Dr. Reddy's Laboratories Limited
Q2 FY17 Earnings Conference Call

October 25, 2016

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 Call for the Second Quarter of Fiscal 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 a transcript shall be available on our website soon.

Just a reminder: The discussion and analysis in this call will be based on the IFRS consolidated financial statements.

To discuss the business performance and outlook, we have the leadership team of Dr. Reddy's comprising Saumen Chakraborty - our CFO; Abhijit Mukherjee - our COO; Anil Namboodiripad - Senior Vice President and Head of Product Development and Commercialization of our Proprietary Products Business and the Investor Relations Team.

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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 statements. For more detailed information on the risks and uncertainties associated with the company's business activities, please see the company's Annual Report filed in Form 20-F with the US SEC for the year-ended March 31, 2016 and the Quarterly Financial Statements filed in Form 6-K with the US SEC for the quarters ended September 30, 2015, December 31, 2015 and June 30, 2016 and our other filings with the US SEC.

After the end of the call in case any additional clarifications are required please feel free to get in touch with the IR team. I also wanted to inform you that a new member, Amit Agarwal has joined the IR team and his contact details are available on our website.

Now, I would like to turn the call over to 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 are translated into US dollar at the convenience translation rate of Rs.66.58 which is the rate as of 30th September, 2016.

Consolidated revenues for the quarter are Rs.3,586 crores or $539 million and grew 11% sequentially. All our major businesses have shown sequential improvement. On a year-on-year basis, it has declined 10%. Revenues from our Global Generics segment are $435 million and PSAI segment are $87 million.

Consolidated gross profit margin for the quarter is 56%. Gross margin for Global Generics and PSAI were at 62.3% and 22% respectively.

SG&A spend including amortization for the quarter is $177 million, an increase by 6% year-on-year. Following the dismissal of the writ filed with the Bombay High Court contending the validity of certain notification issued by the NPPA, a potential liability of $5.2 million has been recorded. Normalized for this, the net sequential decline is primarily on account of reduced remediation cost and the product launch expense by Proprietary Products segment. On a year-on-year basis, after normalization of the Venezuela base effect, the increase is largely attributable to normal salary increments, headcount and other costs. We continue to explore avenues to optimize this spending.

R&D expense for the quarter were at $78 million, representing 14.5% to revenues. This spend is in line with the ongoing set of development activities as planned. As we have discussed earlier, we have initiated further development activities on the recently in-licensed IPR&D assets from XenoPort and Eisai as well as the acquired ANDA filings from Teva, which has incrementally added to the same.

EBITDA for the quarter stands at $96 million, which is 18% of the revenue. During the quarter, we generated $61 million of cash flows from operations. We concluded the portfolio acquisition from Teva by paying $350 million and thereafter concluded the quarter with net debt-to-equity ratio of 0.34. Effective tax rate for the quarter is 23%. We expect the annual effective tax rate to be in the range of 20% to 22%.

Key Balance Sheet Highlights are as follows: Our operating working capital increased by $38 million during the quarter. Focus remains on rationalizing working capital across locations. This will obviously be done after considering necessary build-up of the impending new product approvals and launches and geographical expansions. Capital expenditure for the quarter was at $46 million.

Foreign currency cash flow hedges for the next 6-months in the form of derivatives and loans for US dollars are approximately $150 million, largely hedged around the range of Rs.67.6 to Rs.71.7 to the

dollar. In addition, we have balance sheet hedges of $123 million. We also have foreign currency cash flow hedges of RUB600 million at the rate of Rs.1.03 to the ruble and €3 million, largely hedged around Rs.75 to Rs.82.05 to the euro maturing over next 6-months.

With this, I now request Abhijit to take through the Key Business Highlights.

Abhijit Mukherjee:

Thank you, Saumen. Greetings to everybody and welcome to the earnings conference call. Overall performance of the quarter is in line with what we expected. Every business has grown sequentially on the back of new launches or volume gains. Broadly, this gives us comfort on the base business. Let me take you through each business to discuss the performance and some key things: Reference to financial numbers will be in respective local currencies.

Our North America revenues were $245 million grew marginally on a sequential basis. Combination of in-house and partnered new product launches coupled with volume normalization in few products has countered the adverse impact of McNeil business and competition in some key assets. On the pricing front, we have not seen much movement on a sequential basis. From our side, it is logical to expect some competition in a few of the top products; however, at the same time, we hope to see traction in new product launches and grow further as the year progresses.

Coming to Europe, our revenues for the quarter are €24 million and it sequentially grew by 11%. We are building on our strategy to leverage our global portfolio and set up a robust institution business in the EU5 that is profitable, stable and lean.

On the Emerging Markets front, the macroeconomic stability risks have receded and we expect it to be stable for some time. This is likely to have a rub-on effect on the pharma sector as well as on the respective currencies. Any appreciation in the local currency will be meaningful source of growth. Specifically to this quarter, our Russia business grew 11% sequentially in constant currency. At H1 level, the business grew by 7% in constant currency. Performance over the last 5-6-quarters indicate that stability is gradually coming back to the marketplace. At an overall level, the team continues to focus on productivity enhancement and portfolio augmentation. Ex-Russia the other markets in the emerging markets business performed in line. Further, we are on track to expand our geographic presence to leverage our institution business portfolio. As explained earlier, we did not have any revenues in Venezuela. We continue our efforts to actively engage with the Venezuelan government to provide affordable medicines to the country, but with an assurance on payment.

Domestic Formulations business revenues are Rs.625 crores and grew 14% year-on-year. This is good growth considering the season pickup while continuing to face the challenging NPPA pricing requirements. Portfolio acquired from UCB has also performed in line with the plan. Team continues to focus on increasing the productivity and augmenting the portfolio.

PSAI business posted revenues of $87 million and grew 22% sequentially. The sequential improvement in the business can be attributed to improvement in supply situations and order inflow.

On the quality front, we are actively focusing towards universal compliance of the global quality management systems. Specific to the three warning letters affected sites, we have addressed all the commitments and we await inspection by FDA. Simultaneously, we are trying to ensure that critical products have alternate sites assigned to them.

On our Proprietary Products business, we are closely monitoring the market for our newly launched brands, Zembrace and Sernivo. Several initiatives to accelerate volume growth have been put in place and we are seeing a gradual increase in prescription growth. On the R&D front, the pipeline is continuing to grow. Several programs within neurology and dermatology have achieved clinical proof of concept and plans are in place for initiation of pivotal registration studies.

To Summarize: We have improved sequentially, but at the same time we remain cautiously optimistic of the approvals and launch scenario for quarters to come. Management focus is primarily on new launches in North America Generics market, improvement of productivity in the Branded Generic business, deliver on the quality improvement initiatives and strengthen product pipeline for the respective businesses.

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

Manoj Garg: I have a few quick ones: One, any abnormalities in US pricing? Two, timing of the FDA re-inspection? Lastly, I saw a new filer on revlimed. Can you confirm if that is Reddy's and whether you would expect to get sued there?

Abhijit Mukherjee: Pricing erosion has become a part of the US business model. Currently, there are essentially four customers and consolidation has taken it to that level. Having said that, it will not be uniform quarter-on-quarter, last quarter was very harsh. This quarter was certainly much better. But having said that, to say that it is on the wane would be too optimistic. Inspection, we mentioned that we have done our part of it, in terms of completing all the remediation activities, keeping in touch with agencies with the updates and as we mentioned we have requested the agency for reinspection. It will follow the process and has to fit into the calendar and we will have to wait for that. Meanwhile, we are also trying to engage with them for face-to-face. REVLIMID, I would not comment on that.

Manoj Garg: So back to the pricing, downward pressures is a common place of the US market, but it sounds like you are saying in this fiscal Q2, it was a little bit less than fiscal Q1?

Abhijit Mukherjee: The erosion is little subdued this particular quarter. Having said so that if there is one more approval coming in any of the top assets, it could see an upswing. Largely Valcyte was the biggest impacted molecule, the injectable is also seeing pressure, but in the nature of this business there is some long-term contract and so on and so forth which helps us to hedge to a certain extent. But having said that we will have to take it in our stride.

Manoj Garg: Then so just a clarity on that, so you have asked FDA for reinspection. So you are waiting for them to get back to you?

Abhijit Mukherjee: Yes, we are following the usual process. This is what that follows for all companies.

Manoj Garg: So does not that have a clock… is that not 180-day clock on that?

Abhijit Mukherjee: Nothing at all, no. I think it depends on how agency feels about responses. But you can take statistically, typically, how much time it takes, it follows a certain timeline.

Kumar Saurabh: So the US business sales sequentially have marginally improved, even though the McNeil impact as well as competition on the Injectable side has worsened. So does that mean that apart from the new launches which we have seen, how has the base business fared, apart from these Injectable portfolio, couple of products which we have?

Abhijit Mukherjee: Erosion as I mentioned has not been severe in this quarter, but McNeil business we had messaged last time. It saw the full blow impact of the McNeil business pretty much going away in this quarter, it is in double-digit. So, beyond that I think as far as the broad launches are concerned, you are aware that if you take first half - two assets, are moderately attractive - between $20 million to $30 million range. The rest we have launched our base model. That is the overall picture.

Kumar Saurabh: We have earlier guided for better 2H compared to the first half. Do we stick to that, in terms of US launches?

Abhijit Mukherjee: We are cautiously optimistic, I think we will stick to that, the assets have litigation aspect, have FDA approval pathway aspect.

Neha Manpuria: Just a follow-up on the last one. Previously you have mentioned you expect a brisk pace of launches in the second half given we have derisked a lot of the launches from the impacted facilities. Does your cautiously optimistic comment incorporate that? Should we still see launches improve and how many of these do you think could be meaningful?

Saumen Chakraborty: Launches will be there, it will be improved. Meaningful means, you at least know one specific launch is litigation-outcome dependent. So that we will have to know when actually the verdict comes up. Overall second half we expect to be better than first half for FY 17.

Neha Manpuria: My second question is on VIDAZA. We did see competition come in, but the numbers do not seem to suggest too much erosions. Is it fair to assume that we did not really see too much erosion in Generic VIDAZA due to this new entrant and that could start coming through these long-term contract that you talk about go away?

Abhijit Mukherjee: No, I think price per vial has taken some hit for sure, but competition, I think as you are aware, one is 505(b)(2), in when generics available, having traction

there maybe a little difficult, but otherwise other one which is plain ANDA is certainly nibbling share. But as I said, institution businesses have a slightly different nature of erosion. So I will just leave it there.

Prakash Agarwal: So just trying to understand the Proprietary Products that you have launched couple of products. How is being the traction, has they reached double-digit sales and what is the expectations in terms of second half and next year?

Saumen Chakraborty: We have Anil on this call. So I will request Anil to respond.

Anil Namboodiripad: This is Anil Namboodiripad. So let me talk about the two new launches in Proprietary Products. We are continuing to see traction with those prescribers and in terms of total prescription over the last three months July-to-September, that is when we measured it. We have doubled the number of prescribers and 40% of those prescribers are actually repeat prescribers, so which is a good sign. Second, just in the month of September, prescribers grew by 22%. Prescriptions are also growing consistently, but let me specifically talk about Zembrace and then I will come to Sernivo. Prescription for Zembrace are growing consistently and have crossed the 1,000 prescriptions per month mark, which is a milestone for us, with a four-month growth rate of 54%. Similarly, for Sernivo, prescriptions have crossed 2,000 prescriptions per month and the number of prescribers have also grown to about 2,000 with again 40% of those prescribers being repeat prescribers. These are all some of the benchmarks that we look at early stages of launch, because these indicate how the product placed to perform. The growth rate of prescriptions have also in case of Sernivo has been 50%. The base business is on track to budget and moving forward especially the Sernivo we expect to see a significant increase in the coming months due to favorable seasonality of this particular product usage.

Prakash Agarwal: But any color in the sales would have also helped, because we are seeing a very flattish YoY, QoQ movement in the same?

Anil Namboodiripad: In case of neurology, we are new to the market as Promius Neurology. It has taken us a bit of both - time and expectation in terms of establishing our presence in the market. We had not significantly done pre market or market development activities prior to launch. So as a consequence what we are focusing on right now is to build volumes and increase the number of prescribers and the number of patients who experience our product, because

our top belief is that if we are able to increase volume, then as we continue to get listed across all the managed care formularies, these will all turn into revenue spread. So there is a significant effort in terms of sampling as well as certain experience programs that we are conducting in the field. So you are not really seeing that translated into numbers, but as we continue to get manage care coverage… right now we are at about 50% manage care coverage. As you know you are working with each of the specific manage care bodies to get listed in that formulary and that is a process of its own where we negotiate rebates and things like that. So that is taking its time. Once we are able to get adequate manage care coverage, you will start seeing the numbers. But the previews to those numbers, it is basically the volume growth.

Prakash Agarwal: What kind of peak sales we are expecting by when?

Anil Namboodiripad: The peak sales as we had originally indicated, we expect it to be somewhere in the range of $50 million for both products and we expect it to happen in the next three years.

Prakash Agarwal: Second question is actually on Reditux. So in Russia are we on track to launch this in 3Q as indicated earlier and as you mentioned currency impact is largely getting over, so do we expect a very strong 2H?

Abhijit Mukherjee: This is a tender. It is slated to be in Q3 and we will certainly participate. Beyond this if we win, we will certainly see revenues.

Prakash Agarwal: So these tenders are one-time or this can continue quarter-on-quarter?

Abhijit Mukherjee: I think that the biggest national tender is twice in a year.

Prakash Agarwal: This is the longest contracts, so this can see the impact in the next quarter and follow on quarters as well?

Abhijit Mukherjee: Yes, I think it is yearly sort of it goes through. Currently, there are three sort of approvals, the innovator is there, another is a Russian player and us.

Anubhav Aggarwal: Abhijit, one question on PSAI business. This quarter benefit from delayed shipment from 1Q, I just wanted to understand that is this the new rate which work with or just because of delayed

shipment this PSAI sales in this quarter are much higher?

Abhijit Mukherjee: This is B2B business, you should not read always very deep into a quarterly figure. But having said that it is not that is a delayed shipment or something, because sometimes it is also part of the PSAI business, the custom pharma business, where the orders come sometimes in chunks. More importantly, since you ask the question, let me clarify… the health of the business - I feel very satisfied about. I think overall the gross margins look certainly better than what it used to be 6-quarters back. That is important. Supply situations are broadly under control, new products are kicking in, and last but not the least, standalone figures are important for this business, but we will always have to remember that this is strategically important to the base business.

Anubhav Aggarwal: So just one more clarity on this product you bought from Teva, NuvaRing. Now when you bought this product from Teva, in your internal calculation, for how many years you think it will remain at two generic player market, just as a rough idea, because I just want to see that, what was the amount that you paid for the 8-products. If the situation continues for more than two years as a two player generic market, then it is a very sweet deal.

Abhijit Mukherjee: Let me make a broad commentary before I come to NuvaRing. I think we feel reasonably satisfied with this, as things stands today. The two major assets have litigations and some of the information is in public domain and overall the going is good. In terms of our expectations and diligence, I think it is playing out well and we have reasons to be satisfied. NuvaRing is a drug device type of combination and to hazard a guess that when is the third player coming in, I would not be able to do that. That will be a shot in the dark. So it does not make any sense. But, overall we feel good about the two lead assets and some of the other assets as well.

Anubhav Aggarwal: Saumen sir on the interest cost, now for the Teva net debt we have taken for this deal, how much is the interest roughly cost for the debt, because two sub questions there, because sequentially our interest cost is down. Has that Teva debt contributed to interest expense in this quarter?

Saumen Chakraborty: Yes, to the extent we took in middle of the quarter, the interest expense is there, but so far it is a short-term borrowing, the interest rate is low.

Anubhav Aggarwal: Why would our interest costs were down sequentially?

Saunak Savla: As per the accounting requirements, certain portion might get capitalized also. So it is a net impact of that.

Anubhav Aggarwal: Maybe I will take a detail offline.

Surya Patra: Just one clarification. Whether the rising shares from Nexium have supported this quarter in the US business?

Abhijit Mukherjee: I think it is stable and double-digit and nothing major to report at this juncture, it is going fine, but as and when new competition comes in, there may be some erosion.

Surya Patra: Secondly, in fact, I just wanted to know something more on the NDA launches that we have talked about. So whether the kind of expenses what we are currently incurring on that is sort of stabilized and we should be seeing a kind of a similar trend going ahead in the subsequent quarter or it can see a kind of spike also, by what time we should be expecting a breakeven for this division?

Saumen Chakraborty: We have earlier told that for rest of the year in Proprietary Product, because of the In-process R&D assets that we acquired, we will be spending additional roughly around $25 million. So, we will be very much within that kind of a range. That will expand incremental R&D spend that we are doing overall for the organization. Proprietary Products, you had a detailed commentary from Anil in terms of the two products that we have launched in the market. That is how one is focusing in terms of generating more prescription. We will have to now see the movement both in terms of our existing organic R&D as well as in process R&D and depending on that the overall breakeven timeline could vary.

Surya Patra: So in that case, whatever the growth on the prescriber front that we have seen in the recent quarter and recent months since the launch of the division, whether we have captured already 20% of the total potential key prescribers or it is like 30%, 40%, some sense can you provide on that?

Anil Namboodripad: We have right now captured roughly around 15% or so in Neurology and slightly higher in Dermatology, but we intend to capture much more over the next coming months. As I said, we have seen a significant growth month-by-month actually, and if this trend continues, then we will be able to capture a significant proportion of our key prescribers within the next several months.

Surya Patra: What is the kind of update that we received from US FDA on the earlier communications that we have already provided to them, any clarity that you have so far received sir?

Abhijit Mukherjee: No, normally their interim updates not come in. So there is no interim update, but certainly we are in the process of trying to organize face to face, which is moving ahead. Beyond that there is no update.

Sameer Baisiwala: Abhijit, if you can update us on three key opportunities, one is Aloxi court case, second is Copaxone 20 mg refiling, and the third one is on Gleevec the site switch and potential launch in the 4Q?

Abhijit Mukherjee: Aloxi hopefully we will hear something in Q3, I think there are enough predictions made by various people who are knowledgeable on the subject. So let us see how that works out and then that will be a very big event for us, but we will see how it pans out. The second is Gleevec. We had mentioned that sometime in Q4 and the site transfer, etc., has been submitted in time and I think that should not come in the way of approval. Currently, as you know, two more have launched, and I think also some of the public domain announcements from innovators, there could be one more at least coming in and then let us see. So beyond that your guess is as good as mine. The third question, Copaxone 20 mg, the validation batches are complete, it looks good. Compilation of the response is going on, we are behind schedule by a couple of weeks, but because the amount of analytical data to be generated is fairly heavy. But we again feel good about the way the whole thing has panned out, I think the work done is good and this would be hopefully, by let us say by second week of next month we should respond back on the DMF and this is the same DMF for 40 mg.

Sameer Baisiwala: Abhijit, on Aloxi, it would be a district court decision. Assuming if you get a favorable one, would you rather wait for appeal or would you be prepared to launch at risk?

Abhijit Mukherjee: Would not comment on that, Sameer. Let this be debated internally and we will see whatever happens.

Sameer Baisiwala: Abhijit, in your opening remarks, if I am not wrong you mentioned that some of your top products, there could be more competition coming in and there could be more downside. So do you think there is more vulnerability left in say your

top five, top six products over next two to four quarters in a material manner, not small here and there?

Abhijit Mukherjee: I understand where you are coming from. In North America generics, the order of the day is to always be prepared for some downside. When you ask me that, do we have concrete sort of visibility on competition coming in, maybe not, but you always hear that someone is getting ready on this, we hear Nexium, several people so on and so forth. I would not be able to back it up with specifics. But I think in today's terms, market is getting crowded, it is consolidated market shares, you defend, you lose, you do not defend, you lose. So always it is better to be prepared for the worst.

Shyam Srinivasan: I think on the opening remarks you talked about the working capital days has actually stretched. Can you just tell us how much of that is because of the channel part and how much would be for the launches that you are anticipating in the second half?

Saumen Chakraborty: So mostly for the launch preparation as well as geographic expansions that we are doing, there is some volatility which is there in our payable. Last quarter, it was an increased kind of payable days, which has again run back to our normal range. So, that has an impact in terms of the working capital.

Shyam Srinivasan: So nothing from the consolidation of the channel you think, that has played out largely.

Saumen Chakraborty: There is no exceptional kind of this thing.

Shyam Srinivasan: Second question is on this NPPA provisions, I think Rs.34 crores. Can you just update us on the several cases that are happening for not only you for the several other players, just your thoughts on the whole thing?

Saumen Chakraborty: The NPPA case is primarily what IPA has filed and that was initially rejected in the High Court and then recently when the attempt was made by IPA to get it admitted in Supreme Court, that has all been defeated. So we have now accrued that potential liability which is Rs.34 crores on that, and definitely half of the products we are already complying, so remaining half immediately we will start complying from now.

Shyam Srinivasan: So do you foresee more such provisions?

Saumen Chakraborty: It depends on some other cases which are going on in terms of the method of computation. So one has to wait and find out some of those cases. We right now accrued the liability as what is very logical and right kind of provision.

Nimish Mehta: Just a few product updates on Cubicin, that is Daptomycin and Diprivan, which is Propofol, when do you think we will be launching those products?

Abhijit Mukherjee: Specific comments we would not be able to give you.

Nimish Mehta: The other one, among the facilities which are actually under US FDA warning letter, have we seen any regulatory update from any other regulatory agency other than US?

Saumen Chakraborty: Yes, Health Canada audited our CTO facility, Chemical TechOps facility which is in the Srikakulam district and they have indicated compliant status now.

Nimish Mehta: So this is in the API part?

Saumen Chakraborty: Yes, this is good news for that plant, because the last audit happened by the Australian authority, that also went well and now Health Canada has also done well.

Nimish Mehta: Does that in any which way increase the chances of US FDA, can you see it earlier?

Saumen Chakraborty: We do not want to comment and speculate on US FDA actions, we would be eagerly waiting for any reinspection that may happen.

Abhijit Mukherjee: Any regulatory agency, it is completely their prerogative. There is absolutely no connectivity between the different regions. Since you asked, we just gave you that data point.

Manoj Garg: Abhijit, just since there is a recent ruling where Actavis had joined the litigation for NuvaRing. So just would like to understand, do you think that probably you see higher visibility and possibility of you guys launching these products in the next fiscal year?

Abhijit Mukherjee: Not impossible, but it is under litigation. So there is one data point as you know in the public domain which you can look up which has gone in favor of Generics.

The file has clearly good position but it is in the court of law. But as I mentioned overall we feel good about the current stage, things may change.

Manoj Garg: The second thing as a part of risk mitigation, since most of the key assets which were from the affected facilities, you have already done the site transfers. But are you also now looking to do the similar thing for even some of your key assets in FY18 as well?

Abhijit Mukherjee: We will have to continue, we have a program, we closely oversee and I personally chair those meetings. It is an important activity for this company, and we are continuing to do those things. I think we would not like to take chances. But it takes time, even after they transfer, when you submit it, goes through some timeframe which the agency may take for going through the data of stability and all that, but the activity continues completely in full swing.

Manoj Garg: Particularly. like the Russian guy. like BIOCAD has put an allegation on Roche that they have been taking very high price cut for some of their biosimilar assets in Russia in order to make sure that generic companies goes out of the business. With your backdrop and obviously you are participating now in one of the products with tender, what is your view on that and how do you see in terms of overall pricing environment for Rituximab in the Russian market?

Abhijit Mukherjee: First of all, any allegation is prerogative of that particular company. We will go through the normal process; we will participate in the tender and see what happens. It is not just about Russia. As we speak we feel we are fairly excited about many markets where we have filed. I think we are seeing traction in terms of regulatory agencies receptive to quickly to review these files. I think from the access affordability angle it is an exciting journey in many of these markets where the penetration is hindered by the price and we would like to play a role while creating our own business.

Saion Mukherjee: Abhijit, on the US side, the new launches are quite critical as you keep facing competition. So slightly from a longer-term perspective maybe FY '18 and '19, can you just help us understand how should we think about, because last two years we have not seen any major launches from Dr. Reddy's and particularly on product-specific Copaxone, since you are going to re-file it, how confident you feel about the approval, given that there is already one generic in the market, do you have enough visibility now, some guidelines from FDA that makes you feel

or now when you submit it would be in a stage where it can be approved quickly?

Abhijit Mukherjee: So let me give you the broad picture first; overall the filing - approval scenario is clearly moving in the right direction. There are always ifs and buts as I mentioned. So without those disclaimers, I think we are feeling good about next year as well. So let us see how this pans out. I know it is a combination of our filings, it is a combination of some of the partnerships, these partnership activities started sometime back, gaining traction, some of them are thoughtfully done and it should be an important part of the business as well. So all in all, I think again we remain optimistic. Copaxone, I think as I said, validation is complete, from our angle I think we have done a fair bit of job, detailed. Let us submit and see. These are complex assets, just one approval and I think we have done, we took our time to sort of go through the response and let us see how that progresses.

Saion Mukherjee: In terms of your patches and soft gels, etc., when do you expect those launches?

Abhijit Mukherjee: Moving on, there is some settlement in one product, these are new areas, but I think the learning curve is slowly getting behind us, I think we are moving okay. That is why I am saying some of this hopefully next year should be seeing and let us see.

Saion Mukherjee: Related to OctoPlus and complex injectable filings from there, any progress on that front?

Abhijit Mukherjee: Progress is happening, injectables pipeline overall is shaping up well, it is not just complex, there are carefully picked opportunities. If you do the portfolio management as well the opportunities we take some bets on, some of them are good. OctoPlus is a combination of semi-complex and complex. The complex story is yet to play out in full, but there are lots of assets which are value-accretive still which are some of them filed, some of them filing.

Saion Mukherjee: On Proprietory Products and Biosimilars, Xeglyze approval has not yet come through. Any reason for that? Secondly if you can update on your Biosimilar program?

Anil Namboodiripad: The Xeglyze approval is pending, the feedback from the FDA on our plants, because the API is manufactured in one of our plants. So, we anticipate that as

soon as we get positive feedback, we will be able to contact the FDA for approval and eventual launch. So it is tied to the timelines of when we get FDA clearance.

Abhijit Mukherjee: On Biosimilars, the story is progressing well on the emerging markets while the regulatory markets is slightly long-term, and emerging markets I think as I mentioned probably next year we will see meaningful launches coming up.

Saion Mukherjee: Just a clarification on Xeglyze, you mean it is from Srikakulam and that is the reason you are not getting an approval?

Abhijit Mukherjee: That is what I said, yes.

Saion Mukherjee: Is there a possibility to do site transfer for this product?

Anil Namboodiripad: Until we get clearance from the primary side, it will be difficult to do a site transfer at this time.

Nitin Agarwal: On the Biologics side, can you please let us know in terms of what is the size of the Biologics business that we are doing right now? Secondly, how many assets are we currently selling in the emerging markets?

Abhijit Mukherjee: Currently three, the earlier assets Reditux, Pegfilgrastim and Darbepoetin, so these are the three give or take revenues in the range of $40-$50 million. But as I said, the bigger ones hopefully in near future, Russia, Venezuela, maybe Algeria, maybe few other countries. Currently we are selling in several markets like Chile, Vietnam. Ukraine, we just launched just about a quarter and a half back, doing very well. So let us see.

Nitin Agarwal: This $40 million or thereabouts is across including Indian sales also, the sales in India?

Abhijit Mukherjee: That is $50 million, yes.

Nitin Agarwal: In terms of the pipeline, how does the Biologics pipeline would look like for us?

Abhijit Mukherjee: Again without going to specifics, the two more mabs are well in clinic, progressing well. So based on certain amount of data we will go ahead with emerging markets and keep moving that further. So that is going well both in clinics.

Abhishek Sharma: Sir, I just wanted to ask you about the base business and its impact that it had on account of warning letter. Was there any loss of volume on any of the existing products that you would hope to make up once the warning letter is lifted?

Abhijit Mukherjee: Volumes, I am not sure it was impacted, because of the letter, but certainly, we lost opportunities and some of it is history now and I have mentioned in earlier, we were in the first wave of Nexium, which was a big thing and there are a few other products which certainly we missed out, and wouldn't quantify the figure here, but I think it has been a significant impact, but hopefully most of it is behind us and we will be able to sort of here on move the needle up. I will leave it there.

Abhishek Sharma: The second one is around SG&A cost. Apart from remediation, is there any other cost line item which helped reduce the number on an absolute basis sequentially and can this go down further?

Saumen Chakraborty: We have a cost excellence program and operational excellence program to specifically see that where there is a possibility of improvement. So that is why year-on-year basis you see that the increase is very nominal which is actually mostly for the annual increment that we would have given effective 1st of April. Going forward, this is one area we are going to continue to drive and see that how we can get a better productivity, but a lot of productivity depends on actually the revenue line increasing. As we see if the revenue goes up, we can expect a better EBITDA margin.

Saunak Savla: Thank you all for joining the call. In case of any additional clarifications, please feel free to reach out to Ashish, Amit or myself. Thank you Anil for joining in the call, thank you, sirs.