Dr. Reddy's Laboratories Limited
Q3 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 third quarter of fiscal 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.

Just 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 Vice Chairman and Managing Director; Saumen Chakraborty – President and Chief Financial Officer; Abhijit Mukherjee – President and Head of Global Generics Segment; and 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 Saumen Chakraborty – our CFO.

Saumen Chakraborty

Thank you, Kedar. Good morning, and good evening to everyone. Let me begin with the key financial highlights. For this section, all the amounts are translated to U.S. dollars at a convenience translation rate of Rs.61.92, which is the rate as on 31 December 2013.

I am pleased to report a successive quarter of profitable growth despite an unexpected low performance of the Pharmaceutical Services and Active Ingredients segment. Revenues for the quarter were at $571 million and grew by 23% year-on-year. Revenues from our Global Generics segment were at $475 million and grew by 41% year-on-year, primarily driven by performance of our recently launched products in the US market, sustained growth in emerging market territories and benefit of rupee depreciation against multiple currencies. Revenues from our PSAI segment were at $82 million, registering a decline of 29% on a year-on-year basis, primarily due to lack of new launches and subdued demand.

Consolidated gross profit margin for the quarter is at healthy 60.5% to revenues vs. 52.7% as registered in the same quarter of the previous year. Corresponding values for the Global Generics and PSAI segments were at 68.3% and 15.7%, respectively. Such significant improvement in the Global Generics margin profile is primarily attributable to a greater share of Limited Competition products in our US portfolio, which was driven by both pricing and gain in market share. PSAI gross margin declined as a result of subdued demand.

SG&A expenses, including amortization for the quarter were at $169 million and grew by 22% year-on-year. As a percentage to revenue, there is a decline of approximately 30 bps over previous year. The cost increase in absolute terms is largely due to annual increments, additional manpower deployment in select areas, incremental promotional efforts on the OTC portfolio and sales and marketing spend for events specific to this quarter. Also, approximately one-third of the increase in cost is on account of currency movement.

R&D expenses for the quarter were at $48 million, representing 8.4% to revenues vs. 7.1% in the corresponding quarter of the previous year. The increase in R&D spend during the year is in line with our planned scale-up in activities.

As part of our usual impairment accounting checks, we are required to assess the carrying value of certain intangible assets on the balance sheet vis-à-vis their recoverable value. This exercise resulted in the reversal of the impairment charge recorded in earlier quarters, pertaining to product intangibles in our generics portfolio, amounting to $8 million. This reversal is in accordance with the requirements of IAS 36 'Impairment of assets'.

EBITDA stands at $162 million, which is 28.4% to revenues and registered strong year-on-year growth of 67%. Profit before tax for the quarter at $141 million, is 24.6% to revenue. While the current quarter's effective tax rate is higher at approximately 30%, the annual effective tax rate for FY 14 is likely to be around 20%- 22%.

Key balance sheet highlights are as follows: our working capital balance increased by $47 million over that of September 2013. Capital expenditure for the quarter was at $38 million. Foreign currency cash flow hedges for the next 18 months in the form of derivatives and loans are approximately at $331 million, largely hedged around Rs.56 to Rs.61 to a dollar. In addition, we have balance sheet hedges of $497 million.

Net debt at $292 million represents a net debt-to-equity ratio of 0.21.With this, I now request Satish to take us through the key business highlights.

Satish Reddy

Thank you, Saumen. Good morning, and good evening to everybody and I extend a warm welcome to you on this earnings conference call.

I am pleased to report continuing strong performance and our highest ever sales and profitability achievement in the quarter. This profitable growth is an early reflection of our progress towards a greater mix of Complex Generics and Limited Competition products in the portfolio. While US generics influenced this performance to a great extent, our key emerging market geographies also continued their growth momentum in a challenging macroeconomic environment.

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.

Revenues from North America Generics for the quarter were at $265 million, with an impressive 49% year-on-year growth and 21% sequential growth. This can be attributed to the full quarter contribution as well as market share stabilization of our key recent launches – namely, azacitidine, decitabine, donepezil 23mg, metroprolol and divalproex ER. This was made possible by a seamless coordination between our customer-facing teams in the US and robust and flexible supply chain operation in India. As you are aware, we have recently received the final approval for sumatriptan auto-injector and we will launch the product soon in the market. Our anti-allergy OTC and antibiotics portfolio are on a gradual improvement path on a sequential quarter basis, considering the seasonal demand pattern. This quarter also saw the bunching of customer orders and initial billings for some new accounts, which increased the overall level of sales. While in Q4, we do not expect a material increase in competitive activity on the new launches mentioned above, our sales are likely to see some dip sequentially for the reasons that I mentioned above.

Revenues from our India business were at Rs.391 crores with 5.2% year-on-year growth. This quarter witnessed a full quarter impact of the lower price regime and an increased competition across few of the product lines. The business continues in its endeavor to introduce new differentiated products in India to enrich the portfolio mix and address existing unmet medical needs. Of late, you would have noticed the launch of the brands Metsmall and Optidoz. Both are in the chronic therapy space and we hope to scale up in the coming quarters. Our MQT December'13 growth, as per IMS, is at 12.2% against the IPM growth of 10%. We continue to be the fourth highest growing company in India. We believe that with better field force execution, enhanced portfolio mix and presence in the growing institutions business, our India business will sustain its growth.

On the emerging markets front, Russia revenues were at $70 million for the quarter and grew by 6% in the constant currency. After a robust second quarter performance, this quarter has seen some delayed pickup with respect to the onset of winter. This is also evidenced from the low market growth rates in volume terms as per the IMS reports. The OTC portfolio in Russia is consistently growing and is now approximately 37% of our portfolio there. We have seen significant improvement in rank by 6 places over the previous year and we are the second fastest growing company in the OTC space in Russia. CIS markets grew by 27% on a year-on-year basis on the back of new product introductions in Ukraine and expanding base in the other regions.

Our PSAI business registered de-growth of 29% on a year-on-year basis. Challenges on the external market front continued through the quarter. Nevertheless, being vertically integrated, this business division continues on its primary objective to support our Global Generic launches. Though it's a bit early to talk, we are witnessing some positive lead indicators in the

form of improving status of the order book and lock-ins for some upcoming launches. This provides us with comfort of improved performance in the coming quarters. With this, I would now like to open the session for Q&A.

Saion Mukherjee: On Russia, we have seen good growth in the past. Now, we are seeing a slowdown and OTC has also scaled up to 37% of sales. How should we think about growth in Russia, from the next 2 years perspective?

Abhijit Mukherjee: Growth in constant currency terms is 6% and in rupee terms is at 17%. Given the market, which is flat on value and declining on units, it's a significantly good performance. We have gained ranks, 2 ranks overall and 6 ranks specifically in OTC. So overall we are satisfied with Russia. Emerging markets are going through some challenges but, if you are ahead of the pack, you are ahead of the pack.

Saion Mukherjee: Do you think OTC as a percentage can further increase for Russia?

Abhijit Mukherjee: A couple of years back, we were in the range of 31-32%. We have reached 37% of the overall revenues. There have been switches last year. Pain, fever products like Ibuclin, Novigan went to OTC and they are growing in a robust fashion. Very recently, we have got the approval, first time in Russia, of Omez into the OTC sector. We are very optimistic about OTC growth in Russia.

Saion Mukherjee: My second question is specific to some product opportunities in the US. Firstly, on Copaxone, if you have heard something from the FDA and what is your take on generics having to do clinical trials on that? Secondly, Dr. Reddy's had been sued on Imatinib recently, are you surprised with this because this was the first lawsuit that I have come across?

Abhijit Mukherjee: On Copaxone, the file continues to be under review and beyond that, we would not be able to give you further details. Imatinib is part of the generics journey, we are not surprised and it is one of our good filings.

Anubhav Aggarwal: Out of the total R&D spend, we have been spending about 40% on innovative products. Just wanted to get some idea about the proprietary product pipeline, how many molecules are we working on? How many of them are in Phase-III right now?

Satish Reddy: There are several programs in the Proprietary Products segment. To be specific; two are in clinical trials right now, Phase-III.

Anubhav Aggarwal: When do we expect the Biosimilars European clinical trials for you to start – first half next year, second half next year, some timing will be very helpful?

Satish Reddy: For one of the products, it has already started.

Anubhav Aggarwal: So the expense of that was already part of $48 million the number you are reporting this quarter?

Satish Reddy: Some portion of it, yes.

Anubhav Aggarwal: The R&D spend this quarter was at 8.5%, of course on very high sales. But would you cap the R&D spend at around 9% to 10%?

Satish Reddy: As far as this year is concerned, we indicated 8-9%. So by the end of this financial year, it will be around that kind of number, but we are not capping it at anything. One of the things which you will see from quarter-on-quarter, depending on these products moving into clinical trials and the bioequivalence studies with, increased spend in three areas: a) complex generics, b) biologics and c) Proprietary Products - the trend is on the increase. So there is no cap in terms of a number at this point of time. We can only indicate the range.

Anubhav Aggarwal: On the PSAI, I agree it was weak, but what led to sequential decline of 20% in PSAI sales? Was it further price erosion from specific molecules or it was more on the contract manufacturing part, which part was it?

Satish Reddy: It is on both accounts. We have to see the trend in terms of what has been happening since the first quarter. There have been no major launches, also customers rationalizing the inventory and further there have been various other reasons. So that is why we indicated that the order book from now onwards looks better than the previous one and we hope things will improve, but the current decline is on both accounts –innovators as well as the generic companies.

Anubhav Aggarwal: Abhijit, you mentioned in Russia you are growing still above the market, but your market share is very low, right? Just wanted to check that how many products have you launched in Russia let us say in last 12 months both on OTC and Rx side, roughly?

Abhijit Mukherjee: Each year, I would not be able to give you the exact number, but in the range of about 4-5 every year.

Anubhav Aggarwal: This is what you launched in last 12 months, roughly 4 to 5 each in OTC and Rx?

Abhijit Mukherjee: No, not each in OTC and Rx. It is a branded market, so together about 5 products.

Anubhav Aggarwal: Typically, with your market share and you are launching about 4 to 5 products a year, you should be growing much ahead of the market, not at 6 versus market remaining flat, right?

Abhijit Mukherjee: We are growing far ahead of the market. I just mentioned that the current IMS data shows the Russian market in value terms to be completely flat and in unit terms, it is declining.

Kedar Upadhye: Anubhav, there could be quarterly fluctuations. On a 9-month basis in Russia, in Ruble terms, we have grown at 13%. We had a strong Q2.

Anubhav Aggarwal: Yes, because I had the impression that IMS acquired from expert, and this was a calibration exercise. So I am not too sure whether the market is really-really negative right now.

Abhijit Mukherjee: Overall, based on what they are showing, and that might be true for everyone else, overall rank, we have gained by 2 ranks. Two ranks in a year is pretty good actually. If you look at the top players in Russian market, we are doing quite well and especially in OTC segment we gained 6 ranks.

Nimish Mehta: Can you throw some light on the possible launch of sirolimus i.e. Rapamune. What I understand is that Watson has the 180-day exclusivity, but they have not been able to launch probably because of the approval not being granted. So, are we likely to see a forfeiture of the 180-day and is there a launch by Dr. Reddy's and Cadila?

Abhijit Mukherjee: Your guess would be as good as ours on this. You have all the details. So there is a first-to-file player not having launched the product. We have no clue when they would launch, what is the status, FDA does not give any visibility of that. We are all set to launch, but unfortunate.

Nimish Mehta: Will you have to wait for Watson's FTF to get triggered or you can launch let us say, in the worst case after 180 days?

Abhijit Mukherjee: No, current understanding is that we'll have to wait, but, let us see, we will be in touch with the agency.

Nimish Mehta: On Avelox, that is moxifloxacin where we have the FTF, what is the latest on that –because we do not have the tentative approval or are we likely to launch?

Abhijit Mukherjee: I cannot comment on the FTF status, but we are all set to launch on the specific date.

Nimish Mehta: Can you just broadly let us know when do you expect the first product to be launched from the OctoPlus subsidiary that we have acquired, any general color on what is happening there?

Abhijit Mukherjee: The exhibit batches for the first product should be in a few months from now and there is a clinical trial to follow. These are complex injectables which would need clinical trials. So roughly 4 to 5 quarters from now.

Surya Patra: Just wanted to have an idea on what is the progress on the Injectable portfolio in the U.S. for Dr. Reddy's? What is the kind of market that we have achieved for at least the 2 products - azacitidine and decitabine?

Abhijit Mukherjee: In azacitidine there is Sandoz as the Authorized generics, ourselves and Novartis. We have a fair market share of azacitidine considering the play. In decitabine, there is an approval, which is not exactly equivalent. We are yet to see the impact of that in the market. We have a fair market share in dectabine considering the play.

Surya Patra: On the US pipeline front, can you give some sense of what you see? So far we have seen a much better growth than anticipated in the US business because of the steady kind of funds from the limited competition products and other the sustained products, but what is the likely growth that you expect, or what is the kind of product approvals or launches that you anticipate for the subsequent year?

Abhijit Mukherjee: We have a pretty healthy number of launches in over the next 4-5 quarters. However to the best of our assessment, they are not really blockbuster launches. They are good products, but they are not likely to be $ 25 million plus type of products, however we do have a pretty healthy number of launches.

Surya Patra: Can the visible products sustain the growth that you are currently seeing in the US business on a constant currency basis?

Abhijit Mukherjee: The generics market is not predictable to that extent. It all depends on not just what you launch but what you lose as well. How much and what we would lose would only be a guess. We do not have visibility. We have good products. There would be erosion as other players come in. So it is a factor of erosion and launches. Even on the launches side there are good products, but not one of the blockbusters. So hence, I think this momentum will be maintained, but difficult to put a figure to it.

Surya Patra: Sir, when do you really expect your Injectable portfolio to achieve critical mass there in the US? What is the visibility that you are currently having for new product launches so far with Injectables?

Kedar Upadhye: Currently, all the injectables put together are approximately 30% of the portfolio and it would be tough to give any number in the future for that.

Surya Patra: 30% of the pending pipeline?

Kedar Upadhye: No, overall marketed US portfolio.

Surya Patra: The kind of margins, that we have been seeing since last couple of quarters is definitely much better than expected, but what are the kind of sustainable margin that one should look at, since the swing that we have seen in the gross margins has been quite significant in the last two quarter period?

Abhijit Mukherjee: It will mainly depend on the Injectable products erosion. How they behave in the next quarters would decide how the gross margin would swing. In the other products we had our share of erosion. There could be a little bit more, but they would not be leading to wild swings, but how the injectables would behave with the entry of other generics will have to be watched.

Surya Patra: The core margin, if I were to look at for the 9-month period, it is more than 25% excluding depreciation and amortization. The margin is much better compared to the last year number? Is

it a sustainable number even for the subsequent period or you do see some sort of implication of some other factors?

Saumen Chakraborty: It is the EBITDA margin you are really talking about. One thing you must have noticed that the margin expansion has helped us when we have focused quite a bit on R&D, there additional R&D coming out of the margin expansion. Of course, our focus will remain not only in R&D, even we are creating capacity in other areas like Injectables, so we were late at start of the year, caught up quite well. So there are areas where we are going to spend even on capex, it will be around topicals, peptides or several other things. So we will continue to invest for the future and that is the resolve that we have taken. Having said that, the kind of portfolio that we are building up and the strategy that we have adopted on Complex Generics which, of course is the early success indicators of how it has happened in the past. We will hope that our margin stabilizes beyond a certain acceptable level of EBITDA. Will there be a fluctuation here? There could be fluctuations, but we hope that we do it. For longer-term we will expect when differentiated formulations of proprietary products start coming in, then we could see some improvement.

Neha Manpuria: Sir, in terms of our SG&A, you did mention that there were some amount of related to the quarter expenses in terms of increments and some others specific to the quarter. What is the normal base that we should take for SG&A going forward if not the current quarter level?

Saumen Chakraborty: So if you really look at SG&A as a percentage of sales year-on-year, there is a marginal improvement and we expect better SG&A leverage but what happens when we get some benefits on the top line, when there is a currency movement in terms of dollar/rupee, but there is SG&A increase also happening because of the same currency movement and quite a substantial part of our SG&A increases, approximately 30% or so and it gets impacted. We expect better SG&A leverage going forward.

Neha Manpuria: You talked a little bit about CAPEX, your focus on topicals and peptides. Based on how much we spent year-to-date, how should we look at CAPEX going forward, what would be the focused areas and on what are we spending the year-to-date CAPEX?

Saumen Chakraborty: We have actually invested a lot of money in our facilities and in several – both on the chemicals side, as well as on the finished goods side and on Injectables (both Cytotoxic and non-Cytotoxic) - we have actually spent more Capex than what initially, in the beginning of the year, we thought we will spend. But we always felt that this is something which helps us with much better supply chain situation when we are launching a product. If you have seen earlier years, there would have been some difficulty in supply, we have got even penalty for failure to supply and we have improved tremendously. So, I think some kind of additional money which we are spending on Capex is helping us even in the longer-term. So we have spent more than Rs.230 crores in this particular quarter. We may even spend another Rs.200 crores plus in this current Q4. But going forward in next one year, we can even spend higher than what we have spent in this year on Capex. Maybe in the next result time, we will give

some figure, but at the moment, it definitely looks like we will spend more than Rs. 1,000 crores in Capex in FY 15.

Neha Manpuria How do you see the channel consolidation in the US impacting our US business, obviously, there is a talk about possible pricing pressure offset by volume, what is your view on that and especially impact on Dr. Reddy's?

Abhijit Mukherjee: The retailer-wholesaler merger which is happening, last year was Walgreens and ABC and then recently you have CVS-Cardinal. Depending on how much customers a company has in each of these segments and the ratio of that would impact those section. So we will also have an impact, we have factored that into our plans going ahead and it is part of the erosion in the generics business.

Prakash Agarwal: My question is on a couple of products – Cymbalta and Aciphex which we got during the quarter, what are the launch plans for the same?

Abhijit Mukherjee: Cymbalta, we are surprised by the way it has panned out in the market. We are backward integrated. We have initiated plans to quickly catch up considering the amount of time it takes in terms of getting the API and validation and going ahead. We would be planning to get in at some point.

Prakash Agarwal: So, it would be fair to say during this quarter?

Abhijit Mukherjee: Not in this quarter.

Prakash Agarwal: Moving to divalproex, we fairly got decent market share during the quarter. Just wanted to understand the market landscape. My understanding is the market itself has gone 2x to 3x upwards. Could you confirm if this is due to price increase?

Abhijit Mukherjee: Yes, one of the earlier players took price increase, we came in thereafter and some supply situations have changed as well after that. So overall it is a good product. From India there is Zydus and us. We have been choosy about the market share, more value sensitive than share sensitive.

Prakash Agarwal: Would it be fair to say that $180 million market size has become $500-plus million market size?

Abhijit Mukherjee: Do not go by IMS figures, there is always substantial factor you will have to apply when we convert IMS to actual values. All I can say that this is an important product for us.

Prakash Agarwal: Moving to Copaxone, there was a Teva conference call held recently, they talked about thrice weekly that is being launched and they expect that 30% to 50% Rx switch in the first year itself. What is our thought on that? So does it considerably reduce the size of the addressable market when we get approval?

Abhijit Mukherjee: These switches are not easy for us to predict, sometimes it works quite well, sometimes it does not. At the moment, we are very focused on the asset we have filed. That is the important thing and certainly there would be players who have filed on this asset, would like to follow-up with other asset as well. So broadly, at the moment we are focused on the journey to move ahead with our existing filing.

Prakash Agarwal: Would it be fair to assume it is a second half calendar '15 event for us?

Abhijit Mukherjee: Difficult to put a date, this is a complex product and the agency has to do a lot of work. There are, to the best of my knowledge, 2 filers are ahead of us. We are probably the third one. So depending on how well it has been characterized, we will see the outcome.

Prakash Agarwal: On the competitive landscape of Dacogen and Vidaza, we have seen one approval coming in though 505(b)(2), do you think that is a competition threat and can you give some outlook for Vidaza as well?

Abhijit Mukherjee: Here again how the market will play out, I would not like to hazard a guess at this juncture. The approval has just come through. We will see how it plays out in the next few months. Normally, equivalence to innovators has advantages in injectable space, but we will see. On Vidaza, currently we do not have any further information. I mentioned there is an AG, there is innovator and ourselves. We will see how this goes through, we are tracking closely.

Prakash Agarwal: On tax rates, any guidance for the year end and the next year?

Saumen Chakraborty: No, we have earlier said our annual effective tax rate will be between 20%-22%, we are holding onto that.

Sonal Gupta: Could you talk about in more detail in terms of your Biosimilar timelines as to what you are looking at and when do you expect more products in the clinic as well as when do you expect the first potential approvals in the European market or somewhere?

Satish Reddy: It is a bit early to talk about and we do not want to be specific because we are part of an alliance. We can just indicate that the clinical trials have already commenced and next year also we will see the spend going up for two products. The earliest launch is some years away.

Sonal Gupta: On R&D, Prasad in some function mentioned that people should be looking at potentially spending of double-digit in R&D. Is that something that should we expect for Dr. Reddy's in the coming years that the R&D continues to go up as you start with more clinicals, etc.?

Satish Reddy: Yes, we started off in the beginning of the year indicating 8-9% of sales and then now we are indicating around 9% plus in terms of the sales. If we see the existing trend and the growth plans you could expect to touch double-digit. This is a reflection of our commitment to increase the R&D spend based on these three factors that we are talking about, in terms of where the increase is coming from. The complex generics in terms of the portfolio plus the clinical trials which come out of that, is one substantial increase. Then there is biosimilar

spend, I just mentioned that we commenced clinical trials on one of the products, the second one also is on the way, that is another substantial increase. Then you have the Proprietary Products, as and when we see more and more products getting to clinical trials besides the existing two, there is going to be substantial increase. The percentage to sales also depends on the sales growth. So in terms of our existing estimated spend and the sales that we anticipate, we indicate that it could be low double-digits.

Sonal Gupta: There is a big increase in QoQ almost 9% increase in employee cost, which is I do not think that would have any FX effects. Could you just elaborate on why we are seeing such a sharp sequential increase?

Kedar Upadhye: I can separately come back to you on that.

Sonal Gupta: You are operating at very high at margin levels now, in terms of your overall portfolio, in terms of geographies, other that US, is there any other geography which is above the company level margin, or is this all completely being driven by the US?

Kedar Upadhye: Emerging markets and US will be above the company average EBITDA.

Ranjit Kapadia: My question relates to peptide pipeline. If you can throw some light on the potential of these products and the number of products in the pipeline? My second question relates to the European business Global Generics so far, what are the plans for this since it has de-grown during the quarter?

Abhijit Mukherjee: We told you about Glatiramer, but other peptides which are in pipeline, we would not like to comment at this juncture. We will continue to sharpen our skills in this development, which means we will keep targeting some of these products. These products are also in complex injectables areas, it's not about the peptides and synthesis only, there are larger challenges in these products in complex injectables area. On European Generics business, the strategy to keep away from tenders especially single tenders with low margin continues. Even if we do not grow, we are not going to move into the commoditized area of single tenders, especially the bigger ones. The strategy then is also to leverage our complex generics pipeline. Once we develop a product, we will extend these to the European geography. Having said that, that geography has its own challenges, the value out of the asset is quite different from what one gets from the US. As a result, in the short term, the important thing is to ensure that we do not deteriorate further and we consolidate and gradually improve. In the long-term, we are looking at some specific products which are fairly complex and value accretive over the next few years.

Ranjit Kapadia: Sir, can you elaborate on addressable market size of Peptides?

Abhijit Mukherjee: I am not sure. You are talking of the Generics business?

Ranjit Kapadia: Yes.

Abhijit Mukherjee: To club peptides as a separate group is difficult nor will we be able to carve it out. As I said, peptides go into various types of injectables and we are going to target a few, nothing which will drastically change the immediate scenario.

Anant Padmanabhan: On the supplier consolidation. One of your larger competitors, Actavis, has hinted that development such as CVS-Cardinal will make consolidation among generics inevitable in the longer-term. So how should we think about the Generics industry longer-term especially for mid-tier firms such as yourself?

Abhijit Mukherjee: I do not know about Actavis's comment on this, but yes, there will be some erosion as I said, it is part of the Generics business. But would that change the broad aspects of the way we operate, way we look at business- I do not think so.

Anant Padmanabhan: On Generic Copaxone, have you had any recent interactions with the FDA since the filing, what are the FDA approval requirements and where is the FDA with these applications?

Abhijit Mukherjee: We filed about 2 years back. It is a complex product. The agency has to do a lot of work as well on how they would progress. Beyond that, on specificity of our file, we will not be able to comment but work-in progress and it is not going to be something which is just around the corner.

Anant Padmanabhan: So internally, are you expecting Mylan or Sandoz, or maybe both to receive approval in May of this year?

Abhijit Mukherjee: One of the companies have gone in public domain stating that initially they would, but we cannot comment on behalf of others. The work we have done is high-quality work in characterization, we will see what happens.

Sameer Baisiwala: Just to confirm the previous speaker, you said Copaxone filing was done two years back, right?

Abhijit Mukherjee: Roughly.

Sameer Baisiwala: The question is on the overall business model, sir. If I look at your 9 months the overall sales number, this year is Rs.97 billion versus last year of Rs.83 billion, and if we compare the US 9 months this year and last year, Rs.40 billion and Rs.26 billion. So you can see the Rs.14 billion change which is happening is almost entirely coming from the US business, which is now 45% odd of the overall business. Thinking 2-3 years out, do you think your dependence on US is going to go down/go up and how do you want to balance the overall business model?

Saumen Chakraborty: There is a neutralization that has happened because of the decline in PSAI, otherwise there is a growth in emerging markets and there is some growth in India markets as well.

Sameer Baisiwala: That is a very small number, it is about Rs.3 billion plus/minus, but growth in FY'14 overall is coming from the US business. It looks like a fairly imbalanced model from a growth perspective and therefore the question.

Satish Reddy: You are right, at least for this year that is true, in terms of the growth that came in from the US plus what Saumen just said has contributed to this kind of a thing. I do not think it will drastically change in the very near-term, but over a period of time because in terms of the kind of growth rates that you have seen this quarter, in Russia a high base country, also in some of the emerging markets and in the Indian market currently we have just seen 5%, that is not entirely indicative of what is going to happen in the future. However, it would not dramatically alter but over a period of time things will balance out to a certain extent.

Sameer Baisiwala: On Vidaza and decitabine you have already given us a fair bit of color, but in terms of pricing, you being the only player in the generic space, is the pricing more or less similar to what one would get for 180-day exclusivity for example?

Abhijit Mukherjee: Yes, given the competitive landscape I mentioned in Dacogen-we and the innovator, it is likely to be healthy and similarly, Vidaza is also fairly okay.

Sameer Baisiwala: When you say healthy and okay, is it more like a single dynamics?

Abhijit Mukherjee: How can we give you exact details on pricing? The results are good and these molecules have got full momentum. Naturally, it has a role to play in the US margin increase as seen in the results.

Sameer Baisiwala: You mentioned there are two drug candidates right now from proprietary pipeline, which are undergoing Phase-III clinical trials. Is it possible to share anything more on this in terms of what categories or what kind of products are these?

Satish Reddy: Sameer, it is bit too early. I think once we progress on that, probably we will disclose more.

Surjit Pal: Given that you have $ 571 million for Q3 and the 9 months you have around $1.5 billion, if I assume that in Q4 you will have 550 million, overall it will be similar to what you have last year whereas in FY '14, you had pretty good products like Vidaza and Dacogen. Suppose for FY '15, I remove Copaxone, since there is an uncertainty, overall, it will be mainly a balancing act for the company in terms of maintaining the same sales given that there are only few products available and not many blockbuster at this stage to launch.

Abhijit Mukherjee: It is a healthy number of launches, as I mentioned. It is not always fair to put figures for each of the launches, they are not huge, but they do add up. So FY'15 is going to grow, not as good as this year. A lot depends on how the erosion of these 2 assets and the other assets which are already matured. North America will continue to grow but every year cannot be as good as this.

Surjit Pal: Given that you were increasing your capacity in heparins and peptides, does it include also some natural heparins like Lovenox or you are basically in synthetic or semi-synthetic brands?

Abhijit Mukherjee: No, we are also looking at other heparins as well in the pipeline and in the process.

Surjit Pal: So in case if you have any filing on other non-synthetic heparins, when could it be possible?

Abhijit Mukherjee: These details cannot be given but as I said, there is two other heparins and we are targeting both.

Surjit Pal: Just need one update; is there any development on the Doxil from your side to FDA in terms of filing?

Abhijit Mukherjee: In the complex injectables could be, could not be. We would not be able to comment on that.

Dheeresh Pathak: Is it possible to share what percentage of our R&D are we spending on Biosimilars, and how much are we spending on Proprietary?

Saumen Chakraborty: Overall it is a 60-40 ratio; 60% we spend on Global Generics and PSAI and 40% on Biologics and Proprietary Products put together out of the total R&D spend.

Dheeresh Pathak: Can you split further between Biosimilar and Proprietary?

Saumen Chakraborty: Little higher on Proprietary than Biosimilar.

Kedar Upadhye: Good night and thank you everybody, for joining Dr. Reddy's senior management for the third quarter of fiscal 2014 earnings call. In case of any additional clarification, please feel free to reach the Investor Relations team. Thank you!