

“Dr. Reddy's Q1 FY 19 - Earnings Conference Call”

**July 26, 2018**

**Saunak Savla:**

A very good morning and good evening to all of you and thank you for joining us today for Dr. Reddy's earnings conference call for the quarter ended 30 June 2018.

Earlier during the day, we have released our results and the same are also posted on our website. We are conducting the live webcast of this call and the transcripts shall be available on our website soon.

The discussion and analysis in this call will be based on the IFRS consolidated financial statements. To discuss the business performance and outlook we have the leadership team of Dr. Reddy's comprising Mr. G V Prasad – our CEO; Mr. Erez Israeli – our COO; Mr. Saumen Chakraborty – our CFO and Mr. Anil Namboodiripad who heads our Proprietary Product Business and the Investor Relations team.

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Before we proceed on the call I would like to remind everyone that the safe-harbor language contained in today's press release also pertains to this conference call.

Now I would like to turn the call over to Mr. Saumen Chakraborty – our CFO.

**Saumen Chakraborty:**

Thank you, Saunak. Greetings to everyone. I am pleased to inform that our financial performance for the quarter has been good across all key geographies with an improvement seen in the overall profitability.

Let me take you through the key financial highlights. For this section all the amounts are translated into US dollars at the convenient translation rate of Rs. 68.46, which is the rate as of 29<sup>th</sup> June 2018.

Consolidated Revenues for the quarter are Rs. 3,721 crores that is \$543 million and has grown by 12% year-on-year and 5% on a sequential basis. The growth is primarily on the back of the strong performance revival in Russia, consistent performance across businesses and contribution from gSuboxone. As you are aware during the quarter, upon gaining effective FDA approval, we launched the generic version of Suboxone film. In response to motion from Indivior, the US District Court of New Jersey granted a Temporary Restraining Order (TRO) enjoining us from further sales. In the intervening period between the FDA's approval and the issuance of the TRO, we were able to ship some launch quantity in response to market demand for generic Suboxone.

Consolidated gross profit margin for the quarter is 55.7% which is higher by around 230 basis points compared to the sequential quarter. The improvement in gross margin is majorly due to the benefit from the depreciation of Rupee against US Dollar and Euro, overhead leverage due to improvement in sales on a similar cost base and the margin contribution from gSuboxone sales which was partially offset with the price erosion in the base business. Gross margin for Global generics and PSAI were at 61.2% and 21.9% respectively.

The SG&A spend for the quarter is Rs. 1,211 crores i.e. \$177 million and is flat on a sequential quarter basis. It has grown by 3% compared to that in the previous year. We remain committed in our journey towards building higher cost consciousness across the organization and an improvement in the spend productivity.

R&D spend for the quarter is Rs. 416 crores i.e. \$61 million representing 11.2% to revenue. The spend has been lower during the quarter due to (a) quarterly variation in the milestone payment and other spend activity and (b) conscious effort towards enhancing the R&D spend productivity and prioritization. However, we expect the current year R&D spend to be around similar levels as the preceding year.

On the cost rationalization side, we are progressing in line with the internal expectations. A lot of work has happened around rationalization across the manufacturing network, portfolio, R&D sites, manning levels etc. It is a massive effort to reorganize systems and processes to help optimize our global cost structure and help us focus on other business priorities to drive growth.

On the same subject during the quarter we have entered into a definitive agreement to sale our antibiotic manufacturing facility and related assets. The conclusion of the deal is subject to certain closing condition that are being worked upon.

The EBITDA for the quarter stands at Rs. 807 crores i.e. \$118 million which is around 21.7% of the revenues. The effective tax rate for the quarter is around 9%. It is lower primarily on account of profit mix and favorable resolutions of certain tax related litigations pertaining to earlier years.

On a full year basis, we expect the annualized effective tax rate to be in the range of 21% to 23%. EPS for the quarter is Rs. 27.45. During the quarter operating working capital increased by around \$160 million mainly due to a temporary surge in receivables and inventory for new products. Going forward our free cash flow is expected to improve. We invested \$34 million towards capital investments and our net debt equity ratio is 0.29 as on 30th June 2018.

Foreign currency cash flow hedges for the next 9 months in the form of derivatives for US dollars are approximately \$300 million largely hedged around the range of Rs. 65.80 to Rs. 69.54 to the dollar. In addition, we have balance sheet hedges of \$386 million. We also have foreign currency cash flow hedges of Ruble 1,215 million at the rate of Rs. 1.12 to the Ruble maturing over the next nine months.

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

**Erez Israeli:**

Thank you Saumen. Greetings to all the Ladies and Gentlemen and I extend the warm welcome to you on this earnings conference call. Let me take you through the performance highlights across key markets and businesses for the quarter. Please note that in these sections all the references to numbers are in respective local currencies.

Our North America generics revenue for the quarter are at \$237 million, registered a sequential growth of about 7%. The sequential increase is largely attributed to the launch sales of gSuboxone film prior to the temporary restraining order coming into effect. This was marginally offset by value erosion in the base business. Further on 13th July 2018, the District Court of New Jersey in its opinion instituted preliminary injunction enjoining us from any further sales of gSuboxone film. We disagree with the decision and have appealed it in the Court of Appeals for the Federal Circuit. We have also requested for the Federal Circuit to lift the District Court's injunction while the appeal is pending and consider the appeal on expedited basis. Overall, we remain confident of our IP position and look forward to a favorable outcome in the appeal case.

On the base business, during the quarter we continued to witness incremental competitive pressures around some of our limited competition products. While the price erosion is continuing, the rate of the decline is not as steep as seen in the last few quarters. At the same time, it will be very difficult for us to speculate on the likely behavior of the market participants and their impact on the pricing environment over the coming quarters. Overall, the base business has performed reasonably well and we remain optimistic about the eventual stabilization in the generic market space over the medium-term.

We are quite excited about the growth outlook for the North America generics business owing to the depth in our complex generics portfolio pipeline and continue to execute on our game plan to accelerate the launch timelines for key high value products. As highlighted earlier we are anticipating a healthy new product launch calendar with the visibility of 15 to 20 launches in FY19. Continuing on the same lines, let me also update you on the status of our big ticket launches of generic Nuvaring and generic Copaxone.

On generic Nuvaring, as anticipated we recently received a few additional queries from the agency. We feel reasonably positive about the type of queries and also has a follow up call scheduled with the agency seeking additional clarifications. We are working on the response and plan to submit our response back to the agency in the next couple of months. We remain optimistic about the potential approval and launch for this critical asset in the first half of calendar 2019.

On generic Copaxone also, in line with the update shared during previous earnings calls we are on track to submit our CRL response in the next couple of weeks. While we feel good about the work accomplished during such accelerated timelines and considering the complexity of the product on hand, it is likely that there may be additional queries from the agency as part of CR response review. Consistent with extensive review timelines involved in such complex assets we are gearing towards potential approval and launch of gCopaxone during second half of calendar 2019.

Our Europe generic business revenue was €25 million. As you would recall the previous quarter we had some supply issues. The same are in the process of getting addressed with ramp up in supplies continuing.

Our Emerging market business has shown strong growth during the quarter. The revenues from Russia market are Ruble 3,501 million and has grown 14% year-on-year and 55% sequentially. As discussed in the last earnings call, there has been strong revival in the buying pattern following a soft Q4. This aside we continue our strong focus on key strategic growth levers. (1) New product launches, (2) Deepened presence into newer markets such as Brazil, Columbia and (3) Geographical expansion of our Oncology institutional business. Performance in other emerging markets is also in line with our expectation. Overall, we remain optimistic towards healthy growth in FY19.

Our India business revenues are Rs. 607 crores and has grown by 30% year-on-year and marginal decline of 1% sequentially. We have seen some good launches in this quarter and would continue to strengthen our portfolio. As announced recently we also brought five biosimilar to the Indian market, with the launch of Hervycta which is Trastuzumab, a biosimilar of Roche's Herceptin. We are quite hopeful of growing our India business better than the overall market in FY19.

PSAI business revenues are \$81 million and largely in line with our expectations.

Our Proprietary Products business, with the DFN-02 filing, we have been granted the PDUFA date in January 2019. Pre-launch preparations are ongoing for an estimated launch around Q1 of FY 20. Overall, we continue to focus on building on our existing commercial footprint and also enriching the development pipeline. On the commercial side we are continuing to see an increase in prescriber base in volumes for our lead neurology product, Zembrace. We saw a slight decline in volumes for Sernivo over the previous quarter but corresponding improvements in gross to net realization set off this volume decrease. We expect to see growth across dermatology portfolio over the next few quarters.

Overall, I feel positive that we are heading in the right direction. Strong performance during the current quarter has been a result of our ongoing efforts towards focusing on growth as well improving the productivity levels. It is a journey and we will continue to build on it for a sustainable growth for the company.

And with it I would like to open the floor for Questions and Answers.

**Manoj Garg:** Can you talk about (1) how much Suboxone you were able to ship in the few hours that you were in the market and if the entirety of that was booked in Fiscal Q1? (2) You talked about the appeal process. Can you provide some color around the timing or your timing expectations for the appeal and then lastly within the release you talked about price erosion but we actually saw a healthy uptake in gross margins? Is this entirely the benefit of Suboxone or you are starting to see some price stabilization in North America?

**Saumen Chakraborty:** For the first question we are not disclosing the exact sale of Suboxone. And second I did not understand the question, if you can repeat again?

**Manoj Garg:** So, the follow up to the first question. So, that is fine that you are not releasing the sales of Suboxone. But whether the entirety of it was booked in Fiscal Q1?

**Saumen Chakraborty:** Yes, whatever shipment has happened that is being part of revenue recognition.

**Manoj Garg:** The second question was just around the timing expectations for the appeal?

**Saumen Chakraborty:** Erez, you would like to take it?

**Erez Israeli:** Yes, so as we mentioned we have submitted an Appeal and we are asking for a date. We don't know naturally the date so we cannot comment on that, but we hope that it will be as early as September but of course it can go also to the next quarter as well.

**Manoj Garg:** The last question was on gross margin, was the uptick entirely driven by Suboxone or you are actually seeing some price stabilization?

**Saumen Chakraborty:** No, I already read out in the script that sequentially the gross margin has gone up by around 230 basis points and there are four factors, three positive and one negative. Positive will be the depreciation of Rupee against the US Dollar and Euro. Positive will be the overhead leverage due to improvements in sales on a similar cost base and the third positive is the margin contribution from gSuboxone and the negative is the price erosion in the base business.

**Anubhav Agarwal:** You guys have exhibited great cost control. I had a question on personnel cost. This quarter we have seen a 4% increase year-on-year basis. I was looking at our Annual Report. Last year we have added about 4% to number of people, average salary increase except managerial increase was about 8%. So, I am just trying to understand just putting context this 4% number versus the numbers which I just talked about average increase of 8% still adding people, what do you think will be the trend of

personnel cost? Can this trend on personnel cost remain low single digit or does it has to go to high single digit to low double digits?

**Saumen Chakraborty:** There could be some increase due to the annual revisions which we have not undertaken from April as usual. That has been deferred till July. So, on account of that there will some increase. But at the same time, we have been focusing on organization design and improving the efficiency of organization design and consequently since we are attacking both the span of control and the layers, so we expect some reduction in the personnel cost and what finally will be the trend we will be able to give you a better guidance probably next quarter. But definitely I do not expect more than single digit at all. But we will have to find out the exact, how there is low digit or what exactly, next quarter I may be able to give a better guidance.

**Anubhav Agarwal:** Second question. About the receivables you mentioned temporary increase. But can you just talk about which region they were? It is a very sharp increase, what led to this such a sharp temporary increase?

**Saumen Chakraborty:** Multiple reasons. There would have been some credit period increase for key customers in USA. Also, there have been Suboxone sales itself happened wherein entire thing would have gone to receivables and also the sales fluctuations and more sales. So, as I said that it is a temporary surge which will normalize in the coming quarter. So, our free cash flow situation is expected to improve for both in terms of the surge in receivables as well as in the inventory.

**Anubhav Agarwal:** But the subsequent clarity here is that excluding Suboxone the credit term increase, etc., you talked about most of the increase is all related to the US or this is ex-US?

**Saumen Chakraborty:** Primarily US.

**Neha Manpuria:** First on Nuvaring. Just to clarify you mentioned that we have just received queries from the agency. But this isn't in a CRL, is the understanding correct? Therefore, you are expecting launch in first half of FY19?

**Erez Israeli:** So, we do have a CRL and we are responding to it and we maintain what I said about the timing of the launch.

**Neha Manpuria:** Second question is on Srikakulam. Have we heard back from the FDA after the queries that they had on that?

**GV Prasad:** We are in constant conversation with the FDA. They have asked us to do some data investigations and analysis. We are providing them that. One phase of it is done but

there is a remaining phase which will be completed by September. And at that time, we will know the path forward with the FDA.

**Neha Manpuria:** So, we are still not sure whether re-inspection would be required or not after we submit this data. Is that understanding correct?

**GV Prasad:** I think that determination will be made after we complete this round of supplying the information that they have asked us.

**Neha Manpuria:** And my last question on the cost saving bit, you had indicated that lot of the cost saving benefits will start reflecting in this quarter and you had also mentioned sale of certain facility. Is part of that already captured in the gross margin expansion that we saw in terms of facility rationalization on manufacturing level cost improvement or we should start seeing more of that benefit probably in the second half of the year?

**GV Prasad:** Let me answer this in two parts. The efforts have started. We have started seeing some flow into the numbers and that is reflected in the operating margin of this quarter. But the major impact will be felt only in the second half.

**Nimish Mehta:** First of all, I just wanted to understand besides Suboxone have not we been benefited by the 180-day exclusivity launch of Aloxi and if you can broadly tell us what is the performance ex both of these products so basically the base business performance in US?

**Saunak Savla:** Basically, if I understand you correctly you are asking for ex-Suboxone the performance for the base business as such?

**Nimish Mehta:** Suboxone as well as ex-Palonosetron?

**Saunak Savla:** So, without these two I would say the base business kind of taken the hit with respect to Dacogen and little bit on Toprol. But without that I think at this point in time there is no additional development on the market place which can lead to any different visibility.

**Nimish Mehta:** What is the outlook on the competitive landscape on Palonosetron? Are we expecting more players once six months are over and also if you can also comment, if I am not wrong the case, the litigation has been accepted in the Supreme Court. Is there any cause of worry or may be my information is not right? Please correct me.

- Saunak Savla:** At this point in time we will not be able to comment on that in a comprehensive way. We are little bit too early to comment on that, so we will just wait and watch on those issues.
- Nimish Mehta:** Okay, do you expect competition after 6 months is over?
- Saunak Savla:** Yes, it is a generic market.
- Nimish Mehta:** Okay, lastly on Duvvada we were expected to invite USFDA in this month?
- Saumen Chakraborty:** We had already invited and that has been there in our annual report that is published.
- Nimish Mehta:** Any timeline that you can propose or anything new that you can tell us that will be great?
- Saumen Chakraborty:** No, we have invited, we are yet to hear from USFDA.
- Surya Patra:** Just a clarification. On the biosimilar front as of now what could be our domestic revenue share that will be coming from the biosimilar?
- Saumen Chakraborty:** We are not disclosing product specific revenue. But today itself we have again launched a product in Biosimilar that is T-MAB and as you know we already have four products in India. So, there have been competition which has come in for some of the products we were early to launch or first to launch so may be more details you can refer to our 20F document where therapeutic area basis we disclose what is our revenue.
- Surya Patra:** Can you give some sense even on the Russia? In what manner these biosimilars are contributing to the growth of Russia?
- Saumen Chakraborty:** Again, on a product specific we will not be able to give but you know that we have got Rituximab approval in Russia and we have been participating in the tender process and time to time we are supplying and recognizing revenue, but it is not uniform across quarters.
- Prakash Agarwal:** Question on Suboxone, just trying to understand this landscape better. So, the appeal you mentioned that is expected by around September-October but suppose we win and we launch at risk again, just trying to understand the competitive landscape, do you expect that the other parties which have also settled, could they also come in, it could be more than one player market, any broad sense?

**GV Prasad:** We cannot predict that. We do not know the nature of the arrangement between the innovator and the other generic companies. So, we certainly cannot comment on that.

**Prakash Agarwal:** Okay and on Suboxone, if my understanding was right the product was purchased and would we not have to provide for the amortization given the product is now commercialized?

**Saumen Chakraborty:** We have started that. In this quarter number reflect the amortization that we have done in Suboxone.

**Prakash Agarwal:** And lastly on the approvals you have mentioned 15 to 20, just the launches that you mentioned so this is not subject to the FDA clearance you are saying any which ways we will be able to launch these products. Is that right?

**Saumen Chakraborty:** Yes, we have already launched 4 out of this 15 to 20 that we have alluded to.

**Erez Israeli:** No, it has nothing to do with the FDA approval of the sites.

**Prakash Agarwal:** And fair to understand that we would have some chunky launches as well?

**Saumen Chakraborty:** You are familiar with the significant launches and so we cannot comment anymore on that. Every launch is important for us and we look to execute well both on approvals and launches.

**Prakash Agarwal:** The filing data is missing. How many ANDAs did we file in this quarter?

**Saumen Chakraborty:** ANDAs we have filed 4.

**Girish Bakhru:** Just a clarification on the appeal side. I could not get. There are two motions if I understand correctly. One is regarding appealing the PI and other is regarding lifting the stay till the appeal is decided. Which one are you commenting could get decision by September-October?

**Erez Israeli:** We hope to lift the injunction that much we hope to get as soon as we can. By the way we said the earliest is September it can be a drag over, it can be even beyond October. We do not really know because we do not have date.

**Girish Bakhru:** But this is regarding challenging basically the PI issues which you are commenting on September-October, right?

**Erez Israeli:** Correct.

**Girish Bakhru:** On 15-20 launches is it fair to assume some of these launches could be site transfer from the Duvvada plant?

**Saumen Chakraborty:** Yes, it is inclusive of that.

**Sameer Baisiwala:** First question is on Copaxone. You plan to do the comprehensive submission in next couple of weeks but you already expect FDA to ask more queries. Why do you think so?

**Erez Israeli:** Normally when you are submitting a CR response the agency may have questions on that. It is not that we are anticipating, it is just normal process of registration.

**Sameer Baisiwala:** How do you see the year-on-year Fiscal 18 versus Fiscal 19 US business dollar revenues? Do you think new launches 15-20 versus the erosion do you expect to grow or not grow?

**Saumen Chakraborty:** As you know in USA there is a pressure of price erosion and the new product launches we expect both to offset the price erosion and to grow further. And you know that we do not provide guidance, but we remain cautiously optimistic about growth from FY18 to FY19 in US generics business.

**Sameer Baisiwala:** You touched upon rationalization of businesses from manufacturing site, R&D center and some products as well. Can you be a little bit more specific other than this antibiotic site and also could this also result in loss of some revenues? So, some more color here would be useful?

**GV Prasad:** We cannot give you that level of specificity but overall in the medium to longer term some of our urban sites we will close down, both as a measure of reacting to the urbanization around our plants as well as rationalization. That is one part. The other part is there are sites which are bit outdated and we are shifting those products to our newer sites. So, we will do all this with the minimal impact on revenue and we will do a combination of site transfers as well as arrangements of continued supply as we sell these sites.

I cannot predict when these things will happen, but we are on the process of looking at the whole network and moving forward with some rationalization. One site we will sell in this next few weeks that is Antibiotic site. Hopefully we will start selling one or two sites in the rest of the year. But we do not expect any major impact to top line or bottom line as a result.

- Surjit Pal:** Saumen, if I remove your revenue as well as the profit in Suboxone, your gross margin as well as your EBITDA margin, they are very much at the average of, if I take Q2 and Q3. That looks like you are in the same range of gross margin of 54.5% around?
- Saumen Chakraborty:** I can only say that if we would not have got Suboxone opportunity for the quarter, we have improved on our performance both sequentially and year-on-year. That much I can tell you.
- Surjit Pal:** And how big that improvement? I am not without getting into any specification, if you can give some idea that how big that improvement?
- Saumen Chakraborty:** There is improvement and of course there are some added benefits of the forex also. You cannot take out that. That has also helped us.
- Surjit Pal:** In the light of increasing competition as well as price erosion in US, do you observe that some of the companies or competitors are also indulging into working capital funding of your channel partners?
- Saumen Chakraborty:** I do not want to comment on that.
- Surjit Pal:** What could be your normalized domestic sales in FY19 because this quarter definitely is an abnormal it is because of last year destocking so what is to consider?
- Saumen Chakraborty:** You are talking about the growth rate?
- Surjit Pal:** Yes, in domestic?
- Saumen Chakraborty:** So, we would be expecting a double-digit growth from last year overall.
- Vishal Manchanda:** On the proprietary side, you have been expecting payment of \$30 million from CHD Bioscience for an out-licensing deal, so is that due in the next few quarters? And would that happen?
- Anil Namboodiripad:** One of the conditions from CHD Bioscience is that they are supposed to raise a certain amount of capital, so there is a cap that would trigger that \$30 million. We are closely watching that and we will be able to have a better idea of whether that payment will be realized in the subsequent few months. So, that is all we can comment at this time.
- Vishal Manchanda:** So, as we understand they are yet to file for an IPO. If they file for an IPO any time now can that happen in the next 6 months?

**Anil Namboodiripad:** If they file, yes, but they have not done that yet and we are closely observing where they stand.

**Vishal Manchanda:** On Zenavod which you out-licensed to Galderma, any color on that, when is that going to be launched?

**Anil Namboodiripad:** So, the original understanding was that Galderma will be launched within 24 months of signing the contract. So, what we know so far is that Galderma is making plans to manufacture products which implicit in that is that they have plans to launch. So, we are estimating that they would launch sometime in calendar year 2019. We do not have a specific date yet, but we do know that they are taking actions in the direction of a launch.

**Vishal Manchanda:** There was some litigation also, one of the licensing, one of the royalty owners in Croatia has litigated the settlement you did with Galderma, so has that something to do with the launch?

**Anil Namboodiripad:** We cannot comment on that. That is between Galderma and the litigator, so I would not like to make any comments in that regard at this time.

**Vishal Manchanda:** Can that potentially delay the launch time?

**Anil Namboodiripad:** I cannot comment unfortunately until we have a better read out on where they stand.

**Vishal Manchanda:** And finally, on Sernivo. Is that going to pick up or we should expect that like kind of peaked out at current levels?

**Anil Namboodiripad:** No, Sernivo no it is not by far peaked out at all based on the demand for the product. The issue lies in coverage, so we continue to make efforts to expand our coverage. There are a number of initiatives that are in place and our expectation is that in the coming weeks we will hear more about coverage from some of the major plans. Sernivo is very clearly linked to coverage. If there is more coverage there would be a proportionate increase in volumes and revenue. So, it is a wait and watch but in terms of the overall demand in the market Sernivo has not peaked by any means.

**Vishal Manchanda:** So, for coverage do you have to reduce prices, is that the case?

**Anil Namboodiripad:** No, it is not about reducing prices, it is about the managed care, the organization continuously change their definition of what they want to include within their formularies. And it is the manufacturer that has to make a case for it and establish the economic argument the Pharmaco economic argument. So, that is the thing, it goes

back and forth until we reach a point where we are able to convince players to include in their formularies. So, that is what is going on. It is not about price, of course you cannot price exorbitantly and expect to get on the formularies but we have by far not priced above what a typical branded tropical product would cost. At the end of the day it is about the rebate or negotiating on what kind of rebates can be given negotiating on the value proposition of the product and ultimately that decision is made. So, it is a long process and it does not apply only to this particular class of products, I think it is across the industry, every product now is going through that process.

- Navin Baid:** What has been the price erosion in the base business for this particular quarter?
- Erez Israeli:** So, we did not specify a specific number.
- Navin Baid:** Broad sense would be okay?
- Erez Israeli:** We are not specifying a number. But what we are saying that it is a less steep as it used to be last year.
- Navin Baid:** If you compare the same with the last quarter on a sequential basis?
- Saumen Chakraborty:** Earlier we were experiencing mid to high teens, compared to that what Erez has said it is slightly less steeper.
- Kunal Dhamesha:** I think I just missed on the launch expectation for NuvaRing and Copaxone. I think I am confused between calendar year and the FY fiscal year. So, if you can just provide clarity on that?
- Erez Israeli:** As we mentioned, NuvaRing we expect to launch in the first half of calendar 2019 and on generic Copaxone, we said that we are expecting right now a launch during the second half of calendar 2019.
- Kunal Dhamesha:** Okay and following on that on generic Suboxone does all the strengths approval for the DRL, does it give you any edge compared to any other players?
- Erez Israeli:** I am not sure I got the question, can you repeat?
- Kunal Dhamesha:** So, DRL has got all the four strengths for generic Suboxone approved right and if I compare with others as compared to Mylan I think they have got two strengths of approval. So, does it give you any advantage?

**Saunak Savla:** Okay so basically if you take the case of the Suboxone market the 8mg one is the primary volume driver. So, without getting into the specific, if you generally concentrate around 8mg you are largely addressing a significant portion of the market.

**Kunal Dhamesha:** And just one clarification. So, earlier you just mentioned double-digit growth for FY19, so is it in India or is it for DRL as a whole?

**Saumen Chakraborty:** No, we do not give guidance for DRL as a whole, because North America generics is always sometime difficult to predict what can happen. Normally based on our branded generics market because of fluctuation or delays we share our confidence level. So, in that we say both in India as well as in emerging markets we can expect a double-digit growth.

**Aditya Khemka:** Just the one from me. Saumen, if you can comment on this Mylan cutting the list price of Copaxone by some 50%, 60% is what I heard in the media. How does that impact your addressable market for Copaxone? I understand that the list price is not exactly the same as realized price, but my sense is that if the list price is down 60% the realized price cannot go up?

**Saumen Chakraborty:** So, you can draw yourself as much inference from what can happen because of that. One can expect more generics sales to happen because of this so we will have to see. As and when we enter the market we will have to analyze what is the value of the overall Copaxone and how much share we can get. Right now, there is no point in getting too much into what will happen by specific action by any single player.

**Aditya Khemka:** No, my question actually was that let us say the Copaxone market was \$1 billion now with this 60% price cut in the list price has that \$1 billion has gone to 800, 700, 600, 900 where is that market size now?

**Erez Israeli:** So, what is the question?

**Saumen Chakraborty:** What would be generic Copaxone market size now. You can discuss offline with Saunak to discuss about it.

**Anubhav Agarwal:** I have one question about raw material inflation. Now given the news flow of increase in API prices from China. Saumen sir, just look at your company on a like-to-like basis can you just indicate what kind of inflation are you seeing, are you seeing in high single digit, double-digit what kind of inflation are you seeing in API prices?

**Erez Israeli:** Indeed, some raw materials that we receive in from China but again it is offset by other places in which we are actually see savings over. I do not see major impact from this.

I will repeat. Indeed, we are buying some stuff from China where the cost was increased but against that the stuff that we are buying the price must decrease so overall no major impact from that specific issue.

**Anubhav Agarwal:** Okay that is helpful. And the other question was our capex which is roughly about Rs. 1,000 crores in a year, can you just broadly outline where you are spending that capex like which I am not expecting you to mention that which facility you are spending how much, but which kind of new capacities that you are putting up where this largely Rs. 1,000 crores are going on?

**Saumen Chakraborty:** You are talking about the previous year or you are talking about the current year?

**Anubhav Agarwal:** Even for current year I am assuming our capex expectation will be about Rs. 1,000 crores?

**Saumen Chakraborty:** So today, in the press meet I said that this year it will be less than Rs. 1,000 crores, earlier we talked about more than Rs. 1,000 crores.

**GV Prasad:** Yes, so there is normal CAPEX which is modernizing facilities, improving and upgrading that is one part of it. Then we are creating one new injectable site in the Pydibhimavaram area outside our SEZ which will be injectables primarily and beyond that there is a little modernization, line balancing and that kind of stuff overall. There is no one major project going on, in the thing and there is a project some ongoing work that is going on in the biologics facility which will be capitalized this year.

**Charulata Gaidhani:** I wanted to know how much is the constant currency growth in the US business?

**Saumen Chakraborty:** In USA it has risen 7% because it is the dollars revenue that we get there in dollar terms.

**Charulata Gaidhani:** Okay and how much would be volume growth in that?

**GV Prasad:** Volume growth is across number of products.

**Charulata Gaidhani:** Okay. My second question pertains to Suboxone. In terms how much would be the inventory that is at risk because of the injunction order?

**Saumen Chakraborty:** We have considerable shelf life of Suboxone so right now we do not find anything.

**Anupam Agarwal:** I just wanted to know that how much Suboxone contributes to the total profit reported in the quarter, if I can have the absolute number?

**Saumen Chakraborty:** We are not disclosing that. This is a repeat question and the answer is also repeat, we are not disclosing molecule specific.

**Pranav Tendulkar:** All my questions have been answered.

**Surjit Pal:** Saumen, just following the previous questions in case we lost the case in Suboxone how much inventory possibility of write off going forward?

**Saumen Chakraborty:** I cannot comment at this point of time, because we will have to see when it happens, and we will have to see what is the expected when finally the normal IP case is going to materialize. Currently let us see what the result. Right now, I cannot comment. But mostly whatever finished goods inventory was there that has been sold.

**Saion Mukherjee:** Just can you comment on the performance of Zembrace and you also mentioned that you expect, Sernivo to also improve, so how much more time you think it will take for these two assets to reach to the peak revenues from now?

**Anil Namboodiripad:** I will answer your first question about the performance of Zembrace. Zembrace continues to perform well. The prescription volume grew by 10% quarter-on-quarter and also, we saw the increase in the prescriber base. We are as I mentioned we answered the previous question we are facing certain challenges with Sernivo at this time and it has to do with coverage.

To answer your second question, how long will it take to peak, we are estimating anywhere between 24 to 36 months before we get to the peak and we are following certain trajectories and that has been closely linked to the investments that we make in the market in terms of patient outreach and the coverage patterns that happens. So, based on that we expect to get to peak in about 24 to 36 months.

**Saion Mukherjee:** And just a related question on DFN-02 which you mentioned will be commercialized in the first quarter of fiscal 20. In terms of the trajectory there as well, do you think it would take as long or you think it can be faster, and the question is when you launch the product what kind of cost implication we should factor in, in the early stages of launch?

**Anil Namboodiripad:** So, Saion, to answer that question we are at this time evaluating various launch scenarios. The value of the DFN-02 goes beyond what we have seen within the narrower specialist community. So, we are evaluating as to what our launch would be whether we launch within a limited space and find a partner to go into the expanded space of position to get the maximum value or should we do it ourselves? So, all of

these discussions are ongoing as to what types of investments we need to make, what makes economic sense for us today.

So, that is the question that we will have a better understanding as we get closer to launch. Meanwhile we are making investments in terms of pre-launch. We have been very active in conferences, we are speaking with payors, we are taking the clinical data which is quite robust to payors and explaining to them. So, we are doing all of those work but the ultimate decision on how much we will invest and whether we will go on it on our own or we will go with partners that is something that we are still modeling out. And that will determine how the uptick, and everything would look.

**Saion Mukherjee:** And just one last question, can you update on the PEG-GCSF file any timeline on that for the US market?

**Saumen Chakraborty:** No further development since we last spoke.

**Anik Mitra:** My question is one pipeline drug CA-170, what is the current status of this particular drug and what is the tentative period of the expected filing?

**Anil Namboodiripad:** Sorry I did not get the question which product are you talking about?

**Anik Mitra:** CA-170.

**Anil Namboodiripad:** I am not sure which drug you are referring to.

**Anik Mitra:** Okay sir, then one another question regarding Repatha. Can you throw some light on sales of Repatha since the sale price of Praluent has been lowered by Sanofi and Regen which is your competitive drug?

**Saumen Chakraborty:** Okay I think the previous question Anil he was asking refers to Aurigene, it is not a propriety product. Anyway, what is the next question please?

**Anik Mitra:** Can you throw some light on the sales of Zembrace and DFD-06?

**Anil Namboodiripad:** You are talking about Zembrace or you are talking about DFD-06?

**Anik Mitra:** Zembrace and DFD-06 both?

**Anil Namboodiripad:** So, Zembrace I had already mentioned that Zembrace continues to grow. We have made progress in terms of prescription volume growth. We expect to end this year north of \$20 million and on DFD-06 by the way the brand name is Impoyz, our partner – Encore Dermatology has launched the product but it is too early to get a read on

sales. The product was launched in May of this year. So, we will start getting a better read once we get into two or three quarters into the launch.

**Saunak Savla:**

Thank you all for joining the call. In case you have any additional clarifications, feel free to reach out to the investor relations team.

**\*\* End of Call \*\***