“Dr. Reddy's Q4 FY-18 Earnings Conference Call”

May 22, 2018

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 fourth quarter and the full year ended 31st March 2018. 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 made available on our website very soon. 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 Mr. GV Prasad – our CEO; Mr. Erez Israeli – our COO; Mr. Saumen Chakraborty – our CFO and Mr. Anil Namboodiripad who heads our Proprietary Products business; and the Investor Relations team.

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Before I proceed with the call, I would like to remind everyone that the Safe Harbor language that is contained in today's press release also pertains to this call.

Now, I would like to turn the call over to Mr. GV Prasad – our CEO.

GV Prasad:

Thank you, Saunak. Good morning, and good evening, friends. Thank you again for joining us today.

We have concluded a challenging year with relatively muted fourth quarter performance, primarily on account of disruption in the channel sourcing pattern in Russia and higher competitive intensity with respect to some key molecules in our North America Generics business. During fiscal '18, we invested significant effort on resources in the foundational areas mainly strengthening our manufacturing and quality system, optimizing our cost structure and of course revitalizing growth. I am satisfied with the progress we are making on this journey, and I do expect to see the results of these efforts during the current year. There is, of course, more to be done and we remain firmly committed to this path.

I'd like to take this opportunity to introduce you to our new COO, Erez Israeli. As you are aware, Abhijit Mukherjee has retired recently and after his retirement, Erez joined us in April this year as Chief Operating Officer and Global Head of Generics and PSAI business. In addition to the responsibility that Abhijit handled, Erez also handles the R&D function as well as the biologics business. Erez joins us with over 25 years of experience in the pharma industry and proven leadership in general management and handling large scale global operations. He joins us from Enzymotec where he was President and CEO. Prior to that, he spent 23 years in Teva Pharmaceuticals where he held several leadership positions and he has also had stint in certain corporate functions and briefly as the Head of the Global Quality Function for Teva. Erez will be based out of Hyderabad and he will lead all aspects of the global generics and PSAI businesses.

We are pleased to have him on the management team and look forward to his contribution to bring us back to industry leadership with sustained growth and profitability.

I now invite Saumen to take us through the key highlights of the quarter.

Saumen Chakraborty:

Thank you, Prasad. Greetings everyone. Let me begin with the key financial highlights. For this section, all the amounts are translated into US dollar at the convenient translation rate of Rs. 65.11, which is the rate as of 30th March 2018.

Consolidated revenues for the year are at Rs. 14,203 crores i.e. $2.18 billion. Consolidated revenues for the quarter are Rs. 3,535 crores i.e. $543 million and declined 1% year-on-year and 7% sequentially. Though the sequential decline was on expected line, there was further softness in the Russia and North America generics business. In Russia, we witnessed some shift in the channel sourcing pattern emanating from seasonal variation. Also, if you recollect, we had a one time out-licensing fee with respect to DFD-06 in the previous quarter to the tune of $20 million. During this quarter, we accrued a follow-on milestone of $2.5 million.

Revenue from our global generics segment were $428 million and PSAI segment were $96 million.

Consolidated gross profit margin for the quarter is 53.5%. The above mentioned sequential decline largely addresses the reduction in the gross margins. Overall, on account of the lower revenue base, there is also an element of manufacturing overhead deleverage which needs to be factored in. Gross margins of Global Generics and PSAI were at 59.3% and 24.2% respectively.

The SG&A spend for the quarter is Rs. 1,207 crores i.e. $185 million. This is on the same line as that of the preceding quarter and 10% higher compared to in previous year. This quarter spend also considers some of the year end activities around ANDA filings and hence it is a bit higher. Overall, as we have mentioned earlier, we continue on our journey to improve the spend productivity and the resulting impact will be more visible during the quarters to come.

R&D spend for the quarter were at Rs. 435 crores i.e.$67 million, representing 12.3% to revenues and is in line with management estimate. For full year, it is 12.9%. Overall, there is no change in the focus on the long-term strategic outlook. However, we are taking a calibrated approach in terms of the project prioritizations and selections.

Resulting EBITDA for the quarter stands at Rs. 578 crores, i.e. $89 million which is around 16.3% of the revenues. For the full year FY18, it is 17%.

The effective tax rate is coming to around 19% for the quarter and 32% for the full year. Normalizing the impact of the recent amendment in the US tax laws, the effective tax rate for the full year is 22.6% which is within the range we guided earlier.

On a reporting basis, we end the year with an EPS of Rs. 59. Again normalizing for the impact of the US tax law amendment, it would be around Rs. 67 or so.

Overall for FY18, we generated operating cash flows of around $277 million and reinvested $140 million towards capital investment. During the quarter, we generated operating cash flows of around $83 million and the operating working capital decreased by $13 million. Our net debt equity ratio is 0.24 as on 31st March 2018. We continue our focus on optimizing the same.

Foreign currency cash flow hedges for the next 10 months in the form of derivatives for US dollars are approximately $255 million, largely hedged around the range of Rs. 65.1 crores to Rs. 68.23 to the dollars. In addition, we have balance sheet hedges of $219 million. We also have foreign currency cash flow hedges of 1350 million Rubles at the rate of Rs. 1.12 to the Rubles maturing over next 10 months.

With these, I now request Erez to take through the key business highlights.

Erez Israeli:

Thanks, Saumen. Greetings to all ladies and gentlemen and I extend the warm welcome to you on this earnings conference call.

For long, I have known Dr. Reddy's from the outside. I am honored to be part of Dr. Reddy's team. Dr. Reddy's has high focus on innovation and fine balanced approach to the market between pure generics and branded generics. Over the coming few months, we would continue to focus on growth opportunities and optimize our cost structure.

Let me take you through the performance highlights across key markets and businesses for the past quarter. Please note that in these sections, all references to numbers are in respective local currency.

Our North America Generics revenue for the quarter are at $222 million, registered a sequential decline of approximately 10%. As indicated earlier, the sequential decline was predominantly driven by high one-time sales of Sevelamer launched during limited competition phase in the third quarter coupled with full quarter impact of WBAD-Econdisc price harmonization activities for our base portfolio. The value erosion driven by incremental competition in some of our high value assets like decitabine and azacitidine, further contributed to this decline.

On the new launches front, we have fairly decent quarter. Overall, we launched three products in North America during the quarter, including the commercialization of the first-to-market assets of Palonosetron for injection and OTC levocetirizine. Beyond the performance this quarter, overall base business is held up reasonably well in line with our expectation and we remain optimistic about eventual stabilization in generic market space over medium term.

On the pipeline front, coming quarters are likely to see a fairly good number of new launches scheduled including some high value assets. We continue to make reasonable effort towards bringing first-to-market generics for the complex assets in our pipeline.

Let me update you on the status of three key near term launches, gSuboxone, gNuvaring and gCopaxone. On generic Suboxone, we had responded to the agency. We are closely watching the IP scenario and our actions would be in accordance with the developments that are on the litigation forms. On the second asset, gNuvaring, we understand that the file is in active review. However, given the fact that this is a complex drug-device combination product, we will wait for agency feedback on this. We remain optimistic on the launch of this asset in this fiscal year.

Finally, on gCopaxone, we are shortly going to submit our comprehensive response to the agency on earlier DMF related queries. Overall, we continue to actively engage with the agency on many complex assets in our pipeline. Beyond these new term launch opportunities, we are committed to augment our pipeline with complex assets to sustain long-term growth for the company.

Our Europe generic business revenue was € 22 million. The quarter revenue was impacted by temporary disruption in supplies of few of our products. This is expected to be back on track soon.

Our Emerging Market business performance for the quarter got impacted by lower offtake of Russia. Russia revenue is Ruble 2,258 million, declined 25% year-over-year. This was primarily attributed to a temporary shift in the channel purchasing pattern led by seasonal variation. Through subsequent periods, we are witnessing improving trends. This aside, we continue our focus on new product launches, entering to new markets such as Brazil and Columbia and geographical spread of our oncology institutional business. Performance in other markets has been in line with our expectation. Overall, we remain optimistic towards the double digit growth in FY19.

Our India business revenues are at Rs. 614 Crore. Though the growth is flat sequentially it is 7.5% year-over-year, normalized for the GST transition related adjustment, it's around 16% year-over-year. We are seeing progressive improvement in the business performance over the last few quarters and we strive to perform better than the market through fiscal 2019. Overall, we remain optimistic towards the double digit growth rate in FY19.

PSAI business revenues are $94 million. Our efforts are directed towards improving the supplies and building a healthy order book.

Our Proprietary business during the quarter received a follow-on milestone of $ 2.5 million with respect to DFD-06. As you are aware, towards the end of the quarter, we have filed DFN 02 with the USFDA and we are awaiting grant of PDUFA date which is estimated towards the end of January 2019. Pre-launch preparations are ongoing for an estimate launch of the product in Q1 FY20. Overall, we continue to focus on building our existing commercial footprint and also enriching the development pipeline. On the commercial side, we are experiencing increase in the prescriber base in volumes for our lead products Zembrace and Sernivo.

And with that, I would like to open the floor for questions and answers.

Manoj Garg: A few questions from me. So with the ongoing structural changes that you talked about and that we are seeing in the US market on the buying patterns, can you talk about how you are adjusting your cost infrastructure or portfolio to reflect these new realities and I will just quickly ask my other ones and then go back on mute. On the Russia, the 25% year-on-year declined on account of lower offtake by the channel, is that mean destocking and then lastly on generic Copaxone, you had indicated on your last call that you had received queries on this and that you would have a response in 4 to 5 months. So I was wondering if you could provide us an update there in terms of whether those responses have been submitted to the FDA. Thank you and I will go back on mute.

Erez Israeli: This is Erez. Thank you for the questions. On the first question on the adjustment to the US recent trends, naturally is on the portfolio side, the main thing is naturally to continue to work on very promising portfolio and we are diligently working on this, plus naturally to clear up with the FDA the certain quality issues from the past. These will serve us well in the future. And we are actively engaging on the cost as well and naturally looking into cost optimization in many assets that we may have. On the Copaxone, we are targeting to respond to the CR in the next couple of months, we did not submit it yet. Post that, we will be having a new goal date, right now for it, we do expect approval sometime in the first half of the next fiscal year. And also for Russia, yes, it is an offtake of the trends that we believe this is temporary and we believe that we will be in normal patterns in the next coming quarters.

Manoj Garg: I am sorry, it is little bit difficult to hear. So on Copaxone, you are saying that you expect to refile the data that the agency had requested in the first half of fiscal 19, is that correct?

Erez Israeli: No, this is different. So let me clarify. We are targeting to respond to the CR in actually the next couple of months already in this fiscal year with anticipation that the launch of the product will be sometime in the first half of the next fiscal year.

Manoj Garg: So in the first half of fiscal '20?

GV Prasad: Yes. That's right.

Manoj Garg: Thank you.

Neha Manpuria: Can you please update us on the status of Duvvada and Srikakulam? One, when can we expect us inviting the FDA for an inspection in Duvvada? And second, what is our sense in Srikakulam? Would that's require a re-inspection too?

GV Prasad: So on Srikakulam, we are not yet clear whether it will require a re-inspection because the inspection, which happened was fairly straight forward. The FDA has asked us to do some additional work with respect to last year of working on the investigations and data. We are doing that. And we expect to fulfill the request that FDA made with us in the next month or month and half. And after that, we will have to ask the FDA what next step should be. Duvvada, I think we have done a lot of work on remediation over the last 12 months. We expect to go back to the FDA end of June and request for re-inspection. So we cannot predict when they will come, but it should be in certain months before they come back and inspect us.

Neha Manpuria: Fair enough. And my second question is on Nuvaring. Did I understand correctly that we are going back and forth with the FDA with more queries after our response to the query that we had received as per the last earnings call? Sir, would that mean this would probably be a second half, late FY '19 product?

Saunak Savla: So the point is, what we are trying to put out is that in the earlier call we had mentioned, if you recollect that there are certain queries, which are coming and we were working on them. So at this point in time, we are closer to the endpoint. So that's why we said that on the same set of queries, we have balance around couple of months of working before we reach out to the FDA and provide them the comprehensive inputs. So that is the beginning and then hence from that point in time, we will wait for the FDA to guide us further.

Neha Manpuria: So that would mean this is a later second FY '19 opportunity in that case?

GV Prasad: Naturally.

Sebastian Sauter: So you may have mentioned this in the business highlights earlier on, just more by the sigma, why my line went a bit funny. So I was just wondering if you could provide a little bit of color around the generic Suboxone, please. If I have heard correctly, you said you have spoken to FDA and you closely watching

the IP situation. I am just wondering if I heard that correctly. And if you could just provide a bit of color around this? Thank you.

Erez Israeli: So as we stated in our last earnings call, we received a minor CR in the mid of January. We responded to this CR in mid of March. And basically now we are in discussion with a new goal date probably mid June for that. So we believe that the file is progressing in the right direction. As for the launch, again we believe that we have a good IP position, but naturally we need to see how this will fold out. And so on that perspective, whatever this will fold out, it will create an opportunity to us.

Sebastian Sauter: So the new goal there is around mid-June. Is that right?

Erez Israeli: This is for the FDA.

Sebastian Sauter: And just so what sort of launch date do you think you could, would be really.

Erez Israeli: It depends on the IP situation. Unfortunately, we cannot commit the date in that respect.

Sameer Baisiwala: Beyond these three key assets that you talked about, what else do you think you have for launch pipeline for fiscal '19?

Saumen Chakraborty: Sameer, we have not been generally discussing specific products in our portfolio.

Sameer Baisiwala: No, without going into names.

Saumen Chakraborty: So if you are specifically asking, say, FY '19, what could be the number of launches in U.S. market? Normally every year, we say based on our portfolio and our R&D investments, we prepare for 10 to 15 launches. But this year FY '19, it could be 15 plus.

Sameer Baisiwala: And of this 15 plus, other than these three, could there be more niche launches or others are all me-toos?

GV Prasad: It's a blend. It's not all me-toos, not all special products.

Sameer Baisiwala: And couple of products, which you had exited, and which are sort of in public domain products, like Zenatane where you had two-year supply issues. So

when do you think you can come back in the market and on Gleevec and Daptomycin, if you can just update on that?

GV Prasad: Zenatane, we had some issues, we are re-filing that. So it will come back in a few months. We had finished our work and we are filing soon probably.

Sameer Baisiwala: Okay, gleevec and daptomycin?

Saumen Chakraborty: Gleevec also will be a launch in this fiscal year hopefully.

Sameer Baisiwala: And, sir, just one more for, with your permission. So I am a little confused on your commentary on Nuvaring and Copaxone and here it is. So Nuvaring, I thought the TAD was, I think, somewhere around July. And given that this is a first ever generic approval, FDA generally accelerates these kind of launches. So why do you think you would be coming in end of fiscal '19? That's question number one. And question number two on Copaxone. Once you do respond to FDA in next couple of months, again, we are looking over June, July, why do you think your launch would be first half of fiscal '20, which is giving another 9 months to launch? I mean, why do you think after multiple submissions on Copaxone, why would still this submission take that so long?

Saunak Savla: So, Sameer, on the Nuvaring question, the thing is that, as you all know it is a drug-device combination. And as far as the FDA protocol goes, there is the filing review goes through multiple sections and departments and considering that drug device also goes through additional rounds of clearances, so the point that we were trying to emphasize more in terms of that we acknowledge the complexity of these products in and let's see it up. We don't know either ways. So the point we wanted to make was that from our side, we have responded to the queries in and we wait for FDA.

GV Prasad: We might get one or two more queries.

Saunak Savla: So that's more from that perspective. The second one, you are putting on Copaxone. So if I understand you correctly, the thing is that in the last call if you recollect, we mentioned there is additional set of activities that FDA had asked us to do, something which will take around four to five months, at that point in time, what we have commented. So a large part of the work has been done. It is ongoing. We now have a very clear cut view of what exactly needs to be done. And based on that, we have a visibility that within next couple of

months, we should be in a position to reach out to FDA, provide the info. Now then it rests with the FDA and as you all know considering if it is the major CR, the turnaround time can be anywhere between 8 months to 10 months from the FDA perspective. However, we will definitely engage with them, try to push them for an early clearance. And so that's how we are kind of looking at this asset. And just to be on safer side, we have put that view.

Saumen Chakraborty: We can only get a new goal date after we file our CR response. So when it comes back, then we will know what is the TAD. So a commentary that we can have in the first half of next fiscal year is more kind of a conservative timeframe of 8 to 10 months.

Vishal Manchanda: I was seeing on your Proprietary portfolio. So basically on DFN-02, just wanted to understand how this asset is differentiated with when compared to other nasal sprays in the market?

Anil Namboodiripad: Yes, I will take that question. DFN-02 is a nasal formulation of Sumatriptan as you know. We have established that the pharmacokinetic profile of DFN-02 is comparable to that seen with injections. We have also established the efficacy profile through a clinical study that was conducted and completed more recently. The difference from other nasal products is that, no other nasal product that exists within migraine has been able to show the type of efficacy that DFN-02 has shown in terms of comparison with an injection. If you look at the original nasal product that was launched by GlaxoSmithKline, the Imitrex nasal, because of the absorption of the drug or lack of absorption of the drug through the nasal mucosa, the efficacy was only slightly better than the oral and therefore, it did not see much uptake. In contrast, with DFN-02, we believe that given the absorption pattern and the similarity of efficacy or closeness of the efficacy to what we see with injections, we will see a completely different receptivity to the drug. Hope that answers your question.

Vishal Manchanda: In absence of head-to-head data comparing DFN-02 with Sumatriptan nasal spray, would this be claimed exceptional?

Anil Namboodiripad: Yes. I mean, if you look at most of the studies that have been done in the space, they have been done against placebo and that is what is required by the FDA. But given just the absolute patient experience, we believe that physicians would

be convinced to prescribe the drug. On the pharmacokinetics; we do have head-to-head data against the injection by the way.

Vishal Manchanda: So you mean that translates into clinical benefit to and that has been observed in clinical trials?

Anil Namboodiripad: That's correct.

Vishal Manchanda: Okay. And secondly on Sernivo and Zembrace SymTouch, what are the milestones that we should look for, which should kind of put more growth into these opportunities because it seems like they have been stagnating at current levels for a while?

Anil Namboodiripad: Yes, actually they are not stagnating. Let me give you some metrics that will provide more clarity on the two products. I'll start with Zembrace. If you look at the performance in FY '17 versus FY '18, prescription volume grew by 88% for Zembrace, and the prescriber base grew by around 48%. So that's one metric to follow. What is the rate of growth of prescription compared to previous quarters or previous years? The second is, how many new prescribers have we added in this year? So in FY '18, we added 1,400 new prescribers for Zembrace. What that tells you is that, the product as is being experienced by patients' gives physicians or encourage physicians to prescribe more. The other part is coverage. Coverage as in insurance companies willing to pay for the drug. If you look at that, for Zembrace, in fiscal '18, we were able to get a few big wins in terms of large managed-care organizations or insurance organizations that were willing to reimburse the drug. So those are the metrics that you need to continue to follow, that is prescription growth and prescriber growth. Now the Sernivo, it was a bit more muted than for Zembrace. The prescriptions grew by about 13% in FY '18 compared to FY '17. However, number of new prescribers was around 1,800 for FY '18. So that's another metric showing that Sernivo does have the potential. What really held back Sernivo in FY '18 was that we were not able to secure coverage by some of the larger plans that would be required in order to drive prescription or volume growth for this asset. But in FY '19, we expect to see more coverage. As I had mentioned in previous quarters, we have put in place a systematic process to approach insurance companies and negotiate with them. We have a team in place for that, and we believe we have strong capabilities now moving forward to ensure appropriate coverage. Does that answer your question?

Vishal Manchanda: So it's like, should we expect the numbers also for your Proprietary products to move up in tandem, because they haven't moved up as much?

Anil Namboodiripad: No. I mean, actually that you will see improvement in the numbers as we move along. And again, it is contingent on how we do on the coverage front. But I can just give you an example of Zembrace, where there is a clear correlation between coverage and performance. Zembrace, we tripled the net sales between full year of FY '17 and full year of FY '18, and we expect continuous growth. Sernivo, based on how we do on coverage this year, you should be looking for revenue numbers to grow as well.

Surya Patra: So just wanted to have a sense on the base U.S. business. So we have already seen the kind of impact of whatever the channel consolidation and all that. So the challenges what we have been discussing since last one year or so. But going ahead, what is the kind of visibility that we are having about your base business apart from the new launches that we are talking about?

Saumen Chakraborty: So it's very difficult to speculate what would be the scenario of price erosion in U.S. market. As you know, consecutively for last three years, it has been a double digit, moving up to mid-teen to high-teen. So last year, at the same time, we said within the 2 consecutive years, it has happened, probably it is a kind which will stabilize. So this time also we can just hope it will stabilize a bit, but we cannot say emphatically. Only thing we don't see more consolidation happening, as you have said. So that it forms a factor of customer consolidation and new competition. So we will have to just watch and observe and appropriately respond to the competitive scenario.

Surya Patra: Sir, just differently if I ask the same question like, see whatever the kind of erosion or whatever that normal erosion, the base business weakens every year. It's a factor that, and if we just leave apart the kind of a special product, what we have been talking, then based on the kind of a new product, new me-too product or Para III product, what we are planning to launch, so put together whether there is a positive delta in the base business or in the U.S. business or not? If I ask that way.

Saumen Chakraborty: Given that we are hoping that there could be 15 plus kind of the launches, which happens and some of that whatever we have launched in the last three years, every year than in the consecutive years that become part of the base. Again, it

depends a lot in terms of price erosion. This is very difficult to respond straightaway. If price erosions come back to a single digit kind of thing then probably we can grow even in that. But normally, we factor in that there will be price erosion, there will be a decline in base, and we focus more on approval and launches to make it up. And actually, there are significant launches, then we can grow. And that's how we factor in terms of US business.

Surya Patra: Okay. And in regards to the Proprietary product or the NDAs, what we have launched or we are planning to what we have been discussing, so what is the kind of, whether the NDA contribution has become like relatively meaningful as of now?

GV Prasad: For the Proprietary Products business to become meaningful, I think we will have to wait another couple of years. With the DFN-02 launch, it would be the first uptake and after that, we should see significant growth.

Surya Patra: Just on the biosimilar, if you can update us? That is the last question from my side.

GV Prasad: It is a very broad question, update. What update do you want?

Surya Patra: So like, is there any progress that we are filing here in terms of, or entering new market or any product?

GV Prasad: We have been rolling out Rituximab to many emerging markets. We are planning a trial in the U.S. And it's a bit early, but we are planning to take Rituximab to the developed markets.

Surya Patra: And so whether there is a kind of a planned R&D spend program has already been set for the biosimilar for current financial year or?

GV Prasad: So we know how much it costs, but we are looking at how we should finance it, ourselves or partner with somebody. But the asset is moving forward.

Nimesh Mehta: Just two questions. One, on Suboxone. With the evolving litigation landscape, are we still confident of making at-risk launch if we get an approval? Or has there been any change in that strategy?

GV Prasad: We cannot give you that level of specificity in the strategy.

Saumen Chakraborty: First, we need to get the approval. So we are focusing on that. We are not going to, at this point of time speak further on our strategy.

Nimesh Mehta: Is it fair to assume that approval is the only hurdle here?

GV Prasad: No, we cannot give you that level of detail. We will be giving away our strategy, just cannot do it at this point of time.

Nimesh Mehta: Okay, fine. No problem. And just one understanding on the domestic piece that you mentioned that adjusted to GST, the growth has been higher. So, I mean, why are we adjusting to GST in this quarter? I mean, I thought it was over last quarter. So just for our understanding.

Saumen Chakraborty: So this GST adjusted growth will continue from the time GST has been introduced that was from 1st of July. So one more quarter, we will have to do the same kind of a thing, which is what happened with GST, the excise duty, kind of thing, is changed and so we do a very like-to-like kind of the impact. Has GST not been there, what would have been the growth? And that's why we keep the figure**.**

Nimesh Mehta: So in that we only kind of factor in the reduction in excise duty component. I mean, in gross-to-net, is that the only adjustment we make? Or is there anything else?

GV Prasad: If you compare like-to-like, we remove GST and ED, and compare the normal growth.

Saumen Chakraborty: So you can discuss offline with Saunak to get further details. So it will be only applicable for only one more quarter. After that, of course Q2 onwards,it will be like-to-like.

Karthik Mehta: I had a question on the R&D cost. How do we see this in absolute amount? There has been a reduction on a YOY basis. I think it was in the Q2 call or in the Q3 call we had mentioned that second half R&D cost is likely to recoup back. That in absolute terms is almost the same as we had in H1. In fact, it is actually lower. So how should we look at this Prasad and in terms of ...

GV Prasad: You should take the full year numbers, don't look at quarter-on-quarter because that depends on the timing of what we do and how we pay and how we incur

the cost. So at the absolute level, this 12% to 13% is something that we should have at the same level even going forward.

Karthik Mehta: Do you see any areas where you can still maybe bring it down as we did in FY '18 over (FY'17)?

GV Prasad: We are doing, but at the same time, we are investing in clinical development of proprietary products or biosimilars that will offset the savings we have. There will be some reallocation of how we do our R&D spend, in absolute level it should remain as where it is.

Karthik Mehta: And on the tax rate, is there any guidance that you can give for FY '19?

Saumen Chakraborty: So in terms of the effective tax rate for last few years as well as this year, what we have guided to and what we have actually done, adjusting some of the one-off events which is happening for the year is between, say, 22% to 25% - in this range. So it will remain in similar kind of things. This year even though it is not a tax, a kind of a tax, but because of Trump tax law which came up in USA, we had to take deferred tax assets adjustment, which happened partly in Q3 and partly in Q4. So overall, 130 crores additional impact has been there. So that has taken the ETR off for the year. But if you adjust that, then overall ETR for the year is 22.5%.

Saion Mukherjee: Prasad, in the last call, when you came last, you talked about hundreds of crores of cost saving, which will be visible by fiscal '19. We are halfway through that. What do you say we have achieved so far of whatever your targeted cost saving was? And how much is left in which we can see in fiscal '19?

GV Prasad: So cost saving has been successful. We have seen relatively flat cost structures in multiple areas and also reduction in some areas. It's a journey. We will save in the range of hundreds of crores, and it's an ongoing journey. We will continue to do that.

Saion Mukherjee: I was just wondering like has a large part of it has been achieved or will be achieved in the next year?

GV Prasad: A significant progress has been made and we will start seeing the effect in 2019. In 2018, we saw partial effects. 2019, we will see a full effect of the same.

Saion Mukherjee: On biosimilar peg G-CSF, can you share some timeline with respect to when you can make filings for the U.S. market?

GV Prasad: Later on this year, I think Fresenius should file the biosimilar application. The clinical trial is over. I think they are just finishing the report. In the next few months, it should be filed.

Saion Mukherjee: In next few months, okay. And finally, on the PSAI segment, I was just wondering in general there has been this comment of API prices moving up because of certain capacity constraints in China? How does this impact for the whole business and for the PSAI segment, in particular? And how should we think about growth and margins in the following year?

Saumen Chakraborty: So yes in some of the key starting material or ingredients that we would have been importing from China, had seen some increase in their price, because of certain Chinese government states and some of the industries closing down there. So you see our overall cost optimization initiative, you will not get to see the full reflection in SG&A line because there is something, which comes and then we will seek in the Cost of Revenue. Now in one hand, you see so much of price erosion in North America market, but if you see the overall gross margin, the reduction is much less compared to that. So we will have to look at overall how much effect is going on cost optimization and the benefit that you are getting may not be completely visible to you only through the SG&A analysis.

GV Prasad: But the absolute amounts you will see.

Saumen Chakraborty: Yes. Absolute impact in terms of the profits that you will see. Yes, some of these things have gone up, but we have been trying to see wherever there have been opportunities otherwise.

Saion Mukherjee: And any comment on growth and outlook for PSAI you would like to make?

GV Prasad: We are not going to be that specific.

Anmol Ganjoo: I have 2 questions. One is that from a regulatory calendar standpoint, how does FY '19 look like? What is it that you consider to be the most significant regulatory timelines from an FY '19 perspective? And my second question is again slight repetition of the earlier question. On the cost optimization front,

just trying to understand it better, you have had a 2, 3 quarters since you embarked on this program, embarked on this journey of saving hundreds of crores in cost. What is the lowest hanging fruit that you've seen to have identified? And are there any very visible or stark noncore areas out of which you would like to exit and how should we be thinking about it?

GV Prasad: So in terms of the most important assets, it is clearly generic Suboxone and Nuvaring. Glati is there, but further down. These are the big assets. So to your question on cost, there is opportunity in many areas - from rationalizing the manufacturing network, optimizing our portfolios, removing wastefulness in many areas - including manning levels and multiple places. And we so far have not touched the core, it's only looking at areas where we can save without any impact on operations. Moving forward, we will actually see divestments of some sites and also other non-contributing expenditures that we have. So it's a programmatic approach, and we will continue doing that.

Anmol Ganjoo: And I think you didn't hear my first question properly. I was referring to the regulatory calendar, not the big product assets as such.

GV Prasad: What do you mean regulatory calendar? What do you mean by that?

Anmol Ganjoo: Sir, for example, in Srikakulam, Duvvada, what is it that we expect in terms of inspections

Saumen Chakraborty: Prasad, already responded to it.

GV Prasad: I already said this several times. There is no calendar as such. FDA has asked us for information, on Srikakulam. We are working on providing that back. We hope to complete the request in June. And after that, we have to talk to them about going forward. The Duvvada site has to be inspected. We have done a lot of remediation work and the inspection request will go to them in the end of June, early July and then we will await a re-inspection.

Alok Dalal: Mr. Prasad, so if you look at the last three years for the company, it's been a very difficult journey. There have been investments made in R&D and compliance, but results are yet to be seen. So do you believe some time in fiscal '19 will be a turnaround year for you? Or you feel the company will take more time to achieve results?

GV Prasad: I certainly hope to complete this request that we have from the FDA by this fiscal. I remain optimistic about the work we do. I think the delays have been due to probably from disconnect between the expectations that the FDA had and what we did. We are now completely engaged and we hope that we can satisfy the regulator in the upcoming few months.

Alok Dalal: And, sir, any response on R&D because what we hear from the company is about, let's say, Nuvaring and Suboxone and those are acquired assets whereas we don't hear a lot about internally developed assets. So do you feel R&D to some extent the productivity is not there? And hence only these 2 names are being spoken about?

GV Prasad: No. We don't tell you everything. For competitive reasons, we don't disclose all our assets. We have a very rich pipeline. We have over 100 ANDAs pending, many of them first-to-file, many of them complex assets, both at the API level as well as the finished dosage level. The fact that we don't talk about them is, so we cannot disclose everything that we do for whatever reasons. Of course, there has been a shift in our strategy towards complex generics in the last few years and as a result, there will be a little bit of a lull because complex assets are like, which are difficult to crack. And there are lots of certain progress assets as well as some, which have been filed. And as and when they become public, then you should know about the progress.

Alok Dalal: Sir in the past, company has done some very good products. Do you think that phase will come back for the company again?

GV Prasad: Actually, the complexity of the assets we have today is multifold of what we had in the past. So I would say that the work in progress R&D assets that we have are among the highest value that we ever had in the history of Dr. Reddy's.

Alok Dalal: Sure. And in between you had people leaving you. And then there was some gap in the team. So those issues have been addressed now?

GV Prasad: I don't think that we ever had a gap in our team. We replaced the people who left with even better people.

Alok Dalal: So more or less you are saying it's more about timing now that company should be back on the recovery path?

GV Prasad: Yes.

Ranvir Singh: Just wanted to understand this gross margin in this quarter. We have separated that for Global Generics and PSAI. So the remaining portion of gross margin when I tallied with your reported number is related to Proprietary products. That's what the math is, right?

Saumen Chakraborty: Yes. Proprietary products and others, yes.

Ranvir Singh: So that was like some 98% of gross margin. So should I believe there is no manufacturing cost or raw material cost, then it is purely like a royalty or licensing type of income from there?

Saumen Chakraborty: So there is what we have more or less $2.5 million of milestones. Within this quarter, we have accrued. I read out in the script.

Ranvir Singh: Yes, fine.

Saumen Chakraborty: And further to that, there has been some milestone also in our Aurigene, which is a 100% subsidiary.

Ranvir Singh: Okay. That's the only difference I think. And another thing, in U.S. now what would be the contribution of top 10 products if I say or if you would give some, just I wanted to understand the product concentration, vis-à-vis the last year we had?

Saunak Savla: We can speak about this offline. I will guide you on that.

* * End of Call * *