Q4 FY'16 & Fiscal 2016

Earnings Conference Call Transcript

May 12, 2016

Kedar Upadhye:

A Very Good Morning and Good Evening to all of you. Thank you for joining us today for Dr. Reddy's Earnings Call for the Fourth Quarter of Fiscal 2016. 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; Abhijit Mukherjee – our Chief Operating Officer; Dushyanth – Head of Corporate Development & Sales and Marketing of Proprietary Products Business and the Investor Relations Team.

Before we proceed with the call, I would like to remind everyone about the Safe Harbor: This discussion will contain certain forward-looking statements which are based on management's current beliefs and expectations and involve a number of known and unknown risks and uncertainties that could cause our future results, performance or achievements to differ significantly from what is expressed or implied by such forward-looking statement.

For more detailed information on the risks and uncertainties associated with the company's business activities, please see the company's Form 20-F for the fiscal year ended March 31, 2015 and Form 6-K for the quarters ended June 30, 2015, September 30, 2015 and December 31, 2015 and our other filings with US SEC.

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 Key Financial Highlights: For this section, all the amounts are translated to US dollar at the convenience translation rate of Rs.66.25 which is the rate as of 31st March 2016.

Consolidated revenues for the year are at Rs.15,471 crores or $2.34 billion and grew by 4%. Consolidated revenues for the quarter are Rs.3,756 crores or $567 million and declined by 3% year-on-year. Revenues from our Global Generics segment are $465 million. As we had expected and in line with what we had discussed in our last call, this quarter witnessed a series of headwinds. This includes sequential decline in the rouble, moderation in the injectable offtake post higher third quarter and continued constrained operations in Venezuela. The North American Generics base business continued to be strong and domestic formulations business sustained. Revenues from our PSAI segment are $87 million and declined year-on-year by 22%. This reflects, in part, the impact of delay in dispatches on account of the on-going quality improvement activities related to the USFDA's observations.

Consolidated gross profit margin for the quarter is 56.6% recording an increase of 180 bps over that of the previous year. This is majorly contributed by relatively favourable business mix. Gross margins for Global Generics and PSAI were at 63.2% and 20.6% respectively.

SG&A spend, including amortization, for the quarter is $176 million, and increased by 15% year-on-year. As guided in our previous call, this increase is primarily on account of the ongoing quality improvement activities. Also, during the quarter, there was sizable outlay towards launch-related activities by our Proprietary Products business. This is for the launch of Zembrace, which has been already launched in April and targeted launch of Sernivo in the coming weeks. Normalized for these charges, the increase in SG&A relates to manpower and other spends and is marginal.

R&D expenses for the quarter are at $74 million, representing 13% to revenues vs 13.3% in the corresponding quarter of the previous year. This spend is largely in line with the ongoing set of developmental activities.

As you are all aware the Venezuelan government recently announced the long pending devaluation of the Bolivar. As per the announcement, the erstwhile official rate of 6.3 bolivars to a US Dollar is now devalued to 10 Bolivars per US Dollar. Over the year we have not received approvals to repatriate amount beyond $4 million. While we continue to engage with the Venezuela Government, however, in the interim it is appropriate to use the DICOM rate (i.e. 272.5 Bolivars per Dollar) instead of official 'preferential' rate (i.e. 10 Bolivars per Dollar) for translating the monetary assets and liabilities of the Venezuelan subsidiary as at 31 March 2016. Accordingly, the resultant impact for Q4 FY 16 and Fiscal 2016 is Rs. 431 Cr and Rs. 509 Cr respectively.

After considering the above adjustment, EBITDA for the quarter stands at $73 million which is 12.8% to the revenues. Normalized for this change, the adjusted EBITDA would have been 24% for the quarter.

Tax expense for the quarter is high, primarily on account of proposed distribution of profits by our subsidiaries and exceptional translational loss provision with respect to Venezuela. Normalized for these two, the annual effective tax rate is within the range as guided earlier.

Key Balance Sheet Highlights are as follows: Our working capital further decreased by $33 million during the quarter. Capital expenditure for the quarter was at $49 million. As of 31st March 2016, we have net cash surplus of $97 million. Our net debt to equity ratio is now at (-) 0.05. During the year we have generated Rs 2,668 Cr of free cashflows vs Rs 1,468 Cr generated last year.

Foreign currency cash flow hedges for the next 12-months in the form of derivatives and loans for US dollar are approximately $290 million, largely hedged around the range of Rs.64.4 to Rs.69.3 to the dollar. In addition, we have balance sheet hedges of $253 million. We also have foreign currency cash flow hedges of RUB 900 million at the rate of Rs.0.94 to the RUB and EUR 6 million, largely hedged around Rs.75.00 to Rs.82.05 to the Euro, maturing over next 12-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.

As you would remember, in the last call we had alluded to many external challenges and this quarter has been more or less in line with those. You would also acknowledge the trend of fourth quarter numbers witnessing a sequential dip in the offtake for US injectable portfolio, seasonal dip in Q4 across branded markets of India and Russia. Irrespective of these quarterly movements, I believe that the underlying performance across key geographies was quite resilient this quarter. Further, we continue to spend considerable amount of time and efforts towards ongoing quality improvement and risk mitigation activities.

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

Our North America revenues are $ 285 million and grew by 4% year-on-year. FY 16 revenues at $1.17 billion and grew 12%. As alluded earlier, the sequential dip is primarily on account of higher offtake of injectable products during the third quarter and marginal adjustment wrt the competition coming in valganciclovir. Overall we were able to sustain pricing and market shares across our key molecules. We further consolidated our market share position in metoprolol, sumatriptan auto injector and esomeprazole. Recently USFDA approved our ANDA and 505b2 filings of palonosetron. Overall, approvals have been an issue through the year - partly on account of the ongoing FDA matters and partly as an impact of the calendarization of our filings. However, we believe that the approval scenario to improve going forward more skewed towards the second half of the year. On the OTC front, Habitrol® is well integrated now and we have started working towards increasing the customer base and also expanding the overall franchise further.

During the quarter, macro-economic factors continued to impact most of our Emerging Markets territories. Despite these headwinds, in constant currency terms Russia business grew by 12% year on year in Q4 and 1% for the full year 2016. Through the year, focus has been to improve the productivity, broadening the product portfolio and entering new geographies by leveraging the current portfolio. Recently, we received the registration for our brand of rituximab, Reditux in Russia. We are now working towards the pricing approval and preparation for tender participation. In Venezuela, as discussed earlier, repatriations at significantly low levels and hence we chose to apply the official market exchange rate to record the translation loss that Saumen explained. However, we will continue to actively engage with the Venezuelan Government to provide affordable medicine to fulfil the need of people of the country, subject to repatriation of funds.

India business revenues are Rs 527 Cr and grew by 11% year-on-year. Portfolio acquired from UCB has been fully integrated into our supply chain. FY 16 revenues for India market at Rs 2,129 Cr and grew by 19%.

PSAI business posted revenues of $86 million and declined 28% year-on-year. This decline is primarily attributable to the delayed dispatches on account of the ongoing remediation activities. However, sequentially we grew by 11%. Our efforts are directed towards building a healthy order-book.

On the Proprietary Products side, post the final approval from the USFDA, we are happy to announce the launch of Zembrace. Sernivo will be launched in the coming weeks. We all are really excited about this new journey. This is a critical milestones in our bid to establish a portfolio of differentiated assets in the United States.

On the ongoing quality improvement activities, we submitted our first update to FDA on January 28, 2016, followed by the second one on March 30th this year, stating our progress towards sustainable compliance. We believe most of the commitments made to the agency will be over by this quarter post which we will request the agency for the re-inspection.

With this, I open the floor for Q&A.

Manoj Garg: Just trying to better understand your commentary around quality improvements. Can you update us on the remediation efforts at Srikakulam and the associated timelines there? Two, it sounds like you are pointing to an improvement in the pace of approvals in the second half of the year. So, in general, is that when you are expecting some resolution there? Three, lastly, we saw about 200 basis points of gross margin erosion Y-o-Y. The US guys are definitely talking a lot about price erosion. So maybe if you can spend some time and just update us as to what you are seeing in the marketplace in the US on the pricing front?

Abhijit Mukherjee: On the quality front, as I mentioned, post Warning Letter in the first week of November our first update went towards the end of January, and the second one towards the end of March. We are planning to provide the third update towards end of May, by which time very large part of the commitments we made, to the agency would be completed and soon after we intend to seek an audience and thereafter request for re-inspection. Beyond that we cannot comment and it is up to the agency when they would come and see. Broadly, as we had mentioned earlier, I think the resources spend, the management bandwidth put in is very-very substantial both from the manpower side and also financially. We feel quite good about the progress made while, of course, this is a journey. So this is on the quality.

Launches, as usual, we will not get into numbers, but this is likely to be certainly much better than last year. Last year was a very tepid year, and it is going to be brisk, a little loaded towards the second half starting second quarter. So, this is not to do entirely wrt the sites to come back or something of that sort, because filings are from various locations, and also launch through partner sites and so on and so forth. Of course, when I am making the comment that it is going to be a brisk year for launches, we are taking into account the uncertainties related to regulatory aspect, litigation aspect, but of course, based on reasonable assumptions - We are cautiously optimistic on the launches. Third, in price erosion, I mentioned that we have managed to contain erosion, but to give you a little more flavor on that - of course, there is the value erosion, but what has happened is by and large the same amount has been counterbalanced by increase in volume of the base business, which basically means that we had to adjust prices in a few, we gave up a little bit somewhere in some places, and we won several new bids as well, broadly, the two nullifying each other.

Manoj Garg: Can you give us a number in terms of what kind of pricing erosion that your base business is seeing in the US? Just a follow up on the regulatory. So this past quarter just gave us some confidence that the agencies are not concerned with the system wide issues. Were there any successful investigations this past quarter?

Abhijit Mukherjee: So back to the erosion, last couple of weeks have seen various companies talking of price erosion and we are pretty much in agreement with those figures. Standalone price erosion - high single digit, but as I mentioned the volume increase nullifying similar amount. So that probably broadly gives you some indication on price erosion. On quality and remediation, I gave you the brief about those three types. But, you are asking about more general things. Probably we mentioned in the last call as well that EIRs, most of other sites which were audited are coming in one-by-one and there is nothing adverse to comment at this juncture. Overall, one or two other sites got EIR, closure of audit etc. So we are not able to read anything negative.

Anubhav Agarwal: Recent deals that we have done on the Phase-III compounds, I just wanted to understand that is there a target that we are working in terms of next 5-years from this kind of division or do we have a target on how much we want to spend on this because when we had the R&D day, we did not even talk about this as a possible segment that we will target. So that appears that this is something new that we guys are pursuing now?

Dushyanth Surakanti: So broadly we have been building a significant pipeline organically across Medical Dermatology across multiple disease areas and also in neurology across Migraine, Epilepsy and Parkinsons. Our intent is to continue to prosecute these development stage assets and bring them to market to commercialize as we have shown success exemplified by Zembrace approval and Sernivo approval. So over the next five years, our goal is to continue with the success that we have demonstrated over the past several years and continue to address the needs of patients across these multiple disease areas. As far as our investments, they will be in line with the guidance that both Saumen and Abhijit have shared with you for these assets. As far as business development, those will be in line with our objectives of continuing to address the patient needs in these disease areas.

Anubhav Agarwal: Just following upon, the areas remain the same that we were doing so far in Proprietary Products, but the profile changes certainly now we are looking at moving away from the incremental innovation we are now looking at absolute innovation here. Is that a change in strategy? What prompted us to take the decision of absolute innovation?

Saumen Chakraborty: So it is still not absolute. It is still in the line of really taking care of under-met medical need. If you are really alluding towards - are we putting more capital allocation for Proprietary Products business segment to fuel growth for the company in the period beyond 2019 then yes, we are doing that. While bulk of it will happen through the organic R&D route, we have also tried to expedite early

commercialization opportunities as well as investing further on something which is in advanced R&D pipeline in a similar area.

Anubhav Agarwal: Just one clarity on the results also; the depreciation number that you guys report that sequentially have moved up very sharply by almost Rs.38 crores. What have you commercialized that such a sharp increase in depreciation, because our annual CAPEX is Rs.1,200 crores that cannot lead to such a sharp increase in quarterly depreciation of Rs.38 crores?

Kedar Upadhye: I think that is in line with some of the high value capitalization of some of our assets, some of those are in SEZ, some of those are in Hyderabad. It is a combination of both.

Anubhav Agarwal: But that will be captured in the Rs.1,200 crores CAPEX that is we are doing, right?

Kedar Upadhye: No, the Rs. 1,200 crores would be the cash flow, Anubhav. The capitalization converting CWIP into gross block, so that accounting charge would have created this kind of thing. I can connect with you separately, Anubhav.

Anubhav Agarwal: Sure. On the Venezuela write-off that was taken, is that all in the net interest cost number… is that all below EBITDA number?

Kedar Upadhye: A large part of that is in 'F' line. So we have chosen to follow this treatment for all the assets. So there is a part in the COGS line as well. Large part in forex line, little bit in COGS and SG&A. That is how it is split.

Anubhav Agarwal: How much was the number above EBITDA?

Kedar Upadhye: So when we compute EBITDA, we take the entire thing as part of EBITDA. So we only take out the interest and income from mutual funds out. But if you want the split - more than 85% is booked in 'F' line, balance 15% is booked in COGS and SG&A put together.

Girish Bakhru: First on Rituxan registration in Russia. Can you give a color on what size of the market that is and when do we expect the launch of the product?

Abhijit Mukherjee: Post the price registration, approval is there, so that is in the process. The tenders come with a certain calendar frequency. So we would not be able to comment exactly which one we would be able to catch, but the good news is the process has started. At the moment, certainly this will be few tens of million dollars for the company, but

beyond that how much will be the erosion, how much of this thing, very difficult to say.

Girish Bakhru: Just a clarification here; given the amount of sales BIOCAD's SLB is doing, I think it is in the order of over $100 million. Your number seems fairly low. Is it because it will take time to ramp up?

Abhijit Mukherjee: No, it is a tender market, fully government. This falls in the 7 nosologies as is called in Russia, so it will be fully covered by the government. First of all, we have to see which tender we are able to catch and what part of the year we are getting in. As much as we will try as quickly as possible. Secondly, there have to be certain correction in pricing based on the principles followed in Russia on how they would look at the various market pricing and so on and so forth. Naturally, the competitor would have to match similar pricing and no, it is not about share or anything, but pricing correction.

Girish Bakhru: Second on the FDA front. You said that probably your remediation will be over by end of the quarter. So when you are inviting FDA, ideally, one would assume you would invite for inspection for all three sites simultaneously, right? Is that something that you think is a very possible scenario that FDA visits all three sites together?

Abhijit Mukherjee: How agency would inspect sites, it would be difficult for me to comment. But your question probably is that, are the remediation activities going in parallel in all sites? The answer is 'yes'. Are they progressing satisfactory in all sites? The answer is 'yes'. When we go and meet up and request, we naturally would give overall three sites as well as our extension of many of those things in other sites, the whole picture and then it is up to the agency how they want to audit.

Girish Bakhru: On India, I mean given the growth that we saw last quarter, bit surprised by a lower growth this quarter. Any particular element why India did not do that well -- was there a particular impact from recent price correction in the market, any color on that?

Abhijit Mukherjee: One is the Institutional Oncology business was little slow in Q4 and second is quarter-to-quarter, the quarter end cutoffs vary to a certain extent. So that had some more impact. Not that much about all the confusion and turmoil that is there in the market, not so much. But overall, I do not read too much into the quarter. Overall, the year has been a robust year and this year also by and large mid-teens type of a thing is not unusual, we would look forward to it.

Girish Bakhru: So how much portfolio is currently under DPCO?

Abhijit Mukherjee: More or less our NLEM impact is in line with most of the peer group companies. Probably the first one we got a big hit when Omeprazole came in, but the rest ones, we are probably tracking a little bit lower than some of the peer group companies. The good news is, on the FDC issue which has been another topic, which is much in news these days - the FDCs which are not scientifically justifiable - our impact is almost negligible. It is not so much about the financial impact, but we are feeling good that it vindicates the scientific approach in our product selection.

Prakash Agarwal: Sir, a question on US business. You did mention that you are expecting approvals picking up from second half of the year and given the fact that the couple of your key products in the market has started to see some more competition. Would you be able to give some color on the US business panning out for fiscal '17?

Abhijit Mukherjee: In general term, I cannot give you again quantified guidance, but in general terms, yes, we have started with a little bit of a negative note. As you will know Valganciclovir, in March, went generic, fairly steep correction with just one player in. So that certainly has major impact. Generic Vidaza has also seen Mylan's approval and 505(b)(2) as well, but that is yet to be felt. There would be some impact, but certainly Valcyte was steeper. Regarding going ahead on the launches, again, I will say it will be a brisk year of launches, subject to all the cautionary notes and assumptions, etc. It is certainly going to be a year like what we used to see a couple of years back - series of launches, similar thing, but it will be little back loaded. The breakup would be probably about 40%-45% Injectables, about 40% Oral Solids and the balance being Patch and Cream.

Prakash Agarwal: So I mean given the fact that you already saw some margin pressure coming up and with the facts that you just stated on your key product seeing competition, so just trying to understand the margin trajectory as well?

Abhijit Mukherjee: As far as the last year was concerned, I told you that the fall in pricing was counterbalanced by volume gains. Since the year has gone past behind us, roughly about $100 million fall in prices, about $100 million volume increase counterbalancing each other. Now going into next year, as I said, Valcyte has an impact, but it all depends on the launches, some of them are not so bad and depends on how it pans out, the margin will play out. Look, the honest answer is it will be foolish to even put in a conjecture here… of course, we have a budget, but how North America generics work, in the phase of launches, there is always that possible upside and possible not-so-great upside. So margins I would not be able to give you guidance on that.

Prakash Agarwal: Some color on the Nexium pickup. Are you seeing the market really stabilized now… you do expect still some market share ramp-up? On the Copaxone update please?

Abhijit Mukherjee: gNexium for us at least there is some good news and there is some shakeup in the market because of Semlar issue in Bangalore. So, some part of the market got vacated and because our entire supply chain was pretty well poised, we could take advantage of it. Now I think it will play out in the next few weeks, we will see the shares, certainly we are going to have due share in the market. By the way, for Nexium, the pricing has eroded, but still attractive enough. On Copaxone, I think we will try and see whether by the end of Q2, we are able to comprehensively answer the CR, we are working towards it. So unless we see more unforeseen things and there is a whole deep characterization, some done here, some done in various parts of the world and various other locations, we are able to put in together, We will give it a shot whether by end of Q2 comprehensively, the answer is 'Yes'.

Manoj Garg: Abhijit, while you have alluded the generic pricing scenario in the US over the next one year, but just would like to pick your mind from a little long term perspective that how this whole thing is likely to play out once you start seeing the acceleration in approval and even people are talking about maybe potential combination of express strip at Walgreens. I just would like to see over the next 2-3-years how do you see the whole scenario panning out?

Abhijit Mukherjee: So life is going to be very eventful if I can say the least. Firstly, erosion at the bottom-end with multiple approvals coming in, impact due to ongoing expectations of the agency for everyone to ramp-up the quality levels. So these two would be a continuing factor in the whole game. To summarize, I think finally certainly where things were much better earlier when it was less crowded and one could get more upsides. Here unless the assets are good and I probably repeat what I have said all along that everything would be in the type of products which we file and get approval. In what timeframe, with the consolidated customer end, if you are very late, you can probably lead erosion of price, but you may not benefit in the process. So finally back to R&D and the productivity and success of R&D.

Manoj Garg: Abhijit, I think a couple of quarters back you have made a comment on Gleevec, like probably you are seeing the launch maybe a couple of quarters after Sun Pharma's exclusivity. Now, given the fact that Gleevec is there in the market and even Novartis has made a comment that they do expect 4-6-players post-exclusivity, where do we stand and do you see Gleevec probably launch this fiscal year itself?

Abhijit Mukherjee: This fiscal year, yes. Number of competition in between? Anyone's guess. 4-6? In our view is little high. Beyond that we would not know.

Manoj Garg: On your Proprietary portfolio, we understand like you have the dump field force. But with regard to your CNS, are we going to use separate field force or like probably you feel that the current field force could be good to even promote the CNS products as well?

Dushyanth Surakanti: For our Neurology portfolio, we have deployed a dedicated sales force for Zembrace. This sales force calls on primary migraine treatment providers. So this is a distinct force from the Dermatology sales force.

Manoj Garg: Can you share the number like how many reps or the people who are directly going to call the doctor?

Dushyanth Surakanti: Yes, the strength of the team is around 50.

Neha Manpuria: My first question is you alluded to having some remediation cost in this quarter. One, how much was this cost? Second is this all in the SG&A, is that the right assumption or there are some other parts where this cost is reflected?

Saumen Chakraborty: This is part of SG&A, so mainly it is consultant cost and it will be to the tune of around $20 million.

Neha Manpuria: Since we are talking about completing remediation towards the end of this quarter, I am assuming we will see additional cost in this quarter and then probably that will normalize?

Saumen Chakraborty: It will not become zero, but it will substantially reduce.

Neha Manpuria: In terms of R&D, we indicated that we are increasing investment towards our Proprietary Products portfolio and I read somewhere that our guidance still remains again 11-12% of sales and we are adding more assets. So, how should we look at R&D going forward? I would have assumed that this number would inch up as we are looking at more novel products now?

Saumen Chakraborty: Yes, if it is going to be successful then we take it forward, it may.

Neha Manpuria: But currently we are sticking to 11-12% guidance. Is that correct?

Saumen Chakraborty: It can go up beyond 12%, but it will all depend on the reaching milestone and being successful and taking it forward and accordingly we will decide.

Neha Manpuria: We have seen very strong cash flow generation this year of course even after a buyback we have a healthy balance sheet. How should we look at inorganic growth opportunities… are we evaluating and what would be our areas of interest?

Saumen Chakraborty: Buy-back process has started, it is not yet completed. Whatever has been earmarked for buyback, we will have to take it from the current balance sheet. But we have been focusing a lot on growth both organic and inorganic. So at any point of time there will be a few targets, which we are looking for, but at the same time as I have alluded to earlier, there are very strict set of criteria we apply. So if there is a meaningful target, we will definitely consider.

Neha Manpuria: Would US be our primary market of focus or we are open to doing deals in other markets too?

Saumen Chakraborty: India also will be very open if there is a good target available.

Surya Patra: Again, continuing on the R&D aspect, can you just give us some update on the Biosimilar portfolio for the advance market, what is the kind of a developmental progress that we have seen so far?

Abhijit Mukherjee: Nothing different from what we have been saying. The journey with Merck Serono is progressing satisfactorily. As I said that none of those launches are in near term. But while on that the clinical development is progressing satisfactorily on the assets.

Surya Patra: So those are like in Phase-III?

Abhijit Mukherjee: If you are talking of finally the launch it is still a few years away.

Surya Patra: As you have indicated in the initial remarks itself that you are seeing some price correction and all that in US and possibly that is the reason for a sequential decline in the gross margin. So should we consider that this is the kind of a new norm what gross margin that we are seeing for the quarter or even for the full year?

Saumen Chakraborty: Maybe a quarter or two before the new launches pick up as told by Abhijit in the second half of the year.

Abhijit Mukherjee: First two quarters, as you can guess from whatever we spoke so far, couple of assets coming under competitive pressure, our launch is a little more heavy towards the

second half, given this, naturally it is safe to assume a muted first half. Also the remediation costs which Saumen mentioned, some of it will come in this quarter and substantially do down thereafter.

Surya Patra: Venezuela side, after this kind of a write-back, so is there any kind of negative surprise still there or what is our stance on that, can you just give some clarity on that front?

Saumen Chakraborty: No, after these entire translation loss in Indian rupee terms all that we have is very negligible… less than in Rs.15 crores. So actually we have taken a complete provision. By chance if any repatriation comes, it could be on the reverse side then we will have to reverse the provision.

Surya Patra: The likely decline on the revenue side that would be how big on Venezuela side?

Abhijit Mukherjee: Last quarter, we did not sell anything, almost, because now here onwards the game is completely different, as we mentioned. We remain very-very focused to the geography, because we think there is opportunity, there we have signed two deals with two government organizations. They are keen to have the biologics in, because it is a win-win for them and for us, because we bring in healthcare savings substantial. So we will stay very-very focused. But only thing the game has changed that it is always established, advanced through certain route i.e. LC etc, before we dispatch. But we stay fully committed. In fact, President Maduro mentioned our company specifically that they are very happy to done a deal. That is all fine, but there is turmoil in the geography, so till we see business rolling in, we cannot bank on that.

Saion Mukherjee: On the Proprietary Products side, on the XenoPort asset, which you have licensed in, can you give us some indication on the timeline and cost involved in development for the drug for psoriasis and also for multiple sclerosis if there are any thoughts at this stage?

Dushyanth Surakanti: With regard to the clinical development timeline, our plan is to very quickly within this fiscal to initiate the Phase-III study. As you know, this asset had completed a large Phase-II. So our intent is to continue the momentum and enter the clinic very soon. As far as MS is concerned, we were able to incorporate that as part of the deal where we see it as an upside. So at this moment, we are evaluating the potential clinical design and strategy for that indication.

Saion Mukherjee: Just on the Phase-III trial, how long will that take in your view and what is the cost involved?

Dushyanth Surakanti: With regard to the timeline, we see this in line with those who have conducted psoriasis studies within moderate to severe patient population, that roughly is in the 18 to 24-months' time period. As far as cost is concerned, we also see that as in line with those studies required to get the label indication we seek.

Saion Mukherjee: Since you have launched Zembrace, any initial feedback that you have?

Dushyanth Surakanti: We have only been on the market for a couple of weeks, and the feedback from our constituents, physicians and patients have been very positive as far as data and scripts, that take some time to go through adjudication and the reporting databases have a lag. So we do not have that data as of today.

Saion Mukherjee: On your gross margins, if I see the material cost as a percentage of sales, they have in fact come down little bit Q-o-Q, the other expenditure as part of COGS has gone up substantially. So what is the nature of that expense if you can just explain that?

Saumen Chakraborty: So one will be the business mix, which is there. If you see the Global Generics the pie is much higher, then the weighted average gross margin for the company becomes significantly improved, compared to if the PSAI business mix moves up, then it goes in the reverse way.

Saion Mukherjee: Abhijit, you mentioned about the kind of launches you are looking for fiscal '17, and as we move into fiscal '18, will the mix more or less remain same like 40-45% Injectables or you think there would be more of Injectables and Patches as you go into FY'18? Also in terms of number of launches, how would FY'18 compare to FY'17?

Abhijit Mukherjee: FY'18 would be early to comment, because naturally there are always every year some overflows from the early year to next year, but the nature would be somewhat similar, the makeup of the whole thing and I said about 40-45%, it should be the same range. That itself is very high given the fact that overall the generic portfolio worldwide is 80% Oral Solids, and the rest is all between injectables, topicals, devices and other things. So this itself is substantially skewed with a purpose and a design and I think broadly if we can maintain a similar one, I think we should be good.

Abhishek Sharma: I just had one around your commentary on the prior year's change in the US dynamics. You said that there was fall in prices and then that was compensated by volumes. Just wanted to understand where exactly did you see this volume uptick -- was it in the same products where you saw the price erosion, or was it a different set of products and whether that could be extrapolated to the next year?

Abhijit Mukherjee: There are two parts of the volume increase. Actually volume meaning eventually translating to value. The first is some supply failures by the other competitor companies. That would account for a significant part, which happened to be in the portfolio and our supply chain is geared to take it. As you know in US, someone may have supply failure, but you need to have the supply chain robustness to swiftly capitalize, because no one is waiting for anyone. So that has been one part. The second part is of course some companies as you know going to piecemeal here and there, some win in the bids added up balance.

Abhishek Sharma: So it was largely on account of disruption at competitor?

Abhijit Mukherjee: I do not have an exact breakup, but I am just quickly trying to put things together, yes, reasonable part of that is supply failure.

Abhishek Sharma: In the RoW ex of Venezuela, would it be fair to say that your business has grown at (+25%) kind of a number? My rough calculation gives me a very high number.

Kedar Upadhye: So the RoW outside Venezuela is largely Australia, South Africa and a number of small-small markets. There has been a currency hit there as well. I think the local currency number could be double digit, but eventually in rupees it is smaller.

Chirag Dagli: As you look at your US portfolio in FY'17, do you think price erosion for the base business will be much larger than in FY'16?

Abhijit Mukherjee: So, again, erosion per se without taking into account new launches, etc., certainly will be higher, because as you have said itself is for a reasonable hit. So the answer is yes, and hence it is important that we have the launches.

Chirag Dagli: Post our entry in Russia for Rituxan, what will be the price discount versus the innovators product at the final level once we are in the market?

Abhijit Mukherjee: Sir, actually the market is more with BIOCAD actually as you know. Earlier in the call someone mentioned some figures. So there would have to be a discount and it is a partnership launch. So I gave a rough indication of low tens of million on an annualized basis. So let us see how it pans out.

Chirag Dagli: What would be our CAPEX for next 2-years?

Saumen Chakraborty: Around Rs.1,200 crores for FY'17, maybe a couple of years it could be at that level and after that it may come down.

Chirag Dagli: My only point is that last three years CAPEX has been significant, so have been the R&D investments. If you can give us some color of what broad buckets does this CAPEX say last couple of years and the next couple of years' broadly fit, where do they fall, what is this CAPEX for?

Saumen Chakraborty: When we really launched our Injectable business, it was all getting outsourced from others. Then we have developed the whole capacity in-house now, then, we have also built up facility for topical, others that we did not have. Even on OSD side, the requirement to expand the capacity, because you cannot have a capacity constraint when there is an opportunity in the market, because if you cannot cash on opportunities, then it is a double whammy. Also, going forward, there will be requirement to expand our Biologics capacity, particularly, on the Emerging Market perspective if there are more and more countries if you are going to get approvals. There are CAPEX also in other areas, for example, we are considerably stepping up investments even in IT, more from robustness of quality, some automation, and then even on the cyber security perspective. So, all these add up to that.

Chirag Dagli: Do we continue to do business in Venezuela?

Saumen Chakraborty: As Abhijit already said, we are very actively engaged with the Venezuela government. There are two contracts, which have been signed with both government companies. Only condition to the contract is that, we will dispatch only when we get either the LC or some advance. The moment we get we will then have that business there.

Chirag Dagli: Then the profits on that business will be converted at this lower rate or at the higher rate, sir?

Saumen Chakraborty: No, the thing is now we always position ourselves as a company coming from India where the medicine is more affordable; accordingly, our pricing will be on that. So far as the thing is there, it is on official preferential rate and when we get LC and thing, it will be on the preferential rate.

Abhijit Mukherjee: So, these contracts largely will be in US dollars, simply put.

Chirag Dagli: We will continue to record at the higher rate and then we will wait and see if we get the money?

Saumen Chakraborty: No, what Abhijit is saying - the contract itself - the money that we get we will straight away get the dollar(s). So there is no need to have Bolivar and then have a particularly rate of translation.

Surajit Pal: Could you please give some idea that if remediation cost is not there, how much benefit could be seen in EBITDA margin? What could be your effective tax rate in FY'17 and FY'18? Number of site transfer you have done till date or in FY'17 where you could expect or that could help your launch in FY'17 and '18 as planned?

Saumen Chakraborty: It will be very easy for you to compute what would have been the EBITDA if you take out that $20 million that I alluded to for the remediation cost for the quarter. Then in terms of the effective tax rate even for this year, it was within 21% to 22% as I explained earlier. The adjustment which has happened because of two reasons -- one is this whole translation loss (provision) wrt Venezuela; other we look forward to repatriate some money from subsidiaries. So that changes your tax rate.

Abhijit Mukherjee: About four or five have already been executed in the site transfer, one or two approved, few already submitted and as we speak some executed and (few more) just to be in the process of being submitted. Whatever we have lost we lost, as I said last time. But going ahead we are trying to mitigate the balance.