base have higher number of pending approvals and now everybody is focusing on difficult to manufacture products, complex generics et cetera. I was just trying to understand how you are thinking about it?

Abhijit Mukherjee: We are deeply committed to the complex generics journey.

Alok Dalal: If I heard you correctly on India, you mentioned that you have launched the first wave of differentiated products. Is that kind of a game changer now when it comes to India?

GV Prasad: It is too early to say if it is a game changer. It is the direction we are going to take. We will try to add value to the products through innovations and that is how we will create a little differentiation but it is very early to say that we have hit the new wave.

Alok Dalal: Mr. Prasad in which areas have you launched these products?

Abhijit Mukherjee: A couple of them are in cardio and blood pressure management and then we have also launched a range of gastro products for pediatricians, so on and so forth. There are various products. We are increasing the breadth of the portfolio of in terms of therapy and we are trying to broaden the therapy.

Alok Dalal: For FY15, is the CAPEX going to be Rs.1,000 to Rs.1,500 crores?

Saumen Chakraborty: That is the range we have given. This year we spent 1,000 crores and there are quite a few projects which are going on. Hence the spend is likely to be higher in FY15 compared to FY14.

Alok Dalal: Saumen, should we assume that with this that a $2 billion size company would require such kind of recurring CAPEX going forward?

Saumen Chakraborty: Not a recurring CAPEX but the capacity that we were required to do for all the areas that we are getting into. In another couple of years more or less will be done with that. Recurring CAPEX will be much lower.

G V Prasad: The big project for our fixed dosage as well as API in Vizag, which not only reflects a new site, but also new technologies. There are also new philosophies in the site which are requiring much higher CAPEX than what normal plants would do. Here we are investing in making those plants better in terms of quality compliance, robustness and safety.

Manoj Garg: The R&D investment which we have started doing for the differentiated products is largely being attributed to last one, one and a half years. The dividend of the same will be outlined over next two or three years. Do you believe in between maybe for the next 18-24 months we probably will have more consolidation of the business in the US and then probably again have to start taking off from thereon?

GV Prasad: It is hard to predict. One or two assets launched can make a huge difference. The average value of our assets is going up dramatically. Given all that it will be very lumpy and it is hard for me to say that whether the business will go up or down. We remain confident that the products that we are working on are very interesting. The overall journey is going to be sustainable.

Manoj Garg: From where I am coming to if you recall in 2013 when you were expecting some of these launches which ultimately happened in FY14, you used to indicate that probably we will have one or two years of consolidations. Now has the outlook changed from thereon?

G V Prasad: Outlook has not changed but the timeline uncertainties remain in this business.

Manoj Garg: Looking from the long-term aspirations, how do you see the margin going over the next two or three years?

GV Prasad: If you exclude the investments that we are making for the future in increased R&D and things like that the gross margins are expanding.

Manoj Garg: Do you expect the trend to continue?

GV Prasad: Yes.

Saion Mukherjee: On the Biologics front, Prasad, a few years back you used to mention about one biologic every year in India. We have not seen that. Can you just throw some light on the development programs that you have for the emerging markets like India and how should we think about launches in India and other emerging markets going ahead?

GV Prasad: We were a little too optimistic when we said one product a year. We do have a number of products in the pipeline and at least in the near term there are two products getting into the clinic. These two are both MAbs, and they should be launched in the next two years in the emerging markets. We are also debating, how we should focus on developing a global program for developing products both for the emerging markets and telescope the same trials for the regulated markets. We are in the middle of developing the strategy for our portfolio and we will clarify to you as and when we go down.

Saion Mukherjee: The test case of Rituxan which was launched in India a few years back, when you are now going for the US market and also for the European market, is there a big difference in the product that you had for India and what you want?

GV Prasad: We are developing the products incrementally. We will have one product for the world. We have had some learnings from Rituximab in terms of how to do the trials, how to sequence the trials and how to do the biosimilarity characterization in a way that we do not have to redevelop. We are putting all those learnings into our R&D programs and that is why R&D programs are taking a little longer. That learning will also help us in the next wave of launches in the MAbs.

Saion Mukherjee: For Rituximab in Russia, are you on track and are you seeing a launch there in FY15?

GV Prasad: We hope so but it is all in the hands of the regulator.

Saion Mukherjee: Prasad, you mentioned that the average value of assets is significantly higher. When you look at those 60 odd products which are there in the pipeline in the US, you think per product revenue on an average will be materially higher than what you have in the market currently?

GV Prasad: I need to verify that this was a comment, but the average values of the assets that we are developing have been rising over the last few years.

Abhijit Mukherjee: What Prasad meant was more when we compare value per asset which we launched few years back to what it is now. It has virtually doubled. That is what he was trying to mention, not so much measured from the outside in his perspective.

Saion Mukherjee: Sir any update on Copaxone? Have you heard from FDA or any complete response letter? Can share something on that?

Abhijit Mukherjee: No, cannot share the details. We reiterate that the quality of filing is very good and it is in the hands of FDA at the moment. It is progressing step-by-step.

Saion Mukherjee: Do you see a possibility of an approval in FY15?

Abhijit Mukherjee: Cannot comment on that.

Saion Mukherjee: On the Indian market, you mentioned that for the NLEM products there is a significant volume expansion that you saw in Q4. The question is how sustainable is that? Is that something which was seen across in the industry as such for those products where the prices have come down or it is limited to some very specific products of Dr. Reddy's?

Abhijit Mukherjee: No, overall it will play out for some other companies as well. There also it is not uniform across all products. Depending on some products it seems larger volume growth and for some products not to that extent.

Krishna Prasad: Relating to the global consolidation in specialty pharma generic world. Could you share your thoughts around how does Reddy's is viewing the situation and if we choose to act at this point in time? A related question would be, is your decision to hike R&D spend and invest more in what you see as relevant assets to actually buy at this point the risk-reward changing action on buy versus build?

G V Prasad: Broadly, our approach has been to focus on organic development in the last few years. We are not an aggressive consolidator. We are building the capabilities through partnerships, acquisitions and own R&D investments. We expect this trend to continue. We remain open to acquisitions but we are not an active acquirer as of now.

Krishna Prasad: Do you not think this has really changed given the external circumstances?

GV Prasad: I do not see any reason for it to change today.

Krishna Prasad: Could you give an update on our Rituximab approval in Russia where are we at this point?

GV Prasad: We are awaiting approval. We do not have any updates now. We hope to launch it in FY15, however that depends on the regulator's permission.

Kedar Upadhye: Thank you all for joining Dr. Reddy's senior management for our Q4 FY14 Earnings Call. In case of any additional clarifications, please feel free to get in touch with the Investor Relations team. Good day to all of you and thank you.