

Dr. Reddy's Laboratories Ltd.  
Q4 FY17 Earnings Conference Call  
**May 12, 2017**

**Saunak Savla:**

A Very Good Morning and Good Evening to all of you and thank you for joining us today for the Dr. Reddy's Earnings conference call for the Fourth Quarter and Full year ended 31 March 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 CFO; Mr. Abhijit Mukherjee – our COO; and Mr. Anil Namboodiripad, Head of Proprietary Products Business and the Investor Relations Team.

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Before we proceed with 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.

**Saumen Chakraborty:**

Thank you, Saunak. Greetings to everyone. Let me begin with the financial highlights. For the section, all the amounts are translated into US dollar at the convenience translation rate of Rs.64.85 which is the rate as of 31, March 2017.

Consolidated revenues for the year are at Rs.14,081 crores or \$2.17 billion and declined 9% year-on-year. Consolidated revenues for the quarter are Rs.3,554 crores or \$548 million and declined 5% year-on-year and 4% sequentially. This is broadly in line with what we had alluded in our last earnings conference call. This decline is primarily on account of continuing pricing pressure, no new significant product launch in the quarter together with supply constraint impacting our North America Generic business. On the other side, the Branded Generics market performed better, especially the Russian operations which had the benefit of strong Ruble and stable economic outlook. Revenues from our Global Generic segment were \$449 million and PSAI segment were \$83 million.

Consolidated gross profit margin for the quarter is 51.2%, gross margin for Global Generic and PSAI were at 58.4% and 10% respectively. Relative to the previous quarter, this is a sharp decline. There are a few important triggers during the quarter bringing down the gross margin by approximately 400 basis points. These are a) impairment charge recorded at our anti-biotic manufacturing facility at Bristol; b) incremental provision of inventory built-up in anticipation of new product launch that failed to materialize, for example, Palonosetron 505(b)(2); c) Failure to Supply penalties incurred due to supply disruption for example, Isotretinoin; d) unprecedented level of price erosion; and e) higher levels of repairs and maintenance charges incurred in order to renew some of the manufacturing facilities.

Moving on, SG&A spend, including amortization, for the quarter is \$169 million, a decrease of 6% year-on-year. After normalization of the Venezuela base effect, it is approximately at the same level that of Q4 of FY'16. Overall, we continue to explore avenues to optimize SG&A spend.

R&D expense for the quarter were at \$71 million, representing 12.9% to Revenues and is in line with management estimate. It is 13.9% for the full year.

EBITDA for the quarter stands at \$97 million which is around 18% of the Revenues. Lower revenues and gross margins primarily impacted EBITDA margin. During the quarter, we generated around \$150 million worth of cash flows from operations. Our net debt-equity ratio is 0.25 as on 31<sup>st</sup> March 2017.

The effective tax rate is around 18% for the year and 2% for the quarter. The lower tax rate for the quarter is primarily due to resolution of certain tax matter pertaining to prior year. However, we anticipate the effective tax rate for FY'18 to be in the range of 23-25%.

Key Balance Sheet highlights are as follows:

Our operating working capital decreased by \$72 million during the quarter. We would continually focus on optimizing the working capital cycle. Capital expenditure for the quarter was at \$36 million and for the full year it was \$179 million.

Foreign currency cash flow hedges for the next 12 months in the form of derivatives for US dollars are approximately \$235 million, largely hedged around the range of Rs.66.78 to Rs.69.23 to the dollar. In addition, we have balance sheet hedges of around \$273.5 million. We also have foreign currency cash flow hedges of RUB150 million at the rate of Rs.1.137 to the Rouble maturing over next 3-months.

With these, I now request Abhijit to take through the key business highlights:

**Abhijit Mukherjee:**

Thanks, Saumen. Greetings to everybody and I extend a warm welcome to you on this earnings conference call. As you recall, in the last earnings conference call we had alluded to a softer fourth quarter, this was largely in line with our expectations.

Let me take you through some of the Business highlights for each of our key markets. Please note that in this section, all references to numbers are in respective local currency.

North America Generic revenues for this quarter are \$228 million. We closed the year at \$956 million. During the year, we witnessed increased competitive intensity in few of our high value assets. Normalizing for that, the base business has held up reasonably well in line with our expectations. The approval of high value launches continued to remain challenge during the fiscal. The timelines for review of complex products and subsequent approvals from the agency have been getting deferred. We continue to work with the agency and remain optimistic about eventual approvals. Our new launches for coming fiscal looks healthy and we expect 10+ launches in the next 12-months. The current quarter also witnessed initiation of monetization of the Teva deal through our commercialization of gVytorin, the first product from the transaction. This is a limited player market and we are excited about this opportunity. During the quarter we have filed 13 ANDAs taking the total to 26 filings for the fiscal year. This is indicative of our continued focus on investing for long-term growth and R&D productivity.

Continuing on pure generics, our Europe business is fairly stable now and well poised to deliver a profitable growth on the back of new product launches and traction in new markets.

Our emerging markets business is on track to a gradual recovery. Russia business closed the year with 8% constant currency growth and 26% for the quarter. This is broadly in line with the expectations. We continue to focus on improving productivity and augmenting the pipeline. During the quarter, the much awaited national tender of Rituximab was announced and we secured share and we have commenced supplies in the current quarter. Ex-Russia, the performance of the other markets 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 have now started gaining meaningful traction. We remain optimistic of building this momentum further.

India business revenues are Rs.571 crores and grew by 8% YoY. We closed the year at Rs.2,313 crores and grew by 9%. Normalized for NLEM impact, the results are in line with the expectations. We continue to focus on productivity announcements and portfolio augmentation.

PSAI business posted revenues of \$80 million. The business is gaining traction in Emerging Markets with healthy margins. Our efforts are directed towards building a healthy order book. CPS business has done well this quarter.

On Proprietary Products, we continue to grow the business and we are witnessing improving trends for Zembrace and Sernivo. As of date, we have two pending NDAs with the agency and one NDA recently approved, that is Minocycline Hydrochloride extended release tablet.

Further, during the quarter, we have settled the ongoing litigation on Doxycycline (Zenavod) with Galderma. Consequent to the settlement and out-licensing arrangement, we received an upfront amount and there are annual royalty performance linked milestones.

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

**Neha Manpuria:** First on the gross margins. You mentioned quite a few sort of one-off in the quarter. Some of this could be recurring, but in terms of impairment of the Bristol facility and provision for new <inventory>, how much of the impact in the quarter is one-off or is this likely to be recurring for a few quarters?

**Saumen Chakraborty:** The impairment of the facility does not recur. So we were earlier carrying a value of almost \$12 million for the Bristol facility. Now after this impairment, value is around \$6 million. So this is, of course, done with all anticipated future earnings. You know this is only an antibiotics facility. So there have been some specific API supply problems also were there. So, we are not getting much business out of that facility. So, as per the impairment trigger, we had to take this impairment. Whenever there are such triggers one has to see but normally we do not expect that. What I talked about the material inventory write-off provision that happened, several times it happened. But this time, the incremental one is much higher because we built up in anticipation of launch which has not happened. So we had to take the entire write-off during the quarter.

**Neha Manpuria:** How much would this be sir roughly?

**Saumen Chakraborty:** We will get back to you the numbers later.

**Neha Manpuria:** No worries, sir. On the Isotretinoin supply that got disrupted, by when do we expect this to normalize ... would this take a couple of more quarters?

**Abhijit Mukherjee:** We have applied for PAS. As and when that gets approved. Wouldn't put a date exactly but I think your question was more on FTS incurred. I think that tapers down. That happens only after discontinuation. So that is also one-off this quarter.

**Neha Manpuria:** Last question was on the launch. So if I remember correctly, last quarter you had indicated about 15+ launches in FY'18 and we are now talking about 10+ launches. Is this because we are expecting some delay due to the inspections that have happened recently?

**Abhijit Mukherjee:** This is indicative. At the beginning of the year your guess is as good as mine. In April, we have been able to do two - gVytarin and Progesterone generic. Okay, let us take it 10-15, somewhere in between. We do not have the right answer. We do not know what's this figure.

**Prakash Agarwal:** Just trying to understand the filing run rate has been pretty significant despite, Duvvada, Bachupally and all the other facilities having some observations and the earlier one still stuck up. So from which facility are these filings happening?

**Abhijit Mukherjee:** Mixed all over. So this is some from partners, some internal distributed amongst various locations. We have two oral solid location, topical location, then we have injectable location and several partners as well.

**Prakash Agarwal:** So most facilities are under some US FDA, still having some FDA issues. So we continue to file. What I am trying to understand is we do not expect any escalation into Duvvada, Bachupally and all.

**Abhijit Mukherjee:** First of all, the API facilities, mostly, have gone through good audits, all three of them. Duvvada has observations but we have responded well and let us see how proceeds. But that does not prevent us from filing. It is our judgment, but we continue to file, yes. We also filed some injectables from partners as well. As far as Bachupally is concerned, we mentioned that in our view these are procedural and will deal with the necessary response and whatever interventions.

**Prakash Agarwal:** Srikakulam, is there any update sir?

**Abhijit Mukherjee:** Probably, the observations are in public domain. Only two - very relatively easy to answer observations and we had three from the Miryalaguda; two API sites which were impacted and the third API site had zero observation. Update from Miryalaguda, we have just got a CBE30 approval which was earlier stuck. So that is in a way we take it as a positive. As I mentioned, Srikakulam audit happened after this we respond and then whenever the file comes up for approval, we will know.

**Prakash Agarwal:** From our side do we expect resolution within this financial year, sir?

**Abhijit Mukherjee:** Depends on what you are talking about resolution because in our view we start getting approval in any form, that is the resolution. So one Miryalaguda as I said, we have got one earlier CBE30, that just got approval, so that audit happened two months back. That is the only data point we have.

**Prakash Agarwal:** Lastly, sir, on the amortization, just trying to understand, Vytiron was one of the products that we have got from Teva/Actavis. So the amortization would start for these assets that we acquired and the timelines that we are looking for the other two big ones?

**Saumen Chakraborty:** Yes, amortization will start/happen as and when we commercialize.

**Prakash Agarwal:** I am just trying to understand that the assets that we purchase for \$350 million. How are we actually amortizing the entire piece since the first product has already started and then...?



**Saumen Chakraborty:** There is a purchase price allocation which has been already disclosed. So based on that the amortization will happen for specific products whenever it is getting commercialized.

**Prakash Agarwal:** The larger piece happens only when the large two products get approved and launched?

**Saumen Chakraborty:** Yes, absolutely right.

**Anubhav Agarwal:** One question on to Abhijit sir on Vytorin. When do you expect the next round of competition in this product and currently after the launch roughly what market share Dr. Reddy's have got into?

**Abhijit Mukherjee:** Very fair market share for three players currently. Next round certainly I do not know, so I cannot comment. The only I think in public domain from Mylan's concall is they are impacted because of the Nasik – its in public domain. Beyond that I have no idea.

**Anubhav Agarwal:** I am aware of Mylan. That is exactly I was asking beyond this. But do you expect this to be as good a product for fiscal '18 and as good a product for fiscal '19 as well based on your intelligence right now?

**Abhijit Mukherjee:** How can we predict? You would not be knowing who has filed with FDA and all that. So far so good, so let us continue to sell.

**Anubhav Agarwal:** On the PSAI, the margins were very weak this quarter. Because all the gross margins in fact, Saumen sir talked about, were largely on the Global Generic side, what happened in the PSAI side?

**Saumen Chakraborty:** The CTO which is our Chemical TechOps, which supplies both to the external API as well as to our internal for captive consumption. So, the entire overhead - how does it get allocated. There would be a considerable movement which happens and that is a primary reason for the impact on the PSAI gross margin. Number two has been - we have spent much higher level of repair and maintenance than normally we spend and that we have done specifically to renew some of the CTO manufacturing facilities because compared to the finished dosage, the CTOs were our earlier plants. So we spent quite a bit to on repair and maintenance.

**Anubhav Agarwal:** Can you also help with employee cost? Your employee cost is down like 18% in the March quarter versus the December '16 quarter. That seems such a sharp decline, there seems to be some one-off there?

**Saumen Chakraborty:** As a company, we always believe in terms of putting much higher stake for our senior management, top management in terms of variable pay, LTI and various other things which we put at stake. So if there would have been higher profits, then there would have been higher variable pay. To the extent, it is not there, we suffered. So individually we suffer but company incurs lower employee cost.

**Anubhav Agarwal:** But this is a phenomenal which happens in this fourth quarter every year or will this...?

**Saumen Chakraborty:** It all depends on the trigger. Suppose we would have got the Palonosetron 505(b)(2) the result would have been different for us.

**Anubhav Agarwal:** But seems a very sharp decline, 18% sequentially?

**Saumen Chakraborty:** Maybe we can discuss offline later.

**Abhijit Mukherjee:** Essentially during the year you count and then you take calls towards the end of the year on the variable pay. Yes, to that extent, it has some bit of fourth quarter impact.

**Anubhav Agarwal:** Just one more clarity not on this question but on Duvvada and Bachupally facility, in your corrective action plans, just some clarity if you can provide, what time do you plan to finish remediations from your side at least on both the plants?

**Abhijit Mukherjee:** Remediation as such we have mentioned last year we have spent whatever had to be spent in terms of remediation. Now there are some observations have come in. These are to a large extent to do with operator, training, certain observations on areas which need special intervention to a certain extent which will be largely internal. I am not sure there is cost, but I do not think there was significant cost involved at this stage. Bachupally as I mentioned, these are more procedural and less so in terms of cost that we planned it.

**Surya Patra:** Sir, just a clarification about all these remediation activities or preservation that we are anticipating for all these three facilities which are currently under issue. So is the resolution to happen, then it will happen at a time for all the three facilities or it can happen separately also?

**Abhijit Mukherjee:** Look, specifically, we cannot comment. We can only give you data point which I just repeated. We had Miryalaguda, we had Srikakulam and Duvvada. So Miryalaguda, the first one to get audited and we got CBE30 which is earlier stuck because of GMP and now just got a few days back the approval for that. So that is the only data point we have. Beyond that we would not predict.

**Surya Patra:** Since it is covered under one issue, so not necessarily the resolution has to happen at a time for all?

**Abhijit Mukherjee:** This is the data point. Interpretation is yours.

**Surya Patra:** About the US pricing scenario for the base business, how is it and do you really feel that okay there is a kind of stabilization in the pricing scenario there and what would be the base business price erosion if you can share for your portfolio?

**Abhijit Mukherjee:** This year as Saumen mentioned has been somewhat bad. It will get rather exaggerated and visible when you do not have launches overall in the impact wise but overall this year has been particularly bad but these things will vary from quarter-to-quarter company-to-company. Average annualized, we still feel that it will be in the range of high single digit, very low double digit type of thing but can vary from quarter-to-quarter. Yes, we have taken most of our erosion this year, not able to see very large one coming through immediately but you never know.

**Surya Patra:** My point was that post this election phase in US and post major of the channel consolidation happening in the recent past, so are we still seeing at this current movement some issue of pricing correction or increased competition?

**Abhijit Mukherjee:** This is all about the consolidation of the front end which have happened and the channels got consolidated, impact are showing. Price increase / price adjustments are not there at all. So overall I do not think dynamics specifically have changed.

**Sameer Baisiwala:** Abhijit, is it possible for you to give a broad color for fiscal '18 on the top line and on the EBITDA margins?

**Abhijit Mukherjee:** Overall I told you 10+ launches in US and now it is well known that depends on which launches and what launches, one which has just gone in has played out well, let us see how the rest of it plays out. US will continue to be dominant and most unpredictable in many ways because depending on launches, depending on approvals, depending on resolution, etc., and all those things. Other markets, I think we expect clearly northward results, Emerging Markets the currencies have stabilized. We have put in significant effort in increasing footprint. Biologics more and more traction, so expect very healthy growth there. India, well-known maybe 10, 12% range type of a thing. Europe is broadly in control, will grow this year, it has been flattish last year to this year, but this current year it will grow significantly but again small pie. PSAI - also we expect to do certainly much better than the last financial year, but lot would still depend on how North America plays out.

**Sameer Baisiwala:** On the 10-15 launches that you expect, how many are going to be substantive as well as specifically also on the thoughts on Copaxone and Nuvaring.

**Abhijit Mukherjee:** I will go to the second one. First one, I would not know, I would not be able to answer - how many would be sort of meaningful. Copaxone as we mentioned, 20mg DMF response has been sent quite a few months back, I think December probably. So we have received the TAD which is give or take six months from now. So we will wait for hopefully IRs in between and may be CR, I do not know. But as we mentioned, I think we have done reasonably thorough job. Let us see how that plays out. Nuvaring, I think on the IP side, it is becoming less and less critical because in any case, it is somewhat clear and then anyway, the specific IP gets over by April next year. There is a CR which we are planning to respond in what about few weeks from now and then let us see how that progresses.

**Vishal Manchanda:** Sir, in the initial commentary, you had said on licensing of ZENAVOD. I could not hear that clearly. Is there a settlement that you have entered not, if you could give more color on that?

**Saumen Chakraborty:** Yes, settlement that we entered. You are talking about the income recovery from this Galderma deal?

**Vishal Manchanda:** Yes and when is the launch schedule and ...?

**Anil Namboodripad:** So this was the settlement followed by a licensing and that was done with Galderma. So the launch is upon Galderma and the intent they have expressed is to launch it at the earliest possible. We do not have a specific date.

**Saumen Chakraborty:** We have received some upfront cash payment but in terms of the revenue recognition, we followed strictly the accounting standard and accordingly part has been taken to Q4 income.

**Vishal Manchanda:** Could you like also talk about value of the Rituximab tender you would have received for Russian market?

**Abhijit Mukherjee:** The market has eroded a lot, it has been somewhat aggressive with now Innovator, a Russian player and us. So let's not talk of this tender, but overall I think for the year, high double-digit million dollars (15-20mn range), let us say. I am assuming that we have share there as well so with that.

**Vishal Manchanda:** If you could guide on how many emerging market approvals should we look at this year for your biosimilar portfolio?

**Abhijit Mukherjee:** Specifically, we would not comment on this but one more reasonably a large country, yes, two more smaller ones. This thing depend on how the regulatory pathway proceeds but these are certainly not as big as Russia, but there will be organic growth also in this product.

**Nitin Agarwal:** On the emerging markets, you mentioned about some significant effort being put in for improving footprint. Can you throw some light on that -- are you referring to the efforts in existing markets or are you talking about opening up some new markets on the emerging markets side?

**Saumen Chakraborty:** Both are done. There are certain markets where we are present. So that is done internally or certain markets where we are not present through our alliance partner. So similar opportunity that way is explored through both means.

**Nitin Agarwal:** So the emerging markets story is now largely being driven through the biosimilar route in terms of any expanding in emerging markets presence, that is the thought process?

**Abhijit Mukherjee:** That is one major growth driver. The second is we are building an institution business in various countries. We have opened up in Brazil and Columbia, and Columbia we have already launched few products last year. This year, we will see more and more launches and traction and growth on that. Brazil, what is interesting for us, we are getting institution business with the first launches just starting as we speak, and in the year, probably 3 to 5 launches this year. Those would be the major ones and then few North American markets, few Asian markets through partnership, etc., So overall, we are trying to build an institution business with global footprint, largely led by Oncology products.

**Nitin Agarwal:** These would be pretty much the products that you are already commercialized in the US or Europe I guess?

**Abhijit Mukherjee:** Largely leveraged, yes, and that process will continue as we keep filing, we will continue to leverage and see how we can. The only thing is there are several markets we are building the footprint and it is important that we build the footprint so that we are able to get through the institution ourselves.

**Nitin Agarwal:** Of the 10 to 15 products that you talked about launching in the current year in the US, are any of them sort of contingent on the resolutions on the Inhouse facilities?

**Abhijit Mukherjee:** We would be providing all the details and subsequent questions somewhere what. So I think let us just leave as that, let us take 10 plus. I was forced to commit 10-15. So wherever you want to sort of take this thing. So let us just leave it at that.

**Aishwarya Agarwal:** Can you please help us with this 483 where we have repeat observations written, so just want to understand how serious this repeat observations are, what do you expect from it... you will be able to overcome with whatever procedures you are supposed to do or will it get escalated?

**Abhijit Mukherjee:** I think the observations are in public domain right now and if I take your call by consulting people, but we will give you some broad view that currently the interpretation by the agency on repeat is not specific, but let us say, something is called out and it falls in a category, and later in that category, you have observation which may be a different observation, but it is still said it is considered as a repeat observation. This is again with changing trend of the audits. I think we are seeing this happening repeatedly. For Duvvada which is probably as I mentioned where we had sent pretty large comprehensive response, the first repeat observation is on the investigation quality. That particular observation is probably half of the whole observations we have in terms of number of this thing. There are various incidents - we continue to investigate and continue to make reports. So naturally there is scope for improvement and we are putting all efforts, but there is indeed, as a broad category, it can come up even in future and similar areas, not to say that we are putting in all efforts, we are trying to make it as broad umbrella effort to remediate in our facilities, but as a whole category sometimes this may come out.

**Aishwarya Agarwal:** Sir, my next question is have you filed Copaxone Formulations?

**Abhijit Mukherjee:** I just mentioned that as committed, it was filed and we have got a TAD and the TAD is give or take six months from now.

**Manoj Garg:** Abhijit, you have alluded a couple of times in this call regarding your EM strategy both on the Biosimilar side as well as on the Injectable business. Just want to have maybe a broader sense that 3-5-years down the line, how big this opportunity could be for us from both the segments in the emerging markets?

**Abhijit Mukherjee:** Fairly significant. I would not put a figure to it but it is one of the core strategic thrust areas. We will put in efforts, money, resources behind this and we are doing it building this systematically 3 to 5-years. The question is good and valid question. I think fairly significant. Beyond that I would not go any further.

**Manoj Garg:** If we can get some sense in terms of like the overall size of the opportunity for rituximab, within those emerging markets, where either you have filed or you are awaiting for the approval, how significant that could be if you want to put some numbers out there?

**Saumen Chakraborty:** I will request not to pressurize to give any kind of financial guidance which is against our policy. Rather to give the color and efforts which we are putting in to build in future business growth.

**Manoj Garg:** This question is for Anil. Like if you look at for our proprietary business, I think last year we had an EBITDA loss of around \$80-90 million. So given the kind of ramp up which we are seeing plus more approvals which we are anticipating over the next few years, how do you see the P&L of your Prop business moving over maybe two-three years down the line?

**Anil Namboodiripad:** Right now, we have a fairly rich pipeline of assets in late stage clinical development, many of them are high value assets. With the launch of these assets and the number of NDAs that we expect to file over the next few years, we anticipate to start seeing positive revenues within the next 3 to 4 years.

**Manoj Garg:** In terms of getting the breakeven for this business like from \$80-85 million kind of EBITDA loss, when do you see the breakeven?

**Saumen Chakraborty:** We wanted to mean positive cash flow, revenue is even positive today.

**Anil Namboodiripad:** It is a positive cash flow. So that is what I meant. That we will start seeing positive cash flows over the next 3 to 4 years.

**Manoj Garg:** Just on India, Abhijit, you spoke about 9-10% kind of growth for the domestic market. Does it mean that probably we will be largely in line with the market growth, I think in the past you have alluded that we have done lot of course correction in the domestic market and going forward we expect probably to accelerate our domestic growth higher than the industry growth, so is it because of GST at conservative or overall like you feel that maybe some 2-3-years kind of things, the growth will be it that range of 9-10%?

**Abhijit Mukherjee:** You are right, actually, there is so much one is hearing, reading, seeing and uncertainties are all around GST and various other things. So, I am just putting out a figure because I would not go beyond that at the moment, but yes, there could be a little bit higher if everything goes well.

**Abhishek Sharma:** Did I hear correctly you said you have received CRL on Nuvaring?

**Abhijit Mukherjee:** We received and we are responding to the complete response letter within a couple of weeks, yes.

- Abhishek Sharma:** What is the nature of observation, sir, does it relate to manufacturing or....?
- Abhijit Mukherjee:** Like normal CRL, this is drug device combination, so there are questions on all sections and we have to do a lot of work and we are responding. Let us see if there could be a few more questions, but let us see how that goes.
- Abhishek Sharma:** Sir, the other question is on Aloxi. Is there any further visibility on when you would be able to launch it now?
- Abhijit Mukherjee:** You probably have seen some interesting development on the litigation side driven by another company and we will be watching this closely. This is not the 505(b)(2) but on the 505(j) side. So let us see, how that unfolds. As far as (b)(2) is concerned, we have appealed but it all depends on as I said on the other side on how that unfolds over next give or take say 60-80 days.
- Abhishek Sharma:** Your approach would remain 505(b)(2), right?
- Saumen Chakraborty:** We have both the options.
- Karthik Mehta:** Just on your inspection which happened in Duvvada, could you quantify all the products which are manufactured from there, have been effectively transferred to some other side in the event that we receive an import alert there, talking of the existing commercialized products?
- Abhijit Mukherjee:** I think we mentioned, the two major injectables have core site in a partner site as well but that probably answers and there is one more Oral Solid where we do not have a partner site. I really sincerely hope that it does not go the direction you mentioned.
- Karthik Mehta:** Again, just to maybe stick on the reinspection, in your consultation with your advisors, do you feel that as per the global CAPA, all three plants would receive any EIR at the same time, I know you just mentioned about CBE30, but then in your view, can the other two plants remain under warning letter and any one of the other under...?
- Abhijit Mukherjee:** You have seen the observation, it is in public domain, you will have to make your interpretation on this, and the data point which we give is from one plant we have received CBE30. Based on that, you have your interpretation, and you are probably I am sure have seen the observation from the three plants, right.
- Karthik Mehta:** Yes sir, the reason I ask is because I am not able to make observation because all the three plants were given one warning letter which is why it is addressed to you?



**Abhijit Mukherjee:** That is why, I cannot answer the question in specific, but I can only give you a data point, the data point is, from one site, we have got CBE 30 approval which was the first one of it and let us see how the rest of it unfolds.

**Karthik Mehta:** Is there a change in expectations due to the recent competition in the US intensifying (ClaurusOne)?

**Abhijit Mukherjee:** Yes, the most recent consolidation you are talking about, right. So I think this is not new anymore for anyone. So I think we will deal with the way we dealt with the previous one. So, as I said, I think whatever erosion market has seen in that range would continue. We will have to deal with such consolidations the way we have dealt in the past.

**Saion Mukherjee:** Sir, one question on the Proprietary Products side. If you can Sernivo and Zembrace, how are they doing, you had guided for \$30, 50 million earlier as peak potential. When do you see that coming through for these products? If you can update us on the filings on the prop side that you have done this year, how many are pending approval and what kind of launch calendar that you are looking for FY'18 and '19?

**Anil Namboodiripad:** So let me start with how the business is doing. Both Zembrace and Sernivo have significantly picked up since the last time we spoke which was the last quarter. With Zembrace prescriptions in Q4 increase by roughly around 33% over Q3, we see more than 500 prescriptions per week by the end of FY'17 and that is what we were targeting and we are on target, serving as a launch pad for FY'18. Number of prescribers has grown nearly 50%, which is all good indicators of how the product is being taken by the market. Similarly, on Sernivo, we have more than 850 prescriptions per week which is quite healthy. That is how we ended FY'17 and 40% volume increase over Q3s highest week. So these are some indicators for you to explain that these two products are now positioned for further growth through FY'18. The base business has also been doing steadily. So your question was around the peak sales and when we will get there. So as I had mentioned to you, in FY'17, there were some delay in terms of getting managed care of insurance coverage. As of now, we have 75% coverage with insurance plan, there is still room to grow, but we believe that will happen. Peak sales, we expect in the next three years or so for both products. The other part of your question was around key launches. So we have two pending NDAs for FY'18 -- one of them is Xeglyze which is contingent upon clearance of one of our facilities and the other is a topical product for Dermatology, and that is expected to be approved - the PDUFA date later in the year, and then there are several other NDAs that we expect in FY'19. So we are not commenting on it at this time.

**Saion Mukherjee:** So, can you throw some light on the Xenoport asset, how that is progressing and any timeline that you have visibility on in terms of filing?

**Saumen Chakraborty:** This will be further off in terms of the timeline on the immediate distinct, this has to go through its development. So maybe we can take it at a later stage.

**Rahul Sharma:** Just wanted the clarity on what could be the sustainable gross margins going ahead for the company?

**Saumen Chakraborty:** Again, you are taking financial guidance. So last time also I said normally the way we manage our business is supposed to have north of 50% as a gross margin but for the last couple of years, 55% is what was there, maybe in few quarters, we got even higher. But this quarter has been specifically lower, the reasons I have explained. So it could be within this range, take a few hundred basis points, plus or minus but 55% could be a normal effect, you cannot be so accurate, we refrain from giving any financial guidance, there is a lot of uncertainty, you cannot be absolutely certain about the pricing conditions, the contracts that you will quote and the flow, so all these things affect in terms of your margins but yes, normal expectations if you wanted some kind of a financial modeling, I am saying here and there a few hundred basis points but 55 could be normal expectations.

**Rahul Sharma:** If you would add up all those one-offs which were there, then what would be our gross margin for the quarter?

**Saumen Chakraborty:** I said, this has declined by 400 basis points. So if you add 51.2 plus 400 basis points it would have been around 55-point something.

**Rahul Sharma:** Another thing was how has been the price erosion in the existing portfolio on YoY basis and QoQ in US markets?

**Saumen Chakraborty:** Abhijit already told you that this year particularly in FY'17, it has been severe, but it will vary also from company-to-company depending on portfolio launches and everything. But we have seen FY'17 over FY'16 is a bit unprecedented because we have never seen earlier on gross level going beyond the high single-digit for this year, it has been in the double-digit, and this quarter specifically has been higher. But going forward, the expectation is that it may not be that level of erosion getting.