“Dr. Reddy's Laboratories Limited Q2 FY18 Earnings Conference Call”

October 31, 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 second quarter ended 30th September 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 on 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. Abhijit Mukherjee – our COO; Mr. Saumen Chakraborty – our CFO; Mr. Anil Namboodiripad, who Heads our Proprietary Products Business and the Investor Relations team.

Before I 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.

So now I will hand over the call to Mr. Saumen Chakraborty – our CFO.

Saumen Chakraborty:

Thank you, Saunak. Greetings to everyone. I begin with key financial highlights. For this section, all the amounts are translated into U.S. dollar at the convenient translation rate of Rs 65.30, which is the rate as of 29 September, 2017.

Consolidated Revenues for the quarter at Rs. 3,546 crores or $543 million, grew 7% sequentially, however marginally declined 1% year-on-year. The sequential growth was primarily driven by part-normalization of the channel inventory for our domestic formulations business and the improvement in the PSAI business after a subdued Q1. This was partially offset by the continuing pressure of price erosion in our North America Generics base business. Revenues from Global Generic segment is at $438 million, and PSAI segment is at $87 million.

Consolidated gross profit margin for the quarter is at 53.3%, sequential improvement of 170 basis points. Gross margins from Global Generics and PSAI were at around 59% and 20% respectively. Sequential improvement is largely attributable to the overhead leverage benefit.

SG&A spend, including amortization, for the quarter is Rs. 1,103 crores or $169 million representing a sequential decrease of 6%. A part of the improvement reflects our ongoing efforts on optimizing spend base. SG&A spend is at 31.1% of sales now as compared to 32.8% for Q2 FY 17 and 35.5% for Q1 FY 18.

R&D expense for the quarter is Rs. 418 crores or $64 million, representing 11.8% to revenues. Lower spend was primarily on account of deferment in some of the milestone payouts towards the balance part of the year and this does not reflect any change in our R&D strategy. On an absolute scale, we expect to close this financial year in line with the previous year levels i.e. around $300mn or so.

EBITDA for the quarter is Rs. 689 crores, which is $105 million and is around 19.4% of the revenues. During the quarter, we generated $130 million of positive cash flow from operations. Our net debt to equity ratio stands at 0.30 as on 30th September, 2017.

The effective tax rate is around 26.5% for the quarter; however, 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 decreased by Rs. 100 crores or $15 million during this quarter. Capital expenditure for the quarter was Rs. 281 crores or $43 million. Foreign currency cash flow hedges for the next twelve months in the form of derivatives for U.S. dollar are approximately $240 million, largely hedged around the range of Rs. 65.9 to Rs. 68.3 to the dollar. In addition, we have balance sheet hedges of $322 million. We also have foreign currency cash flow hedges of Ruble 600 million at the rate of Rs. 1.131 to the rouble, maturing over next six months.

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

Abhijit Mukherjee:

Thank you, Saumen. Greetings to everybody, and a warm welcome on this earnings conference call. Let me take you through the business highlights for each of our key markets. At an overall level, we have seen recovery on a sequential basis and we believe that we will be able to build on this further.

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

Our North America generics business revenues for the quarter are at $221 million, a decline of 4% on a sequential basis, mainly driven by accelerated price erosion for the base business. The generics market is undergoing significant structural changes leading to adverse market conditions in the short term. On the other hand, we have had a good year in terms of new launches with 8 product launches in U.S. and 2 in Canada. Many of these launches have been in limited competition space and expected to contribute meaningfully to our business. We are on track to achieve our target market shares for key assets like Liposomal doxorubicin, Bivalirudin with revenue recognition reaching peak potential by end of next quarter.

As you may be aware, we launched Sevelamer Carbonate towards the end of 2nd quarter with revenue recognition expected to begin Q3 onwards. This has been yet another significant launch for us in limited competition space and we're in the process of ramping up our market share. The remaining part of this fiscal is expected to remain busy on few new launches side as we continue to work with the agency on the approval of our assets and remain optimistic on two to three launches per quarter.

Our Europe business recorded sales of € 32 Mn with a year-on-year growth of 35% and sequential growth of 10%, supported by new product launches. As you may be aware, this quarter we faced marginal supply issues following the German Regulatory audit at one of our Formulations facility in Bachupally. We are now focused on addressing the concerns as per committed Corrective and Preventive Actions.

Our Emerging Markets business performance has been consistently improving on the back of new product launches, entry into new markets, such as Brazil and Columbia, and supported by stable currency. Russia business grew 13% Y-o-Y in local currency. Performance in other markets has also been in line with our expectations. We are working towards strengthening our portfolio across the Emerging Markets with a focus on Biosimilars and leveraging our strong institution business portfolio. We remain optimistic of building this momentum further, leading to a healthy and sustainable growth in these markets.

India business revenues are at Rs. 637 crores, and grew 2% Y-o-Y and 36% on a sequential basis. After normalizing for the adjustments post GST implementation, the like-to-like Y-o-Y growth would be around 10%. While there has been gradual pickup by the channel, the inventory holding hasn't fully recovered to the pre-GST level.

The PSAI business posted revenues of $86 million, and has grown 20% on a sequential quarter, on the back of improvement in customer orders and supply situation. The business has undergone strategic realignment in last couple of years with focus shifted to value accretive segments. We believe that this shift will help sustain the growth for the business in the long term.

On our proprietary product business, we continue to execute our strategy of maximizing our in-market portfolio. In FY18, we saw significant increase in the prescriber base for our lead products Zembrace, Sernivo and Trianex. Our near-term imperative is to accelerate the commercial business' path to profitability through volume growth initiatives and managed care strategy for

base business, and, at the same time, optimization of the portfolio through selective licensing out strategies. We are also focusing on doubling-down on the development of late-stage, high-value assets that have the potential to be transformative for the business

Before I conclude, let me reiterate on our three key priorities as laid out by our CEO in the last earnings call.

First, strengthening our manufacturing and quality systems: here the key task is to systematically implement our Quality Management System. We continue to make meaningful progress on this journey. For our critical sites including the sterile injectable plant in Duvvada and oral solids plant in Bachupally, the remediation activities and continuous improvement efforts to strengthen the quality processes at these sites are on track. We are putting our best efforts to resolve these quality issues in the next few quarters.

Second, focus on building a healthy pipeline of complex products: For our near-term pipeline assets pending approval, we are actively engaging with regulatory authorities to address their concerns and taking all possible action to secure timely approval and launches.

Third, optimizing our cost structure: We believe we have made a firm start here and progressing well on the journey to realize significant cost savings in coming quarters.

With this, I conclude my section and open for Q&A.

Manoj Garg: It's good to see the business start to stabilize. So, I have a few questions. I'll now just go through the questions and then go back on mute. One, can you segregate the 11% revenue decline in North America into volume and price? Two, I believe that you have a target action date for the 20 mg glatiramer acetate product in November. Just what are your expectations there, especially in the wake of the recent Mylan Natco approval? And then three, post the EIR at Srikakulam, which was I think about a month ago, what's the status of getting that backlog cleared there? And did you have any correspondence regarding glatiramer as a backlog at that site?

Abhijit Mukherjee: On the 11% decline, we would probably send you a breakup of the price and volume, but this is the value which has been reported. Maybe we'll come back. Let me take the other questions, which you mentioned. The second one was the target action date on glatiramer. It's 10th November for 20 mg, and sometime in March for the 40 mg. I think the last we've heard that post-Mylan's approval, our file is in active review. Beyond that, we can't comment and so we hope to hear something next month in terms of, certainly there would be follow-up questions and some of those questions will be mostly on the DMF side, which will be applicable for the 40 mg as well, and hence to that extent some of the work would be done ahead of the 40 mg.

Manoj Garg: Just to interrupt, I didn't catch that. You were expecting questions on what aspects of the file?

Abhijit Mukherjee: The asset is very heavy on the drug substance side. So I think some of the questions which we receive would be also be applicable to the 40 mg asset. Your next question was on the sites. You asked about the Duvvada site or Srikakulam site?

Manoj Garg: I asked about Srikakulam. So, the EIR was issued about a month ago, I think on September 28. So just wanted to see what the status was, starting to get the backlog cleared there. And then the follow on to that was is glatiramer also filed out of there?

Abhijit Mukherjee: So, there are two dosage sites in Srikakulam. So, both have been through in the audits and one is an oral solid site and the second one is topical and few other dosages. So, this is not the site from where glatiramer has been filed. So, the manufacturing has always been on. We earlier had an EIR, the audit happened and so the approved status continues and gRenvela has been launched from this site, so that continues. This is the finished oral dosage site. And you also asked about the German inspection; I think we have provided details about that. This was the Bachupally site, which we had a series of adverse observations, and we are at the moment sort of, we have responded and we are implementing the commitments we made to the authorities. We will have to go through another audit, maybe sometime in Q4. We wouldn't exactly be able to let you know the date and we'll see where it goes from there. But we're putting in concerted efforts to sort of make sure that we remediate all the observations.

Manoj Garg: Okay. This is very helpful. Thank you for the color. And then perhaps, if later on in the call, if you're able to provide that break up in terms of volume versus price.

Abhijit Mukherjee: Okay, alright. Maybe, Saunak will respond to you separately on that.

Anubhav Aggarwal: Abhijit, just one question on the market. Several companies have mentioned that with the price erosion happening in the U.S., companies are reaching a pain point where returns are less. I just wanted to get some understanding that if you look at your portfolio roughly, very roughly what would you indicate that what percentage of portfolio now, if you just put it threshold as return of capital or let's say some return as 10%-15%. What percentage of your U.S. portfolio will be making returns less than that? Just to understand that when companies say it's a pain point, is it just making lesser margin versus what they were making earlier or we come to a point where we are not even covering our cost of capital?

Abhijit Mukherjee: I don't think we are or maybe any other companies are at that point where return on capital is getting challenged. I mean where we are is, compared to the margins, industry were used to during the past, has taken a very severe hit. The various companies have messaged the erosion. Base business is eroding and will continue to erode, I think, with the consolidations happening. Plus, once in a while we would have, that I think Teva pretty much mentioned that in their conference call that there will be a hit for every company and for them as well which are more meaty, which will once in a while take a higher hit. So, return on capital is at least for established companies is not that big an issue I would say, but certainly for someone putting up Greenfield site starting from scratch to approval, that's going to be a challenge, can't speak on behalf of those companies.

Anubhav Aggarwal: Yes. But just to ask this further. So, my question was not on your total portfolio in the U.S. Let's say of course there were some products like for example, Doxil or Decitabine, which are pretty good products, but even if the products which are let us say in quarter four or quarter three in terms of returns even are we not making money on those products or should we assume that if you are not making return you are simply exiting those products already?

Abhijit Mukherjee: It's true for every company. I think the moment you are not making money, in the sense, the moment even the gross margin dropped below a certain level, I think every company tends to exit at least organized companies I think. And it's true for us as well, most are true for us.

Anubhav Aggarwal: Sure. The second question was on the India growth. So even if you take adjusted growth of 10% given restocking this quarter, doesn't this number looks little lower. We have seen a mix trend. Some company is reporting 20% like-to-like. Most of the guys have been around 12%, 13%, so somehow this 10% number looks little low. What happened in this quarter?

Abhijit Mukherjee: No, I mean look, firstly I wouldn't challenge your observation. Are we happy with the existing state of business, No. Certainly there are some parts, some divisions where there is scope for improvement. But where from the lows of last quarter, I think there has been substantial catchup. But overall, India business, I think we have some more work to do. We certainly have some more work to do. Certain areas we're doing well. Oncology, Amgen assets launched, getting

great deal of traction, and certain parts of the business, gastro, etc., are doing well. On some other parts of the business, historically Dr. Reddy's have not been very strong. There is some work to do for us in the India business, yes.

Anubhav Aggarwal: Sure. And if I can just ask one question to Saumen sir, employee cost was down 3% year-on-year this time. Historically, we've seen our employee costs increasing. Just wanted to ask that what's the outlook here? The full year number if I look further, we had one off lower sales in the quarter four last year, but like-to-like, what kind of employee cost increase should we build in on an annual basis?

Saumen Chakraborty: This year, we have focused a lot in terms of optimizing our cost structure and that includes even the manpower cost. The kind of increment which we have given this year is also comparatively much lower than what our people were used to for the previous years and all. And we know there is some part of the manpower cost which is completely performance linked, and based on our Q1 performance, which is quite a bit of disaster, there will be definitely to that extent that part gets impacted. So, we will try to control. So, the thing is the kind of growth we are accustomed too in terms of the manpower cost, we don't expect that kind of thing to happen this year. So, which is a healthy sign in terms of controlling, but beyond manpower cost overall, the SG&A productivity we would like to improve and that is what is something which Prasad also alluded to last time that one of the key priorities is on optimizing on our cost structure, which we're just seeing some early development.

Neha Manpuria: Sir, is it fair to understand that the U.S. business seem neutral this quarter despite having some good launches, launches like Doxil etc. probably didn't contribute too much into the quarter and therefore we should expect that to ramp up fully into third quarter?

Saumen Chakraborty: So, one thing I would like to clarify that Sevelamer we launched on 29th of September which is beyond the cut-off date for the revenue recognition. So, there has been no revenue recognition on account of Sevelamer. Okay.

Neha Manpuria: No. I was talking about Doxil sir, because I would have assumed that would be a good product to sort of start gaining ground in the quarter. Is it fair to assume that Doxil hasn't contributed at all or the contribution is very minimal in the quarter and therefore we should start seeing an improvement in that contribution of sales as we go into third quarter?

Abhijit Mukherjee: No, Doxil is not insignificant this quarter. Doxil is in double digit, early double digit this quarter and it has been a good launch. Would it be a little more, it could be, I can't comment on that. But it is not certainly insignificant this quarter.

Neha Manpuria: And sir second on the cost savings. From what I've understood, you've already seen if I exclude the one-off, we have seen about 10% cost saving already quarter-on-quarter. My understanding is that the cost optimization networks will be more gradual from your last call. Is it fair to say

that a lot of the low hanging fruit is probably captured in the cost saving that we have seen in the quarter and you can't build as much as you have, or save as much as you have shown in this quarter?

Abhijit Mukherjee: So, I'll comment in generality first and then Saumen can add some specifics on that. I think you'll have to look at cost savings in a broader perspective. I think there is serious effort in changing the cultural context of our spend base. And we are trying to be diligent and frugal in many ways. The model is changing, not just in North America, in the home country as well - there is pricing pressure. So, we'll have to realign ourselves and we are seriously putting efforts. Now that's playing out in SG&A, that's playing out in manpower, and that will play out in many other activities. It is being led by a very competent team internally. It's driven by internal managers and showing traction. So, beyond that Saumen you want to comment on anything of the figures?

Saumen Chakraborty: Yes. Some of the things which we try to focus on includes manpower cost, includes like travel costs, power & fuel, repair & maintenance and all such things. But having said that, selling cost, there will be fluctuations quarter wise because in some quarter there would be specific set of activities, which would be planned. But there is a concerted effort in terms of structural cost, which will eventually get realized, some of them may be this fiscal, some of them maybe in next fiscal or so. So, it'll be a continuous effort. Yes, I know, low hanging fruits are something which would have immediately given us some impact.

Surjit Pal: Saumen, my questions actually I was going through your IndAS consolidated numbers and I have two questions. One question is that if I go by your cost items and if I see the total expenditure to say it is 90 in Q1 and Q2 it is 81. So, quarter-on-quarter 8% is quite a big jump in terms of improvement. And if I go further, I see that your raw materials I mean, all items, purchase of finished goods I can understand, but be it raw materials or be it employee cost or be it selling expenditure, be it other expenditure everything quarter-on-quarter has down. Optimization is one thing. But how come it has come down so drastically, I mean, if I compare almost Rs. 50 to 60 crore on an average of the item. So that is one. Second thing is that your receivables, if I go by your current receivables in the last six months from March to September, it has been increased by Rs. 411 crore. And if I go by first half year-on-year growth of your sales that is Rs. 42 crore. Could you tell me what are the source of high receivables?

Saumen Chakraborty: Yes, I will take the second question first. Because of customer consolidation which is happening in USA, the credit period there would have been various ranges. So now the moment consolidation takes place, all the terms would go towards which is beneficial for the customer. So that's why the credit period itself is going up. And any sales in USA where there is a quite a bit of charge back and all, the actual receivables effectively is much more than the credit period. So that is something which has impacted in terms of receivables, but very specifically for the quarter there is some more receivables than normal which we have seen in both PSAI business

and Russia business which will get corrected. But the credit period impact in terms of receivables for North America is there to stay.

Surjit Pal: I am sorry I want to interpret over here. You said what is the current receivable days in U.S.?

Saumen Chakraborty: The credit period you know earlier there was a range, but actually now most of the contract it is now 90 days kind of a credit period, but in effective credit period as you take the charge back impact which we need to pay immediately, it goes beyond 110 days effective DSO. With that, if you take 90 days it goes beyond 110 days. And then to come to your first question, the material cost will definitely depend a lot on the business mix so that means if GG to PSAI, if there is a variation in the ratio, that will have an impact. And second, there are some parts which have the quality related provisions which happens from quarter-to-quarter, there would be definite fluctuations there. In terms of the other improvement that we have seen, we were just stating to Neha earlier - selling expense this specific quarter is low and which does not mean the other quarters' selling expense cannot be higher. As I said this will be activities which are planned quarter specific and specifically for the branded business there are calendars.

Surjit Pal: So from that perspective, do you want to mean is that Sevelamer where the sales you have not booked in this quarter, but cost you have booked fully this quarter right?

Saumen Chakraborty: The sales and cost matching always takes place. Way to do it will be if you look at on the India standalone and vis-à-vis consolidated, there may be a different impact. But so far as consolidated sales are there, every dollar of sales we have to match with the cost of revenue.

Surjit Pal: Abhijit, could you throw some light on Suboxone and NuvaRing current status?

Abhijit Mukherjee: Not a great deal of change. I think we messaged that in the Q4 we have the TAD for Suboxone. On the litigation side, you are aware I think, we remain fairly optimistic and let's see where it takes us. So, we have responded to the CR about four, five months back, in June I think we responded. So, we'll see how that goes. And nearer the TAD date whether there are some more questions, but we remain optimistic on the litigation front. As far as NuvaRing is concerned, our TAD is in March and anyway the concerned IP is expiring in early April or something. So, if that becomes irrelevant, so it all depends on whether we'll get approval on time. It's a drug device combination. Again, we have responded few months back on the CR and let's see how that goes. So far so good.

Nimish Mehta: Just wanted to know U.S. GMP status on Bachupally as regards the 483 have you heard that on whether we have VAI, OAI or anything on that front,that will be helpful.

Abhijit Mukherjee: So, if you recall, we had quite a few observations in that site. So, we received a query from the agency on specifically on one observation dealing with the investigation and validation and we provided that data about a couple of months back, if I recall correctly, and then we had received

another follow-up to the same question, some more data requests and which we have compiled and all that is going out towards the end of this week. Beyond that, we will see how that sort of goes. So, we are just sort off done with the process of compilation of that data, and will send it out. So out of all the observations, one specific observation they had more questions which we are responding which is in the area of, basically, validation and litigation.

Nimish Mehta: Have we not heard anything from USFDA on the regulatory status of the facility, I am specifically asking whether we have got OAI?

Abhijit Mukherjee: So still the questions normally happen if there are more observations. There are questions on observations. Till the questions are satisfactorily answered, we will not get the approvals going through. So, the questions we have to answer and then if the agency is satisfied, then it's sort of approval start from this site.

Nimish Mehta: Okay. Any timeline you see by the time you will be able to clear this and also if you can give some color on the number of approvals dependent on that facility over the next 18 months, more sort of the important ones, important of course from the site, that will be helpful?

Abhijit Mukherjee: So specific timing on anything we're dealing with the agency will be difficult for us to comment, because our job is to turn it around on the committed date and sort of engage with them as and when any questions come up. As far as approvals and launches are concerned, we have eight so far, eight from North America and two from Canada. It's why I'm mentioning Canada as well because it is clubbed under the same geography and give or take may be six more or so till end of the financial year. Well, specifics we'll not get into and we'll see how that unfolds.

Nimish Mehta: No, I was asking about Bachupally specifically as to how much, I mean, how many approvals are dependent on Bachupally which we expect over the next 12 to 18 months?

Abhijit Mukherjee: That we will not be able to comment. I just mentioned that we have another oral solid dosage site where EIR is with us and many filings have been taken from that site. Bachupally site was our erstwhile site and we wouldn't be able to specifically give the breakup of what else is pending. But yes, overall for the company there are quite a few assets between Duvvada and Bachupally, that are complete in terms of review and some of them are certainly mid-sized potentially, which had been impacted because of the GMP status.

Nimish Mehta: Finally, last one if I can squeeze. The gross margin has been almost fluctuating over the last 2-3 quarters and I understand the reasons there are many, so is this the gross margin we can consider to be sustainable from here on, obviously depending on the product mix, but is there any one-off in this gross margin or is this kind of the working level ?

Saumen Chakraborty: See, last quarter we said that it will improve from Q1, but we cannot hope to go back to a level of like a 60% kind of gross margin that will be very difficult because of the price erosion which

has happened. So, depending on the business mix and new product launches, one can see the range between say 53 to, at a very good quarter it could be around 55 that's kind of level.

Nimish Mehta: I see. But there is no one-off related to let's say, the resolution costs or any other thing, right, all I'm saying?

Saumen Chakraborty: I said, there is a lot of overheads leverage benefit which happens when your sales goes up. So, the first quarter, the cost of the overall sales and of course the GST transition impact in India was a major contributor there, which was low. To that extent, it impacts several products.

Saion Mukherjee: Sir, you mentioned two, three launches every quarter. I'm just wondering given all the uncertainty around the sites for Duvvada and Bachupally, what kind of visibility you have. Can you just take us through mitigation steps that you would have taken. And what kind of confidence you have on the key assets which are out of these sites that they will ultimately get approved even if let's say there is a delay in resolution?

Abhijit Mukherjee: So, as I mentioned that we certainly have few assets which are with reasonable earnings potential, which are at the moment 'review completed' and unfortunately waiting on the sites. So, the priority on hand is to do very active site transfer not just for these, but prospectively for the important assets and which is going on as we speak. But some of this impact as we are already seeing in the current moment, but we would continue to do here onwards much more proactive site transfer. Not to say, that doesn't mean that we are not, we are very actively working on the site. We remain eventually optimistic where we will be able to mitigate these and go to the other spot. We will always continue to put high focus on derisking especially the important assets.

Saion Mukherjee: Okay. And sir, if I go with this run rate like you are talking about maybe around 15 launches over the next 18 months, how many would you say would be like high-value assets that we should expect?

Abhijit Mukherjee: That could be difficult, same answer which I have been giving, because first is the destiny of assets are better known after the launches come through or the approval comes through, one. Two, the uncertainty on even in the assets where there is no site issue, uncertainty in terms of what questions you will have and what types of CR you will receive has been varying a lot and I think from our expectation angle. And so, it will be completely incorrect to sort of comment on that how many would be high value. But the pipeline which we have continues to be very good. We have great confidence on the type of assets which we have filed. So, let's see what destiny has installed for us.

Saion Mukherjee: Okay, great. And so just one thing on the proprietary product if Anil sir can answer. I mean we have talked about trying to get the sales there. We have stopped the discounts etc. It has been almost like a year now more than a year. So isn't it like for a reformulated asset that you have

launched, it's taking just too long to get those sales and you talked about I think $30 million, $40 million both for Sernivo and Zembrace as peak sales. Do you see risk to that given what has happened so far in the market?

Anil Namboodiripad: So, let me try to answer your question - the first part of your question which is reformulated assets and performance in the marketplace. First of all, it is not about reformulated or a new chemical entity. It is more around the payer landscape which is changing in the United States. It is evolving and manufacturers such as us and many others in the market need to adapt to these changing landscape. So again it's not about reformulated assets. Second, so what that means is that, as opposed to in previous years three, four years ago - today the difference is that it takes a little longer in terms of getting listed on formularies. And what we have done, both with Zembrace and Sernivo, is that we have made significant progress since last year. For example, if you just look at the overall Promius sales as compared Q1 to Q2, we have jumped 30% in terms of our revenue. Why that has happened? Well, first of all volumes, I mean, physician uptake has been catching up. Second, in case of Zembrace, we've got coverage with some of the bigger plans. In this case CVS Care markets now covered Zembrace. Sernivo, we are waiting for that coverage, some of the bigger plans. So, Sernivo slightly slower than Zembrace, but Zembrace has been doing well. So, to your question of the peak sales, it is too early to comment right now because as we speak, we are continuing to get coverage across multiple plans and we hope that by end of this fiscal year we will have a significantly better coverage than, when we started out. The bottom-line to note here is that the business has been progressing and we are seeing quarter-to-quarter increases and significant increases in terms of sales.

Sameer Baisiwala: Abhijit, four big TADs over next five months, so holding your breath, I guess. So, are we looking at a blockbuster year next year or philosophically speaking how should we think about the final approval? What FDA give out many questions to you and then again goes into multiple months or would it be a shorter period to respond and hence approval getting quite quickly?

Abhijit Mukherjee: Let me try to be as specific as I can, within the limit of whatever we know. Broadly the two assets I already covered, Suboxone and NuvaRing, I think we have answered well. But both are not me-too straight forward asset. So what question the FDA would have, we will probably know only when we get the CR. But overall, we feel reasonably good about the way we have responded to this CR and hopefully should the IR, but let's see. Glati, I mentioned that we have done the best of our capability of very good job. But then this one certainly will have some questions which we are proactively working on a few things and trying to advance as much as possible. And the rest of the assets few are not in public domain, again we are prioritizing these activities is all I can tell you, Sameer. We are prioritizing a lot organizationally trying to sort of put our best scientific minds together to sort of pre-empt as much as we can. There is a lot of uncertainty today in terms of how questions are being asked at times and how those assets are progressing, made more complex by the site issues and all that. So beyond that, I wouldn't be able to throw much light whether it would be a blockbuster or rather average year, but let us see wherever it goes.

Sameer Baisiwala: And more specifically Abhijit on Copaxone. Now I'm talking about Srikakulam API site, why we've not received EIR over here. And I think the Copaxone API is coming from this site, so does that put the product at risk. And second follow-on on Copaxone. My understanding is that Teva had got fantastic patient support system and nurse call center which is so critical to getting the market share. So, would you be having the same?

Abhijit Mukherjee: So, let me take one by one. So, the API we're going by two site strategy. I will respond your API plant compliance status. But we're going by two sites strategy and there is next to it another site which we received EIR and very soon we are half way through validation and we are just sort of updating the file. But having coming back to specifically about Srikakulam site, so what we have heard from the agency is regarding that last specific audit, there doesn't seem to be further question. As we had mentioned, the audit has gone well. But there are a few questions further agency wanted regarding details about post WL some more details. Now those are sort of put together in the form of a questionnaire and we are going to probably receive that in about a week or so. And we have a fixed date telecon in the month after, towards third week of December on that. So that we will answer those telephonically, once we receive those. And then we'll see where it goes from there. But it's hopefully moving in right direction. But as I mentioned, we are anyway, we are getting to a two-site strategy for the glati API.

Sameer Baisiwala: And on the patient support system and nurse call center?

Abhijit Mukherjee: Yes. So to that extent, I think Mylan's approvals have paved the way, by the way, we are also absolutely ready, we know the support system. We will be certainly ready as and when we get through the asset, but with one more generic coming in, I think that path will be hopefully smoothened.

Sameer Baisiwala: And Abhijit on your Duvvada facility, I thought that you had mentioned that you were expecting a re-inspection end of this calendar. So, what's the update over there?

Abhijit Mukherjee: That's by far the most important site for us and as I was mentioning assets which are completed review, we are waiting approval fewer from there. So high management focus, substantial activity going on, some consultant's help also being sort of taken at the moment as we speak. We don't want to rush into absolutely, that's not right. We want to be absolutely certain, that it's not about the compliance, it's also about the sterile site all over the world are being scrutinized very heavily. So we want to make sure that the work, culture, the way people operate as much as we can sort of spend time on that and make grassroots improvement, and we are focused on that. Specific question on the timing of audit, more like towards the end of Q4.

Sameer Baisiwala: Abhijit my understanding is the problem was the warning letter was for the oncology block, but why are you not getting approval for non-onco block at Duvvada?

Abhijit Mukherjee: The way agency looks at it, it's deliberate one site. So, we will have to deal with, although the other site has not been audited, but we will have to get through this site to sort of go through the other one as well.

Sameer Baisiwala: Okay. One final question with your permission. Renvela, is it still an exciting opportunity because soon after you, Impax and Cipla have got the approval and maybe a couple of more coming or do you think this should get a lot diminished?

Abhijit Mukherjee: It is significant and it is exciting and being the second in front we have our fair market share. The entry you can see happening in a sequential manner and it depends on how the competition sort of looks at it. But Yes, I think it is still going to be significant and exciting.

Sameer Baisiwala: Abhijit, sorry, one more. Aloxi, any thoughts on it? I thought it was IP was getting a lot resolved, so approval was coming closer. So, any update on this?

Abhijit Mukherjee: So, the enbanc decision, I think one of the first things in morning one opens up a mail one is looking at it. Beyond that what I can say Sameer, I mean that anytime I guess. But we don't know what the outcome is going to be of course but you know we hope to hear soon enough.

Prakash Agarwal: Sir, question on Doxil. You did mention you would have done about early teens on Doxil. I'm just trying to understand what was Natco's role here? I mean the filing is in your name and what kind of, if you can add roughly what kind of sharing agreement we have?

Abhijit Mukherjee: So, the file is ours and it was developed and we probably had mentioned a little bit that we have put in a lot of effort in characterization capability in this company. And these products need a very large amount of characterization. So, we played a big role in that in terms of sort of proper characterization and working with agency, to see that it gets approved. Specific details of business deal, we won't able to share but we are the dominant of the two partners.

Prakash Agarwal: Fair enough. And going to Copaxone, is the understanding clear that even if the TAD is there and as you said the facility, the API facility Srikakulam is yet to be cleared. So, what happens if the TAD is due and facility still not, so do we get…what happens really?

Abhijit Mukherjee: Firstly said, that the recent audit went well and there were no further questions on that specifically. We are answering pending questions from the last WL and there is a clear pathway. So, let's see what happens. I can't really comment on the outcome, but we await optimistically on the progress of the sites. Having said that, as I mentioned we are certainly, by another couple of months, we have the new API filed in along with the T0 data as well. And then we will see, depending on how things go as both sides just rely on the new sites.

Prakash Agarwal: Perfect. And one clarification on the R&D comment that you made that there has been some deferment of milestones. So, this is related to the TEVA, you already paid the TEVA piece so what does this refer to?

Saumen Chakraborty: No, there will be lot of our developments happened through external partners as well. So, there will be some which will trigger in a specific quarter and some activities, planning and all so it is not evenly spread across the year, but as I alluded to, for the whole year in terms of absolute R&D spend, it will be similar to that of FY17.

Prakash Agarwal: Thanks, and Saumen lastly for you on other expenses, you did mention there has been optimization measures that is being taken. I'm just trying to understand with the proprietary product expansion and new launches that are happening plus India, Russia. So, is this the base and we should build some cost inflation here or how should we look at it going forward?

Saumen Chakraborty: Some of the things done for example in Colombia has already being factored in terms of because we have incurred last year, Brazil also now whatever we required. These kind of countries now we've gone with a business model where there is a lot of reliance on institutional sales and also the biosimilar and complex products. So, it is not an intensive salesforce kind of a thing unlike Russia, India, where it is a completely different model. So, having said that, we have plans on almost every aspect of our each categories of spend, we are analyzing in great detail. We are doing a lot of analytics driven kind of cost optimization which will continue.

Prakash Agarwal: Okay. So, this is likely to be the base about 20% to 23% of sales?

Saumen Chakraborty: Which one?

Prakash Agarwal: The SG&A as a total group?

Saumen Chakraborty: No, SG&A is at 31.1% this quarter, which actually if you see last year, it was 32.8% and in the previous quarter it was 35.5%. From 35.5, it has been brought down to 31.1.

Prakash Agarwal: And this 31% plus minus 1% or 2% is possible I mean?

Saumen Chakraborty: That is the range we are looking at. Yes.

Shyam Srinivasan: Just two short ones. One on generic REVLIMID, the patent, IPR filing dates, one of them is passed October 20th I thought. Do you have any specific strategy or how is Dr. Reddy's thinking about this opportunity?

Abhijit Mukherjee: Big asset for us, in litigation, so how that will play out, it is just early stage. I think that we have a good position, but too early to comment on this. As you know, the product patent goes in 2020 I guess and others are in litigation, so difficult to comment, but yes big asset for us.

Shyam Srinivasan: Okay. So, you think it's a medium-term opportunity. Would that be a fair comment on?

Abhijit Mukherjee: No. I just said it is in litigation.

Shyam Srinivasan: Sure. Okay. My second question is on again Suboxone just to follow-up the TADs in Q4, you said, the district court has given it in your favor, if all things come through and if the FDA gives the approval, do you think there is a potential for, a launch at risk, sometime next year, do you think?

Abhijit Mukherjee: I think we are very focused on the approval of the asset at the moment. As I said, we remain very optimistic about the litigation part of it and what's the current focus is - getting the asset to approval.

Shyam Srinivasan: But I thought that you don't have the first to file on this one, right? So, do you know how the FDA will treat this case because the other guys are all stuck up? So, any thoughts there would be helpful.

Abhijit Mukherjee: My information is as good as yours. Within 30 months the approval did not come through for the first filer, beyond that how to be treated is of agency's prerogative.

Shyam Srinivasan: Sure. Okay, my last question, you've given a lot of the numbers on margins and stuff, would you also venture to give us some kind of an EBITDA margin guidance for the FY 2018?

Saumen Chakraborty: No.

***** End of Call *****