Dr. Reddy's Laboratories Limited
Q3 FY16
Earnings Call Transcript

Kedar Upadhye:

Good Morning and Good Evening to all of you. Thank you for joining us today for Dr. Reddy's Earnings Call for Third Quarter of Fiscal 2016. 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 Saumen Chakraborty - our Chief Financial Officer and Abhijit Mukherjee - our Chief Operating Officer, along with the Investor Relations team.

Before we proceed with the call, I would like to remind everyone about the Safe Harbor. This discussion will contain certain forward-looking statements which are based on management's current beliefs and expectations and involve a number of known and unknown risks and uncertainties that could cause our future results, performance or achievements to differ significantly from what is expressed or implied by such forward-looking statements. For more detailed information on the risks and uncertainties associated with the company's business activities, please see the company's Form 20-F for the fiscal year ended March 31, 2015 and Form 6-K for the quarters ended June 30th 2015 and September 30th 2015 and our other filings with the Securities and Exchange Commission.

Now, I would like to turn the call over to Saumen Chakraborty - our CFO.

Saumen Chakraborty:

Thank you, Kedar. Greetings to everyone!

Let me begin with the key financial highlights: For this section, all the amounts are translated to US dollars at the convenience translation rate of Rs.66.19, which is the rate as of 31st December 2015.

Consolidated revenues for the quarter are Rs. 3,968 Crores or $599 million and grew marginally by 3% year-on-year. Revenues from our Global Generics segment are $507 million and grew by 7% year-on-year despite currency challenges faced by EM geographies and constrained operations in Venezuela. The growth story is primarily driven by US, Europe and India. The growth in US is aided by sustainable performance of the base portfolio. Europe business grew on the back of launches and India business continues its momentum which was also benefitted by the full quarter contribution of the brands acquired from UCB. Revenues from our PSAI segment are $77 million and declined year-on-year by 17%. This reflects, in part, the impact of delay in dispatches on account of the on-going remediation activities related to the USFDA's observations.

Consolidated gross profit margin for the quarter is 59.5% vs 58.2% in the corresponding quarter of the previous year. The increase in margin reflects the continuing high quality of our commercialized portfolio in US. Corresponding values for Global Generics and PSAI were at 65.6% and 17.4% respectively.

SG&A spend, including amortization, for the quarter is $182 million and grew by 8% year-on-year. During the quarter, the company settled an ongoing patent litigation with Novartis on zoledronic acid. Consequent to this settlement we have accrued $5.46 million as a charge towards past sales. Normalized for this charge, the balance increase is largely due to remediation costs, and certain routine items related to manpower and other spends.

R&D expenses for the quarter were at $62 million, representing 10.3% to revenues vs 11.2% in the corresponding quarter of the previous year. The expenses have declined year-on-year largely due to the receipt of our share of development costs and other contractual amounts from Merck Serono for biosimilars development program.

In continuation with our practice to translate certain net monetary assets in Venezuela subsidiary at the SIMADI rate, a charge of $9.6mn has been considered during the quarter. Balance continues to be recorded at the preferential rate of 6.3 VEF per USD.

As discussed earlier, we continue to evaluate the arrangement entered into with the Government of Venezuela, which may facilitate the repatriation at the above mentioned preferential rate. If future developments indicate that the CENCOEX rate is no longer appropriate, this could have a significant impact on the consolidated financial statement of the company.

EBITDA for the quarter stands at $153 million, 25.5% to the revenues. Tax rate for the quarter is 23.6%. Effective tax rate for the year is expected to be in the range of 21-22%.

Key balance sheet highlights are as follows:

Our working capital marginally decreased by $7 million over that of the previous quarter, and is largely in line with our expectations. Capital expenditure for the quarter was at $47 million. As of 31st December 2015, we have net cash surplus of $68 million.

Foreign currency cash flow hedges for the next 18-months in the form of derivatives and loans for US dollar are approximately $370 million, largely hedged around the range of Rs.64.4 to Rs.69.45 to the dollar. In addition, we

have balance sheet hedges of $345 million. We also have foreign currency cash flow hedges of RUB 470 million at the rate of Rs.1.06 to the RUB and EUR 8 million, largely hedged around Rs.75.31 to Rs.81.03 to the Euro, maturing over next 15-months

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

Abhijit Mukherjee:

Thank you, Saumen. Greetings to everybody, and I extend a warm welcome to you on this Earnings Conference Call.

I believe that our financial performance this quarter is satisfactory despite a number of internal and external challenges that we faced, and also considering the fact that comparable quarter of previous year had a high base in terms of both sales and profitability. As you would have seen, the base business in key geographies has been quite resilient which played a major role in quarter's performance. Considerable amount of time and efforts are being diverted towards the important remediation and risk mitigation activities pursuant to USFDA's observations.

Now, let me take you through some of the Business Highlights for each of the key markets. Please note that in this section all references to numbers are in respective local currencies.

Our North America revenues are $298 million and grew by 11% year-on-year. Key molecules contributed meaningfully to the quarter's performance in absence of any notable new product approval. We experienced sustained pricing and market shares across our key molecules. As you are aware we re-launched esomeprazole towards the end of December and are actively working towards gaining market share. In view of lower number of launches in the coming quarters, we need to be watchful of competitive pressures on the base portfolio. On the OTC side, Habitrol is well integrated now and we continue to target new accounts.

During the quarter, macro-economic factors continued to impact most of our Emerging Market territories. In this situation, the team continues to focus on broadening the product portfolio in existing countries and entering new geographies by leveraging the current portfolio. Russia revenues are $47 million for the quarter and grew by 5% year-on-year in constant currency. In Venezuela, we continue to be cautious and have significantly calibrated our supplies. Over the past couple of quarters, there has not been any meaningful repatriation of funds allowed by local exchange control authority. As explained by Saumen, we remain cautious in our approach towards the geography.

India business revenues are Rs.581 crores and grew by 34% year-on-year. Portfolio acquired from UCB has been fully integrated into our supply chain. Further, you would have noted that in the second quarter, some sales spilled over to October. Normalize for this as well as the UCB portfolio contribution, the growth for the quarter is in line with the recent trend of above market performance.

PSAI business posted revenues of $77 million and declined 17% year-on-year. This decline is primarily attributable to delayed dispatches on account of the ongoing remediation activities. Our efforts are directed towards building a healthy order book.

On R&D front, we stay committed to building a strong pipeline. As you are aware, we received final FDA approval for two NDAs - ZEMBRACE SymTouch, which is Sumatriptan 3 mg Autoinjector device and

SERNIVO, which is a Betamethasone Dipropionate Spray. We also received tentative approval for our NDA for ZENAVOD 40 mg Capsules for Doxycycline. These approvals are critical milestones in our bid to establish a portfolio of differentiated assets in the United States for our Proprietary Products business.

Before I end, I want to give a brief update on the ongoing remediation activities. Post receipt of the warning letter from USFDA in early November 2015 for three of our sites, we submitted on December 7, 2015 a Comprehensive Corrective and Preventive Action Plan, which in short is called "CAPA" to address all the issues raised. The CAPA Plan includes site specific CAPA, manufacturing network-wide CAPA and CAPA to sustain enhance and enhance our quality and compliance performance on an ongoing basis. As of January 31, 2016 all the CAPA which were due for completion have been completed.

We have submitted a status update to the Warning Letter response on January 28, 2016 stating our progress on accelerated remediation efforts towards sustainable compliance. As part of this quality journey, we have engaged well-respected third-party consultants, US-based Lachman consultants to provide necessary compliance and remediation support for assuring robust implementation and verification of the CAPA plan.

With this I open the floor for Q&A.

Manoj Garg: One on the regulatory front - our regulatory consultants here believe that the issues sited in the warning letter would take about 18-24months to clear. Just wanted to get your thoughts on that timeline assessment. Then two, can you specifically break out Venezuela sales. If I heard you correctly, I think you said, you continue to book revenues at VEF 6.3. Other Pharma companies have devalued or booking at an exchange rate as high as VEF 200. So just wanted to better understand the thought process there?

Abhijit Mukherjee: I will take the first one and let Saumen deal with the Venezuela part. So, on the remediation, we certainly cannot provide you any explanatory guidance on the timelines because on our side we are doing whatever we can to mitigate, workout on the CAPAs, update FDA and the overall journey we think is progressing satisfactorily. Beyond this is completely the agencies prerogative.

Saumen Chakraborty: We have certain arrangement with the Government of Venezuela. We are staying quite hopeful that we get some repatriation during this quarter. If that does not happen, then we will have to reconsider what will be the right kind of rate for future accounting consideration.

Manoj Garg: What is the current exposure there?

Saumen Chakraborty: $60.7 million pending for repatriation.

Saion Mukherjee: My first question is on Venezuela. Can you specify the sales booked during the quarter? What is the EBITDA contribution?

Saumen Chakraborty: During the quarter it is $18 million. We are not giving any specific country wise EBITDA disclosure anywhere.

Saion Mukherjee: Sir, the second question is with respect to your cash flows, which is running at almost Rs.2,500 crores free cash flow. What are your thoughts on that in terms of increasing dividend payout or looking at the new acquisitions if you crystallize anything if you can share that?

Saumen Chakraborty: Of course, our growth agenda includes both organic and inorganic opportunities which we have been trying to pursue. We have enough in our balance sheet today that we can leverage for such acquisition(s). But having said that, we are treating each of the opportunity on its own merit. Just because we have cash, it does not mean that we will dilute the criteria that we have set for ourselves for meaningful acquisition. But if acquisitions are not there we may think of any other corporate action(s), which as and when we find some alternative options we will get back to you.

Saion Mukherjee: This is on export incentive. I understand you recognize this as cost of goods sold. Can you quantify that number and is there a substantial increase versus last year?

Saumen Chakraborty: Yes, there is a substantial increase vis-à-vis last year. So overall on annualized basis, it could be roughly Rs.150 crores plus.

Saion Mukherjee: How much was last year?

Saumen Chakraborty: It is incremental.

Prakash Agarwal: If you could highlight any updates on the Biosimilar portfolio that we are building for regulated markets?

Abhijit Mukherjee: On the regulated markets, we have a few assets which we are working with Merck Serono. Saumen just mentioned that there was a milestone recognized that we got during this quarter, which has been adjusted against the R&D investment for the quarter. The more exciting story on this is our efforts to put these into the Emerging Markets and we had mentioned earlier and we still stand by that. We are pursuing approval in Russia. We are filing in quite a few important Emerging Markets and discussions with the regulatory authorities are in early advance stage and we may seek slightly more expedited review of those. We would like to build on this while our journey on regulated markets continue. Specific assets, we will not get into, at this stage.

Prakash Agarwal: But we have talked about Rituxan and Pegfilgrastim. Yes, so these two assets as what you are talking about for the year in the filing stage?

Abhijit Mukherjee: Yes, the more important is Rituximab, they will be, naturally having worked on Rituximab and taken into the market. There will be a few follow-on mABs which are in the clinic at the moment.

Prakash Agarwal: For regulatory markets to enter the clinics, so what kind of filing dates we are looking at?

Abhijit Mukherjee: So at the moment, these assets we are not taking ahead ourselves into the regulated markets. That we had mentioned earlier, it still continues to be under partnership. Emerging markets – we will take these assets ahead ourselves. From data perspective - already large part of it is in hand and we are filing depending on the requirement of specific country wise regulatory agencies. But as far as regulated market is concerned, the strategy continues to be partnering.

Prakash Agarwal: There is no timeline as of now for that?

Abhijit Mukherjee: The journey continues at the moment. On a short-term, there is nothing coming.

Prakash Agarwal: On the USFDA again, just trying and understanding after having assessed the warning letter and having consulted your third party, if there is any supply disruption in order to have third-party validation of goods or delay in shipments or because US run rate seem to be very much on track. Do you anticipate that happening or any disruption in supply or any delay in shipments?

Abhijit Mukherjee: As we had mentioned earlier that PSAI business had some impact of batch releases. We are closely in touch with the shortage loop if there is anything. But there is nothing major to be reported at this juncture from the existing set of products. For future - we do not want to comment, but currently there is nothing meaningful. PSAI part also is largely behind us, it is now back on track.

Prakash Agarwal: Just a clarification here on PSAI; the decline is largely due to one off impact, because warning letter you were clearly supplying and there is no issue as such for the upcoming quarters?

Saumen Chakraborty: No, we mentioned that because of the remediation thing there were some delays in dispatches of API from these facilities.

Prakash Agarwal: But you are back on track?

Saumen Chakraborty: Yes.

Abhijit Mukherjee: There is also a product where we have a profit share arrangement with our customer with a dominant market share position. More generics have come in. So to that extent, that has made an impact as well.

Neha Manpuria: First, you mentioned that there was some impact on SG&A due to remedial cause. How should we look at that aspect going forward? I know third party auditors that we have got in that will be recurring. But I am assuming there would also be some cost related to either side transfer, the derisking, etc. So how should we look at the margin impact when we look through the next few quarters?

Saumen Chakraborty: We are not giving any specific amount for it, but whatever is our SG&A for the quarter, it includes both kind of the payments that we have been making to the consultant for remediation as well as there is certain site transfer related activities which have been happening already. But our SG&A this particular quarter has also some other aspects

like what we mention about the settlement of Zoledronic Acid that was a product we launched at risk and now we have settled that, meaning there is no risk that we will carry on that, and that has gone to the SG&A spend. Also there is some recurring kind of legal and professional expense which will be incurred by us. But we are not giving any specific amount and it will not have a huge impact.

Neha Manpuria: Second, FY'16 overall has been a tepid year for us when it comes to approval. Now that you are doing site transfers, etc., How should we look at our launch pipeline for FY'17 -- will it be similar to FY'16 given it will take time to get these approvals from the USFDA despite site transfer or should we expect it to be better?

Abhijit Mukherjee: So Neha, on the first question slight addition to what Saumen said, although remediation cost has been there in this quarter, but it was not full blown, there will be some more impact as we continue because the number of people has increased in the sites and that will be there. So that is one. The second thing is on approval. I think this year has been a tepid year. No doubt. But next year we expect this to be definitely better than this year. Now two kinds of assets; one, which are date specific launches; one which are not date specific and needing approval from the agency or being contingent on some of the activities which are ongoing in terms of what we just mentioned, part of the transfer etc., some are litigation oriented. But all in all, I know there is a probabilistic aspect to it, but I certainly expect next year to be better than this year.

Neha Manpuria: Our India business even if I adjust for the slippages that you mentioned, it seems like a very strong quarter with the UCB assets. If you look at our business ex-UCB this one-off what is driving that very sharp improvement in the last three quarters?

Abhijit Mukherjee: If you take out the cut off impact from Q2 to Q3 and the UCB related growth then on a base business the growth will be around 19%.

Neha Manpuria: That is pretty strong and it has consistently been improving quarter-after-quarter. So just wanted to understand what is change particularly on the ground to drive the strong improvement and can we see more improvement from these levels or the 18% to 19% base business is what we should be assuming going forward?

Abhijit Mukherjee: There is no one specific reason which I can attribute. For the last few years we have been working as a team, quiet a lot, on India business. Several efforts on prescriber connectivity, patient connectivity, retail connectivity, portfolio distribution. Overall we used to be much more acute. We have over the last few years become pretty well balanced between Specialty Chronic and Acute. All these and coupled with good

execution is yielding result. So going ahead I think we are hopeful of maintaining growth in this range which should be a few percentage points higher than the market growth.

Chirag Dagli: In your opening remarks you mentioned about base business price erosion. If you can help us understand what sort of base business erosion should we be sort of pencilling for your business given the larger products? Generally, when we talk to peers they talk about high single digit kind of erosion. Is that what is applicable to Reddy's as well or is there anything different in your base business erosion?

Abhijit Mukherjee: Broadly what others perceive we (also) perceive the same way except for the fact that we have quite a few big assets. So far we have been doing well. It could be in that zone but it may not be even, that is a biggest concern for all of us, it can vary from as and when we get the hit. So certain quarters could be better, certain quarters could be little worse. So far actually destiny has been kind.

Chirag Dagli: So when you sort of take a three-year view on this base portfolio, this high single-digit number should hold?

Abhijit Mukherjee: The channel is consolidating. What everyone else is commenting is normal when the channel gets consolidated. Their ability to negotiate and demand, goes up to that extent. So wrt some of that we are all on the receiving side of. Finally, the Oral Solids and more areas which are crowded unlikely to see anything lesser than that going ahead.

Chirag Dagli: So, we will see more than this or lower than this, sir?

Abhijit Mukherjee: Very difficult to make a very definitive statement on this. Broadly, I gave you the headwind associated with it which is big time consolidation of the channel. So more or less will depend on which assets you are in.

Chirag Dagli: On the EBIT base for PSAI, it is lower because we said there were obviously delayed and one lower profit in one of the key products. But both these should sort of continue at least over the near term right,?

Saumen Chakraborty: Abhijit has already commented we are back on track on that.

Anubhav Aggarwal: Saumen one question on Venezuela, I was looking through your notes. This quarter you had FOREX loss from monetary assets about Rs.63 crores, this is much higher than last two quarters. Was there no sales done from India and that is why this is such

a large number this quarter? Secondly, would you say the Rs.63 crores would largely correspond towards including of Venezuela and EBITDA this quarter?

Saumen Chakraborty: First, we are not giving country wise EBITDA, but yes, net monetary asset we have taken provision of Rs. 64 crores this quarter. Our dispatch has been not there during this quarter, we have completely calibrated.

Anubhav Aggarwal: Then Rs.64 crores would have been only generated this quarter right, that is why it is coming here?

Saumen Chakraborty: Rs.64 crores get generated, there is an overall impact on the way we compute the net monetary asset. We take as on 31st December, the total scenario and based on that we compute, but a large part will be attributed to this quarter.

Anubhav Aggarwal: One more clarity on the way you report gross margin on the segment side. Sharp decline in gross margin for the Global Generic segment sequentially from September to December quarter about 170 basis points. Regional mix suggests that it is largely coming from the US market. Was there any large inventory write-off more than normal or any other reason for that sequential decline in gross margin?

Saumen Chakraborty: There will be always some kind of the quarter-to-quarter inventory write-off which happen, but there is nothing very significant to report.

Kedar Upadhye: Anubhav, it is largely currency related impact on a sequential basis.

Anubhav Aggarwal: Which you mean to say that is basically coming from EMs which is impacting it?

Kedar Upadhye: Absolutely.

Anubhav Aggarwal: Abhijit, just one clarity on this, your response to warning letter to FDA. Is there any third party kind of risk assessment report that you need to submit for the non-impacted plants. Why I am asking this is that we have got warning letter on 5th of November. It has been three months. We have not seen any final approval from Dr. Reddy's any plants so far, except the proprietary products which I am assuming is not from the Indian plants. I do not know whether there is a correlation or not but I am just checking that when you submitted the CAPA response, is there anything you promised that you need to do on non-impacted plants as well?

Abhijit Mukherjee: No, I think there was no specific request on that front formally. But certainly we are extending a lot of the CAPA, which we have out of these observations to other sites now. Coming to approval, I think we did have tentative approval during this period. It

is little bit of a lean patch in development, few approvals got slightly delayed as well. Because these were from this size, we mentioned last time very specifically esomeprazole now got delayed by about six months, very expensive for us. Xeloda was all set, but it is not going to come in because both are from impacted sites and a few others which I am not going to detail, not that impactful. However, there was some period the audits which happened in the earlier period where EIRs were taking some time to come in, in a very recent past most of the audits which happened EIRs have come in for the other sites.

Anubhav Aggarwal: If I can just ask a related clarification on this. On the PSAI business, is there impact from any of the customers after you have got the warning letter, not in this quarter, but anyways in future, one or two quarters because anyways it takes time for anyone to shift capacity or source of supply. Is there any potential impact that you have experienced so far since the time of warning letter.

Abhijit Mukherjee: When the letter came in, there were a lot of questions. Both from the retail channels as well as the API customers. We worked overtime in providing the complete transparency and clarity of the status. I think most of the concerns are mitigated. Having said that new filings from the site would naturally be impacted. People would be hesitant to immediately take samples of those important ones. We have the SEZ site next over where we are filing. All the filings in API are from the new SEZ site. So those are impacted but whole site whatever product we develop, of some of those there are some impact, not struggling to put any figure to that, but there would be certainly some impact, yes.

Abhishek Sharma: Sir, out of the total pending ANDAs how many would you have which are not dependent on the three sites which have got a warning letter?

Abhijit Mukherjee: We have approximately 79 pending ANDAs and many of them are with certain later dates based on IP, etc., The near-term ones whatever we lost, we lost. A few are pending at the moment with everything complete and impacted which I just covered in my earlier answer to the question. The rest of the ones we are trying very hard to ensure that the delay is not due to the site. Of course, the remediation of the site is always priority one and all the efforts are going in, but specifically on those approvals we are trying to see what we can take transfer before that becomes a bottleneck for the coming sets.

Abhishek Sharma: But a large number of these 79 today, you are saying are directly or indirectly linked in some way to the sites which have got the warning?

Abhijit Mukherjee: I did not say that at all. I said on the impact. We have 12 sites which are regularly audited by FDA, so these are the 3 out of that - 2 APIs and 1 injectable site. Also there are many products which are partnered outside for manufacturing. So certainly I did not say large part of it, in fact a small part of it probably.

Abhishek Sharma: On the Injectables existing business, you have been using vendors, which appear on your label. So does that derisk some of your existing Injectable business as well as future filings? Could you use them going forward probably for site transfer or for making future filings?

Saumen Chakraborty: Yes.

Abhishek Sharma: One question on Venezuela. So how much unsold inventories there in the system and when was the last shipment that you made to Venezuela?

Saumen Chakraborty: We have been calibrating the dispatch and sales also, accordingly, is becoming low at every quarter. But whatever inventory that we have on hand it can cater to next 6-months of sale.

Abhishek Sharma: Which has already been shipped to Venezuela?

Abhijit Mukherjee: First of all, we are not manufacturing anything fresh. We have stopped manufacturing probably 6-months back. Whatever inventories are there – are being tapered out, the sales are pretty much going to drop to a very, very low level by the end of this quarter. In fact, as we speak this quarter itself is very, very low and naturally we need to calibrate that in the impact vis-à-vis when you do YoY. So it is pretty much being tapered down to zero level. No further manufacturing and not a whole lot of inventory in the system. But having said that since you are on this topic, I wanted to clarify a couple of things that what are we exactly doing on this geography. There are two deals we have signed specifically with two companies owned by the government their specific names… I am not getting to the specific details on the names of those companies. One is on supply of an oncology biologic product, the second is a whole host of very important medications for the geography which at the moment is very acute shortage of medication. So one we have said, which we will take it to government factory, we will do secondary packaging there and maybe at some point in primary packaging at a certain pre-discussed cost, which will be lower than the current price prevailing in the market substantially. So the country get the benefit. This is a legal deal which we have signed, whether and how it is executed, I do not know. Currently, it is a little bit of chaos in the country you can well imagine, but if it comes through,

then we will be able to revive this. But in absence of that we are not going to sell anything more pretty much next year.

Saumen Chakraborty: But if conditional to the days repatriate quite significant fund to us…

Abhijit Mukherjee: Which they signed up.

Saumen Chakraborty: If they do not, we are not going to go ahead with it. That is why I said in the beginning we are hopeful, but we will have to closely monitor and watch what is happening during this quarter.

Abhishek Sharma: Does this deal involve advance payments?

Abhijit Mukherjee: So anything future… Saumen mentioned, one, it is actually part of the deal that significant part of whatever is due to us will have to be paid. Second, any further would be contingent to complete clarity on payment. There are ways and means you can do it. We are not going to sink in anything more there.

Abhishek Sharma: Directionally on Biosimilars your deal with Merck Serono where is it going, when can we see the first program in Phase-3 in the reg market?

Abhijit Mukherjee: Exact data we will come back to you on that but we have got the milestone payment and I would guess it should not be very far in terms of….

Saumen Chakraborty: Maybe later we can check with Kedar.

Girish Bakhru: First question again on the Injectables side. Is the site transfer process complete to derisk the API of some critical products from Srikakulam?

Abhijit Mukherjee: Yes, I think we messaged it last time that we have completed that actually there is one of the two which is from there and we have completed that.

Girish Bakhru: So in terms of the business momentum particularly pertinent to Injectables which was doing something like 20% of US, that run rate we would be largely maintaining, right, or has that changed because of the initiatives or site transfer and all that?

Abhijit Mukherjee: No, at the moment as you are aware that suppliers have not impacted from the site. But, the question is in case that gets impacted, whether we have derisked.

Girish Bakhru: Yes, because that was the assumption that you would anyway preparing for that, is it not?

Abhijit Mukherjee: Supply will not be a constraint, but one cannot give any guidance on what is going to happen in the market.

Girish Bakhru: Why would you not say site transfer some pending Injectable products which probably would not get approved out of Srikakulam at this stage, particular question being Propofol?

Abhijit Mukherjee: Propofol is not from Srikakulam, #1, so that is a specific question. Second is future approvals will not come from Srikakulam because it is under warning letter at the moment.

Girish Bakhru: That part I understand, but I am saying would you have initiated site transfer of some Injectables or the pending injectables filings from Srikakulam to other Injectable sites?

Abhijit Mukherjee: If the APIs from there in case but a few other site transfers also we are doing the process from the sterile site FT07 the Duvvada site. So that is continuing. The broad message you should take is that we have missed a few approvals financially pretty big, which has already gone in into whatever we are declaring, a couple of them I mentioned. Going ahead the effort is depending on the date specific launches, the effort is trying to see whether we can risk mitigate those. The current lull of approvals is a combination of two factors. One is, of course, these sites and the delays which happened. The second is in any case when we embarked on the journey of Complex Generics, the development pipeline 2.5 years back slowed down a bit. Part of that patch is now getting over. My message in earlier one of the questions is that my expectation is next year launches would be better than this year.

Girish Bakhru: If I could just stretch this further to answer specific on Propofol, what according to you has been delaying that -- is it the particular matter where you think some other players blocking your launch or what has been delaying it?

Abhijit Mukherjee: Not really. Broadly, as per our understanding, we should not be too far away from approval.

Girish Bakhru: Just on Transdermals, you have started filing them. Are you doing clinical trials on Transdermal products?

Abhijit Mukherjee: Depending on certain product which mandates, yes, certain products which does not mandate, but quite a few, we have already filed with the clinical trials got accepted. So, the journey of the file is being sort of scrutinized where we have started.

Girish Bakhru: If some of this which would be say very open in terms of the IPR would be in a position to see a launch in next two years, is that a fair assumption?

Abhijit Mukherjee: I will have to get into those details. Specifically, firstly, we will not go as simple as that, but as I said the file has gone in, accepted, the journey is in progress.

Sameer Baisiwala: Abhijit, on your commentary on the risk to the base business, you mentioned a few times in the call, is this just out of caution you are saying or do you see based on your intelligence or what you are seeing in the market that more competition is coming for some of your bigger assets?

Abhijit Mukherjee: Five or six are very big ones. To be very honest, do we have specific names of competition, no. We are hearing a lot on Valganciclovir that we do not know exactly when could be earlier one. But others it has been a while, so just my guess that we will certainly see at some point in time.

Sameer Baisiwala: Can you just share with us how many products for which you have applied for site transfer?

Abhijit Mukherjee: Suppose, hypothetically, we have an expected approval in let us say, six, seven months. If we have not filed already we would be missing it. Normally these transfers are exact sort of application of the API in another site. So if you put the stability data, there is reasonable probability in six months. So more or less keeping that margin of error, we are trying to transfer and submit.

Sameer Baisiwala: This would be low single digit, would you say?

Abhijit Mukherjee: We will have to take both the batches, sometimes it is T0, sometimes we do T3 as well. All put together it will be more than low single digit; it could be 5-10.

Sameer Baisiwala: Abhijit, can you update us on your COPAXONE 20 mg file?

Abhijit Mukherjee: Better than what I said last time, last time I pretty much said that we are struggling with the science part of it, and we have a much better visibility now, slowly getting into trial batches and getting into optimized scale up. 5-6 months or so, we hopefully should be in a position to respond to the CR which we received. This is we are trying to do that.

Sameer Baisiwala: Would you say this is a fiscal '17 launch?

Abhijit Mukherjee: Beyond that. Look, how many more questions FDA would ask. We are trying to do a very deep decent science job on this. We do not want to rush it whatever time gets lost, because pretty much similar things would come up in the next asset as well. So, I would certainly not comment on the timing of launch, but we are trying to do a very good work on our side on the science part of it.

Sameer Baisiwala: You had set yourself two NDA filing every year. How do we stand for fiscal '16 and actually fiscal '17? Do you think you are not trying for that?

Saumen Chakraborty: I would probably reiterate what we said. We would be trying to get to about a couple of filings every year. Now, those things can change a little bit depending on what data we get, but yes, our internal target would be two per year.

Nimish Mehta: If you can give us some outlook on the Gleevec launch? I know it was probably stuck because of the Oncology facility being under warning letter, but have we been able to transfer it to other site or will this be a delayed launch?

Abhijit Mukherjee: We have a date-specific launch as per the deal and the site issue should not be a bottleneck to that in our view, it should be done before that in terms of derisking it.

Nimish Mehta: Right now was it filed from the facility, which are under warning letter?

Abhijit Mukherjee: One part of it, but the work is in progress of shifting, it still gives us adequate time.

Nimish Mehta: Do we have by the way more than one Onco facility which the USFDA approved?

Abhijit Mukherjee: No, we do not have internally. But many of the assets we do not have to do it internally.

Nimish Mehta: Other thing I just wanted to know about the timeline for resolution. You mentioned you have kind of started implementing CAPA Plan. So according to the plan, what do you think how long will it take for you to complete the CAPA processes that you can tell us that will be helpful?

Abhijit Mukherjee: So there are a pretty sizable number of commitments. What we are tracking is when we are sending the updates, at the date of the update are we on track … I think Saumen mentioned in his discussion point, that so far whatever update we send we are completely on track on that. When we send the update we will be on track of doing those. So hopefully in about between 3-6-months we will be implementing the CAPA. In our side, we will do whatever it takes.

Nimish Mehta: Just a clarification; you mentioned that the increase in the export incentive is Rs.150 crores for the nine months or for the year, how should I…?

Saumen Chakraborty: I said annualized Rs.150 crores plus exact we can say in the year-end.

Nimish Mehta: So it is Rs. 150 crores plus of annualized export incentive and a lot of it would be between Q2, Q3, is that a fair assumption?

Kedar Upadhye : It will be fairly spread out, Nimish, actually over the four quarters.

Saumen Chakraborty: So while we will take couple of more questions, just a couple of things I also wanted to say that this time we will be filing the 6-K very early be either today or tomorrow, it will be there. So you can all refer to that for more detail analysis. Second thing in the Q4 the currency, particularly in Russia, it has also come down. Against one one rouble it is only Re. 0.88 per rouble or so. So there would be some pressure from Russia and Venezuela. Already we have talked about that we have not dispatched anything, so there will be pressure which will be there from both Venezuela and Russia front. I thought it will be appropriate for you to take that into consideration when we are looking at the Q4.

Abhijit Mukherjee: A little bit to add - Saumen, so he mentioned about mostly the Emerging Markets, the oil related impact eventually into currency and economy leading to both these large markets getting impacted in Q4. Energy, normally, Q4 is a little weak quarter because Injectables, institution heavy sales normally in Q3, normally gets mitigated with new launches. We do not have new launches, so there will be some impact there as well in North America. Europe, we were doing well, in two products which are slowly getting into tenders as we speak and that will have some impact and we spoke about API as well. So essentially some of these things will certainly have substantially sobering effect on Q4. So just wanted to make that amply clear to everyone.

Manoj Garg: Some specifically on your North American business: One, can you quantify your Nexium sales for the quarter? I believe you are in the quarter for about half of it. And then after you relaunched, how does that market plays look like in terms of pricing?

Abhijit Mukherjee: Again, Manoj, specifically I will not be able to give a figure. We have not lost the share there because of the disruption, but the prices have gone down initially when we came in, now there are five players in the market. Strangely, I think the stock up in the market is still there. So full offtake has not fully happened. We are still looking at more shares. But what is one thing has certainly got calibrated which is the 'price' at the time when we entered Vs now its got substantially calibrated. So I had given very broad indication of our annualized revenue from this asset. I think it will go southwards from there. But,

at the moment, I think this is a somewhat still unsettled scenario. I would not provide you a specific figure. But having said that it still going to be a good asset for us. We still have some share and we are looking for some more share.

Manoj Garg: Let me just try asking the pricing question in a different way; so the 18% growth in North American Generics that you have reported, can you sub-divide that into volume and price?

Saumen Chakraborty: We are not giving that level of details.

Manoj Garg: Last question on North America. Of the three ANDAs that you filed in the current quarter, were all three of those as a result of site transfers to other facilities?

Abhijit Mukherjee: No, none of those are site transfer, these are new ANDAs and two Injectables, one fairly attractive, the second was also good, and third is also a Soft Gel oral asset we can look at.

Nitin Agarwal: Abhijit, the Proprietary Products on the two final approvals that we have got for 505(b)(2)s, we did discuss about in the R&D meet, but when you look at the market now, how do you assess the opportunity for these two products and when do you see them coming into the market?

Abhijit Mukherjee: One is the Doxycycline, I said is still under litigation, the rest two in the course of coming few months, we will get into the market and probably we have said the potential for both these, if I recall rightly is in the range of $50-70 million. But having said that you will have to sort of factor in typically in the Proprietary Products first year with feet on ground, you really have to build the market, but at this point in time you do not have enough prescriptions, but eventually sort of you start making money.

Nitin Agarwal: But you still believe the opportunity has not changed much in terms of….?.

Abhijit Mukherjee: No, I think each of them have its own story. The 3 mg injection is basically trying to capture oral tablet users of migraine, there is a part of the patient pool who are not fully satisfied with that and for quicker on-set of action. So there is a pool of patients for this. For the Betamethasone Spray, it combines all the benefits of, Lotion, Cream, Ointment, etc., I think it shows that it can pretty much has in one form all the benefits of all the other skills. Similarity the doxycycline, there is a specific meal related advantage. So each one has some signs behind it, yes.

Nitin Agarwal: How should we look at R&D cost going forward? What would have been impact of milestone that we got from Merck -- would have been more than 10%, 15% of the R&D cost for the quarter?

Saumen Chakraborty: It was basically out of the biologics currently which it itself….will be to that extent only. So it will not be that. But at the same time our R&D as a percentage of sales will be between 11% to 12% as we alluded earlier.

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