Dr. Reddy's Laboratories Limited
Q3 FY17
Earnings Conference Call

February 04, 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 Call for the Third Quarter of Fiscal 2017. Earlier during the day, we have released our results and the same are also posted on our website. We are conducting a live webcast of this call and a transcript shall be available on our website soon.

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

To discuss the Business Performance and Outlook, we have the leadership team of Dr. Reddy's comprising Mr. Saumen Chakraborty – our Chief Financial Officer; Mr. Abhijit Mukherjee – our Chief Operating Officer; and Mr. Anil Namboodiripad, Head of 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 the 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 would like to turn the call over to Saumen Chakraborty – our CFO.

Saumen Chakraborty:

Thank you, Saunak. Greetings to everyone.

Let me begin with Key Financial Highlights:

For this section, all the amounts are translated into US dollar at the convenience translation rate of Rs. 67.92, which is the rate as of 30th December 2016. Consolidated Revenues for the quarter are Rs. 3,706 crores or $546 million, and grew 3% sequentially. Performance has been mixed across the market. While revenue contribution from Europe and Emerging Markets have registered sequential growth, that from our North America generic business and Proprietary Products have largely remained flat. On a year-on-year basis, overall revenues declined by 7%. Revenues from our Global Generics segment are $451 million and PSAI segment are $80 million.

Consolidated gross profit margin for the quarter is 59.1%. Gross margin for Global Generics and PSAI were at 64.1% and 28.3% respectively. Sequentially, there has been a marked improvement in the gross margin profile of the business.

SG&A spend including amortization for the quarter is $167 million, a decrease by 6% year-on-year. After normalization of the Venezuela base affect and the settlement charge paid to Novartis with respect to Zoledronic acid, there is a marginal increase which is largely attributable to normal salary increments, headcount and other costs. Sequentially also, after adjusting for the NPPA charge that we took last quarter, there is no major variation. We continue to explore avenues to optimize these spending.

R&D expenses for the quarter were at $73 million, representing 13.4% to Revenues, and is in line with management estimates. As discussed earlier, we have initiated further development activities on the recently in-licensed In-Process R&D assets from XenoPort and Eisai, as well as the acquired ANDA filings from Teva, which has incrementally added to the R&D expense.

EBITDA for the quarter stands at $129 million, which is 23.7% of the revenue. Better gross margin profile and controlled SG&A and R&D spending aided the improvement in the EBITDA margins. During the quarter, we generated $77 million of cash flows from operations. Our net debt-to-equity ratio is 0.31 as on 31st December, 2016. Effective tax rate for the quarter is 20.6%.

Key balance sheet highlights are as follows:

Our operating working capital increased by $69 million during this quarter due to the new product inventory built up and increase in receivables in few geographies. We would continually focus on optimizing the working capital cycle. Capital expenditure for the quarter was at $44 million.

The foreign currency cash flow hedges for the next 6 months in the form of derivatives and loans for US dollars are approximately $135 million, largely hedged around the range of Rs. 67.6 to Rs. 70.4 to the dollar. In addition, we have balance sheet hedges of $251 million. We also have foreign currency cash flow hedge of RUB300 million at the rate of Rs. 1.08 to the Ruble and €1.5 million, largely hedged around Rs. 75 to Rs. 82.05 to the Euro maturing over next three months.

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

Abhijit Mukherjee:

Thank you, Saumen. Greetings to Everybody and Welcome to the Earnings Conference Call.

Overall, there have been a marginal growth in the top-line on a sequential basis. We continue to face headwinds in the US business, delay in approvals of our major launches coupled with erosion of the base business has been a cause of concern. On a positive note, currencies across emerging market geographies have stabilized with crude. The business continues to grow on the back of stable macro economy and institution business launches.

Let me take you through each business to discuss the performance and some key themes. Reference to financial numbers will be in respective local currencies.

Our North America revenues are at $246 million. While we continue to face incremental competitive pressures, we have managed to hold on to our market shares across critical product at an overall level. During the quarter, we have launched five relatively small products, most of them being partnered assets. The fourth quarter however is unlikely to benefit from any sizable launch. This coupled with sequential buying patterns and continued competitive pressure would likely result in a softer Q4. Additionally, we are facing a temporary supply disruption of one of our mid-sized asset due to technical reasons which is manufactured at our partner's site. We have already initiated corrective measures to get the product back into the market soon. This will have some financial impact for the quarter or so.

Some major launches anticipated in this financial year are likely to get deferred to the next fiscal. The review of the complex products and subsequent approvals by the agency are moving slower than our expectations. We continue to work with the agency to expedite our approvals. Based on the current visibility, the launch momentum is expected to pick up in the coming year. Overall, we are likely to see 15+ launches coming through next year. With this traction, we hope to be back to our historical trend of business. We have substantially ramped up our R&D productivity. We have filed nine ANDAs in the quarter and expect to close the year with a cumulative 22 to 25 filings.

Continuing on the pure generics business, our Europe business saw some good launches. Overall, the business looks well-poised for profitable growth on the back of key launches and traction in institution business in EU 5 countries.

On the emerging markets front, we are fairly comfortable with a gradual recovery in the market place pursuant to the stable macro environment. Specific to this quarter, our business grew 23% sequentially, Russia business grew 11% sequentially in constant currency. The team continues to focus on productivity enhancement and portfolio augmentation. Ex-Russia the other markets performance was in-line with our expectations. We are on track to expand our geographic presence through leverage of our institution business portfolio and biosimilars. Commercialization of biosimilars across emerging markets has now started gaining meaningful traction. We remain optimistic of building on this momentum further.

Domestic Formulations business revenues are Rs. 595 crores and grew 2% year-on-year. Normalized for base alignment, demonetization impact and NLEM notifications, the performance is broadly in line with the expectations. In this quarter, we commercialized two of the in-license products under strategic collaboration with Amgen. As a business, we continue to focus on productivity enhancement and portfolio augmentation.

PSAI business posted revenues of $80 million. The business is gaining traction in emerging markets with healthy margins. CPS business has done well this quarter.

On the quality front, as communicated earlier, our warning letters impacted sites are scheduled to get re-audited during the months of February and March. A substantial remediation work has been put in place from our side. Our application of Corrective and Preventive Actions or CAPAs were not just site specifics, but they were also network wide and incorporated third party review and assessments. We believe we have prepared ourselves well for the audit. In the process of implementing the CAPAs, we have made significant progress in enhancing our quality systems and instilling the culture of quality and continuous improvement.

That concludes my part. Thank you all and I would now like to open the floor for Q&A.

Neha Manpuria: Sir, my first question is on the gross margins. What drove the sequential improvement, particularly given a flat quarter from US and the issues in India?

Saumen Chakraborty: There will be some degree of operating leverage with the level of sales and we have been focusing on cost control measures, so in terms of reflection of that in both SG&A and COR items will be there. And this year we are trying to do systematically across the organization. But in the currency front there has been definitely some benefit that we are getting. For example, in Russia in the constant currency there is a growth and actual you will see better realization in INR from foreign currency. Last but not the least, our gross margins which is a weighted average completely depend on both the business mix as well as specific products. Sale of products for which gross margin is higher, that gives us overall weighted gross margin better.

Neha Manpuria: Is it then fair to assume that since all of the items that you mentioned were pretty much sustainable that this margin can continue despite your commentary on fourth quarter being very lean?

Saumen Chakraborty: It cannot be taken for granted. There could be some fluctuations which can happen. But our endeavor will be there to protect, but anything above 55% is normally our expectation to keep in the gross margin.

Neha Manpuria: Sir, on the US business, your commentary on approvals being delayed and additional pricing pressure. First on the pricing pressure, are we seeing incremental pricing pressure because of the McKesson Wal-Mart deal or is this related to some of the products in competition? And second on the approvals, have you seen an increasing incidence of probably CRLs from the USFDA that has let to delay in approvals which was not initially factored in?

Abhijit Mukherjee: So, the first question on price erosion, I think broadly as expected and as being experienced by the industry, we are also facing the same thing. I would not be specific to any merger but overall channel has consolidated, we had some high value assets, there was competition coming in and also some of the launches like omeprazole bicarbonate you have seen more people have come in, some of those have seen some erosion. So, expected and has happened and channel consolidation will continue to have margin erosion.

On the relative delay in approval process, yes, I think the complete response letters overall if you have followed the industry is getting a lot, we are having our share. We have been always targeting some of the products which are slightly on the higher end

of complexity and hence more clarifications required. So yes, CRL letters are coming in and we are addressing those.

Neha Manpuria: Sir, one follow-up on the approval point. By how much would you say your entire approval period has gotten delayed because of the CRL, would you say six months to nine months or do you see a longer delay in our approvals?

Abhijit Mukherjee: Asset to asset, case to case, difficult to put one figure. As you see the minor CRs from the agency is three months' turnaround from the agency, major CRs are much longer. So, would not be able to place one average figure but quarter, quarter and a half delay is a fair assumption.

Prakash Agarwal: Sir, just trying to understand your opening comments where you said your working capital has increased in anticipation of new launches. And you continued saying that there has been delay in some of the sizable launches which you are expecting. So, could you elaborate more on this please?

Abhijit Mukherjee: Some markets I can, and some I cannot. So broadly, size wise I think we had messaged that we had the Imatinib launch scheduled as per the deal (settlement), this quarter. So, this was originally from our oncology site but since we had FDA WL we had shifted in time and we had, in a partner site which was scheduled for approval more or less as per in our view. But one of the recent audits in the partner site, there are questions raised which throws in a lot of doubt whether this would get approval on the specific date, so we are again trying to see what we can do to mitigate that - may be bring back to our own site. There is one more injectable which is basically a couple of months delay beyond what we were expecting. So, these two are ones I can mention, but smaller ones are there but it does not really matter in those cases.

Saumen Chakraborty: And the receivables have also gone up in some geographies which will bring it under control by next quarter.

Prakash Agarwal: So, the inventory buildup was not for US but for the other markets is what I understand?

Saumen Chakraborty: No, it includes US. That is what Abhijit just clarified. We will always prepare for launch in anticipation, if the approval gets delayed to that extent inventory built up does not get reduced.

Prakash Agarwal: And secondly, if you could just help us understand the competitive landscape of Nuvaring and Sublingual SUBOXONE®, which would be large opportunities

expected in fiscal 2018. Just a little bit if you could help us broad level like the kind of competition one can expect and the likely timelines?

Abhijit Mukherjee: Yes. These are complex assets and competition is likely to be lean, which means the value is secured but the timelines are, yes, I mean both these have some questions from the agency being addressed. And as we speak, we are in the process of addressing some of those questions. So there may be some delay in these launches, could be towards the end of Q4, could be a little later but I have to remind also that both are in litigation. In case of Nuvaring the generics prevailed in the District Court and hence much clearer on that front and also being appealed but certainly is much clearer. SUBOXONE has a good position but beyond that we can't comment because it is in litigation. So these were the challenges, but your question was mainly on competition, we are not likely to see, sort of, crowded in the near future.

Prakash Agarwal: And timeline you said Q4 of 2018 or 2017?

Abhijit Mukherjee: We are talking of fiscal 2018 Q4, maybe a little delay beyond that as well.

Anubhav Agarwal: Saumen sir, just one question on gross margin, typically we have seen in the past the injectable products stocking in the US is higher in the December quarter. Would you say, that would have contributed to higher margins in this quarter, I mean, a big part of contribution of the delta in global generics?

Saumen Chakraborty: I will not say that that could be a primary reason.

Abhijit Mukherjee: In my speech, I had mentioned that we are seeing some traction in emerging markets, biosimilar supplies. So to an extent those things also have helped.

Anubhav Agarwal: And actually two sub-questions on SG&A, a tremendous amount of saving has been made by the Company over past few quarters in SG&A. I just want to understand that typically in December quarter we have seen more promotions happening in some of the markets, let's say in Russian market just for an example, so would you classify that some amount of saving was lower promotion because in Russia for example we are seeing (-5%) constant currency decline. So would you say that all of the saving in SG&A what you are showing today is not hurting revenue at all and therefore large part of this is sustainable?

Saumen Chakraborty: Whenever we focus on cost rationalization the primary consideration is that it must not impact our business. So, while keeping in view the business consideration we see how we can possibly eliminate any kind of waste. Also focus is both in indirect cost as well

as on direct cost. Direct cost, we also focus beyond procurement, also on health improvement and other aspects. So this is something which we have been trying to drive very systematically across the organizations with required level of incentivisation so that there is much more focus.

Anubhav Agarwal: So would you say that the seasonal promotion which used to happen in some of the emerging markets, that is continuing at the same level what it was and large part of savings we are seeing is ex of that?

Saumen Chakraborty: See, there are marketing expenses, there are cases where there are more marketing expenses than the previous year which were called for. For example, Habitrol kind of thing which we have in USA, or this year brand acquisitions that we have done or what we do in proprietary product. So that way marketing and sales is an item for overall SG&A. There have been newer requirements which have been there. So I will not try to over emphasize shifting from one quarter to another quarter and all, whatever is required to be spent on marketing for our business, we continue to spend.

Manoj Garg: Abhijit, in the opening remark you made comment that you are expecting around 15 plus kind of launches in fiscal year 2018. Are you considering some of those Teva assets like Nuvaring and SUBOXONE® in that 15 plus or they are over and above that?

Abhijit Mukherjee: Yes, a few. To be specific about three, two I mentioned towards the end of Q4 and there is one earlier and we have a whole host of other things. The important thing is not 15 plus or whatever number, there is 20 or 15. Important is how many are meaningful. Actually, it is becoming very clear in US market and since you are tracking, it's all important assets would be few which we will internally track as well to the best extent we can. So those are the important ones.

Manoj Garg: So, out of those 15 as you rightly said, how much could be or how many could be the meaningful launches which we are building for the next year?

Abhijit Mukherjee: The ratio is similar for most companies, I think I guess it would be about four or five maybe.

Manoj Garg: And the second question is on biosimilar, on the R&D day, we have outlined that we are looking around $150 million to $200 million kind of revenue from biosimilar portfolio from the emerging markets. Where are we and how do we see that visibility going forward?

Abhijit Mukherjee: So, good traction, our filings are going on and there is also a pull from quite a few markets because this is apart from the revenue, is bringing in healthcare cost reduction in those markets. To a large extent also the affordability issue is getting resolved and I guess in many of these markets the markets would expand as it has happened in India. So we feel very excited about this both from our mission as well as revenue angle. We are putting all efforts. This quarter saw good traction, Q4 also would see a reasonable traction on that. Going ahead also, but only thing is, it is going to be a little lumpy, based on tenders - depending on how we do. So it is not going to be absolutely smooth, but yes, I mean, Q3-Q4 will continue to have in the similar zone.

Manoj Garg: So just on ALOXI, any update on the litigation and any timeline on that?

Saumen Chakraborty: We are just expecting, nothing has happened so far.

Sameer Baisiwala: Now that you have moved the Eisai and XenoPort assets into the clinicals, what do you think would be your ongoing R&D spend on these, quarterly or full year basis?

Saumen Chakraborty: What we earlier alluded to is for the financial year that is FY17 we will be spending around $25 million on both these assets combined. So, we are sticking to that kind of a guidance on the spend for this year. Overall how much it will be, I cannot give you that specific as of now. But as and when we have further discussions with agency and get more, maybe we can come back later. But as on date 25 million remains very much FY17 R&D expense on these two molecules.

Sameer Baisiwala: Fiscal 2018?

Saumen Chakraborty: I cannot tell you right away.

Sameer Baisiwala: And just on Copaxone, is it possible to update on where your 20 mg file is?

Abhijit Mukherjee: As we communicated, we have filed the detailed response in the second week of December and it has gone into review. Our response also will have to go in but that is not main thing, the main thing is the DMF response. The (ANDA) response will go in by end March or so. And 40mg response will follow soon thereafter as well on the ANDA side. But the main thing, the DMF thing was in the second week of December.

Sameer Baisiwala: So, what is your expectation of approval, both for 20 mg and 40 mg?

Abhijit Mukherjee: That is a difficult question to answer, Sameer. As I said, we have good analytical capability, we think we have done a good job. Beyond that, I mean hopefully things do progress in the right direction.

Sameer Baisiwala: Is it part of your 15 launches?

Abhijit Mukherjee: Look, I mean, these are complex assets right, I mean, depending on what questions agency would be asking us, but there has been huge amount of scientific man hours which have been put in into this.

Surya Patra: Sir, just wanted to check about the gross margin trend that we are seeing for the PSAI business which really is surprise positive to this quarter despite being the growth of the segment is muted only, the gross margin of that PSAI business improved significantly. So, any specific reason and how sustainable is that?

Abhijit Mukherjee: So, I mentioned that CPS business did well this quarter, likely to be generally okay in Q4 as well. Some assets we have done some price adjustments, etc. And overall I think PSAI business in general we are trying to make it value accretive and there is specific strategic focus on this, not on the size that much but more on creating more value out of it.

Surya Patra: But this can be a kind of a lumpy nature business as well?

Abhijit Mukherjee: Yes and no, not hugely lumpy but yes, I mean, CPS will have some bit of this. I think Q4 is okay, but yes, I mean it is possible Q1 will be a little lean, but little bit here or there, I cannot comment exactly about specific for quarter.

Surya Patra: Just one clarification about your initial comments, you commented about two aspects, one is the institutional business launches are something that you said and also about supply issue for a partner product that you have indicated. So, whether the partner product is an injectable one?

Abhijit Mukherjee: No, and it is not partnered, it is our product, manufactured at our partner site but mid-sized.

Surya Patra: And can you comment on that institutional business launches what you have commented in the initial comments?

Abhijit Mukherjee: Yes, so we are trying and putting lot of effort into emerging markets. We opened up Colombia this year, Brazil, quite a few launches will happen in fiscal 2018 in a few

months from now hopefully. We are opening up few other markets, Chili, Algeria, Malaysia, etc. And the whole objective is to leverage the institutional portfolio which we have developed and we have good capability on that, we have good manufacturing capability and we think we can make this business really global. So that is a large strategic initiative on the company, the biosimilars will be add-on to the same front end. For the next few years we will try and sort of grow this business. However, this will not be quarter-on-quarter so lumpy, it will be a gradual build up but we feel excited about it as a sustainable business in the long run.

Kartik Mehta: On your comments on Imatinib, you mentioned that you are trying to mitigate by shifting it to some other site. Can you elaborate on this because if you would do it now, wouldn't that take a fair amount of time or is it on your own site?

Abhijit Mukherjee: We are exploring all options. What I wanted to flag that in the interest of being completely transparent, we had said it is a Q4 launch, it was all scheduled but this is an audit which has to a certain extent derail this and of an external partner site. So we are exploring whatever options we can do to make it as quick as possible, difficult to comment at this juncture.

Saumen Chakraborty: From his question, probably he did not understand what we said in initial times, actually it was originally from our own site because our site got warning letter so we did the risk mitigation earlier. This is what we said earlier.

Kartik Mehta: Saumen, I mean that so are you expecting your plants to be re-inspected and to get approval for maybe Imatinib from your site, because if you have to mitigate to some other partner wouldn't you assume that would take at least two, three quarters or so, this is pertaining to Imatinib only.

Abhijit Mukherjee: So look, I mean, at the moment let's focus, we have three audits till end March, we are focusing a lot on that and we will answer those questions later.

Kartik Mehta: So you have three audits in the end of March?

Abhijit Mukherjee: Yes, all three plants will get audited by end March, yes.

Fatima Pancha: Sir, I know a lot of questions were on gross margins, I just wanted to know that is it fair to say that 3Q margins in terms of all the competition that you have had in VALCYTE® and VIDAZA® that is practically captured in 3Q numbers, so when we will move on to have launches of Gleevec or Aloxi, the margins will build on from this level, is that how one should look at it?

Saumen Chakraborty: As I said, there will be new product launches, if it is from in-house then definitely it adds more to margin but if it is partner it may not. But at the same time there are continuous price erosions and other impact which will be there. So, 59% gross margin which we achieved in this quarter is quite a good one, there could be fluctuations. As I said earlier, in terms of our expectations of gross margins from these, on weighted average across all business combined, as long as it is north of 55% it meets our expectation.

Chirag Dagli: Sir, these 15 products that you alluded to for FY18, I am assuming these are the biggest launches that we are talking about or is this like a total number?

Abhijit Mukherjee: No, I said this is a total number and I also mentioned, someone asked that what is the meaningful part. Hesitantly I said, like in all companies maybe four, maybe five, I do not know, and we will track those more. But mind you, more complex it gets more uncertain it gets and that is why Q4, I had already messaged that we are expecting few, some of the delays have taken place. So, overall I think we look forward to next year but a little concerned about delays creeping in into the assets.

Chirag Dagli: Sir, how many of these four to five are litigation or site clearance dependent, which is something which is not in your hands?

Abhijit Mukherjee: Look, I mean, I would not go into too much details, like there is no free lunch in this world but at the same time it is very, very uncertain I would not mention. But at the same time there is reasonable level of uncertainty. So, North American business has its own challenges. What is more important is, is the R&D productivity picking up, are we still going for the right assets, the answer is yes. Are we putting in those assets and answering the deficiencies properly, the answer is yes. Beyond that where there is channel consolidation, the plain vanilla products are not earning, headwinds of erosion is there and hence it is important we get these through. Beyond that, I wish I knew I had a better answer to your question.

Chirag Dagli: But the four and five are not litigation dependent or site clearance dependent meaningfully?

Abhijit Mukherjee: As I said, I will not fully clarify those. There could be a few which are not litigation, there could be maybe one or two which are litigation, so it is a mix.

Chirag Dagli: And the second one sir, in your opening comments you mentioned that your CAPA is basically work-in-progress and still there is an inspection due, so how should we think

about this because your corrective action plan should have already happened before the inspection was scheduled?

Abhijit Mukherjee: I think you got it completely wrong, I said we have put in all CAPAs in place, not just site specific but also network wide and incorporated third party review and assessment. So, I am again clarifying that to the best of our capability we have done whatever we believe, we are well prepared.

Chirag Dagli: And when is Srikakulam due sir?

Abhijit Mukherjee: From now to end March all the three sites will get audited.

Abhishek Sharma: Sir, just two quick questions. Sir, out of the nine filings that you did this quarter, how many of them are your own filings versus partner filings?

Abhijit Mukherjee: These nine are pretty much, most of it are in-house, eight are in-house.

Abhishek Sharma: Just one more question, apart from the three facilities which are under warning letter and these are getting inspected, have you got intimation of any of your other major sites which is going to get inspected simultaneously?

Abhijit Mukherjee: No, not at the moment. I mean, the sites keep getting audited as we speak, so there is nothing at the moment to report.

Alok Dalal: Sir, just to clarify, the 15 launches for FY18 are not linked to the affected sites, right?

Abhijit Mukherjee: See, I would not be able to give you all the details, this is the overall for the year. We are talking of FY18, right. So there is enough de-risking done, most of it, quite a few of it and a very large portion of it is outside, actually it is 15 plus I said, so there may be a few from the affected site, but maybe there is parallel activity going on. So, overall you can take it as 15 plus launches unless there are very major delays experienced.

Alok Dalal: And sir, similarly if say the inspection does not go favorably, are the FY19 launches linked to these sites, you had a chance to de-risk or it is early to say?

Abhijit Mukherjee: So any de-risking in a normal course is an activity which is, let's say, nine months, give or take. So FY19 is a little far away, so that is all I can say at the moment.

Alok Dalal: And sir one last question, proprietary products have been stuck in a narrow range for quite a few quarters despite two launches that you had. So why is there no pickup in that particular category?

Anil Namboodiripad: I will take that question. So, as we had communicated in the past quarter, our focus in this fiscal year is to grow the prescriber base as well as its overall prescription volume, while we work through listing on various insurance managed care formularies. In the second quarter we implemented a number of strategies to achieve this objective, including refinement of messages, multiple strategic initiatives to improve patient access, etc. So, as a result of these interventions, Sernivo (dermatology product) prescriptions have grown by approximately 30%, from 5,500 to 7,000. Also the prescriber base has grown to about 1,800 and more than half are repeat prescribers. These are all leading indicators to the health of the overall proprietary products business and the pieces of the two products that we have launched. In case of Zembrace prescriptions have grown from roughly around 2,000 in the second quarter to about 4,500 in this past quarter that is Q3, and the number of prescribers have also doubled. As in the case of Sernivo, about half of these are repeat prescribers. So as I said, the volume growth is what we are right now measuring because the revenue growth will follow as we get increasing coverage with our insurance and multiple negotiations are going on with these plans. Our objective for FY17 is to get at least 70% to 80% coverage on all commercial insurance plans by the end of the fiscal year. So starting FY18 we will start seeing the numbers follow these prescription trends, we are also working on other initiatives like minimizing restrictions on some of the plans including prior authorizations, etc.

Alok Dalal: And Anil, how is the pricing here and how many launches you expect in fiscal 2018 in this space?

Anil Namboodiripad: So, fiscal 2018, we expect to have one approval in fiscal 2018 in dermatology and another approval which is pending tentative for our pediatrics product that we in-licensed called Xeglyze™ it is for treatment of head lice. So those are the two assets that we expect to get approved in FY18. Xeglyze™ is, of course, contingent on the FDA audit of one of our sites.

Chirag Talati: Two questions. Firstly, I am surprised with your comment on Imatinib because I thought it could be manufactured in non-onco facility, and one of the existing players in the market is also supplying through the non-onco. So what drove the decision to go to a partnered facility rather than doing the non-onco facility of your own?

Abhijit Mukherjee: In our view this should be produced in an oncology facility, so we feel that is the right practice and hence we transferred it accordingly.

Chirag Talati: Secondly, I am looking at your Aloxi litigation and I can see that you have withdrawn one of your invalidation arguments, does that raise the risk profile in any way should you still have a favorable decision in the district court in the coming months?

Abhijit Mukherjee: No company would be able to answer this, I think June was the trial and now we are waiting. On the chances, how can we comment.

Chirag Talati: No, what I am trying to ask is because you have withdrawn one of your invalidation arguments fairly recently in order to get an expedited decision from the court, there are still some pending issue on invalidation of one of the claims that will still be left. So, what is the trade off that you are seeing there?

Abhijit Mukherjee: So, we are pursuing the non-infringement case more actively and in any case the invalidity, all of the reasons I cannot share but yes, I mean, we are keenly awaiting the judgment on non-infringement case.

Dhiresh Pathak: On proprietary product, to the earlier question I think you said you want to have 80% coverage from the recoveries in FY18. How much coverage do you have now?

Anil Namboodiripad: Right now our coverage is I would say about 50% and there is some additional coverage but there are restrictions on that coverage. So we are working on minimizing those restrictions. So I would say we are at about half and we intend to go to about 70% to 80%, that is our goal based on the trends in negotiations.

Dhiresh Pathak: But in the base business of proprietary products have you seen some de-growth because these two products added, and you have 50% coverage still you are not seeing numbers. So is there in the existing $40 million I think which we did in FY16, has that de-grown?

Anil Namboodiripad: That has not de-grown but there are some products that we have de-prioritized in order to focus on the new launches. So there was a deliberate measure that we had taken, but you can call it a de-growth based on a deliberate removal of promotional activities and transferring them over to these two assets.

Dhiresh Pathak: And last question, in the analyst event in 2015 I think you had guided to about 200 to 300 by 2019, now that you are going through this journey of understanding the market formulation and other things, does that guidance still hold?

Anil Namboodiripad: So, the guidance given in 2015 was based of certain assumptions that we made on the ever changing dynamics of the insurance market place. We continue to believe in the $200 million business the specific year is something that we are working on as to when we will get to that $200 million.

Shyam Srinivasan: Just on the India business, I think in the opening remarks there was a mention of three points, I think one was demonetization. Can you help us actually look through these three points and if possible can we have some quantification of the impacts of these three?

Abhijit Mukherjee: Yes, so base adjustment what I am alluding to, last quarter that we do YoY, last year was pretty heavy Q3, so that is the base adjustment. The second is demonetization, yes it was a little slow for two three weeks and then slowly started picking up and some companies got more benefit which are chronic heavy. We are not so chronic heavy but the normalcy have been fully restored, so again this is not relevant anymore. NLEM, you would know about price reduction, I think this year's cumulative impact is Rs. 36 crores or so annual impact has come in. So some of these is part of business, Q4 back to normal, should have normal growth.

Shyam Srinivasan: Then you said it is satisfactory, where do we guide on say even FY18, is the growth going to come back to where historical rates have been?

Abhijit Mukherjee: Yes, give or take double-digit somewhere between 10% to 15%.

Shyam Srinivasan: My second question is, I know, this is speculative at this point of time on the destination based tax, especially the import of goods and services into the US, if they do not get tax deduction, this is obviously one of the proposals. But any early thoughts on what you think the industry can or could lobby if such a proposal actually comes, materializes, any early thoughts that you can share will be great.

Saumen Chakraborty: I will refrain from sharing any early thoughts, let it first happen and then we will update it.

Abhijit Mukherjee: Look, I mean, the generic industry has hugely contributed from 2006 to 2015, I am talking about generics industry as a whole, $1.5 trillion saving in US healthcare cost. And I think that is what the industry should focus on and probably the government as well. So, I think let's focus on that, what the value generic industry brings into the healthcare costs. And the rest is how can we comment on.

Vishal Manchanda: I have two questions, one on your proprietary product business. You have been developing an intra-nasal migrant spray, so could you share some updates on there, how is the progress happening?

Anil Namboodiripad: Yes, the intra-nasal migrant spray is one of our flagship products for the neurology business, it is progressing well. The program is still in development and we expect to have some important milestones in FY18 and right now there is no concern at all about the product or about the regulatory path specifically.

Vishal Manchanda: It is evaluated on the safety front?

Anil Namboodiripad: Yes, we have finished the safety study and no observations of concern.

Vishal Manchanda: And should we expect a filing early 2018 calendar year?

Anil Namboodiripad: I cannot comment on that, as I said there are some important milestones that we expect to achieve in FY18, but I cannot give comment on the filing date.

Vishal Manchanda: Would you be sharing the final data you achieve on the product this year?

Anil Namboodiripad: Actually we have some abstracts that have already been published on some of the data that we have generated, a number of publications are due in FY18. So you will see a lot of scientific literature coming out of this and also patents have been issued, so that is all in public domain. But overall, I must say that the data is looking appealing.

Vishal Manchanda: And just one clarification on **Sernivo** and Zembrace SymTouch, just wanted to understand why is the volume growth is not translating into the revenue growth?

Anil Namboodiripad: Yes, as I had mentioned in previous question the listing of managed care insurance in the US as you know, a majority of the business comes from insurance and you have to actually get listed in the formularies of every insurance plan, and that process takes time. So we are right now at about 50% coverage. So while patients may be insured but they are not covered, we are making the product accessible to them so that they get to experience the product and experience the outcome of that product, the positive outcome which we are hearing from the field quite a bit, the feedback has been very good. So while that is happening we do not want to prevent patients from accessing the drug while we are waiting for the insurance plan to cover our product, so that is why you see the gap between the actual revenue and the prescription. So as I said, prescription growth is important because once you have patients who experience the

drug and want to stay on the drug, we believe that once the insurance plan starts covering they would continue to stay on the drug.

Ranjit Kapadia: Sir, my question relates to DMF filing. We have about 782 cumulative filings and out of which 16 have been filed during the quarter. So how many are getting affected by Srikakulam and Miryalaguda?

Saumen Chakraborty: There are total 16 but one out of that is US DMF, remaining are in other places.

Abhijit Mukherjee: So the answer is none, I mean, we have not filed from these plants and overall I think that is not a major issue at all.

Ranjit Kapadia: So if there is a delay in getting the approval, what will be the impact on the sales and the profitability?

Abhijit Mukherjee: There are multiple things involved, I mean, difficult to answer this question. Why don't we do one thing, let's sort of wait out this quarter, let's see how we do in the audits and let's focus on that. I mean, let us look at the positive aspects and see how it goes actually. So, at the moment I would not be able to give you a figure on what will happen, etc.

Ranjit Kapadia: And sir, can you elaborate on remedial major cost in the quarter?

Saumen Chakraborty: Most of the remedial cost we have incurred till the last quarter, so it will not be significant.