



“Dr. Reddy’s Laboratories Limited Q3 FY2018  
Earnings Conference Call”

**January 25, 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 third quarter of fiscal 2018. Earlier during the day, we have released our results and the same are also posted on our website. We are conducting the live webcast of this call and a transcript shall be available on our website 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. Abhijit Mukherjee – our COO; Mr. Saumen Chakraborty – our CFO; Mr. Anil Namboodiripad – who heads our Proprietary Products business; and the Investor Relations team.

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

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

**Saumen Chakraborty:**

Thank you, Saunak. Greetings to everyone. I will cover the key financial highlights. For this section, all the amounts are translated into US dollar at the convenient translation rate of 63.83, which is the rate as of 29<sup>th</sup> December 2017.

Consolidated revenues for the quarter at Rs. 3,806 crores or \$596 million, grew 3% year-on-year and 7% sequentially. During the quarter, our Proprietary Products business secured the NDA approval from US FDA of Impoyz, i.e. brand of low-concentration clobetasol cream. This had been recently out-licensed to Encore Dermatology, Inc. for the commercialization of the product in the United States. This approval triggered the recognition of part milestone of \$20 million in this quarter. Normalized for this, the balanced sequential growth was also aided by incremental contribution from new products, partially offset by the price erosion in North America Generics business.

Revenues from Global Generics segment is at \$472 million and PSAI segment is at \$85 million. Consolidated gross profit margin for the quarter is at 56.3%, a sequential improvement of around 300 basis points.

Gross margins of Global Generics and PSAI were at around 59.5% and 23.8%, respectively. Sequential improvement is largely attributable to the better product mix and also the above referred milestone recognition in our Proprietary Products segment.

SG&A spend, including amortization, is Rs. 1,205 crores or \$189 million, a sequential increase of 9%. During the quarter, we settled with the US Department of Justice on the litigation involving packaging related issues against a payout of \$5 million. Barring this, the balance increase is on account of certain sales and marketing and other spend towards the event specific to the quarter. We continue to focus on optimizing cost as an organizational priority.

R&D expense for the quarter is Rs. 467 crores or \$73 million, representing 12.3% to revenues. This is in line with our expectations of cumulative spends of around \$300 million for this financial year.

EBITDA for the quarter is Rs. 806 crores, which is \$126 million and is around 21.2% to revenues. During the quarter, we generated \$136 million of positive cash flow from operations. Consequently, our net debt to equity ratio has improved to 0.25 as on 31<sup>st</sup> December 2017.

As you all are aware that recently the USA has enacted the Tax Cuts and Jobs Act of 2017. Consequent to this enactment, we have reviewed and re-measured the deferred tax assets and liabilities of our US entity resulting in a one-time charge of Rs. 93 crores recorded under tax expense. Normalizing this

impact, the effective tax rate for the quarter is approximately 28%. However, on the adjusted basis, the annual effective tax rate would be in the range of 23% to 25% as guided earlier.

Key balance sheet highlights are as follows. Our operating working capital decreased by Rs. 33 crores or \$5 million over this quarter. Capital expenditure for the quarter was Rs. 221 crores or \$35 million. Foreign currency cash flow hedges for the next 15 months in the form of derivatives for US dollars are approximately \$290 million, largely hedged around the range of Rs. 65 to Rs. 67.8 to the dollar. In addition, we have balance sheet hedges of \$212 million. We also have foreign currency cash flow hedges of RUB 970 million at the rate of Rs. 1.12 to the ruble, maturing over next 15 months.

With this I conclude my section and 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.

This has been a good quarter for us despite challenging market conditions. At an overall level, we have seen some growth on a sequential as well as YoY basis with most businesses doing well. We look forward to building on this growth momentum in coming quarters. 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 \$246 million, registered a healthy growth of 12% on a sequential basis. This growth was predominantly driven by high sales for Sevelamer launch owing to channel pipe-fill. The quarter continued to witness higher levels of price erosion for the base business in low to mid double digits driven by customer price harmonization and increased ANDA approvals. We anticipate the market dynamics will remain challenging in near-term owing to annualized impact of pricing actions and incremental competition in some of our high value assets. On the other hand, we have launched eleven products in US and two in Canada till date. In this quarter we ramped up sales of Sevelamer tablet, launched Clofarabine and Melphalan injection in the US market and Azacitidine injection in Canada market. We continue to gain traction on new launches and have performed well in contracting market share.

On the pipeline front, coming fiscal is expected to remain exciting with fairly good number of new launches scheduled including some high value assets. Let me provide an update to you on the status of three key launches gSuboxone, gNuvaring and gCopaxone. On gSuboxone we have received minor CR recently and expect to respond in a month time. We are closely watching the IP position and our action would be in accordance with the development upon litigation front. On the second asset gNuvaring, we have responded to some additional queries received from the agency and our TAD now is early Q2 FY2019. With IP situation behind us, we feel optimistic about the launch of this product by mid of FY2019. Finally on gCopaxone we have received queries on the DMF; while there is some work involved, we feel we can respond in a few months and continue to progress on the asset.

On Europe business, we recorded sales of €26 million with a year on year decline of 11%. As you may be aware, this quarter we faced marginal supply issues following the German regulatory audit at one of our formulation facilities in Bachupally. The re-inspection of the site by German authority was completed in this month. The audit outcome was positive and the site was cleared by German authorities paving the way for all dispatches to commence. We hope to get back on the job of rebuilding the business in near future.

Our Emerging Market business performance has been consistently improving on the back of new product launches, entry into new markets such as Brazil and Colombia and supported by stable currency. Russia business grew 5% YoY in constant currency and 9% in INR terms. Performance in other markets has also been in line with our expectations. We look forward to augment our Emerging Market footprint further with opening up of few significant emerging markets in coming fiscal year by leveraging our oncology and biosimilars 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. 613 Crores and grew 3% YoY. The channel inventories have now normalized. Our sustained prescription growth has been encouraging and we feel positive about the direction of the business. We look forward to revival in market growth rates back to historical levels of double digits in near-term.

The PSAI business posted revenues of \$84 million and has grown 5% on a YoY basis. The business has undergone strategic realignment in last couple of years with focus shifted to cost rationalization, change in geography mix and leverage of relationship with partners to move into dosage sales of select molecules. We believe that this will provide a sustainable growth for the business in the long-term.

In our Proprietary Products business as disclosed earlier, we were able to secure the approval from FDA on the NDA application of DFD-06. This was a critical milestone and in line with the agreement with Encore Dermatology, and we recognized related milestone value this quarter. Overall, we continue to focus on building our existing commercial footprint and also enriching the development pipeline. On the commercial side, we are experiencing gradual increase in prescriber base for our lead products Zembrace, Sernivo and Trianex.

Lastly, let me provide an update on quality front. We began 2017 with the resolve to improve manufacturing operations and strengthen our quality management systems across the organization. We believe that we have made considerable progress on this journey. On US FDA side, multiple sites were audited over last one year. Agency has sent some queries on the API site in Srikakulam, which have been responded now. Regarding the sterile injectable facility in Duvvada, the quality improvement program is in progress in line with the comments made to the agency. We await the re-inspection of the site possibly in a quarter or two.

Quality and operation transformation will remain top priority for the organization going forward in addition to our focus on growth and cost optimization.

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

**Manoj Garg:** Hi, Thanks for the questions. A few on the US segment. I mean, I will just go ahead and ask the questions and go back on mute. One, what was the approximate contribution of Sevelamer during the quarter, since you did have it for the full quarter? Two, on US price, can you share some additional color other than the one or two lines that are in the press release. And then lastly, I think you spoke briefly about Copaxone and Suboxone. Can you just maybe extend a little bit more color there as well as in terms of the nature of the queries? Or what the agency continues to look for there as well as provide an update on Revlimid. Thank you.

**Abhijit Mukherjee:** Let me take the first one of Sevelamer. Without getting into absolute specific details, we were ahead of the other competitors by few weeks which helped us in launching the product and fill the channel. So it is significant and we will see some erosion in the subsequent quarters, while on the other hand there is the innovator, the percentage of share continues to be high, which also provides some opportunity for the future but more players have entered and prices have fallen to the level with more competitors coming in. The second question was, a little bit of color on pipeline and launches. That was the second question, is it?

**Manoj Garg:** Yes, and US price.

**Abhijit Mukherjee:** Price, okay. Broadly the next year, I think the quality of launches - we feel better than this year. However, this is all subject to approvals coming on time and litigation playing out in the right way. But having said that, clearly better than this year. On the pricing, let me take it in two parts, I will borrow the term from another company, base products and transitional products. Base products erosion is likely to slow down and flatten in coming several quarters, if not immediately. But the transitional products, the intensity of erosion will continue to be fairly heavy. Net of net, I think, we would continue to see annualized erosion in low double digits. But these are predictions and difficult to be very specific about this. The third one was on the specific assets. So Suboxone, I think still IP is being discussed, litigated as you know. There is still a patent curve which is being asserted and then couple others which are coming up. So we will see. But we feel very strong about our position. But on the litigation, let us see how that progresses. Otherwise, asset per se is

progressing in the right direction, in terms of our responses and site and all those things. As far as Nuvaring is concerned, IP is clear, as you know, and it all depends on the approval of the asset. And I just sort of mentioned that it is progressing and we have our TAD in the early Q2 of FY2019. Copaxone, the DMF, you would recall we had a date of November, but it has got 2 months to 2.5 months delayed. We just received week back or so the DMF queries. It involves some work in terms of analytical. But the good thing is our science team feels that there is nothing we should not be able to answer. Having said that, it will take 4 months to 5 months to put it together and respond and we will see whether there are any follow up questions on that etc. So that is where it is at the moment. I guess I have more or less answered all your questions.

**Prakash Agarwal:** First question on the, actually the gross margins flowing down to EBITDA margins, now if we adjust the one time milestone payment that we received, despite the Q-on-Q jump in the US, we haven't seen much of a movement. I mean, it's actually flattish. I'm just trying to understand what has really led to this. Is it the pricing pressure, though we are getting topline, but we have not got the margins? Or how should we think about that?

**Saumen Chakraborty:** If the sequential improvement is around 300 basis points, slightly more than half of it is due to the Proprietary Products milestone-related revenue recognition. So remaining is on account of the US growth as well as whatever other measures that we have been taking. But there will be always some quarter-specific events. So that is why it is very difficult to predict accurately how the margin is going to move from one quarter to another quarter. But if I remember in the last quarter in IR call there were specific questions about margin. So we are targeting to keep in the same kind of range.

**Prakash Agarwal:** Okay. Until and unless your major products start kicking in next year?

**Saumen Chakraborty:** Yes, of course. If there is like a significant product launch which happens with much higher margin, that will help us improve.

**Prakash Agarwal:** And a couple of peer group have talked about some impact of the WBAD pricing from the consolidations. So has that also impacted in terms of pricing apart from the base business pricing erosion?



**Saumen Chakraborty:** Yes, it had an impact. Some of the agreement had its impact.

**Prakash Agarwal:** And it is a full-blown impact or we are likely to see more impact going forward?

**Saumen Chakraborty:** Mostly it is factored in. Some may spillover.

**Prakash Agarwal:** Okay, understood. And secondly, you talked about TAD for Nuvaring I think, which has slipped to 2Q now. Would you have a TAD for Copaxone and Suboxone as well?

**Abhijit Mukherjee:** For Copaxone, we will have to answer the DMF and post the DMF the other dates would come through. It's still a while away. On Suboxone, as I said, our journey towards approval is progressing well in terms of the technical terms. We will have to watch the IP development and that would be governing the destiny of the asset.

**Prakash Agarwal:** And any timeframe we expecting? I mean, earlier we have talked about April timeframe?

**Abhijit Mukherjee:** On the litigation front, it will be difficult for us to comment.

**Prakash Agarwal:** Okay, I understood. And one more question I had was on, you talked about the quality of approvals and launches would be better going forward. So you are factoring in Srikakulam as well as the Duvvada facility resolution or it is without that you are expecting both the number of approvals and the quality of filings to be better?

**Abhijit Mukherjee:** So we have mentioned about few assets, Nuvaring, about Suboxone, now certainly we feel optimistic as we see where it goes from there so these are certainly. Glatiramer that we should be able to respond. These are all in public domain. But there are quite a few which are not, certainly not of this size, but still meaningful. In course of the year (four quarters of next financial year) which can provide good support to the launches. Taking all of it rather than getting into specific site details, why I'm not commenting on the site details because you will appreciate that next year's launches, it would not be fair to factor in too much site level uncertainty, so some tech transferred, some may be towards the end of the year and in the process of being tech transferred so

on and so forth. So given all that, of course, this is always complete maze of what questions we will get from the agency and what intellectual property issues will crop up. So those are uncertainties which remain. But in best of our understanding, I think there are assets.

**Neha Manpuria:** Sir, on Suboxone, is it fair to assume that because we have a minor CRL, our TAD will now be pushed out versus the March-April TAD that we had?

**Abhijit Mukherjee:** Look, I think let me once again talk about the asset. This being the first wave generic, I think, the approval pathway on the technical side in best of our assessment should not be a bottleneck. I'm pointing out to the IP development, which we are watching very, very closely. We will be plugged to it and see what happens. And based on that, will govern the path to approval.

**Neha Manpuria:** And would this have to do with the new patent that has been filed by the innovator?

**Abhijit Mukherjee:** So those details, we would not be getting into, I think, there are several external opinion, views. You can get the details there. And last but not the least, of course, there is not full certainty on first filer and so on and so forth. But again, all this is in public domain. So I'm not repeating most of these. But the only thing I can probably say is overall I think technically we are moving in the right direction.

**Neha Manpuria:** Okay. Got it. And sir, we've talked about cost savings two quarters back. We haven't really seen that much of it come true in our numbers of SG&A, even adjusted for the litigation settlement increased. When should we start seeing the impact of the cost saving reflect in our numbers?

**Saumen Chakraborty:** So if you take away what I said specifically that there was a settlement with the DoJ. So if you normalize that, and I also made a statement there will be always some quarter-specific thing one has to look at. But we internally have been seeing good effect from all the efforts which has been put for cost optimization. And going forward in subsequent quarters, we can see a little bit traction.

**Anubhav Agarwal:** Saumen sir, one question on India and Russia. Despite the higher promotion spend this quarter, we haven't seen the strength of growth in either of these two markets. Especially Russia, the base was weak and India base was not great as well. What's happening in these two markets?

**Abhijit Mukherjee:** The SG&A in branded markets do not immediately translate into sales impact, ok. These are building brands and things of that sort. So it's not exactly immediately sort of replicable. Having said that, the mega brands in Russia, these are very big brands and which are sort of the big brands where we have Nise, Omez, Cetrine, very big and the growth has tapered to a certain extent. But there are new launches. But more importantly, overall emerging market, I think we are feeling good about the institutional business ramping up in the new markets. So both Columbia and Brazil doing well and will further ramp up in Q4. And as we go into next year, I mean, using our forward-looking little bit projection, I think next year we hope to open another four to five markets. And there is a strategy and we want to extend the strategy all around the world. And that part we feel optimistic about. I mean, every quarter we wouldn't be able to explain SG&A to turnover. But given the stability in commodity, especially oil, I think we feel good in next several quarters in emerging markets.

**Anubhav Agarwal:** That's helpful. One question more on the US market. Abhijit sir, that if you look at the US, it's \$246 million this quarter. There were two components like there were some benefit of seasonal sales and certainly Renvela, Sevelamer was a high contributor. If you were just to normalize Renvela and take off seasonal, just to understand what's the true base to look at. Would 5% to 7% correction would be a reasonable number to look at?

**Abhijit Mukherjee:** I guess I will not exactly guide you. I said that it was the first quarter channel filling for Renvela. Some correction prices have come in. On the seasonal sale of largely injectables, this year was certainly not as big as previous years. The fact that the big assets have eroded on the face of competition to a certain extent, lesser market share, more on pricing and hence the impact of that maybe to certain extent but not as big as previous years. But these two factors have rightly picked up. But we do have in US, I mean, there is a possibility of

injectable launch which we will see, and most of it is in public domain and IP development and all that.

And the second thing is we have one-off type of opportunities for couple of quarters also next two quarters. But then there is also price erosion thing, which is still continuing, and there is some more payout of erosion in the next one or two quarters. So we have to take that in totality. So overall there may be some erosion vis-à-vis this quarter.

**Christian Glennie:** Good afternoon and thanks very much for taking the question. I just wanted to clarify, again, if I may on generic Suboxone and just from an FDA and a regulatory perspective, outside of any patent or litigation issue. Just to clarify, it sounds like you received a minor CRL recently. If I understand that's your second CRL on the product. So what does that relate to because presumably all done on a technical level it's not really related to just to patents and outside of things. And then what's your timeframe from here? I mean, I think if I got it right, you talked about responding to the CRL in about one month. And then what would be your projections in terms of FDA reviews timelines of that response?

**Abhijit Mukherjee:** So on the type of questions, all I can say is we think all these questions are easily answerable and hopefully satisfactorily. We would be able to respond to this in give or take three weeks to four weeks from now. And normally we are in the first wave of generics, I think agency is really providing resources to such file. So depending on whether there will be more questions or not, at least technical approval pathway should be verified and you can do your own calculation, yes?

**Christian Glennie:** So I presume there are standard reviews on that in terms of two months or six months in terms of the nature of the response?

**Abhijit Mukherjee:** Yes. I mean, first wave of generics that's a fair assumption from the response. It's normally agency puts priority on such things.

**Sebastian Sauter:** I know it's been asked before. But I think my line went a bit funny. So I just wanted to clarify. If you could update me please on the generics Suboxone film product? I understand you are in contact with the FDA. Has it now been

approved by the FDA? And, if not, how have the interaction progressed? And do you believe you have answered all the concerns that were raised in the CRL? And then the second question relates to Indivior has recently accepted two new patents in the Orange Book. And I'm keen to understand what impact this has on your launch timetable like for your own product? Thank you very much.

**Abhijit Mukherjee:** Yes, thank you. Firstly, on the litigation and the details, we wouldn't be commenting. As I mentioned, we will be watching this very closely. It's certainly on our priority, but we won't be commenting on litigation and patents; and quite a few things are in public domain, you will just have to look up. But on the technical side, I think we're doing fairly well, which I just explained in the last question on the technical side, I would not repeat the same thing. I think we're doing okay. We got the minor CRL. We will be responding in, let's say, four weeks from now. And yes, it's probably a quarter from there I think the technical side, but we will have to watch. That aspect on first filer aspect which we would not have visibility about and I feel we wouldn't comment on.

**Sebastian Sauter:** So basically can I just summarize this? You said you got the minor CRL and you're going to respond in four weeks from now. And you would assume further response from the FDA probably a quarter from here from them and this is basically because you are the first filer, right?

**Abhijit Mukherjee:** I said first wave. Still it has not been clarified that who's the first filer.

**Saion Mukherjee:** Is it possible to give a split between Proprietary Products and others, the \$39 million for the quarter?

**Saumen Chakraborty:** Can you state what Proprietary Products and others mean?

**Saion Mukherjee:** So you have \$39 million. So how much is Proprietary Products in that?

**Saumen Chakraborty:** So basically we're giving segmental revenues, Saion.

**Saion Mukherjee:** Yes. I just wanted to know the Proprietary Product excluding the license.

**Saumen Chakraborty:** So if you have a specific question, you can get back to Investor Relations later.

**Saion Mukherjee:** Okay. And continuing with the Prop Products, can you basically give us the timeline for your filings for Phase-III assets, which are currently under development?

**Saumen Chakraborty:** Can I ask Anil to respond to this?

**Anil Namboodiripad:** Hi, this is Anil Namboodiripad. Let me answer that question. So we have one of our key flagship assets that is expected to be a major revenue driver for the Promius/Proprietary Products business. It's called DFN-02 which is nasal sumatriptan for the treatment of migraine. We expect to file an NDA in the next three to four months with that asset. We have another Phase-III asset that has completed Phase-III. And there are still some other preclinical studies and some CMC activities that are going on. And we expect to file that NDA sometime late in 2018.

**Saion Mukherjee:** Okay. So you have two more Phase-III assets, right? When would you?

**Anil Namboodiripad:** We have a third Phase-III asset, which is currently in Phase-III and that's not complete yet.

**Saion Mukherjee:** Okay. And what's the timeline for the asset which you in-licensed from Eisai, E7777. When is that expected? When is the trial expected?

**Anil Namboodiripad:** That one, the registration study is ongoing. And we expect to have it filed sometime in 2019/2020 calendar year.

**Saion Mukherjee:** Okay, that's helpful. Thanks. And just one last question if I can. On the biosimilar product, what is the current revenue that you're doing? Because you've guided for \$150 million from emerging market by fiscal 2020. I mean, what's the visibility on that number?

**Saumen Chakraborty:** The target remains. So it's a question of whether it gets achieved in FY 2020 or get postponed by a year or so.

**Abhijit Mukherjee:** We are moving well, next year four reasonably meaningful emerging markets we should be able to launch our first MaB, other two MaBs, India approval hopefully one in a quarter and another one in a few quarters. And immediately thereafter we will extend these also into those markets. And meanwhile the

footprint is getting ready in all these markets. On the specifics, I think revenue-wise it's progressing. Every three months are providing us new data points. Beyond that, I mean, just stay tuned. We will keep you updated on how it's progressing.

**Manushi Shah:** I had a question on 3 products. I just wanted to know the status of Sandostatin LAR, Lovenox and Invega Sustenna?

**Abhijit Mukherjee:** You are talking about Sandostatin; octreotide. So it is some time away, it is a complex product we are trying to sort of work on it. It will take time. And Lovenox is already genericized and it is not high on the priority. Yes, third one, we would not specifically comment on. It's not in public domain and we won't specifically comment on it.

**Manushi Shah:** So Sandostatin LAR, is it because of Duvvada that it will take time or it is.

**Saumen Chakraborty:** One thing I would like to say, which we have said earlier that on our R&D pipeline and portfolio, we would not like to comment on specifics, which is not there in public domain. So please don't insist on such questions.

**Sameer Baisiwala:** Just a quick question on Duvvada. You were planning to do some site switches from there. Can you please update us on that? And from your site switched products, do you expect any major one getting approved in fiscal 2019?

**Abhijit Mukherjee:** It's an ongoing process Sameer, ongoing process, not a very easy exercise in pharmaceuticals, but we are taking one by one. Several in the past have happened, I mean, from Duvvada and other site as well. Some of it has, I'm talking of the last 18 months or so. But as we speak, I think more being done, we will not go into specifics on this, but we have mentioned that we had a rich filing list from the site. And we're continuing to sort of site transfer.

**Sameer Baisiwala:** Okay. And on Copaxone, your entire commentary was basically for 20 milligrams or also for 40 milligram? Because for 40, I thought TAD is in March?

**Abhijit Mukherjee:** No, so Sameer, everything will be hinging on the DMF. Okay, as you know, the formulation is less (critical). And follow-up questions shouldn't be much of a problem to handle. And so we are focusing very deeply on the DMF and

once we address it and of course it is applicable to both assets and both assets have been filed. We probably last time said that we had TAD date for both, sort of, we are not so much preoccupied on the dosage thing.

**Sameer Baisiwala:** And just one final clarification on Suboxone and NuvaRing. Suboxone, I think when you say the IP something that you are watching very closely and I know you could talk too much. But just a little bit of nuance for you. Is it your appeal case that you're more worried about? Or is it your competitors' appeal case that you're more worried about? And the second is on NuvaRing, I understand the patent is going to expire in April 2018 and you probably are looking for a launch in fiscal 2Q 2019. So do you still think you will be the first player or do you see a competitor enters before you?

**Abhijit Mukherjee:** Okay. Let me answer the easier one first. Nuvaring, April 2018 it goes off, the patent goes off, it depends on approval. At the moment, we have TAD, the responses have gone in; early Q2. So that's slightly clearer pathway. As far as Suboxone is concerned, again, I mean, anything on IP, Sameer will be difficult to comment because you have to study this. But we are watching this very closely. We feel strong about the position we have taken, very strong about the position we have taken. But then there are views which have come up. So we will see in which direction it goes. And we have to leave it there as far as Suboxone is concerned. And of course, as I mentioned that the first filer exclusivity is not clarified as yet.

**Chirag Talati:** Two questions. A DMF query essentially it means that it's a major CRL. And if that is the case, given that this probably third or fourth cycle of review, there won't be a TAD that will be applicable, right?

**Abhijit Mukherjee:** So it is a major CRL. As I said, that there is technical work, the volume of work is there. But it's not something, which we cannot answer satisfactorily. So I think we will need some time. Beyond this, we will see how that unfolds actually.

**Chirag Talati:** Fair enough. Second question, I mean, if I look at your US sales, you talked about injectables stocking not being very high. But if we look at your penicillins portfolio and also some of your antihistamines or LTR efforts, that



should also have been a seasonally strong quarter. So adjusting for these two, can you give us some sense of how the quarter would have panned out?

**Abhijit Mukherjee:** So on the injectables, as I said the Renvela ramp-up and injectables are the two factors. The other factors are not significant. I mean, when you're talking of fexofenadine and things of that sort, which make a substantial difference, I wouldn't think so. But so the three factors, which I mentioned is scale-up of these two. There is of course, somewhat like price erosion to be playing out. To be counterbalanced to some extent by probably / hopefully an injectable launch and some one-off business. But all in all, I think would we be able to maintain similar level of Q4, less likely.

**Shyam Srinivasan:** My first one is on the US tax changes. This deferred tax in assets and liabilities, I think it's a one-time outstanding event. But can you talk about the flow in terms of the BEAT provision, base erosion and anti-abuse tax. Does it apply to our US subsidiaries for Dr. Reddy's?

**Saumen Chakraborty** No.

**Shyam Srinivasan:** Okay. So there is no incremental impact that we foresee from this act going forward in our business?

**Saumen Chakraborty:** This is just the one-time impact that has been taken. And depending on the inventory which is there, there could be very marginal. How much it gets liquidated during the quarter, it will depend on that.

**Shyam Srinivasan:** Got it. Thank you. Just a second question on the commentary on the Indian business which said the channel inventory has kind of normalized now. So are we working with the lower number than pre-GST? Is it like 25, 30 days now? Where is the new normal at this point of time?

**Saumen Chakraborty:** It is gone past 30 days but it might not have gone back to 40 days.

**Shyam Srinivasan:** Okay. And my last question if I can squeeze in. On the tax rate, you said normalized tax rate is 28% for the quarter. What gives us the confidence that we can do the 23% to 25%. Because I think you've been trending above all those numbers in the first nine months.

**Saumen Chakraborty:** So we said our annual ETR will be in the range of 23% to 25%, we are still holding to that. Of course the annual ETR now will go up because of the US Tax Act. And if you adjust of that Rs. 93 crore, then it will remain within that range.

**Vishal Manchanda:** Can you update us on Aloxi litigation, there has been some recent event happened there?

**Abhijit Mukherjee:** I mean, the whole lot is in public domain at the moment. So everything is in public domain. So just click and read up actually. And we will see. We're keenly watching, as we speak.

**Vishal Manchanda:** I just wanted to understand so can we expect the launch in the near-term?

**Abhijit Mukherjee:** Depends on the way court outcome happens.

**Vishal Manchanda:** Okay. Second one, your out-licensed asset Zenavod, which you out-licensed to Galderma so could you guide us on when this would be commercialized?

**Anil Namboodiripad:** So we are still awaiting commercialization plans from Galderma, they have some internal strategic priorities. But we do know that they intend to launch, so we are still awaiting.

**Vishal Manchanda:** Okay. And finally on this, Sernivo and Zembrace SymTouch prescription seem to have plateaued for a while. So how do we look at it going forward?

**Anil Namboodiripad:** Well, I wouldn't say they have plateaued. For example, Zembrace has actually been growing about 7% quarter on quarter and has grown about 25% over the same time last year. Sernivo has been slightly slower, but more recently there has been a pickup in prescription volumes. And one thing I want to remark here is that Zembrace has actually been trending quite favorably. And one of the key reasons for that is because we managed to snag a major PBM listing back a few months ago with CVS Caremark and that has had an impact on the volumes. Sernivo, on the other hand, we are still waiting to get the CVS Caremark coverage, which I think will make a big difference in terms of the uplift, in terms of prescriptions. And we are continuously working on getting unrestricted payer coverage across several other major plans. So we still are

quite bullish about the uptake of these two assets over the next quarter and beyond.

**Vishal Manchanda:** How long will you take to put the coverage in place and you would wish for?

**Anil Namboodiripad:** So that is something which is hard to specifically put a date on. The reason being that many of these major plans or most of these major plans have specific calendars where their pricing and therapeutic committee meet and make these decisions. So I cannot at this time put a timetable in place. But we are making every effort. We have actually beefed up our managed care group here. We brought in a few industry veterans who have the right set of connections and the right experience with many of these plans. So they are out in the field speaking with all of the major plans. And we are quite optimistic about a positive outcome in the next several months.

**Kartik Mehta:** How should we look at the R&D expense over the next two years assuming that you have a fair lot of filings and lot of proprietary related products? For the year we're still averaging lower than the last year's average. Any thoughts on R&D FY 2018, 2019, 2020? Thanks.

**Saumen Chakraborty:** There could be some reallocation. There have been for last few years, 60% of total R&D spend has been on GG and API. So that percentage, there could be realignment based on the need both on biosimilar as well as the proprietary products. We alluded to right at the beginning of financial year that on an absolute R&D spend basis, FY 2018 R&D spend will be similar to what would have been in FY 2017. We expect Q4 R&D will be slightly higher than the previous quarters. But overall we will be within that \$300 million. It will not exceed. For next year and year after that, for the next two years, maybe next when we are doing the annual result, we will give you broad kind of guidelines on our R&D spend and kind of allocations that we're thinking.

**Kartik Mehta:** Yes. So the first part of your answer, Saumen so would you be dealing any projects. So you refer to different allocation. So I'm just trying to understand, will the absolute amount be stable but there will be higher allocation to one part of your business or the absolute amount increase but allocation may not remain the same? I mean what is it that we should assume here?

**Abhijit Mukherjee:** So let me answer this. Basically deferring or non-deferring is less important. What is important is we are looking deeply into R&D productivity. Now if you defer something, it will not at the cost of an asset which you would go through easily and just for cost reduction we will defer, that's not the purpose. But being less experimental in certain ways and we're trying to be sort of make it a little less risky especially in the GG side. And also I think we're being very conscious on the proprietary as well as biologics side. So overall productivity of R&D is the main focus and then we will see what best we can get out of that.

**Nitin Agarwal:** Abhijit, when we look at the US business over the next two years, outside of three products that you talked about, which is in the public domain, how should we look at? Is all our growth or largely our growth contingent upon how these three products play out? Or there is enough which is at the pipeline outside of these three products which can drive growth on the current levels?

**Abhijit Mukherjee:** I'll just probably repeat what I said. Overall about the launches next year, given IP and approval pathways by and large go to our expectations, it looks certainly richer than the current year, okay. And I also mentioned about these three products are very important on the revenue chart. But there are reasonably interesting midsized products, which will also provide some support. Now I understand that I'm not able to give out much. But within that you have to read that how that likely to progress given the fact that there will be erosion also which will continue in this market. But I think next few years, certainly would be better than the previous couple of years.

**Nitin Agarwal:** Thanks. And lastly on the business, as we talked about the base business or the non-transitional part of the portfolio, where you believe the erosions should probably begin to settle over the next few quarters, I mean, are you seeing any changes in market dynamics that is giving you the comfort in terms of people vacating some of those products? Or is there anything changing out there?

**Abhijit Mukherjee:** People are not vacating. What's happening is that on the base product, which have been pretty much beaten up to a large extent, there isn't much for the generic companies to offer. So what is the symptom the way it plays out is whoever has the majority share in a base product, if you track closely, you will find that the higher market share players is further consolidating, which means that there is lesser play for marginal presence in any product. True for us, true

for any other company, which if you can read from another angle, it goes to say that erosion on stabilized base products will eventually go down over, we're not talking of one quarter, 1.5 quarter but over several quarters because there isn't much more to give up. So that's the basic thing. But having said that, every company will have those so-called transitional products which will always be subject to larger erosion.

**Nitin Agarwal:** And if I just take that one and just finish it off. When you look at your portfolio say for the nine months, how do you roughly characterize between transitional and base products, very roughly?

**Abhijit Mukherjee:** I won't be able to do that, I'm sorry. That would be getting into specifics.

**Saunak Savla:** Thank you for joining us today on the call. And in case if you have any clarifications, feel free to reach out to the Investor Relations team. We will be happy to answer you. Thank you all.

**<<End of Call>>**