Dr. Reddy's Laboratories Limited
Q1 FY 2014
Earnings Call Transcript

***Kedar Upadhye** (Investor relations)*

Thank you for joining us today for Dr. Reddy's Earnings Call for Q1 of FY '14. 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. The discussion and analysis in this call will be based on IFRS consolidated financials.

To discuss the business performance and outlook, we have today, Mr. Satish Reddy - our Vice Chairman and Managing Director; Mr. Saumen Chakraborty - President and Chief Financial Officer; Mr. Abhijit Mukherjee - President and Head of Global Generics business; and the Investor Relations team.

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 Mr. Saumen Chakraborty – our CFO.

Saumen Chakraborty ***(Chief Financial Officer)***

Thank you, Kedar.

Let me begin with the key financial highlights. For this section, all the figures are translated to US dollars at a convenience translation rate of Rs. 59.52 to a dollar which is the closing rate as of 30th June 2013.

Consolidated revenues for the quarter were $478 million. We registered year-on-year growth of 12%. The revenues from our Global Generics (GG) segment were $368 million with year-on-year growth of 15%. This growth is largely driven by a continued progress in North America and emerging market territories. Revenues from our Pharmaceutical Services and Active Ingredients segment (PSAI) were at $99 million with year-on-year growth of 6%. Consolidated gross profit margin for the quarter is at 52.8%, which is largely in line with that for the previous year. Corresponding values for GG and PSAI segment for this quarter are at 61.6% and 19% respectively. GG gross profit margin improved primarily on account of higher contribution from new product launches in North America Generics, whereas PSAI gross margin declined on the back of lower number of launch molecules to our customers and relatively higher overheads during the quarter.

SG&A expenses, including amortization, for the quarter at $148 million increased by 6% over the previous year, representing 31% to revenues. The overall increase in absolute terms was primarily on account of normal year-on-year salary increments and the effect of rupee depreciation against multiple currencies. R&D costs for the quarter are at $41 million, representing 8.5% to revenue versus 6.2% in the previous year. The increase in R&D expense during the quarter was as planned and is in accordance with our strategic plan of our R&D activities across the focused segment. EBITDA for the quarter is at $96 million, which is 20% of sales and registered year-on-year growth of 13%. Profit before tax for the quarter at $70 million is 14.5% to revenues. The annual effective tax rate for FY ‘14 is likely to be in the range of 21% to 22%, which is similar to that of the previous year.

Key balance sheet highlights are as follows: Our working capital decreased marginally by $2 million over that of 31st March, 2013. Capital expenditure for the quarter is at $33 million, out of which the key projects include our injectable facility and biosimilars facility expansion. Foreign currency cash flow hedges for the next 18 months in the form of derivatives and loans are approximately at $510 million, largely hedged around Rs. 56-60 to a dollar. In addition, we have the balance sheet hedges of $300 million. Net debt at $236 million represents a net debt-to-equity ratio of 0.19.

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

K Satish Reddy ***(Vice Chairman and Managing Director)***

Thank you, Saumen.

Financial year 2014 has started on a very interesting note. What particularly gives me satisfaction is the portfolio mix of our new launches. We have been talking about diversifying to other dosage forms like injectables and have a greatest share of complex products in our portfolio. The recent launches of generic versions of zoledronic acid, decitabine and donepezil hydrochloride 23 mg in the US market are the growing proof of this shift in our portfolio. Our increased R&D spent at 8.5% for the quarter is also a reflection of one particular aspect of our strategy.

The Indian Pharmaceuticals market has witnessed the impact of the pricing policy that is aimed at regulating prices of select drugs through the Drug Price Control Order of 2013 (DPCO, 2013). The implementation of this policy is underway. However, pharmaceutical companies and the trade continue to grapple with the disruptions in the marketplace in the form of decreased channel inventory and strike by the trade. The impact of new pricing policy for Dr. Reddy's is expected to be roughly about 4% of the revenues on this count, and we have plans in place to mitigate the impact.

In the emerging markets, CIS countries and Rest of the World (RoW) geographies continue their aggressive market penetration despite concerns on currency devaluation, especially in Venezuela.

In the API side of the business, changes in the stocking and launch pattern of some of our key customers had a bearing on the demand for launch materials during the quarter. The Custom Pharmaceuticals business witnessed a good traction in orders from innovator companies.

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

Starting with the North America Generics business, revenues for the quarter are at $192 million, with a healthy 21% growth on year-on-year basis. This growth is largely attributable to new product launches over the past 12 months and market share gains in select key molecules. This quarter witnessed the launch of 2 new products; zoledronic acid injection, which is the generic version of RECLAST and lamotrigine extended release tablets. We hope zoledronic acid will turn out to be a good opportunity in the medium term. While we had the benefit of these new launches, normalization of finasteride 1 mg sales and seasonal effect on our anti-allergy OTC product and antibiotics portfolio led to a sequential quarterly decline. However, our recent launches of decitabine and donepezil in the month of July 2013 present a good opportunity in the short to medium term.

On the India business, revenues for the quarter were flat at Rs. 349 crores. We saw some amount of market disruptions in the form of trade strike in Maharashtra for a major part of the month of June. While this got resolved towards the end of the month, the subsequent billings made in the last few days got accounted as sales

cut-off as per our accounting practice and got carried forward to Q2. In addition, the implementation of the new pricing policy also caused some amount of destocking in the trade due to which the order flow was weaker. After publication of the revised price notifications in June, we are seeing stability coming back in the market and hope to recover a part of the shortfall in the second quarter. Despite these challenges, our June 2013 MQT growth was 14.5% as against the IPM growth of 10.1%, which gives us confidence on the continuing momentum in our India business. The coming 5 to 6 months will be interesting to watch from the perspective of marketplace realignments.

On the emerging markets front, Russia revenues at $65 million for the quarter grew 3% in ruble terms, primarily because of high base effect of the previous year and changes in the market stocking pattern. Our secondary sales growth data for the quarter indicate a healthy market demand. CIS markets grew by 24% on a year-on-year basis on the back of new product introductions in Ukraine. RoW markets grew by 8% on a year-on-year basis despite the devaluation impact in Venezuela. Performance of our European operation was in line with our expectations. The business model has transitioned to a lean and simplified structure.

Our PSAI business grew by 6% on year-on-year basis. Active Ingredients business had a challenging quarter because of the decrease in new product introductions by our customers. In addition, we are witnessing volume and price compression on the products launched last year, and the general decrease in the stockholding period at our customers' end. We hope this trend to normalize over the coming quarters.

With this, I would now like to open the session for question and answers.

Anant Padmanabhan On the last call, you had mentioned a few high-value product launches in the US that were deferred or pending at the FDA. So could you just talk about how many of these products are still remaining?

Abhijit Mukherjee We will not be able to provide the specifics. As you know we have launched decitabine, first in the market and also donepezil HCL 23 mg. But regarding the products which are likely to come, I do not think we will be able to comment because the approvals are not exactly in our control. However this is going to be a busy year similar to last year.

Anant Padmanabhan Of the 64 ANDAs and 8 first-to-files, could you give us a sense of how many are injectable drugs?

Abhijit Mukherjee On a broader perspective, I think we are gradually moving from just being on oral solid company to a little more diversified, in terms of different types of dosages. In the longer term (FY17 and beyond), of the total revenues around 30-35% would come from non-oral solids.

Anant Padmanabhan Could I apply that to the number of ANDAs as well, would you say about 30% of those ANDAs?

Abhijit Mukherjee I would not be able to give you on the specific number. The values of the assets vary from product to product.

Arvind Bothra On the US regulatory front, we have seen an increased action from US FDA in terms of requirement for higher number of batches for test, and also just wanted your sense on how has been the cost of filing ANDA increasing especially after GDUFA, and has it impacted the approval timelines?

Abhijit Mukherjee Firstly, on the number of batches, so far we are still within that one batch per product. Having said that, the cost of development is not so dependent on the number of batches. As most companies shift from being plain vanilla players to somewhat differentiated portfolio players, having high entry barrier product development, which will require a little longer journey and for some even clinical support. So all in all it is not so much dependent on one batch and three batch type of shift in terms of the cost. It depends on how smartly and how quickly you can get to the end line, and that would sort of decide the cost of development of our product. The second thing you are asking about the timelines of approval. Certainly, the first phase of GDUFA implementation, we are seeing sort of churn in terms of the delays, which all generic companies are also

witnessing, but we are hopeful that going ahead this will settle down and hopefully next year we would see a somewhat faster turnaround.

Arvind Bothra A clarification on your first answer, does this new norm of 3 batches apply to the existing on your pending ANDA filings or that is on an incremental basis?

Abhijit Mukherjee This would all be on the new filings but having said that, the current approach of regulatory agency is to have a very detailed development backup. So there is scale up batches to be taken eventually. That part of it is not the major part of the cost is what I was trying to highlight.

Arvind Bothra Just a quick one on the PSAI front. You mentioned that the new product approvals have been fewer plus we see the patent cliff kind of approaching. What kind of outlook do we have for PSAI business especially in the wake of your much lower margins in this quarter in PSAI?

K. Satish Reddy So this has been an event just for the first quarter on account of few key reasons that I highlighted. One is clearly that some of the launches which were to be done by the customers, who are generic companies, did not pan out the way it was supposed to for different reasons for the customers. In some cases it was just delay in approvals, in some, it was about the formulation not working out, and in some cases they plan to drop the launch of the drug. So that was one aspect of it. The second aspect of it also was erosion in prices of some of the existing products which are already on the market, where we expected higher sales. So that was the effect there. Now we expect these things to normalize. That is what I mentioned towards the end of my script indicating that hopefully, in the next 2 to 3 quarters, we should see some normalization of that. But whatever we lost in the first quarter that will be difficult to make up for the rest of the year.

Sonal Gupta I just wanted to understand in terms of the R&D spending - clearly has accelerated especially over the last couple of quarters. Could you highlight what portion of your R&D spending is going towards clinical trials, etc.? Is that the major reason for the acceleration?

K. Satish Reddy That big number that we talked about i.e. 8.5% of sales covers everything. It covers all the way from the API development to generic development to biologics and proprietary products. Now like Abhijit talked about the shift in the portfolio itself over a period of time where it will be, more difficult to make products and products with entry barriers, there is some cost attached to that as well, you see some reflection of that. There is also

cost from the PSAI front because Octoplus, the company that we acquired is now part of the segment. All put together, I may not be able to give you specifics of how much increased in what, but I am just giving you a general trend which we anyway indicated last year or in the last quarter in the earnings call, saying that this would be the outlook for the year.

Sonal Gupta No, I understand that but I think the thing is that for a company of your size and scale, 8.5% is extremely high. So do you expect it to remain in this range over the next 2, 3 years especially once you really start clinical trials on your Biosimilars, would it accelerate even further from here?

K. Satish Reddy Yes, that is the indication we gave. R&D cost will be 8-9% of sales, and I think it is within that range. Reason is exactly this, saying that as we move towards more complex products, as we get into more clinical trials based on the biologics and also the increased growth in sales, this is the kind of trend that we indicated and we will stick to that.

Sonal Gupta In terms of India, what is your outlook for the full year now given all these impacts? Do you still see yourself still growing close to market?

Abhijit Mukherjee Very broadly, yes. The first quarter as Satish pointed was an aberration in terms of some of the events which panned out. Typically, second and part of the third quarter would be seasonal referring to the India business. Further, some cut-off effect will spill over to the second quarter. So broadly, we would be in the range of our own plans and in line with the market.

Sonal Gupta Could you just shed some light on how do you see the Russian market growing because the growth has been normalizing? Is this the trend that we sort of expect to continue given that in constant currency terms also your growth has now slowed down very significantly, what is the broader outlook and how is the market really growing? And relative to that, where do you see yourself?

Abhijit Mukherjee We do not particularly have a concern wrt the Russian market. Let me give a couple of reasons. Firstly, last year Q1 was quite high and there is a reason for it. There was a shorter winter and once the season changes you have larger sales in anti-allergy and other products which happened in Q1 last year. This year was an extended winter. The seasonal change came later. And we are already witnessing a much better Q2. Secondly there are some changes in Russia in terms of clubbing the holidays. So this quarter, there was a 10-day type of a holiday which had a large part of the country getting into

the holiday season, which also affected the sales in Q1. Overall, Russia, we are fairly confident that we would be pretty much where our plans are, strong Q2 seasonally plus the impact that I just mentioned, Q3 should be good.

Anubhav Agarwal On the R&D, just a clarification, how do you consolidate Octoplus, is it line by line addition or just total expense or the net loss of Octopus just going into entire R&D?

Kedar Upadhye It is our 100% subsidiary now and thereby a a complete line-by-line consolidation.

Anubhav Agarwal So R&D increase is exact, only entirely on that basis?

Kedar Upadhye Octoplus has some sales SG&A as well as R&D, so everything has been clubbed in each of the line.

Anubhav Agarwal In the disclosure which you gave, your Naproxen sales in PSAI has more than doubled in last year. Has the market expanded so much? And if yes, in which geography or you have gained very large in terms of market share?

Saumen Chakraborty We have gained on the market share part.

Anubhav Agarwal So much that your sales have doubled?

Saumen Chakraborty Partly of course is the overall market increase, but mostly it is because of the market share.

Anubhav Agarwal One clarification on the PSAI business. Gross margin disclosure which you gave 19% this quarter versus what you have been averaging about 30% for previous quarters, there is a very sharp decline unless you had a very high concentration of the product where you grossed very significant margin. If that is the case for the next 2 or 3 quarters, should we see about thereabout 20% gross margin for this or was there a very high one-off inventory impact this quarter so that margins would ramp up in the next two quarters?

Saumen Chakraborty Yes, earlier also we have said that for the PSAI business performance, it will be very difficult to judge from a particular quarter, because there could be fluctuations. Overall margin level last year, we kept around 30%. As we get to the next quarters and all, it will be (more) clearer what kind of margin level we can expect from PSAI but definitely, it will inch back towards the normal margin level.

Anubhav Agarwal So there was no one-off inventory write-off or something in this quarter. It was just the margin compression or price compression on the existing products?

Saumen Chakraborty Primarily it's centered around product mix. There are products in various margin brackets. The products we sold in this quarter are of the relatively lower margin as compared to the products sold in the same quarter last year.

K. Satish Reddy Also there was no one-off or inventory write-off this quarter

Anubhav Agarwal The ex-Betapharm European sales have dipped about 30% year-on-year. Is it the impact of price cut in one of the markets or is it expiry of any old contract which was not renewed?

Abhijit Mukherjee It was a conscious strategy that we are moving out of the tender driven business. Actually, with this move what has happened is our gross margins have substantially improved in Europe and we are moving in a direction which is as thought out and will make this business compact, profitable and meaningful. In the process, we are just continuing get out of businesses which do not add to the value upgradation and put pressure on the return on capital.

Anubhav Agarwal Which market are you talking about, UK?

Abhijit Mukherjee We are in Germany and UK and both have similar traits. We are talking of Germany as well, Germany last year, we had several molecules in the tender, which gave a top line without meaningful bottom line. This year those tenders are over. And we have not participated at those low levels. So that has changed the dynamics of the business in Germany.

Anubhav Agarwal If you were to talk only about UK, would your comment remain the same that you have not participated in some of the low margin contracts, that is why your sales have declined 30% in this market?

Abhijit Mukherjee Yes, the UK business as you know is a very small part of the whole thing. We are consciously moving away from sales which have pretty low gross margin.

Bino Pathiparampil May I know the actual US invoicing revenue in dollars?

Kedar Upadhye $192 million.

Bino Pathiparampil Finasteride 1 mg was practically zero or very minimal in this quarter?

Kedar Upadhye Finasteride 1mg was minimal. As we said, it has come off compared to Q4; as Q4 was the first quarter of the launch of Finasteride 1 mg.

Bino Pathiparampil One question on PSAI. You said that there are some changes or some developments like price erosion, etc., that has happened. So now after knowing these things, which are unlikely to change materially as we go forward, would you say that you have enough visibility to have a decent growth over last year's level in constant currency terms?

K. Satish Reddy Yes, what I was trying to indicate was that the first quarter did not go well. All I expect for the rest of year is for things to normalize in the API business. I would not be able to specifically comment on exactly what the growth is going to be at this point of time except to say that things will normalize in due course.

Bino Pathiparampil Your press release mentioned about some stocking pattern change in Russia. Could you just elaborate on that?

Abhijit Mukherjee You are talking about the seasonal impact which I just explained on the call?

Bino Pathiparampil Is it the same thing that is mentioned in the press release that talks about the stocking pattern change?

Abhijit Mukherjee Yeah, broadly, we were alluding to that.

Bino Pathiparampil Finally on the RoW, how big was the impact of depreciation in Venezuela or rather can you give some indication of constant currency growth?

Kedar Upadhye Bino, we will give you the numbers offline.

Girish Bakhru Just on the India side, wanted some color on basically Reditux sales. If you look from the FY'13 numbers you have a Rs. 100 crores biosimilars portfolio. Do you have a number as to of this, would Reditux be a Rs. 100 crore brand going forward or is it stabilizing at current level? I am just trying to assess where you see that number going in say next 2, 3 years. Simultaneously on that, any update on the expansion of Reditux launch in other markets?

Abhijit Mukherjee As you may be aware Rituximab space has more competition now. There is the so-called authorized brand from Roche, there is another competitor who has come in. The good thing is we have the highest market share in Indian market as you see but of course, the growth would be challenged a little bit by the various competition, and of

course organic growth of the molecule as it gets more access into the country. So not a large change, there will be some growth, but not a very large one.

Girish Bakhru What about the possible plans to launch this in Russia and Brazil, where are we there on that?

Abhijit Mukherjee Plans are on, dates not in our control, but certainly progressing as far as Russia is concerned. As far as other markets are concerned, deal with Merck Serono is there, and that would come in due course of time. The progress on the molecule is going on as we have the internal milestones progressing, so that will be global phenomena.

Girish Bakhru The second question is on the Japan deal which was called off. Have any costs related to that been booked in the quarter? What is the strategy now for that market?

Kedar Upadhye In the quarter, for Japan, we did not incur anything for a specific deal.

Girish Bakhru Were there any significant investments that went from your side in the joint venture?

Kedar Upadhye No, nothing very significant.

Vivek Agarwal It seems that Dr. Reddy is the only generic filer for the copaxone generic, as the generic opportunities opening in 2014. I just want to know when we should expect Dr. Reddy's to participate in that opportunity?

Abhijit Mukherjee There are other filers. I think you can look up and do a little more research. I will not name them unless they are in public domain, but there was litigation recently, in public domain, actually Mylan and Sandoz, so we are not the only filer, but this is a molecule big enough to have several filers. It will have to be seen who all finally get to the market but those developments started earlier than ours.

Vivek Agarwal We are expecting in 2014 or 2015?

Kedar Upadhye Vivek, we would not be able to comment on the launch on a specific product.

Vivek Agarwal Another question is your SG&A expenses have turned around 6% growth year-on-year. Any color on that?

Kedar Upadhye Like we explained earlier, as we go forward, we could expect a little bit of operating leverage, and some part of the marketing spend may have been muted in this quarter. As we go forward in the subsequent quarters, a part of this might get incurred, but yes, we are seeing some operating leverage benefit on the SG&A side.

Abhijit Mukherjee Some of the OTC products or seasonal and we were explaining that, hence some of those costs vary from quarter-to-quarter.

Saion Mukherjee My first question is related to the US market. Can you share some color on the Dacogen launch, how it went and what is the market situation like, and how long you expect to be the only player in the market? Also regarding some of the other launches you had like Toprol XL and Isotretinoin, what is the kind of market share ramp up and how far you would go in terms of market share for these products?

Abhijit Mukherjee Dacogen went very well, actually, we were expecting approval a little earlier, goo dthat that it came in and we were the first one in the market. How long before the other competitors would come in, again that certainly is not in our control, we really don't know but so far so good. Metoprolol, you asked, I think we have some benefit of having the full year this year, there is good ramp-up in market share, some of it already in track, and some of it will be seen as we move ahead. However I had mentioned that metoprolol had substantial price erosion with us coming in, we have to take market share at some erosion so certainly these things need to be calibrated when it has been factored in. isotretinoin has not been as big as we were thinking but these things take a little bit of our time, we were late in the market and even the molecule takes a little bit of time. We are moving ahead of our own share plans, but certainly it is not in the same league as metoprolol.

Saion Mukherjee What is your market share expectation for Dacogen being the first player in the market?

Abhijit Mukherjee We are doing very well.

Saion Mukherjee Can you share some number based on the initial orders?

Abhijit Mukherjee IMS will publish this actually very soon, you will get to see those and on behalf of us I hope that we remain a little longer in the market. .

Saion Mukherjee The second question is related to the R&D spend. It is going up pretty rapidly. Based on the disclosures that you have made, a large chunk of thes pend is towards Innovation and Biologics. In fiscal '13, it was like 40% of the total spend, up from about 15% or so in FY 09. Do you think going forward, this ratio is going to go up further? A related question to that is that your Proprietary business, which I believe has the innovation spend included is running in a bit of loss of around Rs. 250-odd crores for the last 2, 3 years. What is the outlook? When do you see these losses coming down?

K Satish Reddy This is how we have planned the trajectory in terms of how the R&D spend is going to be, where it is going to be. Broadly, we are able to say that again based on the growth in sales over the years and all that so we roughly arrived at a percentage of between 8 to 9%. We still remain committed to that i.e. biosimilars, when they go through the different phases of clinical trials, especially since we are adjusting the regulated markets, you will see that we are in line with that. However it is also in line with in-growth trajectory which we also anticipate, so that is how we see it.

Saion Mukherjee As a percentage of your total R&D spend, spend on Innovation and Biologics is increasing from 15% in '09 to almost 40% now. Do you expect it to move further to something like half of your total R&D spend is going on Innovation and Biologics? If yes, then the question is what is the visibility of revenues because on the Proprietary business, we see a loss of Rs. 250 crores every year now? The revenues from Biologics, if it is in the semi-regulated markets like Russia or any visibility that you can give that when do we see these investments paying back?

K. Satish Reddy All I am saying is that for Biologics and Innovation, there are some milestones which are very near term, there are some which are medium term and for proprietary products, the strategy is in place to make the business more viable through series of measures that we are taking. So it will be in line with that. That is why I cannot tell you exactly when this is going to happen because that is very internal in terms of what we are doing. At a very overall level is that this percentage of sales trajectory for R&D is going to repeat.

Ranjit Kapadia My question relates to PSAI business in Europe, how you see this business panning up?

Kedar Upadhye Ranjit, we will probably not comment on region-by-region performance. Satish has already explained on the overall trajectory for the balance three quarters of the year, and we do expect some of the trends to normalize.

Prakash Agarwal My question is related to US market. If you look sequentially, excluding Propecia, we are probably flat despite having good product launches. I also see a comment made that there has been traction in the older products like tacrolimus and fondaparinux, which we have launched some quarters back. What are we missing here in terms of sequential growth in the US business on dollar terms?

Abhijit Mukherjee I didn't mention Fondaparinux in particular, I talked of metroprolol, but however, answering your question, there are erosions in products, you mentioned finasteride

1mg, there is an erosion in lansoprazole and Q1 is the quarter in which you have both the OTC anti-allergy and anti-infective products down as well on account of season. Part of this is being covered by the gRECLAST launch, some price increases taken very effectively and some market share increases, so that is where the whole math works out.

Prakash Agarwal Going forward, is it fair to assume much better sequential growth because our product launches have increased quite a bit?

Abhijit Mukherjee Usual story, there are product launches, there are erosions coming. We are excited about some of the launches which we have done, lamotrigine extended release, decitabine then donepezil 23 mg. Rest of the year, as I said earlier also, there is hope that it will be a busy year depending on approvals that comes by. So overall we are positively biased.

Prakash Agarwal Secondly, your comments on the EU regulatory some framework on the biosimilars, does that help us in being a little on the faster track or how are we placed on the EU launches for our biosimilars section?

Abhijit Mukherjee As I said Merck Serono combined assets development is progressing as per plan. Satish explained that there were internal milestones, and that is progressing as per plan. The understanding and progress hopefully would be systematic, however difficult to put timelines to it.

Prakash Agarwal I understand that. I was just hinting at the EU regulatory framework that we saw a couple of weeks back, which talks about a little faster approval timelines on the biosimilars front?

K. Satish Reddy It does not change anything significantly.

Prakash Agarwal Lastly on understanding the basic questions asked on India, Russia and PSAI where we have probably done weaker than expectations. I understand Russia was a base effect which is expected to come back. India was because of the DPCO and Mumbai thing and expected to come back in the quarter or so. And PSAI, again, we expect a normalization to happen, is that correct?

K. Satish Reddy Yes.

Prakash Agarwal In Russia obviously, we will come back in the near term but what is the outlook for a 2-3 years perspective given the talks on Pharma 2020 and the investments that we might require, any outlook there please?

Abhijit Mukherjee Those aspects of Pharma 2020 i.e. local manufacturing, more embargo on detailing etc., we would go by the changes in the law of the land, but can't say how, when and what would be implemented. In emerging markets every country has some challenges or other, i.e. we faces the challenges on the price control and channel issues, etc. Do we see a massive shift in the short-term or mid-term? At the moment, no.

Prakash Agarwal We are prepared for a local investment there?

Abhijit Mukherjee Of course, if it demands.

Nitin Agarwal In the past, we were talking about R&D cost increases, but how do you calibrate it with the EBITDA margins? I guess in the previous calls, if I remember it correctly, you have talked that you will calibrate it so that whatever EBITDA margin increases that we have, we will probably set up against R&D cost increases. Does that still stay intact or R&D cost increases are independent of the overall trajectory for the EBITDA margin?

Saumen Chakraborty This quarter, our EBITDA margin remained at 20% like last year. So there will be some calibration that we will do, but we gave a broad indication that for a future growth driver, we are going to definitely spend more meaningfully on R&D. There have been questions on which part we are going to spend more and all. Obviously, we will do an overall calibration within the company. We see short-term vis-a-vis, medium term and long term.

Nitin Agarwal So how do you view the EBITDA margin trajectory for the business? R&D trajectory is pretty much defined.

Saumen Chakraborty As we said last time that as R&D goes up as a percentage of sales, we would like to see the SG&A as a percentage of sales to decline, so we will calibrate those kind of things.

Nitin Agarwal Secondly on the PSAI business, when you say normalization in the remaining quarters, do we mean growth coming back in those businesses, what exactly is normalization really?

K. Satish Reddy Compared to the previous year's Q1 anyway, it's not up to the mark. So at least in terms of getting to the growth rates of the previous quarters and on an overall year basis that we should normalize.

Nitin Agarwal In a sense, on a full year basis, you should be able to grow to a closer number that we did last year?

K. Satish Reddy I would not say yet because all I am saying is the first quarter, the sales that we have lost, I do not think we will regain because it is to do with some of the market share declines. We need to discount for that. But overall if you ask me is there a growth in the segment? Yes, there will be growth in the segment.

Nitin Agarwal Lastly, on the custom synthesis business, you talked about traction with the innovators of certain products. Can you give us some sense on the kind of business which we have in the Custom Synthesis, how many products do we have in the lead, where we are working with the innovators in these, late Phase-3 stage or a number of products that you have commercialized that you are working with, some sense on the nature of that business?

K. Satish Reddy So this is a business where we contract out with innovator companies. So the ones where we said we have gained the traction is to do with the existing products of these companies in the market. So these are a mix of off-patent products, certain shift in manufacturing sites, which one of the innovator companies want to do. So it is a mix of all those things. It is not really about early-stage compounds as of today in terms of what I am talking about. I cannot give the specifics on the companies / products.

Nitin Agarwal So it is not essentially early phase of months, it also include late-phase compounds, products which are already commercialized or in the markets for some time?

K. Satish Reddy Yes.

Sameer Baisiwala One question is your ANDA cost versus say 3 to 4 years back, if it was costing you, $1 million per ANDA filing. What is the number for your complex filings that you are doing now?

Abhijit Mukherjee It can vary quite widely. That $1 million is probably for a plain vanilla oral solid where you do one pivotal or few pilot studies. The game is changing and there are products on one end where the clinical cost of the product itself is $10 million. So it varies, but if you are going for products which have high entry barrier there is a very wide range of products. As you know, topicals, we are getting into topicals as well. There are bio-

waiver products where you spend in less, but then upsides are equally limited. But then you want to go for some limited competition topicals, all these products would need clinical studies. Now some of them we have not fully gone into, but we will face those as it comes but those could be in the range of $4 to $5 million per asset. So the development cost per se is not a large factor going ahead. It depends on which asset we are picking up which asset comes in which quarter. Considering the size, mix and scale which we have, as Satish mentioned, the overall R&D cost is not going to shift very drastically.

Sameer Baisiwala A quick clarification on Copaxone. My understanding was that Dr. Reddy's filed the DMF late last year and have not seen any court case on this. So has the company filed an ANDA on this product?

Abhijit Mukherjee Yes.

Sameer Baisiwala And have you been litigated or is it Para-III?

Kedar Upadhaye Some of those details we would not be able to share.

Sameer Baisiwala There was making a big deal out of a probability of these ANDAs and specifically targeting even the genicity for the product. And do you think you would be in time for the first wave of launches?

Abhijit Mukherjee The characterization, immunogenicity etc like all other companies; we are putting in our best efforts in getting done for these assets. There is a lot to these assets actually, not just immunogenicity and characterization. There are other specific things which have to come into play. It is high on our priority. Its is difficult to say where we stand vis-à-vis the competition on a relative ground. Further for such complex product it is difficult to say much on approval timelines. However - it is a high priority product for us.

Kartik Mehta If we have to look at your overall gross margin for the Global Generics business, it was actually the highest in the last 6 quarters or so. With the product pipeline that we have and the overall hedging mechanism in place, is it fair to assume that we will be able to at least maintain this or maybe improve this in the next three quarters or so?

Kedar Upadhye Kartik, we have stopped giving guidance on the sales and margin. The reason we are at 62% in Q1 is because of the product mix and some price increases that we alluded to. The gross margin is a function of several things. We would probably not like to comment on the balance of the quarter today.

Kartik Mehta We have almost hedged between 55 and 60 now, so assuming that the similar type of quality of products and the launches are maintained, is it a fair assessment that we will not go below 60?

Saumen Chakraborty We are not commenting on that. As we said, we would not like to give any kind of a financial guidance.

Kartik Mehta Just on the India business, we mentioned in the opening remark that the impact is about 4%. Did I hear that right?

Saumen Chakraborty Yes.

Kartik Mehta Are you factoring this with any assessment of the volume gains that you will make or it is actually the most pessimistic scenario you will only lose 4%?

Abhijit Mukherjee So the figure is around Rs. 55 crores on last year's base, it is roughly about 3% of the business. Having said that, the largest hit is on one of our large brand called Omez. We will certainly try to see whether the lowering of price can improve accessibility and we are putting effort in that direction. We will see how it pans out.

Mehul Sheth Recently, Andhra Pradesh government has lifted a ban from OTC manufacturing in the state. So what will its impact be on the company?

K. Satish Reddy Probab**ly** you are confusing it. It is a lift on the ban on expansion of capacity for API plants.

Mehul Sheth So what will be its impact?

K. Satish Reddy No impact.

Mehul Sheth Around 60 ANDAs you have filed. Out of which 8 are FTF status. So what market shares are you expecting from it?

Abhijit Mukherjee The brand value of the pending ANDAs is something that we will come back to you offline.

Mehul Sheth Any further expansion plan that you have in terms of geography as well as in terms of capacity?

K. Satish Reddy Nothing is major to talk about right now.

Monica Joshi One is if you could give us a broad ballpark about how your PSAI business is segmented in Custom Synthesis and API? Secondly, your filing status and your litigation status on Rapamune, do you expect to be in the market early 2014?

Kedar Upadhye So the mix of API and CPS is roughly 70-30 within PSAI, and it will keep varying over the periods depending upon product mix.

Monica Joshi Just your filing and your litigation status on Rapamune (sirolimus), whether you are a Para-III filer, have you been litigated if you are a Para-IV, and do you expect to be in the market post-pediatric exclusivity ends in Jan '14?

Abhijit Mukherjee We have a tentative approval, it is in the FDA website. It is in public domain that there is a defined launch for this product.

Monica Joshi Do you have a certain date for launch?

Abhijit Mukherjee We have a tentative approval already and subject to the date, which is in public domain.

Monica Joshi I am not aware of the date. Is it in 2014?

Abhijit Mukherjee Yes, it is in calendar year 2014.

Kedar Upadhye Thanks all for joining Dr. Reddy's senior management for Q1 FY '14 earnings call. In case of any additional clarifications, please feel free to get in touch with the Investor Relations team.