Dr. Reddy's Laboratories Limited
Q2 FY 2016
Earnings Call Transcript

Kedar Upadhye:

Good Morning and Good Evening to all of you. Thank you for joining us today for Dr. Reddy's Earnings Call for Second 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 and Abhijit Mukherjee – our Chief Operating Officer along with the Investor Relations team.

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

Now I would like to turn the call over to 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 the convenience translation rate of Rs.65.50, which is the rate as on 30th September 2015.

I am happy to announce the highest ever sales and EBITDA achievement by Dr. Reddy's in this quarter. Consolidated revenues for the quarter are Rs.3,989 crores or $609 million and grew by 11% year-on-year and 14% in constant currency. Revenues from our Global Generics segment are $500 million and grew by 15% year-on-year despite currency challenges faced by Emerging Markets geographies. The growth story is primarily led by US, Europe and India. Growth in US was aided by new product launches including Habitrol. Europe business grew on the back of recent launches and India business continues its growth journey which also included full quarter contribution from the brands acquired from UCB. Revenues from our PSAI segment are $90 million and marginally declined year-on-year by 7%.

Consolidated Gross Profit margin for the quarter is 61.3% versus 58.5% in the corresponding quarter of the previous year. Corresponding values for Global Generics and PSAI are at 67.3% and 25.8% respectively. Current quarter gross profit margin is indicative of the improved product mix and operating leverage of the manufacturing overheads.

SG&A spend, including amortization, for the quarter is $169 million and marginally grew by 4% year-on-year. Overall, we are able to derive the benefit of operating leverage as the SG&A as a percentage to sale came down to 27.7% on the back of various cost control initiatives that we have referred to in earlier calls.

We continue to invest aggressively in R&D. R&D expenses for the quarter are at $68 million, representing 11.2% to revenues versus 11.5% in the corresponding quarter of the previous year. EBITDA for the quarter stands at $174 million, which is 28.6% to the revenues. Tax rate for the quarter is 21%. Effective tax rate for the year is expected to be in the similar range.

Key Balance Sheet Highlights are as follows: Our working capital marginally increased by $7 million over that of the previous quarter and is largely in line with our expectations. Capital expenditure for the quarter was at $45 million. Our net debt-to-equity ratio is 0.02.

Foreign currency cash flow hedges for the next 18-months in the form of derivatives and loans for US dollar are approximately $300 million, largely hedged around Rs.61 to Rs.65.4 to a dollar. In addition,

we have balance sheet hedges of $135 million. We also have foreign currency cash flow hedges of Rouble 960 million @Rs.1.16 to a Rouble and Euro 6 million largely hedged around Rs.75.47 to Rs. 77.185 to a Euro, maturing over next six 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.

Overall, we are quite satisfied with the performance of this quarter, considering the multitude of challenges faced across the businesses. US business continues to face competitive headwinds on base portfolio coupled with lower number of approvals. However, we were able to sustain the momentum in injectables and other key molecules which supported the performance. Emerging Market geographies sustained the performance despite the continuing sluggishness in respective markets. Second quarter performance in Russia was healthy compared to the significant year-on-year decline in the first quarter. India business continued its predictable growth journey.

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

Our North America revenues are $ 290 million and grew by 26% year-on-year. This can be attributed to low base effect to some extent and sustained pricing and market shares for most of our molecules. As you are aware, we launched Esomeprazole this quarter, although revenues will start reflecting from next quarter onwards. In view of lower number of launches in the balance part of the year, we need to be wary of competitive pressures on the base portfolio. On the OTC side, Habitrol is well integrated now and we continue to target new accounts.

During the quarter, impact of macro-economic factors prevailed on most of our Emerging Market geographies. In this situation, the team is focusing on broadening of product portfolio in existing countries and entering new countries through leverage of our global portfolio. Russia revenues are $45 million for the quarter and declined 29% year-on-year. However it grew by 11% year-on-year in constant currency which is a significant change compared to 22% year-on-year decline in the first quarter. On Venezuela, we continue to be cautious and have calibrated our supplies. The focus is on building a business model which can outlive the current macro-economic situation.

India business revenues are Rs 546 Cr and grew by 14% year-on-year. Portfolio acquired from UCB has been fully integrated into our supply chain. Because of transport strike in quarter end and a week-end around the date of cut-off sales, some part of our despatches spilled over to the month of October. Normalizing this impact, the overall growth is very satisfactory and in line with the recent trend.

PSAI business posted revenues of $90 million with a marginal decline year-on-year. You would notice the sequential gross margin improvement of approximately 200 basis points. We are building on our order books. We are calibrating the business in an attempt to derive more value out of it.

Before I end, I would like to give an update on our API facilities. We have learnt that during the month of October 2015, two of our API customers received ANDA approval rescission letters from the USFDA. These ANDAs of customers were approved in January and February 2015, post USFDA's inspection of our API facilities. Each rescission letter cites that our API facility was classified as 'Potential OAI' on the date of approval of ANDA.

We continue to cooperate with the US FDA in connection with the pending form 483 observations and await further advice from the agency on this matter.

We take the matters of cGMP compliance very seriously and are investing significantly in terms of resources and managerial bandwidth to strengthen our quality processes, operations and culture across the organization.

With this, I open the floor for Questions and Answers

Balaji Prasad: My first question is on Srikakulam. Considering that the ANDA approvals have been rescinded for your customers, does this change your thoughts on the progress that you thought you had achieved or potentially where you are thinking of approaching the FDA for re-inspection?

Abhijit Mukherjee: We do not know. This is for declaration. We received this in the month of October and we thought it is important to let everyone know. These were approved after the audits in the facilities and out of the two assets, one asset we ourselves did not get approval. So we were pleasantly surprised to see someone else got approval. But I think this is being corrected and hence the rescission letters have come. But the rescission letters clearly mention 'potential OAI' which is certainly a concern for us. We continue our journey, we are updating US FDA, we are putting in significant resources in improving systems and quality. But when will the audit happen, what is the next course of action, really cannot comment on it.

Balaji Prasad: Can you also just help me understand, if what exactly does FDA mean by potential OAI? They have three levels of classifications of the inspection observations. Where does the potential OAI stand in that sense? Is this an internal FDA classification?

Abhijit Mukherjee: OAI stands for 'Official Action Indicated'. This basically means that they are considering the observations. This is a standard term. This is not something which is specifically designed for this thing, which in any case you are aware that we are not getting approvals from the facilities. So in that context that classification is expected. How they (FDA) will move ahead in future is more important which is still unknown to us. We are engaging with them and at the moment we cannot comment on it.

Saumen Chakraborty: Actually, he was asked, what does it stand. Actually, if it is voluntary it is better.

Balaji Prasad: Yes, Saumen, so what I was trying to understand was if this is a new classification or something that the FDA uses internally and…

Saumen Chakraborty: They use internally.

Abhijit Mukherjee: There is VAI which is Voluntary Action Indicated and there is OAI which is Official Action Indicated. These are the normal terminologies and is not anything specific for us.

Balaji Prasad: My second question is on Venezuela. It seems that there is a change in your stance from before when you were quite willing to grow albeit calibratedly. Now you are saying that you are more cautious. What drives that change? And secondly on Venezuela itself, where are your current receivables now and how were the progress in the last three or four quarters?

Abhijit Mukherjee: The cautious approach comes from the fact that we have not received anything meaningful after our last discussion which automatically leads us to be cautious. We will not exceed certain levels. We are sticking to that and at the moment we will not be producing anything more but we have some stocks at the moment. In a calibrated way we are selling in the market and if we do not get remittances before that runs out we will have to slow down or even phase out. But the important update which I want to share with you in this context is that we have signed a deal with part of Government of Venezuela on some critical care products which they want tech transferred into one of the facilities which in turn will reduce their healthcare cost and also provides us a new line of business which of-course will be government assured business. If that helps us in recovering the money which is not being remitted, then the whole thing starts all over again, but we are still optimistic but much more cautious from our last update.

Balaji Prasad: Just on that question itself, I asked how have the receivables progressed in the last couple of quarters?

Saumen Chakraborty: Currently, it is standing at around $60-61 million.

Nimish Mehta: First of all, if you can just explain the sharp increase further in gross margin that will help? Is it because of the currency where we have seen US dollar appreciating quite a bit quarter-over-quarter or what is that?

Abhijit Mukherjee: I think largely it's the strength of the portfolio. We have been fortunate that our US assets to have sustenance of the portfolio and there were launches in second half, a few of them built shares, there were some products where we

have gained market share. Of course, consolidation of the channels have led to some erosion as well, but broadly the margin consolidation is business-oriented, there are a few smaller issues which have also helped, but largely it is business-oriented.

Saumen Chakraborty: In fact, business mix also contributed and there has been some leverage out of the manufacturing overhead, specifically yield improvements and all – which has also contributed.

Nimish Mehta: Further real improvement over the last quarter?

Saumen Chakraborty: Yes.

Nimish Mehta: On the US pipeline, we have seen that the case against Novartis on Gleevec has been settled. So, if you can please help us know the date of the launch of that product that will be great?

Abhijit Mukherjee: We will not be able to share the date. Sun and we have settled. Certainly, being the company having settled after Sun the date is a few quarters after Sun's launch. But beyond that we will not be able to give you an exact date.

Nimish Mehta: Do you expect this to be a potentially big launch for you as in you expect more competition, some color would be...?

Abhijit Mukherjee: It depends on how many other people are there. There are other filers and I am sure they are also negotiating. We do not know, it is just not in public domain and there could be other settlements as well. If everyone settles at various dates and as usual like in all generic assets, the value will be lower than what we think. Certainly, it is a big product for Sun but for us I cannot comment.

Nimish Mehta: Will this be bottlenecked because of the Srikakulam facility or this is from a different facility?

Abhijit Mukherjee: No, it is not. The API is from another Indian source.

Nimish Mehta: The second product I wanted to know was about Fosamax Plus D, that is Alendronate plus Cholecalciferol, where again there are no patents, but any timeline regarding your launch would be helpful.

Abhijit Mukherjee: Are you talking of North American market?

Kedar Upadhye: We would not be able to comment on the product.

Nimish Mehta: But is it going to be an important product for you? Some color would be helpful.

Abhijit Mukherjee: Not to the best of our knowledge.

Prakash Agarwal: A question first on the US business. You talked about some market share gains, but if I could see your key assets, which is the Injectable portfolio, Dacogen and Vidaza, there as per the data it seems like market shares have dropped. So, are we seeing that or the other ANDA approvals have seen market share gains and maybe Injectables are coming off, if you can throw some light there?

Abhijit Mukherjee: gVidaza, the drop is fairly negligible, in fact you can read it as error in the quarter-to-quarter movement. However, Dacogen, yes, there is some drop but we are fortunate that we are where we are actually. So it is still pretty high and sustaining. Let us see how competition comes in and there are other few products which have also done well. Sirolimus is scaling up, a few other products as well.

Prakash Agarwal: Would it be fair that there has been price hike across the portfolio given that not much of approvals, but still we are sustaining this run rate despite some base business price erosion due to channel consolidation?

Abhijit Mukherjee: Nothing significant.

Prakash Agarwal: Moving to Russia, we saw very positive commentary about 11% constant currency growth and some demand coming back. So exactly what is happening there? Our understanding was due to oil crisis, demand has also been weakened. So, are you seeing demand coming back or it is more of

channel filling again and it is one time or is this sustainable constant currency growth?

Abhijit Mukherjee: I think the turmoil is over. That is the good news. There was complete chaos when the currency broke the barrier and got devalued and that led to confusion in the market. Retail trade trying to increase prices, so basically on a wallet which was getting leaner it was a double whammy. Since then the channel has corrected. We have increased the channel connect and the sanity is back. We always did reasonably well in Russia. For Q3 on a Y-o-Y basis you may still see the currency devaluation impact but from Q4 we will see the usual business. The base naturally will have to get calibrated with the new dollar rate but certainly the geography is getting back.

Prakash Agarwal: On the Nexium opportunity, I saw some comment from the management about the expectation. So if you could give us broad ballpark how do you think about this asset because I believe that some competition is building up?

Abhijit Mukherjee: We being the fourth player we have just about fair share. Erosion has been there, no doubt. Certainly, we would have liked to get in a month back which probably we would have - had the Srikakulam thing not come up. But it is still a sizable asset for us, pretty sizable and hope that it sustains with more players coming in. Hope it sustains.

Prakash Agarwal: There is a comment about $50 million?

Abhijit Mukherjee: North of that, annualized.

Prakash Agarwal: On the SG&A side we have seen substantial improvement. Is there any currency related savings, how should we think about it going forward, because the business is growing across the board?

Saumen Chakraborty: Some of the things is a result of all the initiatives we have been taking in terms of cost control. If you compare amongst the peers our SG&A cost, as a percentage of sales, has always been on the higher side. There are still lot of opportunities in terms of improving the SG&A productivity. We are mid-way but we are taking actions on all fronts, in terms of manpower, on sales and marketing expenses, on travel, freight and multiple aspects we have been

trying to improve. So far we are happy. There is 200 basis points improvement in terms of SG&A as a percentage of sales.

Q Prakash Agarwal: This is sustainable?

Saumen Chakraborty: We hope so.

Neha Manpuria: My first question is on the comment that you made on the EM front we are probably looking at one, broadening the portfolio and also possibly entering new markets. So two part question there; one, what are these new markets that we are looking at? And would that strategy be more organic-driven or are we looking at potential M&A to build that presence in your markets?

Abhijit Mukherjee: Two markets which we have already gone ahead in an organic way to build a little bit of skeletal team and filing product is Brazil and Colombia. Largely we will be targeting the institution sector. We are banking on oncology and other institution products which we already have in the global portfolio. So that is one organic approach. But we will certainly look at inorganic opportunities. To supplement that nothing to report as of now. Apart from that on Emerging Markets we are trying to look at also Biosmilars. Now we are beginning to have more data on some of the products and some of the regulatory bodies are willing to accept the files. We would scale that up. May not be meaningful in a very short term other than Russia, may be in a few quarters. But that is a key initiative in the Emerging Markets.

Neha Manpuria: On the US, if you could just highlight what has been the base business price erosion that we have seen so far versus last year given the ongoing consolidation, etc.,?

Abhijit Mukherjee: Reasonably steep. Some products where competition coming in, one being Divolproex ER, has seen substantial erosion of value. Some of it will play out in the second half. Apart from that the channel consolidation is also leading to a fair degree of steeper ask from the channel which is becoming a bit of a challenge not just for us, but for most generic companies. So all that is playing out. There are some headwinds, for sure, for all companies.

Neha Manpuria: Would this be in high single-digits, would that be a fair assumption or probably low-double digits?

Abhijit Mukherjee: I would not put a figure. Probably you are talking to most companies, draw an average from what you get between the lines.

Neha Manpuria: You highlighted some amount of slippage in the India business into October would you want to give some quantum as to how much this was?

Abhijit Mukherjee: Roughly, what we are reporting is 14% would have been close to 20% and equivalent amount will flow into Q3.

Surya Patra: Just a clarification; whether we have seen any price correction sequentially in the US portfolio?

Abhijit Mukherjee: Happening product-by-product depending on whichever product is seeing competition. There are approvals coming up which are pretty old once in a while. Whenever that falls in the category whichever company is in, it is either a correction and retention of the account or giving up the account. So those things are happening. The impact is varying between companies and so far we have been by and large okay except for the product we mentioned and a couple of other smaller products. But going ahead this will intensify I am sure.

Surya Patra: Broader base business whether can you say that what is the kind of the decline or whether you have seen or not seen sequentially price correction for the broader portfolio, mature portfolio?

Abhijit Mukherjee: Yes, to a certain extent it is happening again product-by-product.

Surya Patra: Apart from the Srikakulam API unit whether we have any other API unit which is capable of developing or manufacturing these Injectable products, Sterile products?

Abhijit Mukherjee: There is nothing about Srikakulam where this injectables will have to be manufactured. APIs are APIs. They can be made in whichever site. If it is an Oncology product we have another factory there is oncology product. The third oncology factory is being set up in our SEZ which is due for audit

hopefully in six to eight months' time. All these are flexible and fungible to some extent.

Surya Patra: Last quarter we have commented one aspect that after having filed a site transfer application for 5-odd ANDAs or drugs, so we are seeing the Srikakulam unit has been derisked. So whether considering this recent development on that particular plant front, so we are maintain the same stance?

Abhijit Mukherjee: I do not exactly recall 5, but for the future approvals we are continuing site transfers. We are concerned. So irrespective of derisking, irrespective of any issue. We have to mitigate and move on with life. As a company we want to be ahead in terms of all compliance aspects. So this is an area of concern for us for sure. Mitigation and all that is a separate issue in terms of derisking. Those things are going on, that is part of business.

Surya Patra: We have recently settled the generic Aloxi ANDA with an innovator…?

Abhijit Mukherjee: You are talking of the 505J. We have two files. One of 505(b)(2) and 505J.

Surya Patra: I believe the NDA opportunity is still there in the second half?

Abhijit Mukherjee: It is not in the second half. That was what we thought originally a couple of quarters back. The litigation is getting delayed and as much as we are trying to bring it up but everything is not in our control. So, we would like to bring it up as and when possible, but certainly second half is not possible.

Surya Patra: Definitely, it is much before the settlement date for the Generic product?

Abhijit Mukherjee: Depends on the litigation. If we can bring it up and at least now it is a very strong thing to pursue. But till it comes up we would not be able to comment on it.

Surya Patra: Any update on Xeloda or Diprivan, why we are not getting the approval for that?

Abhijit Mukherjee: gXeloda is CTO6 impacted as probably mentioned last quarter. gDiprivan, the file is in progress. Again, cannot really comment, but may be two quarters more if everything goes okay.

Girish Bakhru: First was on the Europe side. Given that we have interaction improving on back of few launches, can you share some color on if there are more launches planned for Europe, how is the pipeline looking there?

Abhijit Mukherjee: We are selective now. There was a time when we were trying to launch anything and everything - going after tender business etc. But all that is gone. So Fondaparinux could be the next one and a couple of others to follow in the next couple of quarters.

Girish Bakhru: Where does Copaxone fit in Europe?

Abhijit Mukherjee: The guidance is not very clear, we are not pursuing copaxone for Europe, let us try and sort things out in US first.

Girish Bakhru: But, is it true that you have launched copaxone that in some of the emerging markets?

Abhijit Mukherjee: Not the product.

Girish Bakhru: So you are saying that for Europe you are not at all pursuing at the moment?

Abhijit Mukherjee: Not at the moment.

Girish Bakhru: The second one was on the Fonda again. You recently bought the IPR. What was the rationale behind that?

Abhijit Mukherjee: There was profit share with this company and the profit share was in the range of middle to high single digit. So compared to that we thought the value we paid was reasonable. More importantly we wanted to move on. we wanted to take this asset to various other markets. It is an interesting asset in all Emerging Markets.

Girish Bakhru: If you could also update on the NDA filings given that PDUFAs are approaching closures. So, any update on the proprietary products?

Abhijit Mukherjee: Assets are progressing well. So far nothing negative to report. One of the assets has a little bit of litigation, but otherwise assets with the agency progressing well. I think by January - February we should probably be able to share more about it.

Girish Bakhru: And you are confident again that Srikakulam will not have any bearing on the event?

Abhijit Mukherjee: These are all linked to CMOs in US. So none of these three assets have an issue.

Anubhav Agarwal: Can you update on progress of copaxone application with FDA? And any potential delay in Srikakulam clearance, will it impact the progress or you have already site transferred that product?

Abhijit Mukherjee: So in the scheme of things, the bottleneck is resolving the characterization expectations. We are still working on it and it will take some more time. Site transfer can be faster and easier and being planned, but I think in the scheme of things the bigger science challenge is the bottleneck at the moment.

Anubhav Agarwal: Roughly I know it is tough, but can we even get approval of this product in FY17?

Abhijit Mukherjee: That I would not be able to comment, we will take certainly, at least, a couple of quarters to resolve the issues and then we respond and then let us see how that goes there on. So 2-2.5 quarters at least for us to resolve and hopefully respond.

Anubhav Agarwal: On Aloxi 505(b)(2), let us say if you win the litigation, it is approved, you launched, will it be a substitutable product?

Abhijit Mukherjee: It's in litigation. I would not comment on any of these things at the moment. We are pursuing it actively vigorously, but again litigation date is not in our control of pursuing it. I understood your question, whether it is equivalent or not, we hope it will be. So that is an agency decision. We will see.

Anubhav Agarwal: And just one more clarity, on SG&A year-on-year increase is 4%, but if you can just roughly indicate what would be the constant currency increase in SG&A?

Saumen Chakraborty: Around 1% difference will be there.

Ranjit Kapadia: My question relates to the FTF Para-IV and out of which 18 FTF opportunities. If you can throw some light, what is the potential market size for this? My second question relates to the Indian business. We have integrated the UCB business and we said that we have some of the 6% of revenue have been delayed because of the transportation strike. So what sort of growth is expected in domestic market going further?

Abhijit Mukherjee: The first question will be a difficult one to answer because it depends on which product you are talking about. Not that we will be able to immediately give you a percentage or whatever the expectations of the asset. But FTFs can be multiple entry FTFs, FTFs can be single entry or a dual entry, all depends on which asset, which product you are talking about. Overall this year understanding your question, I think this year we will be filing at least 30% more products than what we did last year. Coming to India, I can tell you about this quarter. This quarter read 14% as more close to 20% based on the spillover. Q3, again, I would not exactly give you the percentage growth, but momentum is strong.

Sameer Baisiwala: Abhijit, is it possible for you to tell us what is the outlook for the US business over the next few months and few quarters in terms of new approvals?

Abhijit Mukherjee: Not very exciting, as I have already mentioned. I think there will be hopefully a few approvals, but you know well the US market, it is not a number of approvals but 'what approvals' actually. So if you do not have headwinds in terms of competition, it is probably the best tailwind we can have.

Sameer Baisiwala: If I remember correctly, a quarter back you said that you have three to four niche products for which you may get approval and they are not linked to Srikakulam and with niche I imagine they are meaningful products. Does that stand or that does not?

Abhijit Mukherjee: Some of them are litigation - one we just discussed. Litigation is getting delayed. Initially, we thought some of those will come up this year, but litigation is getting delayed. There could be one or two approvals, but as I said, "is it extremely exciting?" probably not in the second half.

Sameer Baisiwala: When do you expect it to get better -- is it four quarters away or what would you say?

Abhijit Mukherjee: Next year is not bad. There are some P3s which I cannot discuss. Some P3s and P2s which are not in public domain which is not bad, but again, I am shy of really predicting anything because there is so much of uncertainty on approvals etc., but next year is not really bad.

Sameer Baisiwala: And there are some a couple of products, which is one is on Gleevec. You said that you are settled to launch a few quarters after Sun. I would have said you had said two quarters after Sun, no?

Abhijit Mukherjee: Never said two quarters - I said 'few quarters'. So certainly not close to Sun. Beyond that I would not say. There is a quite a reasonable few quarters gap between Sun's launch and our launch. And there could be other thing between as well, I do not know, because not everything in public domain, there could be other negotiations, cannot comment on that, but this is a great product for Sun as I said and I do not know what it will be for us, but stay optimistic.

Sameer Baisiwala: Second is on COPAXONE. Are you doing the characterization work and site transfer simultaneously or would you do site transfer after two quarters?

Abhijit Mukherjee: The bottleneck is characterization we are working very hard on it, not just internally, but through several partners and several we will get there. Site transfer would hopefully not become the bottleneck.

Sameer Baisiwala: On Srikakulam, the existing business that you are doing from there and I imagine there are a couple of very important products. Have they been derisked?

Abhijit Mukherjee: Certainly, one or two, yes, but that is not something which is not immediately for consideration.

Sameer Baisiwala: Abhijit, just on that, if God forbid, if you get an import alert over there, what could be the magnitude of loss of existing business that you are running currently in the US.

Abhijit Mukherjee: So we would not quantify that, certainly not. Because this is not probably the right time to think in that direction, I thought you are a well-wisher. So let us do the right things, let us work on it and then let us see what happens.

Manoj Garg: Abhijit, like apart from Srikakulam, do we have any pending 483 on any of other facility as of now?

Abhijit Mukherjee: So there are pending 483s on a few other facilities as well. We are engaging and being addressed.

Manoj Garg: Saumen, if we look at in terms of Venezuela, and we see the sequential numbers, I think that hit which you have taken on account of the exchange conversion it is almost 40% of what we have taken in Q1. So is it fair to assume that probably the supply which has gone this quarter in Venezuela was 40% of supplies which we have made in Q1?

Saumen Chakraborty: Yes, supply has been less, I will not say exact proportion.

Manoj Garg: Ex-UCB in India, there would have been the growth for the base business adjusting to whatever the postponement of supplies or dispatches, like we are seeing the 20% growth including UCB. If we exclude UCB, what could be the growth?

Saumen Chakraborty: It is quite decent. UCB when we acquired we had in mind some kind of annualized about Rs.150 crores. So we are proceeding in that direction to get that.

Chirag Dagli: Have we taken any price hikes in Russia or in the CIS countries?

Abhijit Mukherjee: Yes, one or two megabrands we have.

Chirag Dagli: So when you say this 11% constant currency, how much would this have been impacted by in terms of pricing?

Saumen Chakraborty: Mostly, it is volume growth.

Abhijit Mukherjee: Exact percentage I will not break it up, but it is a mix of volume and pricing.

Chirag Dagli: But you have been able to take some price hikes?

Abhijit Mukherjee: The law is essential drugs cannot be price hiked, but non-essentials you are free to take a price hike.

Chirag Dagli: On Gleevec, post the 180-day or whenever you are expected to come in the market, do you think in your assessment this will be like a multi-player market meaning more than three, four, five players in the market or do you think there will be a phased out kind of generic entry?

Abhijit Mukherjee: Enough data is not there in the public domain. There are filers as we know. So what is happening and the negotiations, etc., we exactly do not know. Some people may be pursuing litigation. The scenario has not been clear. Certainly, there will be more players for sure, but I do not have the answer.

Chirag Dagli: In your assessment, how many filers would be there?

Abhijit Mukherjee: Again, 4-5 at least I guess, but when and how they would come in, I cannot really say.

Prashant Nair: I had a question on the PSAI margins. I think you alluded to it briefly in your opening remarks. So how sustainable are the levels achieved in first half? The reason I am asking is I think last year also first half was (+20%) and then it dipped in the second half. So, is this seasonal or do you think this can now sustain at these levels?

Abhijit Mukherjee: The direction of the business has changed. We are approaching it from a different angle, different strategy, different construct. So I would not think that the margins would drop. We would continue to make it value-accretive. Important thing is to build sales further on the back of high margins. That part we are still working on, but certainly, we will not look at the margins dropping.

Prashant Nair: On Srikakulam, in view of the recent development, would you want to start looking at site transferring some products which I would say further out on the timeline, are you at a stage where you are beginning to look at that or you

think you are still going to wait for some more time and see what the FDA response is?

Abhijit Mukherjee: So irrespective of what we want - bandwidth is the main bottleneck. We will keep doing on priority - rather than long-term, mid-term, short term and such things. So based on our bandwidth we are continuing to address things. Now naturally depending on asset the priority may change and hence the focus and the amount of effort will also change. So, we will first focus on the meaningful ones and then see where it goes.

Nitin Agarwal: Abhijit, on the channel consolidation bit that you alluded to earlier during the call, in your experience what you have seen is are there any specific products which have been subject to more pressure in the consolidation or any particular characteristics of the business which is getting more impacted in this process?

Abhijit Mukherjee: Channel consolidation is not product-specific, it is product-agnostic. Channel consolidation is the negotiation of the channel with supplier companies on different terms, more steeper terms of discount and so on and so forth. So that would be on the portfolio of the entire business.

Nitin Agarwal: You have not seen instances where it is not product-specific, it is pretty much across the portfolio for everyone?

Abhijit Mukherjee: Yes, the discussion is between the channel and the supplier. So it will be on the whole business one is doing with that specific channel whenever that is happening.

Nitin Agarwal: Secondly, on our business I guess over the last four to five-quarters barring the recent approval for Ezomeprazole you have not had too many approvals especially on some of the larger products and we do not seem to be looking forward to too many of them really coming through over the next couple of quarters also. So apart from the litigation, delays which have happened in certain big products or some products which have probably got delayed because of Srikakulam, are there any other reasons the launch schedule being a little softer than it was in FY'15?

Abhijit Mukherjee: Yes, it is, as I said, second half is not going to see very exciting launches, but having said that as I just mentioned while second half is lukewarm a little bit, but we are still optimistic on the portfolio next year as I said, I think we have assets, all depends on how we get approvals and depends on which approval. So, next year I would not say it is going to be okay.

Nitin Agarwal: The only probably something uncertain would be the resolution of the FDA issues which are there in the ongoing facilities?

Abhijit Mukherjee: I guess so, I think that is the biggest thing on our mind and we are working very hard on it.

Fatima Khan: Could you please elaborate on Dr Reddy's Biosimilar opportunity in US considering potential competition from South Korea and US companies?

Abhijit Mukherjee: Biosimilars are a few years away still in terms of the Phase-III data, the studies are commencing. The more important thing I wanted to share which we are all excited about is how do we globalize the portfolio in the Emerging Markets. And I think maybe in hindsight, we could have moved a little faster a few years back. But better late than never and we are putting efforts in trying to see what we can do in making this reasonably meaningful in next 2-3 years.

Fatima Khan: But Dr. Reddy's is planning to spend a better amount of R&D expense in the Biosimilar segment and how do you expect to monetize this going forward?

Abhijit Mukherjee: I think this is certainly going to be useful. Personally I am very-very optimistic about the potential of Biosimilars even in the Emerging Markets and correctly monetize and correctly marketed. I think the R&D expenses can be recovered even from the Emerging Markets. While as a regulated market with our Merck Serono partnership continues and in due course, we will have benefits out of it, but on total percentage in terms of R&D we are not increasing anymore I think. Saumen you want to comment on the R&D expenditure on Biologics?

Saumen Chakraborty: No, as a proportion, Biologics still is around say 15% of total R&D spend that we have and that is continuing at that rate only. And as what Abhijit said

even in the emerging markets itself where there is a huge focus going on, we will be more than recover that R&D spend that we had in Biologics and anything we get approval in US and Europe that will be a real bonanza for us, but that is still a few years away.

Fatima Khan: So what is the kind of a market size which you are looking at in the emerging markets for Biosimilars?

Abhijit Mukherjee: Yes, the bigger markets we will look at Russia, we will look at outlicensing on all the bigger markets, ASEAN countries have large populations, these are drugs which are needed in all countries and government eventually will make sure all patients get the drugs. There is always cost pressure especially in Oncology area. I think all this will add up meaningfully. But, how we execute is a more important question. The opportunity is there.

Balaji Prasad: Just two things; one, the intangible assets seems to have gone up significantly this quarter. What is the composition of this rise? Secondly, you said that you reclassified one product from generics to proprietary segment. I presume that this is not large in size. Am I correct in understanding so?

Saumen Chakraborty: We had the Hatchtech deal that we announce a head lice product, that has going into intangible. and the generics to proprietary product is that brand that we are doing for an Isotretinoin Generics. So that is not a very significant amount.

Balaji Prasad: Does it fully explain the rights?

Kedar Upadhye: Balaji, if you are talking about increase in amortization year-on-year that is on account of UCB and Habitrol coming in now. In the last year, we did not have UCB amortization.

Balaji Prasad: Speaking about the intangible assets in the balance sheet, Kedar?

Kedar Upadhye: This is Hatchtech, Balaji, which is for proprietary products.