Dr. Reddy's Laboratories Limited
Q1 FY 18 - Earnings Conference Call

July 27, 2017

Saunak Savla:

A very good morning and good evening to all of you, and thank you for joining us today for the Dr. Reddy's Earnings Conference call for the first quarter ended 30th June 2017. 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 the transcript shall be made available on our website soon.

The discussion and analysis in this call will be based on the IFRS consolidated financial statement. To discuss the business performance and outlook, we have the leadership team of Dr. Reddy's, comprising Mr. G.V. Prasad, our CEO; Mr. Abhijit Mukherjee, our COO; Mr. Saumen Chakraborty, our CFO; Mr. Anil Namboodiripad, who Heads of our Proprietary Products Business, and the Investor Relations team.

Before we proceed on to the call, I would like to remind everyone that the Safe Harbor language contained in today's press release also pertains to the conference call and the webcast.

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

Saumen Chakraborty:

Thank you, Saunak. Greetings to everyone. Let me begin with key financial highlights. For this section, all the amounts have translated into U.S. dollars at the convenience translation rate of 64.62, which is the rate as of 30th June 2017.

Consolidated revenues for the quarter at Rs. 3,316 crores or $513 million, grew 3% year-on-year but declined 7% sequentially. Sequential decline is primarily attributable to the lower sales in our domestic formulation business due to channel destocking during GST transition and quarterly fluctuations in our PSAI business. Revenues from Global Generic segment is at $425 million, and PSAI segment is at $72 million.

Consolidated gross profit margin for the quarter is at 51.6%. This quarter we had some very good launches in North America generics business. However, considering that most were follow-on launches, their contribution in this quarter is low. There were few key external or market dynamics responsible for pulling down the margin, against our more recent benchmarks. These are:

(1) Incremental price erosion in the base business in US. :In addition to increased competitive intensity in some of the key molecules, enhanced customer consolidation led erosion played out beyond our earlier estimate.

(2) GST transition impact: This transition was characterized by significant reduction in the channel offtake and also higher return. In order to ensure adequate product availability in the marketplace, we had to make certain one-time interventions in the form of selective incentivization /compensation for any loss incurred by them, with respect to the channel inventory. These channel interventions have adversely impacted the margin.

(3) Adverse impact of manufacturing overhead de-leverage: During the quarter, we had lower reported sales, partly as a consequence of GST implementation and partly on account of quarter gating in other businesses. These factor should get normalized going forward.

(4) Adverse movement in currency rates: During the quarter, the U.S. dollar net delivered rate depreciated against the rupee. The USD rate is now stabilized around 64 to 64.5 range.

SG&A spend, including amortization, for the quarter is Rs. 1,176 crores or $182 million, a decrease of 4% year-on-year due to reduction in spend on remediation-related expenses. We continue to explore avenue to optimize the spending.

R&D expense for the quarter at Rs. 507 crores or $79 million, representing 15.3% to revenues. This spend is in line with the ongoing set of development activities as planned.

EBITDA for the quarter stands at Rs. 336 crores, which is $52 million, and is around 10% of the revenue. Our net debt-to-equity ratio stands at 0.29 as on 30th June 2017.

The effective tax rate is around 23.5% for the quarter, and we anticipate it to be in the range of 23% to 25% for the full year

Key balance sheet highlights are as follows:

Our operating working capital increased by Rs. 283 crores or $44 million during this quarter, primarily due to increase in receivables in North America generics business. We remain focused on optimizing the working capital cycle. Capital expenditure for the quarter was Rs. 272 crores or $42 million.

Foreign currency cash flow hedges for the next nine months in the form of derivatives for U.S. dollar are approximately $240 million, largely hedged around the range of Rs. 66.3 to Rs. 68.7 to the dollar. In addition, we have balance Sheet hedges of $374 million. We also have foreign currency cash flow hedges of 900 million ruble at the rate of Rs. 1.135 to the ruble, maturing over next nine months.

With this, I now request Abhijit to take 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. Let me take you through some of the business highlights for each of our key markets.

Please note that in this section, all references to numbers are in respective local currencies.

Our North America revenues for the quarter are at $230 million. On Q-on-Q basis we have managed to sustain the overall business and in fact grew marginally despite multiple challenges. Our base business witnessed pricing pressures driven by enhanced channel consolidation and increased competitive intensity on a couple of key assets: Azacitadine and Valganciclovir. With further consolidation among buyers consortium, we expect the adverse pricing environment to persist going forward.

We had a fairly reasonable quarter in terms of new product with four launches, gVytorin has been a successful launch with strong contracted market share. We also had doxorubicin liposomal injection, our first complex depot injectable. We are ramping up market share and since most of these are follow on launches, we expect to peak in terms of value contribution over next couple of quarters.

With respect to the pipeline, we continue to work with agency on the approval of our assets and remain optimistic on 2 to 3 launches per quarter. However, quality overhang at our injectable facility may impact approval timeline for few of our key assets.

Continuing on pure generics, our Europe business is fairly stable now and well poised to deliver a profitable growth on the back of new product launches and traction in the new markets.

Our Emerging Markets business is on track to gradual recovery. Russia business grew 31% Y-o-Y in local currency. During the quarter, we had our first shipment of Rituximab with a secure share under the national tender. Ex-rituximab, the growth is in line with expectations. We continue to focus on improving productivity and on augmenting the pipeline. Ex-Russia, the performance of the other markets was also in line with our expectations. We are well on track to expand geographic presence leveraging our institutional business portfolio and biosimilars. Commercialization of biosimilars across Emerging Markets has started to gain meaningful traction. We remain optimistic of building on this momentum further.

India business revenues are at Rs 469 crores and declined 10% Y-o-Y, 18% Q-o-Q. The nation implemented one of the largest and significant transitions to a progressive taxation regime in this quarter. We are witnessing a lot of transition challenges and we are working towards those. There was an evident disruption in the normal flow of activities and we had our share of impact. As discussed earlier, the decline in domestic businesses is resulting from channel destocking due to transition to the GST regime, which obviously had a sizable impact on our quarterly performance. There are some teething issues still being resolved and it will take some time for all the industry participants to return to normalcy. Subject to this, we continue to focus on productivity improvement and portfolio augmentation.

The PSAI business posted revenues of $72 million. Our efforts are directed towards building a healthy order book.

On our proprietary product business, we continue to execute our strategy of expanding Zembrace and Sernivo. Over the past quarters, we had several successful initiatives to accelerate volume growth. Effective this quarter we have started focusing on more on improving the net realization through optimal payer coverage. On R&D front, the pipeline is continuing to grow. Overall progress in R&D program milestones are on track.

This concludes my part. Now, I will hand over to Prasad for his comments.

G. V. Prasad:

Thank you Abhijit, thank you Saumen.

From the preceding discussions, you have an idea of the challenges that we face today. Delays in approvals, additional competition, regulatory actions have all combined to put significant pressure on our performance.

Given these circumstances, we have done a strategic review of our various businesses and initiatives and have developed 3 high priorities for the management team.

The first one is of course strengthening our manufacturing and quality system. The first priority is to ensure that our manufacturing systems meet the highest level of quality and compliance. We will need to modernize some of our infrastructure, systematically implement our new quality management system and automate some of the critical manufacturing and quality related processes. To accomplish this, a number of initiatives have been taken up across all locations and this would take us a few more quarters to complete.

The second priority is to revitalize growth. Our efforts to deliver a healthy pipeline of products, enabling sustainable high performance are on, and we are focused on accelerating the development of our complex generics portfolio and also making efforts to ensure that the approvals come in time through appropriate risk management and proactive measures to deal with possible deficiencies. We are also registering our assets in several countries beyond the U.S., in Emerging Markets to drive growth. This is our second priority.

The third priority is really to look at our cost structure and optimize that. Over the years, our fixed cost structures have outpaced our growth in revenue and we feel this must be corrected now to enable us to compete effectively in the market place. We have embarked on a systematic exercise to transition to a leaner and flexible cost structure. Focus on areas such as network rationalization, improving plant operating efficiency, R&D site optimization and productivity, as well as portfolio rationalization will have the potential to deliver significant savings. And we have already made a firm start and we expect to see some results starting this year onwards.

So this concludes my commentary. I'll hand it back to you Saunak.

Prakash Agarwal: Just trying to understand the gross margin, you did mention about India GST impact. Just trying to understand without that impact what would have been the gross margin, given the fact that we have started to see limited competition products in the U.S.?

Saumen Chakraborty: Yes, I basically spoke about four points, which had overall contributed on a year-on-year basis, about 450 to 500 basis points reduction in gross margin. So if you see relatively the maximum impact comes from the North America Generics price erosion. And then second comes from the GST. This is a specific quarter impact that we see. And of course, the third one is that manufacturing overhead de-leverage which is directly attributable to a level of sales. As the sales increase, definitely that will get normalized. And the fourth which is much lesser impact is due to the currency rate.

Prakash Agarwal: Yes, if we exclude the GST impact sir, what could have been the normalized, because that is something which is really one-off?

Saumen Chakraborty: That as well as the manufacturing overhead deleverage, both would be really a quarter specific kind of thing. We will not be able to exactly give what would have been the thing but it will be grossly in the range of around 53% to 54%.

Prakash Agarwal: Okay, is it fair to assume that this is the base case now given the fact that the approvals and launches have begun during the quarter. So you'll have full quarter impact going forward. So this should ideally improve going forward?

Saumen Chakraborty: Yes assuming no further erosions takes place.

Prakash Agarwal: And the erosion is in line with what you have guided in the past. I mean what you have seen in the past?

Saumen Chakraborty: It's more than what we would have expected and in annual report we mentioned that based on last year it is the huge erosion which has happened, which was much higher than the previous year. So we felt that this year it would be more calibrated. But it is more than our expectation, our estimate. Erosion has been more both because of the intensity of competition as well as the customer consolidation between the three players having 80 to 85% of the market and this is the quarter when most of the RFPs happen from different customers. So that impact is felt. We could not have felt it, say in April and May, mostly it happens in June. So then we understand that our initial estimates were lesser than what has actually happened in actual.

Prakash Agarwal: So broadly range of 12% plus minus or?

Abhijit Mukherjee Yes, it is in double digits. Two major assets I mentioned, itself account of $11 million Q-o-Q impact - **gVidaza and gValcyte.**

Kumar Saurabh: So just a follow-up, as you mentioned that only in the month of June we could realize the impact of re-negotiation of RFPs but does that mean that the full quarter impact we will be seeing in the second quarter?

Saumen Chakraborty: No, some of them had a retrospective effect as well as from 1st of April.

Kumar Saurabh: Okay. So, going forward if no further pressure comes from here onwards, ideally the margin should improve, ex of GST, I am talking about, US business only?

Saumen Chakraborty: You cannot take it for granted. Normally, it is a practice of annual RFP. But one cannot take it for granted.

Kumar Saurabh: No, I'm assuming that because we have good product approvals, which have come and which are expected to come in coming quarters, so taking that into account, we should see some kind of respite.

Saumen Chakraborty: Hopefully.

Kumar Saurabh: And sir India business, in the current quarter how confident are we that we will be able to recoup the impact which we witnessed in 1Q?

Saumen Chakraborty: We are seeing some recovery. Confidence level is there that whatever GST impact one has seen, it will be limited to Q1.

Kumar Saurabh: And we should see that full recovery coming in quarter two?

Saumen Chakraborty: I can't comment on full recovery. There will be recovery.

Abhijit Mukherjee: Overall I think couple of quarters, I think the current run rate is very good. It is temporary hit unlike the headwinds of pricing in North America. So I think shouldn't be that big a concern.

Kumar Saurabh: Sure. So sir, as you mentioned that there were couple of one-offs and the US business price erosion was there, so how should we look at what is the normalized margins going forward, we should look at, from second half FY '18 onwards?

Abhijit Mukherjee: I wouldn't comment on that, these are difficult to sort of predict. I think the key issue is getting the approvals and launches. That would be the probably be the most impacting factor. The headwinds which are beyond our control, we can't do much and

there isn't too much of a point trying to predict that. Overall what we are saying is, it has been a little more intense than what we thought. Yes, I do agree that some of the juicy assets have already went down, but hopefully let's see whether it stabilizes a little bit or not.

Kumar Saurabh: And in terms of growth strategy, the high priority which we talked about revitalizing growth and cost control. Is there any change in strategy in terms of focus area, in terms of geographic focus? So U.S. has been our key focus area and now given the challenges which we are seeing, is it fair to assume that the focus should be more in other geographies as well, or in terms of geographic focus we still continue to focus on US and India as our core markets?

G.V. Prasad: The core markets are beyond US and India. US, Russia, some select large Emerging Markets and India. The focus on US continues. Most of the assets that we are developing are targeted towards the U.S., but we will leverage them in Europe as well as in all other parts of the world. We have increased our globalization of select high value assets, including biosimilars. So to that extent we are seeing more activity in the Emerging Markets, in the medium term. So but that's not going to be a hedge against the U.S. The U.S. is such a large market that any other market or even a collection of markets cannot replace the growth that we hope to see in the U.S.

Neha Manpuria: My first question is on the SG&A expense excluding depreciation and amortization. The base seems pretty high for the quarter. Is there some incentive payments etc. in the quarter, or is this the new base new normal for SG&A?

Saumen Chakraborty: If you see year-on-year there has been a decline in the SG&A. Quarter-on-quarter, in the last quarter if you remember, we have talked about certain specific long-term incentives and others which were earlier accounted for but was reversed because we didn't pay due to non-performance. So that with the previous quarter, manpower cost would have been lower than normal. Now what you see this quarter is a fair indication after all the increment cost that has been built in to manpower cost, but our endeavor internally is to continue to improve on these and reduce further.

Neha Manpuria: So for all purposes, this is the new base for our cost going forward, for the time being?

Saumen Chakraborty: We will say this will be something for which we need to improve further quarter-on-quarter.

Neha Manpuria: And sir, when you mentioned our efforts to sort of improve our cost structure to make it more lean and therefore you're expecting certain synergies. Is there a number for this

savings that can be expected from a cost control over the medium term probably not for FY18 but how much do you think we can improve our costs by?

G.V. Prasad: So we are working on this project right now. It is going to be quite substantial. I don't have an exact number but it is hundreds of crores kind of possibility to take cost away. Multiple hundreds of crores.

Neha Manpuria: Okay. And my second question is on the proprietary business, the outlicensing agreement that we announced yesterday for DFA 02. I mean is there a change in the way we are looking at the proprietary business in terms of commercializing these assets ourselves?

Anil Namboodiripad: Prasad, you want to comment first or you want me to take…

G. V. Prasad: Broadly I'm saying that we are looking at more differentiated assets and assets more aligned with our sales force. This is the head line message but I leave it to you to give it more color Anil. Anil, go ahead.

Anil Namboodiripad: Yes, so specifically this particular asset that we licensed is a high value asset, but it was within a therapeutic area that we are not focusing on at this point in time. It's for the acute care hospital markets. So we felt that it is best developed at the hands of somebody else. And we believe the CHD Biosciences is a capable partner to develop this particular asset. The value of this asset is tremendously high, but we made a conscious decision to focus on two areas: neurology and dermatology, hence this divestiture.

Neha Manpuria: Okay. Are there any other such assets that we are looking at in the near term on the proprietary side or now most of the launches would be commercialized by Dr. Reddy's?

Anil Namboodiripad: There are couple of other assets that we believe are high value and do not fall within the preview of our strategic focus. And there are discussions ongoing about partnering those as well. But we cannot disclose at this time.

Anubhav Agarwal: One question is Srikakulam plant. Just wanted to understand that once this plant comes back, once it gets an EIR, how much of PSAI sales is impacted because this plant has a warning letter right now which can get, or which gets recovered. Second, how much is the unabsorbed fixed cost which is impacting our cost right now. So just trying to understand how much benefit we get once the plant comes back?

Abhijit Mukherjee: So the warning letter never prevented us from marketing the product which were there already. So what it will have is some of the assets for the future approval. Some we

have tech transfer and not relevant anymore, but for the future approvals it will have an impact. As far as unused or overheads which are unutilized, it wouldn't make a very material impact. I think for sure the injectable plant, which I mentioned is more important in terms of the launches and it's extremely important to work towards getting it back.

Anubhav Agarwal: Yes, which is I was thinking more in terms of whether it had any impact on the PSAI business not just this quarter, but in general because…

G.V. Prasad: Yes. So, some impact will be there. The flow will improve of products, and we have been heavily focused on remediation. We're trying to now focus on efficiencies on floor. So there will be some impact but it won't be very huge.

Anubhav Agarwal: Okay. That's helpful. Second question on the PSAI business itself, and the composition of the business this quarter was very different from the trend that we've seen so far, where sales in Europe has significantly declined and sales in India has significantly picked up. On both counts, if you can explain that. And secondly, if this trend were to, let's say remain, if when you sell a PSAI sales in India versus Europe, are the margins very different in the two categories or similar.

Abhijit Mukherjee: So this is a B2B business and I wouldn't suggest that we read too much into regional sales from PSAI. These are depending on customers who pick what when. What is more important is the last point we have mentioned that we are very focused on lot of remediation activities which sort of certainly had some disruptive effect on manufacturing and supplies. I think we can focus much more now on managing the supply chain better. So to that extent, I think it'll be certainly beneficial and it will move upwards from here I guess.

Anubhav Agarwal: Okay. Just last question on the US business. You quantified the price erosion year-on-year, Abhijit can you just give an idea sequentially as well the impact of price erosion in the US business.

Abhijit Mukherjee: Sequentially, is not right way to look at. But I'll give you a broad study, which we did in terms of top eight or nine generic companies, if you add their erosion and you can get it from the IMS, and add it up and then take an average that will give you the industry. Because certain quarter we could be very high, other companies will be low and could be vice-versa in subsequent quarters. So overall, the trend for the last eight quarters we studied and it has been fairly steady upwards moving percentage. Two years back, it was probably 5-6, it is trending between 10 to 20 right now. Now having said that, look whether this whole consolidation also has broadly, I think, we have more

or less seen seeing the end of it come going further between three players 85% of the market share. So whether it will plateau out a bit, time will tell.

Nimish Mehta: On the India's business and specifically on the impact of GST, I just wanted to have a few clarifications. One, obviously we got impacted because of the lower sales because of destocking. But you also mentioned about we giving some compensation to the distributor for the kind of losses? So is there and first obviously whether my understanding is correct and if yes, what was that amount or can you quantify that?

Abhijit Mukherjee: Specifically not, I don't think so, but there was certainly confusion in the transition, some amount, is it very significant, no. But yes, there were some efforts to sort of keep the stocks moving. We didn't want also the retail sales to run dry and that would have been apart from anything else, which would have meant secondary sales loss, which was not correct to sort of in this confusion. So it wouldn't be very much, but yes there were some.

Nimish Mehta: Okay, understood. But that's not material, right that is what I understood?

Abhijit Mukherjee: Not really significant.

Nimish Mehta: Okay. And second on the U.S. business you mentioned about two to three launches per quarter here, any guidance about how many high values launches specifically, launches like Copaxone will be appreciated.

Abhijit Mukherjee: Difficult to say, two to three in numbers would happen and I think you're very right. I mean what is the quality of two to three would decide everything, there are a few assets and there are also few concerns after injectable sites delay, but the numbers are there and there are few assets without getting into specific. If things go okay, then we may see a few good launches.

Nimish Mehta: Quantify that number as in how many two-three, three-four, ballpark.

Abhijit Mukherjee: We just can't because the uncertainty is because of intellectual property aspect of it and FDA's approval timelines are not in our control.

Nimish Mehta: Okay. Great. If I may squeeze in one, just wanted to know the fate of our biosimilars strategy now that Merck is opting out of the JV. So any thoughts that could be?

G. V. Prasad: Well, Fresenius who is the new owner of this business is very motivated to continue and we've had our meetings and it is going quite well. So they've acquired this business

from Merck, they paid a lot of money. So we believe that they're very committed to building this business going forward.

Sameer Baisiwala: Abhijit, can you update us on the progress with Duvadda with 13 observations, what's the way forward and would it require a second re-inspection?

Abhijit Mukherjee: This would require a second re-inspection Sameer, so observations were significant, we responded. But it will require another inspection. We are working towards it and normally in a Warning Letter site an observation is found. There is secondary inspection and we can't say exactly when we would sort of invite FDA back again, but we are working towards it, yes.

Sameer Baisiwala: Okay. Is it fair to say that Copaxone filing is being done from here? And that's what you have said few times on the call that because some of the injectables will get delayed? And second are you looking to site switch it?

Abhijit Mukherjee: Copaxone is not from Duvvada. There are other good assets, which are in the process of site switching. But site switching has some timeline delays. So let's see which comes through earlier and we will take.

G.V. Prasad: But optimistically, we expect to have FDA coming by the year-end, December or so.

Sameer Baisiwala: Okay. And just one last question. In the context of complex generics, can you update us the progress with the patches, how many you are working on and what's a sort of filing targets?

Abhijit Mukherjee: Not very significant, Sameer. There was one which we are little delayed, there is one still alive which we have settled and maybe Q2 next year, but these wouldn't really move revenues much. I think we are still banking a lot on injectable products filed both from our site and the partner sites.

Saion Mukherjee: On this cost cut and restructuring, is it possible to share like which business areas this would really come from and which line items are you talking about R&D, employee cost, any color you can give on this?

G. V. Prasad: It's little too early to share such details. We will consider global R&D sites, R&D expenses, manufacturing network, portfolio where we don't have enough margin from rationalization of portfolio, number of different activities. So at this point it's too preliminary to share that level of detail.

Saion Mukherjee: But you think it should come through next year or it will take longer for realizing these savings?

G. V. Prasad: We should start seeing impact from next year onwards and some impact in this year also.

Chirag Talati: Firstly, is it fair to say that this quarter has not seen any impact from price erosion on Decitabine from the new competitor?

Abhijit Mukherjee: Some, yes.

Chirag Talati: That would be marginal in overall context of things.

Abhijit Mukherjee: To an extent, yes.

Chirag Talati: Secondly, if you can help us understand on your Suboxone product, is there any pending CRL, and if there is so what are the timelines for refiling?

Abhijit Mukherjee: We submitted the response on the complete response letter. Now we are awaiting the judgment maybe four to eight weeks as you know it is in litigation. The outcome is important for this asset. Of course, either way this can be, if the generics win, in a way, it can get challenged and vice versa. But that's the next important milestone. On the development front, I think, we feel very good about it.

Chirag Talati: Second, just kind of asking the follow-up, when was the last response submitted to the FDA?

Abhijit Mukherjee: June.

Girish Bakhru: Yes, just similar question on NuvaRing, has the CRL been responded on that?

Abhijit Mukherjee: Yes, around the same time and this is cleaner on the litigation front. We have TAD dates on both, Suboxone and NuvaRing in around Q4 of this financial year. So we will see where it goes.

Girish Bakhru: On the litigation front, there is appeals case going on if I understand, although that's on the Actavis' ANDA , but you don't see that shouldn't be delaying it anyway beyond April 2018, right?

Abhijit Mukherjee: You are talking of NuvaRing, is it?

Girish Bakhru: Yes.

Abhijit Mukherjee: The patent expires in April of next year in any case.

Girish Bakhru: Right, Abhijit any color on, how soon you will see competition in this product, would it be like three year, no competition?

Abhijit Mukherjee: Those are difficult questions to answer. I wouldn't know there is another asset we heard that it is in development. But these are complex assets. In terms of development, FDA may ask questions and they will ask us well, although we feel good about our development but we will see. Difficult to say about others.

Girish Bakhru: Okay, I know on Copaxone again, when are we ready to re-file 40 mg?

Abhijit Mukherjee: Very soon, in couple of weeks.

Girish Bakhru: And just a follow-up on that

Abhijit Mukherjee: You are talking of the response to the CRL, right? I mean the updation of this thing. Yes, couple of weeks.

Girish Bakhru: Yes, so if I understand the TAD on 20 mg is close and if you get positive response, approval on that, would it make you confident on 40 mg as well, or do you think these two are separately linked?

Abhijit Mukherjee: So, firstly we have a TAD but these are extremely complex assets. So naturally, there may not be CRL, but there would be certainly questions, and could be other CRL as well. I don't know, although we think we have done a reasonably good job. But so to assume that everything is done is certainly optimistic but let's see. If the questions are not significant, I agree then that gives certainly a directional signal towards the whole asset because there's not much in the formulation side, it's actually the DMF which is the same and review of that is more critical.

Kartik Mehta: Just if we have to look at the gross margin, which is there for the last two-three years, it has come up from about 60% to now around between 50% to 53%. Is that a reason where there is a structural issue, where we believe that since we are using third parties to manufacture or there is higher competition, is it fair to assume that this now remains here or is there any scope for improvement? I just wanted your thought on this.

G.V. Prasad: Yes, there is certainly room for improvement. The primary reason it has come down is also because of the price competition. And as we launch newer assets with higher margins, the gross margin can go up. Our cost initiative should also help us and if you look at the current quarter there is some one-time stuff also happening there. So I think

gross margin should go up. Your question about manufacturing at third-party, would that erode, I don't think this is a very significant factor, while it is sensitive to cost. It's not a cost which can really change the economics of our business model.

Kartik Mehta: Sure, and if we have to look at the cost saving which you spoke about and you entering into other markets, would M&A be a part of it because we are pretty low on debt and if we have to make an entry to any of the larger emerging markets with the pipeline that you have, would that be something that you consider?

G. V. Prasad: Largely, we are looking at not inorganic entry because we are looking at institutional sales as the vehicle for entry into Emerging Markets. We don't require large sales forces or establishments. So I don't think we really need to do inorganic growth to expand our footprint in the markets that we are considering today. But if there is a good opportunity, we will not be shy of that.

Kartik Mehta: No, I meant in the markets where you are not there now, maybe some other markets in Europe.

G. V. Prasad: Well, in Europe we have already entered 'big five' markets. We have two markets where we are selling products for a long time and we have established our presence in three other markets. So we don't really need to do anything inorganic.

Kartik Mehta: And on Doxil, just this one. So how do we record here the revenue and the profit given that we have a partner and so that would just help us in terms of the margins that could flow in the next quarters? Thanks.

Abhijit Mukherjee: So it is a significant asset, it is certainly without giving a specific number, and we are the dominant partner in the partnership. So based on that you will have to sort of work in.

Kartik Mehta: Yes, so I just actually wanted to know that do we record the revenue upfront and then there is a profit share, or I mean - how is it recorded

G.V. Prasad: We book full revenue.

Aditya Khemka: Sir, what would be the product concentration now in the U.S. business for us, I mean would the top five products account for 30%, 40%, 50% of our sales, just a ballpark number?

Abhijit Mukherjee: It has reduced over the year. Right now, I think if you take comparative figure, we are lower than quite a few peer group companies, if you take the first 2-3 assets type of a thing. But the figure which I have readily available is top two assets is…

G.V. Prasad: Top five would be around 25%.

Aditya Khemka: Okay that's helpful and sir just wanted to verify one number, Saumen mentioned that Q-on-Q because of Azacitadine and one more asset he mentioned. For these two products, the price erosion has been about $11 million Q-on-Q?

Abhijit Mukherjee: gVidaza and gValcyte, I said.

Aditya Khemka: Okay and that was a sequential number right?

Abhijit Mukherjee: That was a Q-on-Q.

Aditya Khemka: Okay, yes, just wanted to check that, thank you. And just one last question on your take on the Bachupally Form 483, have you seen any product approvals since the Form 483 have been issued from Bachupally? And if not, is it fair to say that it is an OAI status with the FDA?

Abhijit Mukherjee: The only one which is pending we mentioned I think last time is Atomoxetine and I think it is immature to conclude anything. I think we have responded adequately and there was just one follow-up question out of many observations, which we have also responded. So we will see where it goes.

Aditya Khemka: Sir, any timeline discussed with the FDA on Bachupally or is it just something that you have to wait for and see what the FDA does?

Abhijit Mukherjee: Timelines, we have responded. So as I said response was sent, there was one clarification on one specific point. We have responded that as well so….

Aditya Khemka: When was this response sir?

Abhijit Mukherjee: Last one was about a month back, I guess roughly give or take. We'll come back to you, month back, maybe about 15 days back or something, 15 days or a month back.

Nitin Agarwal: So you alluded a couple of times about this emerging market strategy. Can you just help us understand a bit in terms of potential of maybe if there are some illustrative examples of what is the kind of potential some of these assets have, relevant to U.S. assets have, will you sort of take them on a pan Global footprint of sorts?

Abhijit Mukherjee: It's significant, I think I would maintain what I said in the earlier call. I think we are getting on the institutional strategy and leveraging our assets globally. We are getting into Brazil as we speak into Q2 and we have three approvals, three products also getting launched. Q3 may see a couple of more approvals. These are big markets, smaller markets like Colombia and ASEAN markets, biosimilars are gaining more momentum. So overall it's not something which will be quick, one quarter type of thing but we're doing it systematically, leveraging these assets globally in these markets, putting the footprint just what is needed because while it's B2B but it is needing our contact with the clinics and all that. So we will be deep into these markets understanding how exactly each of these clinics sort of operate on this area. And hence it is significant involvement / focus which will bear result, I guess in next two to three years.

Nitin Agarwal: Okay, so you think it is going to be take couple of years before it starts to show meaningfully in numbers?

Abhijit Mukherjee: Well yes true, but we will start seeing something even this year itself. Meaningful meaning what is meaningful, for us even 5 million to 10 million is meaningful, we can get going.

Nitin Agarwal: Okay, and secondly on the distribution consolidation angle, was your experience, I mean sense on that part of the business, obviously there is price erosion and the business combination of the asset or erosion because of competition. But if there's a way to sort of dissect that, so what is the distribution consolidation driven price erosion which is probably a little more sustainable normal going forward or any assessment?

Abhijit Mukherjee: Not sure I understood your question. You are aware of the consolidation there are three players, right.

Nitin Agarwal: Right.

Abhijit Mukherjee: ClarusONE, Red Oak and Walgreens, Econdisc, AmeriSource Bergen combination. So what's the specific question?

Nitin Agarwal: Sir I'm saying, we have had erosion in the business on account of compression in our key assets as well as pressure which is brought about by the distribution consolidation. So is there a way to sort of segregate the two in terms of the erosion which has been brought about by the consolidation process and how do you see that playing forward?

G. V. Prasad: It's very difficult to answer your question in terms of numbers, because it's very asset specific. It depends on the number of competitors for the given asset and so on and so forth. But it feels very difficult to give a general answer. But it is a fact that price

erosion is higher than what it used to be because of the high concentration of market shares among these three players. So anybody who has his market shares will hang on to it for a long time and to dislodge that you need a bigger discount and that is where this price erosion is coming from.

Shyam Srinivasan: The first is on Aloxi, is there any update on the launch of this product?

Abhijit Mukherjee: The 505(b)(2), I think we have challenged the lower court decision. So that's one aspect, but the more happening one today is the 505(j) one which is being fought by one company and couple of us are watching that closely. There I think the innovators have asked for en-banc hearing and the generic company is responding to it. So in summary, I think the verdict on that we would see in give-or-take, within eight weeks, or around eight weeks from now, positive then it moves ahead negative then it goes into hearing which is a little long term, maybe another 7-8 months.

Shyam Srinivasan: So and your settlement with the innovator lets you launch with the generic company with Teva perhaps, if all goes well?

Abhijit Mukherjee: You make your own, you are tracking it closely, so I couldn't have your guess.

Shyam Srinivasan: Okay. Sure thank you. My second question is on the new FDA commissioner, not new anymore, Dr. Scott Gottlieb. He's talking about more generics being on the market and priority reviews for the first generic on the market. So there has been a lot of talk but have you seen any walking the talk kind of a thing. So do you foresee more complex generic approvals or limited competition approvals in the next 6 to 12 months?

Abhijit Mukherjee: Look I think firstly, it's difficult to sort of expect rapid action, we are very excited about his comments and think very forward looking in the right direction and I think we will come there a lot. And so he's talking a few really sort of apt and relevant issues and so let's see one, the positive change which has come in as in terms of prioritized / expedited review. Earlier was just one generic, it has been increased till three generics are approved. So quite a few assets are coming into expedited review which is a good move. And then the rest we will see as it unfolds actually, but overall comments are in absolutely right direction.

Shyam Srinivasan: Okay. Thank you. And my last question is on your R&D, what levels should we be assuming for the rest of the year, 15% first quarter and where is the incremental kind of R&D going into, is it going more into clinical trials, if you can give any color that will be useful? Thank you.

Saumen Chakraborty: Instead of taking as a percentage because the sales, if there is a wide fluctuation then the percentage changes tremendously. I think we should take R&D will be in the vicinity of Rs 500 crores per quarter, take 10-20 crores plus/minus.

Alok Dalal: Mr. Prasad, how do you measure R&D productivity in the company, and how has it progressed over the last few years, has it declined, has it gone up? Thank you.

G. V. Prasad: We look at the NPV of assets. We look at the money we spend and NPV of pipeline that we deliver. There has been some fluctuation in the last 2-3 years. It can't be a very smooth year-on-year curve, but last year has been a good year, we hope to continue that this year too. So the number themselves, number of filings while we are not as high as some of our competitors, we believe the kind of assets we have will justify the productivity of the assets. So we have complex assets and then we have simple assets, we have the blend for, it is difficult to have a number beyond our NPV number that we calculate internally.

Alok Dalal: Yes, this is helpful. Sir when do you expect the R&D to get monetized, because the problem is that the R&D spend is hitting your P&L, but the assets have not yet come maybe for multiple reasons. So when do you think whatever you spent on R&D so far is the 2-3 year cycle or is it beyond that.

G. V. Prasad: I think in the next two three years we should see significant growth in the company which will unlock the R&D investments that we made.

Alok Dalal: So, just going back in time, you had a vision of $3 billion by FY 2013, do you think you will realize that in the next three years?

G. V. Prasad: We hope so.

Saumen Chakraborty: We may be even more.

Anmol Ganjoo: My first question is to Mr. Prasad, Mr. Prasad you spoke about these initiatives around costs. I know it's too early to get into details, but as you embark on your initiative to perch costs, what are the strategic areas, what are the areas which you think are non-focus, non-strategic and what will come under your cross-sales first as you move to perch costs?

G. V. Prasad: So we are not looking at divesting or cutting any businesses. So the businesses won't get impacted, but there is a significant amount of inefficiencies due to the way we have grown over the years and we have never stepped back and looked at our networks where we are spending what we are getting out of them and we did that exercise

recently and we found significant scope for tightening everywhere without impacting outcomes. And we believe that we can achieve that in next two to three years a very significant saving over our operating base.

Anmol Ganjoo: Okay, thanks, that's helpful. My second question is that you spoke about whatever approvals you have gotten this quarter, they peak only in subsequent couple of quarters. If you look at this quarter, the impact of the scale up of the market shares thus far how far would be with respect to just these three assets from our peaks, this quarter contains an impact to what 40% of peak, 50% of peak, if you can just help us understand that, that will be helpful.

Abhijit Mukherjee: You are talking about new launches.

Anmol Ganjoo: Yes, so you said.

Abhijit Mukherjee: New launches is small ocean, I mean first quarter it doesn't make very big impact I mean it's not zero but it's not that significant number.

Anmol Ganjoo: No that's not what I meant, what I meant was that in terms of the peak sales potential of these three launches, how far are we, 40%?

Abhijit Mukherjee: So in Q2, let's not talk of Q1, Q2 I think these are two major assets I think we would almost get there like Lipodox may slightly spill to Q3, but by Q2 for these assets, the run rates we should get.

G. V. Prasad: Last quarter, it is very small.

Abhijit Mukherjee: So gVytorin almost there, Lipodox being an institutional asset and sometimes its channel loading so they takes a little bit time but our market share of this asset is very good and so I think it will scale up certainly by end Q2 to early Q3.

Anmol Ganjoo: And my last question is if I may that you sounded optimistic that we will be restocking fairly soon and as far as India is concerned if we look at a full year basis, I know it's early but what's your assessment that on a full year basis, what is the prognosis of Indian market this year, is the lost sales for this quarter going to be compensated in subsequent quarters and to that extent do you think GST is a neutral event from an India growth trajectory standpoint or what are your thoughts around it?

Abhijit Mukherjee: Okay, let me try and answer this. Little early at the moment but as we have seen the momentum coming back in July and I think we are reasonably satisfied. So given that I am not sure this would be a very significant de-railer in terms of India business. Let's

see how the economy unfolds and I think possible for growth to be in reasonable range and all, high single-digit, low double-digit type of a thing.

Saunak Savla: Thank you all for joining the call and in case if you have any additional clarifications, please feel free to get in touch with the Investor Relations Team. Thank you.