Dr. Reddy's Laboratories Limited
Q1 FY 2016
Earnings Call Transcript

Kedar Upadhye:

A Very Good Morning and Good Evening to all of you!

Thank you for joining us today for Dr. Reddy's First Quarter of fiscal 2016 Earnings Call. 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 Saumen Chakraborty — our Chief Financial Officer and Abhijit Mukherjee — our Chief Operating Officer along with the Investor Relations Team.

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

Saumen Chakraborty:

Thank you, Kedar. Greetings to everyone.

Let me begin with the key financial highlights: For this section all the amounts are translated to US dollars at a convenience translation rate of Rs 63.59 which is the rate as on 30th June 2015.

Consolidated revenues for the quarter are Rs 3,758 crores or $591 million and grew by 7% year-on-year. Revenues from our Global Generics segment are $487 million and grew by 8% year-on-year. This growth is after absorbing the continuing impact of the macroeconomic uncertainties and consequent currency headwinds for the Emerging Markets region. Our US business showed sustained performance of its key products, Europe business grew on the back of recent launches and India business continued its growth journey. Revenues from our PSAI segment are $88 million with flattish year-on-year performance.

Consolidated gross profit margin for the quarter is 61.1% versus 59.3% in the corresponding quarter of the previous year. Corresponding values for Global Generics and PSAI are 67.6% and 23.7% respectively. Current quarter gross profit margin reflects positive impact of improved product portfolio and operating leverage of the manufacturing overheads.

SG&A spend, including amortization, for the quarter is $173 million and marginally grew by 3% year-on-year. Net increase in absolute terms is primarily on account of annual increments and other selling, marketing and professional spends for events specific to this quarter. These got offset by depreciation in Emerging Markets currencies especially the Rouble. There has been a good control on SG&A spend which is in line with the cost control initiatives that we have referred to in earlier calls.

R&D expense for the quarter is $69 million representing 11.7% of revenues versus 11% in the corresponding quarter of the previous year. As also mentioned earlier, the increase in R&D spend is in line with our planned scale up in R&D activities.

EBITDA for the quarter is $156 million, 26.5% of the revenues. Tax rate for the quarter is 21.6%. Annual Effective tax rate is expected to be in similar range.

Key balance sheet highlights are as follows: Our working capital marginally increased by $17 million over that of the previous quarter and is largely in line with our expectation. Capital expenditure for the quarter is $40 million. Our net debt-to-equity ratio is 0.05, which is after our payout for UCB portfolio acquisition.

Foreign currency cash flow hedges for the next 18-months in the form of derivatives and loans for US dollar are approximately $353 million, largely hedged around Rs 60.7 to Rs 65.1 to a dollar. In addition, we have balance sheet hedges of $256 million. We also have foreign currency cash flow hedges of Rouble 1,440 million at the rate of Rs 1.16 to a Rouble and €4.5 million at the rate of Rs 74.37 maturing over the next 9-months.

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

Abhijit Mukherjee:

Thank you, Saumen. Greetings to everybody and I extend a warm welcome to you on this Earnings Conference Call.

First quarter has started off with a decent all-round performance across our US, India and Europe markets. In US, our team was able to hold on to and in some cases increase the market share across key molecules. Sustained performance of the complex portfolio over the past few quarters is indicative of the high potential associated with this class of assets. India i.e. the domestic formulations business continued with its predicted growth journey in this quarter. To add, we successfully concluded the UCB portfolio integration and this will reflect as a full quarter contribution effective Q2. Europe team is building up a selective portfolio of oncology and hospital-based assets to enhance the region's growth trajectory. Russia and some other territories in Emerging Markets continued to experience the pressure on growth due to ongoing macroeconomic uncertainties.

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

Let me start with North America Generics: Revenues are $295 million. On a high base, the business was able to deliver growth despite absence of new launches and continuing competitive intensity. This is attributable to sustained pricing, incremental gains in market shares and supply chain robustness. Meaningful contribution from complex assets also had a positive effect on the margin profile. As per IMS MAT 2015 Sales Report we are Ranked 8th in terms of volume which is one rank improvement over last quarter. On the OTC side, Habitrol is well integrated now and reflects full quarter benefit. As you would have noted, in early July, we launched memantine. During the course of the year, we believe our visibility of FDA approvals and launches would improve.

On the Emerging Markets front, Russia revenues are $36 million for the quarter and declined 22% year-on-year in constant currency. Performance for the quarter reflects pressure for volumes on some of our major brands and channel inventory adjustment to some extent. Team continues to explore opportunities for portfolio expansion. As per YTD May 2015 IMS numbers volume share of OTC portfolio is growing by 18% versus a market decline of 11%. In Venezuela, headwinds surrounding various macro factors such as currency and political situation continue. Consequently fund repatriation is slow and we are watchful of the situation. However, we remain quite optimistic of the opportunity available and our actions continue to be guided by long-term strategic view of this market. India business revenues are Rs.476 crores and grew by 19% year-on-year. Our growth and ranking in Prescription terms is also improving. We have integrated the UCB portfolio and business. We announced a number of business development deals including Somazina, Resof and some other assets and we expect such momentum to continue. Also, over the past couple of quarters, our rank improved from 16 to 14.

PSAI business posted revenues of $93 million with a flattish year-on-year growth. Considerable efforts are being put to achieve the twin objectives of sales growth and healthy margins. We continue our efforts to add newer technologies and platforms to revamp our product offering to move higher on the innovation scale. As mentioned earlier, PSAI segment significantly supports our Global Generics business and is a major competitive advantage for us.

Before I end I am pleased to share that we have received PDUFA dates for our three NDA filings done earlier in the year by the Proprietary Products team. Team is geared to get the commercial piece in place and we expect monetization to start sometimes in the next fiscal year.

With respect to USFDA inspection observations in Srikakulam API facility, we believe that we have comprehensively addressed almost all the observations raised. We have periodically sent detailed updates to FDA. Going forward we are awaiting positive response from the agency.

With this I now open the floor for Q&A

Aditya Khemka: On the India growth that we saw for the quarter, so far how many days was the UCB portfolio consolidated during the quarter during Q1 FY16?

Abhijit Mukherjee: It was just about 10 days or so. Not a significant contributor to the quarter's performance. In percentage terms could be about a 1%.

Aditya Khemka: Which means we have basically seen about 18% growth in our base portfolio. Could we split this into how much of this is due to Biosimilars and how much of this is due to our chemical portfolio?

Abhijit Mukherjee: Taking the major products, broadly biosimilars would be around 5% of the total revenue. The answer to your question is that basically the organic business also has grown at similar extent.

Aditya Khemka: On the North American Generics business, as you correctly mentioned, there is no incremental launch during the quarter and we still gained. If I am not mistaken we gained about $25 million quarter-over-quarter in the business. I understand that you have mentioned there is some market share gain, but could you allude to which was the largest? Was Habitrol not consolidated for the full quarter in 4Q? Is this the first full quarter consolidation of Habitrol?

Saumen Chakraborty: No, in the last quarter also we had Habitrol. Valganciclovir has done well for us and our injectable portfolio has continued with its momentum.

Aditya Khemka: The reason I ask this is because our Injectable portfolio has been there for some time with us and of late, we have just seen some incremental competition stepping in and there has been no change in dynamics of other key Injectable products. Could you share as to which of these products are actually moving the needle here for the quarter?

Abhijit Mukherjee: In the injectable business, normally Q1 is stronger relative to Q4. Also if you see - gDacogen share has actually increased for various reasons. Overall there is robustness in Injectables portfolio which accounts for a significant part of the increase. Valcyte generic has done well and we have further consolidated a few other products as well. However, there was erosion due to consolidation of customers and RFPs which came in, so what you see is net of the erosion.

Aditya Khemka: On your PSAI segment, sequentially we have seen about 23% decline again. I understand the business is highly volatile. How should we think about this in our models? How do we build or project the stream of revenues for Dr. Reddy's?

Abhijit Mukherjee: The new strategic intent is to ensure that the business becomes more value accretive and hence we are trying to cut down some parts of the businesses which are not yielding

sufficient return. A flat growth should be read with better margins from this business and we are putting significant efforts in that direction. Last but not the least going ahead we will try and use our presence in the PSAI business to globalize many of the assets which we have developed for the regulated markets. There is potential for globalization of these assets even in the form of formulations in certain other parts of the world. Overall we are not concerned about the flattish behavior of the PSAI business, it is undergoing structural change. It is a major strategic advantage in terms of providing value to the Global Generics business. We are moving in that direction.

Aditya Khemka: If you are calibrating the business to maximize the margins that you can extract, there will be some unused capacity, right? Do we have a plan in place to utilize that capacity in-house or how are we thinking about that?

Abhijit Mukherjee: About 20 DMF plus would be filed during the year. The nature of the business is continuous renewal of products and we are selecting the products correctly. There is a robust activity on the new product front. The capacity non-utilization is not a problem. In fact, we will keep investing.

Manoj Garg: On the Memantine approval, I understand it was an older ANDA. Can you confirm which facility you will be supplying that product out of?

Abhijit Mukherjee: Our Formulations facility which is serving the US market. API is from another unit and not from Srikakulam plant.

Manoj Garg: Has the FDA confirmed a reinspection date for Srikakulam or is it just your assumption?

Abhijit Mukherjee: The FDA has not confirmed anything and we do not even have any visibility whether they would re-inspect. Normally in many such cases they come back for a re-inspection. We have been sending updates. We had made some commitments which we have fulfilled. Almost pretty much everything except for one or two long-term ones are pending. Our expectation is that at some point this would be inspected once again.

Manoj Garg: Your informal guidance for top line growth has been double-digits or low double-digits and we are seeing the top line in the current quarter grow at 7%. That is largely because there were no product approvals. So, absent product approvals is really the run rate?

Abhijit Mukherjee: Like all generic companies dependent on US we are awaiting certain approvals. It is going slow like most of our peer group companies have said. You will have to also factor in that emerging markets took unprecedented hit in this quarter. We hope that with this clear sign of stabilization in Russian market. Based on our secondary and current sales in this quarter, sequentially there will be some recovery on that. Considering all that, on product approval specifically, like all other companies we are also waiting for approvals.

Manoj Garg: Given two of your key competitors especially in the US market are getting together with Teva and the Allergan Generics business, do you see this as a net positive or is there a potential risk that we should be monitoring going forward? The reason I ask, if is it net positive is obviously with the consolidation and with the divestments of some expected files, we can see some uptick in pricing. However, on the other hand, is it a more formidable competitor in terms of just sheer size?

Abhijit Mukherjee: I would probably look at it from a positive lens. These are happening at a very different scale altogether. We are in a different scale. As you mentioned, there would be naturally some assets which would be coming up for divesture, which can throw up some opportunities. Regarding more competition or less competition, let it play out.

Nimish Mehta: Would like to understand what has led to the tremendous increase in the gross margin on a sequential basis. The increase is more than 500 basis points. I understand the adverse currency impact is still the same as we had in Q4 of FY15. What has changed and resulted in this high margin?

Saumen Chakraborty: The business mix was in favor of Global Generics. If the Global Generics has a bigger pie then automatically the weighted average gross margins for the organization improves. About the SG&A growth which I eluded to being only 3% year-on-year has also contributed to overall EBITDA. The manufacturing overhead cost control has also helped in terms of the gross margin.

Nimish Mehta: When you say sales mix, you are referring to higher sales from US?

Saumen Chakraborty: Global Generics business segment, seasonality is much higher than the PSAI business segment. Whenever the mix goes in favor of Global Generics the overall gross margin for the organization automatically improves.

Nimish Mehta: A bulk of it is because of the change in mix in favor of Global Generics, right?

Saumen Chakraborty: I would say that is one of the factors and the other factor is manufacturing overhead reduction.

Nimish Mehta: On the SG&A side, you said it was just about 3% increase. Is that the level that we are looking and what is the outlook there?

Abhijit Mukherjee: To some extent, the increase due to increments which are given in the first quarter of every year got neutralized because of the Emerging Markets devaluation. For the year we expect to control but even sales and marketing we will have to see how much we need to spend. I cannot give any guidance as such that every quarter it will be only 3% or so. Definitely

since we are spending more on R&D we expect that SG&A productivity to offset the higher spend in R&D.

Nimish Mehta: Nexium as well as Abilify if we are targeting, it will be great if you can give the outlook there?

Abhijit Mukherjee: Abilify is not in the pipeline. As far as gNexium is concerned we have responded to all the queries raised, in our view rather satisfactorily.

Nimish Mehta: Any ballpark would be great?

Abhijit Mukherjee: Your guess is as good as mine.

Prakash Agarwal: You made a comment that in one of the Injectables you have gained market share which is Dacogen and you also talked about Q1 being better than Q4. Do we understand this is some kind of bunching up that we also saw in the similar quarter last year and that this would normalize in the following quarters? Is this a correct understanding?

Abhijit Mukherjee: Not really, the assets have held up. Every quarter we are mentioning that we will see more competition coming in. It can come in any time. In fact there is some consolidation in not just injectables but also in some other assets. Difficult to predict. There are no indications to say that there is just a bunch up for this quarter.

Prakash Agarwal: So this run rate could continue is what I understand?

Abhijit Mukherjee: Depends on new entries actually. That is the invisible part. On our side there is no bunching up at all. However, if there is entry obviously, you will get to know and naturally impact like it impacted every other player in the market.

Prakash Agarwal: Any update on Copaxone? Where we are we still believe it is not coming this year. Is it a next year opportunity for us?

Abhijit Mukherjee: Yes, there is some broad guidance in the direction which we have through our deficiencies and the conversations and we are proceeding in that direction. It needs some work which is going on full speed at the moment. We maintain what we told you. It is not very near-term.

Neha Manpuria: My first question is on Russia, the 22% decline. While you have mentioned that second quarter hopefully should improve, what went wrong in the quarter? Was it because of price increases we witnessed market share loss or you mentioned inventory adjustment, too other than that, was there any other factor that led to this?

Abhijit Mukherjee: In a turbulent situation all sorts of strange things come in. First of all it reduces the capability to spend out of pocket. Hence automatically the first thing that impacts is people's ability to buy medicine to that extent. The second thing was the retail chains. They jacked up the margins to offset the currency issue which had a double whammy on the margins. While as patients were not able to buy and the prices further went up, it lead to steep fall in units not just for us, but all top companies had to bear this. The companies which had stronger and bigger brands took bigger hits. This in effect acted against the retail which they realized and they reversed this because the total reduction in units could not compensate for the increase in price. In the mean while Ruble came to a certain level of stability. Both combined we saw the secondary markets gain quickly about month and a half back and which is reflecting into primary in this month. So that gives us some degree of hope but having said that in fact this geography will take a few quarters to come back to full normalcy.

Neha Manpuria: Second on UCB portfolio, given that we have seen 10-days in first quarter and a month in here. How are you seeing it in terms of profitability? How much work would it require in terms of integrating it with the India business?

Abhijit Mukherjee: Excellent integration, everything has gone very smooth so far. July is a proof of the fact that our assumptions are holding good. Integration has gone extremely well and it is moving in the right direction.

Neha Manpuria: Profitability wise how is this versus our existing India business?

Abhijit Mukherjee: It is a good EBITDA business. Been brought in from a multinational, there are a few good brands. What is most important is how well we are able to grow these. Our organic business is growing at a rapid rate and it has to also grow with it.We are quite optimistic, it is in the right hands.

Anubhav Aggarwal: Is typically the first quarter in Venezuela seasonally a weak quarter or what is the reason that versus the fourth quarter I see in rest of world there is a sales decline of about Rs.80 crores? Have you already started reducing sale or it is just a seasonally weak quarter?

Saumen Chakraborty: As we have told all of you earlier that we have been always calibrating sales in Venezuela because on one hand it gives a tremendous opportunity for growth, but at the same time all of you know of a probable devaluation. Of course, last quarter onwards we have started the process of taking the net monetary assets at the SIMADI rate. In Q4FY15 we took about $14 million and in Q1FY16 corresponding hit we have taken is around Rs.10 crores. At the same time there is some repatriation which is happening and we are calibrating the sales against that. The repatriation and the cost of goods that we are transferring from India to

Venezuela is calibrated in such a way that overall exposure remains within our risk appetite.

Anubhav Aggarwal: Saumen, just to understand this better, if you did about $140 million sales from Venezuela last year, we have already seen four months go by, will we do more than $140 million or less than $140 million?

Saumen Chakraborty: It all depends on the rate of repatriation. If we get good repatriation then we can exceed the previous year's number very easily. The opportunity exists. However, if the rate is not very encouraging for us, then we will have to keep on calibrating our exports to Venezuela.

Abhijit Mukherjee: In Venezuela the orders are far higher than what we are supplying to the market as Saumen mentioned but more importantly, there are a couple of efforts which we are putting into the market; 1) We are importer of petroleum and we are exporting medicines. We are involving both the governments to see which way we can resolve the issue and there is immense amount of effort going in that direction, 2) Being a company where our product price per se is not extremely expensive we have given presentations to the Ministry and Venezuela Health Minister as well. We have contacted them to show that our units are growing in spite of the fact that other competing players, units may not be growing to that extent, they are taking price increases, we are not. This is the current situation which they appreciate and this dialogue is on. All efforts are on to see how we can improve and convert this situation to an opportunity. Having said that the uncertainties still remain.

Anubhav Aggarwal: Last quarter we had $38 million pending. How much is that number now?

Saumen Chakraborty: As on 30th June it will be close to $50 million.

Anubhav Aggarwal: On the US approvals, after November we have not seen any approvals. If FDA has 483 on Srikakulam facility, this is just one of our seven API plants. Why we have not seen approvals at all from any other plant?

Saumen Chakraborty: We have launched in Memantine.

Anubhav Aggarwal: That approval we got in 2010 or 2011, right?

Abhijit Mukherjee: There are a few assets which got impacted because of this. As far as gNexium is concerned we have the tech transferred for generated data, submitted answers to all the queries so that takes care of one. For the other two, I am not going to mention the specifics. One is not really worth tech transferring as value wise it is not very big. On the third one, we are discussing what view do we take. Beyond that we are broadly in the process of de-risking. Having said that it is a light year of approvals. What is more important is that rather than the number of approvals, what gets approved. There are few assets which are okay.

Anubhav Aggarwal: Abhijit, my question was on approvals outside Srikakulam. My question was that we are doing derisking in Srikakulam, but what about approvals outside Srikakulam? We are not seeing any approvals for the company for last 10 months.

Abhijit Mukherjee: Yes the filings happen from one site, it is that earlier site we keep moving from one site to another site. Filings have happened from there and some of those are being tech transferred or derisked, but nothing is immediately pending beyond these three which I just mentioned.

Saion Mukherjee: How many approvals or launches are you expecting for this fiscal year in the US?

Abhijit Mukherjee: There are quite a few, how can we give you numbers because these are dependent on FDA's approvals and litigations which are also in public domain.

Saion Mukherjee: Can you share your take on Vimovo and Aloxi in particular, whether these are opportunities you think that can be monetized this year?

Abhijit Mukherjee: They are great opportunities, however both in litigation.

Saion Mukherjee: Is it a possibility, do you have a hearing timeline when do you get the court verdict, any sense, any color you can give there?

Abhijit Mukherjee: Aloxi likely argument would be probably in September and give or take another 2-months for the 505(b)(2) approach for the verdict. The 505J anyway is already heard probably another couple of months but 505J there are a couple of other people as well. So it would mean more competition, 505(b)(2) is around September hearing argument and then it will pick up thereafter.

Saion Mukherjee: So 505(b)(2) is a non-infringing route, is that the difference here?

Abhijit Mukherjee: Yes.

Saion Mukherjee: Therefore you see more probability of that coming through from a litigation perspective relatively speaking?

Abhijit Mukherjee: How can we comment on something in the US court being litigated? It is in our view completely non-infringing.

Saion Mukherjee: There has been a very significant improvement on the gross margins. I was just wondering, you talked about product mix. Is there any raw material cost benefit that you have seen on a year-over-year or sequential basis? If you look at the material cost, it has not even moved up 1% on a year-over-year basis. Is there anything on that front?

Saumen Chakraborty: Raw material which is linked to the crude oil, on that definitely we get some benefit. However primarily, it is a business mix and manufacturing overhead as I mentioned earlier.

Saion Mukherjee: On Europe, we have seen a very strong growth in UK and Germany. Can you give some granularity there, how sustainable it is? Any specific product launches, how should we think about Europe going forward?

Abhijit Mukherjee: We had messaged that we have gone down on the commodity tender business in Germany and we specifically picked two therapies we can promote. We have picked those and we have put in some products in those, moving strategically in that direction. Looks to be a little more sustainable, not that these would last forever, but as tenders come in and these erode, by that time we would have launched a new products. For example, this quarter we have already launched duloxetine which is doing well. In summary, the worst is clearly behind, hereon we will slowly build the business.

Sameer Baisiwala: Abhijit, I am a little confused in the context of your comments on the new approvals for the year. On one hand you said that it is going to be light year and on the other you said you expect quite a few new approvals. If I remember correctly, in the previous call, you had said that you expect three to four niche approvals which are not dependent on Srikakulam. If you can just clarify on this it would be great.

Abhijit Mukherjee: Essentially, Sameer, we are putting more emphasis on the type of assets we get approval on. We have spoken about gNexium, we would not be able to give you dates. As I said already tech is transferred, data submitted, questions asked, questions answered to the best of our understanding in a satisfactory way. There are a few other products. There was a question on Aloxi, which is in public domain, being litigated, depends on which direction it goes. There was a question on Vimovo, which is litigated. We do not know on which direction it will go. There are a few other which may not be mega, but reasonable size. If you are specifically saying numbers, just sheer numbers, it is going to be light. Depending on how these things go, this could be interesting.

Sameer Baisiwala: What you are saying is that, either these opportunities are litigation dependent or it is something like Nexium which is Srikakulam-dependent. Now the question here is, do you not have some products that you can be sure of launching which are niche and which could drive the growth?

Abhijit Mukherjee: Nexium as I just mentioned it is no longer Srikakulam-dependent at all. Some of these products either are already derisked or in the process of being derisked. Having said that, I would not be able to give you more specifics. It has been seven months from the time the audit happened and this is reasonable time for us to do whatever needed to be done.

Sameer Baisiwala: You had given a very abridge to submission on Nexium in terms of tech transfer as in maybe three months or even less, rather than what companies normally do which is much longer — 6 months to 12 months. You obviously cut down a few of these studies. When FDA did come back to you and ask you questions, those are not the requirements that FDA need anymore. Is that a fair comment?

Abhijit Mukherjee: I would not get into details. The statement I mentioned is, after completing the tech transfer, taking batches, there were a few questions, which to the best of our understanding, we have answered satisfactorily.

Sameer Baisiwala: Can you update us on the new manufacturing blocks in Vizag, one, the second Injectable block and the second is the Complex Oral Solid that was almost ready last year. How are they progressing and when do we see the approvals flow through?

Abhijit Mukherjee: Injectables is one site in another part of Vizag. The investments have all gone in. Several products exhibit batches have been taken. Probably, the first filing is just being done with several to follow during this financial year. But, approvals, certainly not, for the plain Injectable side. Oral solids was audited, no observations, we have got EIR, several already filed from there. One or two interesting ones as well. However, no approvals may come in next three months probably, but beyond that, it is possible that we might start seeing one or two.

Sameer Baisiwala: On the ongoing consolidation in the US market the question here is, with Teva and Allergan Generics which is a much, much larger player. What does it do at a product level? Would they be able expand the per product market share or is it just about gaining the breadths in terms of number of products?

Abhijit Mukherjee: Most of these mega mergers, whether it is Teva, Allergan or the one Actavis had earlier, or Mylan, Perrigo, etc - how these will go, we do not know. They do throw up some opportunities wherever there are overlaps. To that extent, it is interesting for us. Beyond that, I am not sure whether there would be a great deal of impact or we need to be worried about these.

Girish Bakhru: On the approvals question, your previous clarification was very helpful. Are you getting any target action dates on the pending ANDAs?

Abhijit Mukherjee: We have, especially post GDUFA regime and it is become more structured.

Girish Bakhru: So per se, the 483 issue does not like really stop you from getting review on the other ANDAs, right?

Abhijit Mukherjee: By no means. This is pretty much one site specific issue. A huge amount of organizational effort is standing for us everywhere where we are. Taking this is a drive to see how else we could more train, more do IT backup etc.

Girish Bakhru: Could you throw some color on Propofol? That was a product that was expected sometime in near-term. Is that also somewhere close to seeing an approval this year or is that something which is delayed now?

Saumen Chakraborty: Not impossible, but having said that it is with FDA at the moment, we have again responded to it and the litigations are out of way.

Girish Bakhru: You said that of course a lot of the impact in Russia in the quarter was because of the turbulent situation, there are a lot of news regarding how the prices are actually very high for customers to even buy drugs. Is there a risk that there could be some government control increase on the pricing front? How do you read that situation really turning on the regulatory side?

Abhijit Mukherjee: I would not think that pricing would be controlled that much. That does not seem to be the objective, but there could be protection to a certain extent to players who are producing in that country, especially the government business, DLO business. Our share of the DLO business is pretty much nothing. We have some hospital play, where some of those may come under the purview, but it is not very significant from our side. Going ahead, we are committed to the geography to see whether eventually we get into local manufacturing. At the moment not a big red flag immediately for us.

Girish Bakhru: When there is a discussion going for in-licensing more in that market, is that more in the OTC side?

Abhijit Mukherjee: Whatever comes our way. There are opportunities being discussed. We will consolidate both on Rx OTC as well as hospital side.

Girish Bakhru: In this whole turbulent situation, basically the inventory issue, is it impacting both Prescription and OTC?

Abhijit Mukherjee: To us, less on OTC, more on Rx so far.

Girish Bakhru: A broad thought on recent pickup in Biosimilars. I know it is the opportunity which is still long indeed, but if you look at the recent data, the Remicade biosimilar is coming at discounts of 70% to the innovator brand price. I know that has helped in terms of market share. With this kind of discount, do you think there is an opportunity in these first and second generation Biosimilars for companies which would be coming quite late?

Abhijit Mukherjee: You are talking about the European play on this. That may not be an absolutely full-fledged data point. Having said that our current major objective this year would be to collect some more data and go to all the emerging markets as much as we can. We have launched in Ukraine, a month ago and are doing extremely well. We will progress on that front first and then, we will see how it plays out on a global side.

Surjit Pal: Could you please tell me was there any kind of dollar-denominated expenditure in Russia, which you might have converted into local currency post this fall in currency?

Saumen Chakraborty: No, we have not changed any practice there.

Surjit Pal: So, basically, this currency devaluation particularly in the emerging markets have helped to reduce your consumption of raw materials cost to that extent?

Saumen Chakraborty: No, that will not impact the raw material. That will impact SG&A to some extent. Our cost of manpower in the Emerging Markets including the increments that you give, when you finally convert it into the functional currency, you get some benefit.

Surjit Pal: Is there any kind of development in Zopinox marketing? You started partnership with Cipla. Is there any kind of update on that and also on Namenda?

Abhijit Mukherjee: Yes, we have a partnership, but it is a very small asset. On Memantine, we have launched, we thought it will be much more commoditized than it is in the market, and so far it is going good.

Surjit Pal: An opportunity cropped up like duloxetine, it was expected to be a 7-8 guys corundum, then cropped up to just 4-5 guys. Do you think a similar kind of scenario is shaping up for Memantine too?

Abhijit Mukherjee: Duloxetine was much bigger, certainly, it is not in that league. First of all, the asset was smaller. In its own small way, it is good.

Balaji Prasad: On your R&D front, glad to hear that you received the PDUFA dates. Can we understand what does that mean? Could we see a launch early 2016?

Saumen Chakraborty: Yes, we have got that for the expected line of FDA for this class of products, it is a specific date. If everything goes well, then we can hope to launch this within the next one year. Of course, since it is a brand, it will take some time to ramp up, but we are bullish on Proprietary products.

Balaji Prasad: Are there any incremental data points that you would get which you will share with us on that? Secondly, are you ramping up the field force or you would use the current 50-odd of sales personnel that you have at Promius?

Saumen Chakraborty: For Dermatology, we do not need to ramp up. For Neurology kind of products, we need to definitely hire. If there is some specific development that happens, we will share with you maybe in the next earnings call.

Abhijit Mukherjee: These are NDAs, so, during the course of the year, FDA would certainly ask questions. If all of the assumptions and everything goes picture perfect then we can see the launch as expected.

Balaji Prasad: I was going through my notes on the Investor Day that you had. I was not sure if I got the status update on DFD-06 and DFN-02. Are they in Phase-III? How close are we to a filing?

Abhijit Mukherjee: We cannot comment on those now. When we have the Investor Day next time, we can open up further on those.

Balaji Prasad: Recently there was some news item about the European Union banning 700 drugs related to GVK Biosciences. Do you have any direct or indirect exposure to any of these drugs?

Abhijit Mukherjee: We had two, insignificant in revenues, but when this started unfolding, we had already stopped and took it out of the market as a matter of precaution.

Balaji Prasad: So, there is no incremental impact then?

Abhijit Mukherjee: Nothing at all.

Chirag Talati: First question on Aloxi. Why have not we seen a tentative approval so far either for the 505(b)(2) or the ANDA. Is it something to do with Srikakulam?

Abhijit Mukherjee: No, I am not sure why it is not approved. Beyond that we would not comment. It is under litigation. We will just leave it at that. I gave you some tentative hearing dates. Let us see where it goes from there.

Chirag Talati: The reason I am asking is that one of the other first day filer received tentative on the 30-month deadline while you did not. Since it is a 505(b)(2) you should be receiving the tentative within 10-months or 12-months. Just wanted to know whether there are any queries or it is Srikakulam API or something else?

Abhijit Mukherjee: As I said, the audit took place in November, 7-months is a reasonable time to take whatever actions needs to be taken.

Chirag Talati: On these gross margins, can you help us understand the ordering and inventory patterns for your Injectable products. Do you have some sort of seasonality when you do primary sales to distributors? Does it go in certain quarters or it is smoothly spread throughout all four quarters?

Abhijit Mukherjee: Broadly smooth, except for when the calendar year opens up, it is a little heavy. Actually not in last quarter but the previous one. In this quarter, you need not read anything into any seasonality.

Chirag Talati: So, this should be sustainable more or less?

Abhijit Mukherjee: It depends on how the competition comes in, which is the biggest variable here.

Chirag Talati: The reason I am asking again is, we would have seen sequential declines in Russia and in Venezuela, both of which I am presuming are higher gross margin businesses than the US. Despite that, why is this sharp move in gross margins on sequential basis?

Abhijit Mukherjee: As Saumen mentioned first of all Injectables is one side. There is some consolidation of shares that has taken place in Isotretinoin as well as in other few other assets. I am not going to those details. Read this from this angle. For quite a few quarters, we are trying to make the business sharp, focused and value accretive. This is a philosophy. Now slowly, it shows up in terms of better margins. On the cost front, as Saumen mentioned, we have been controlling the cost, not by just by removing or shutting down something. That is not the only objective, there is a lot mechanization which is going on, which is leading to certain level of efficiency. One of the major factors of being so dependent on US is depending on what competition comes and what approvals we get. Now, that can change the balance. However, overall we are trying to make the business more focused, more value-accretive, not just in US. Europe, India, all these have also contributed to some extent.

Prashant Nair: I had a question on the PSAI gross margins. There seems to be an improvement on a sequential basis; second half last year was quite weak. Is this something lumpy related to product mix or shipments or is this now where we should assume gross margins to stabilize?

Abhijit Mukherjee: This would stabilize and improve slowly. There could be a little bit of variation quarter-to-quarter, but the clear direction is to make it much more value-accretive. This is a direction which we have chosen to take. There is also competitive advantage and we are trying to see what more value we can create for the internal assets as well. In fact other way round, a little bit of profit share, which earlier was received on certain products has gone down a little bit. The direction of the business is very clear in improving gross margin.

Kedar Upadhye: Thank you all for joining Dr. Reddy's senior management for Q1 Earnings Call. In case of any additional clarifications, please feel free to reach out to Investor Relations team. Thank you and good day.