

Dr. Reddy's Laboratories Limited  
Q2 FY19 Earnings Conference Call

**October 26, 2018**

**Saunak Savla:**

Thank you. 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 second quarter ended 30th September, 2018. Earlier during the day, we released our results and the same are also posted on our website. We are conducting a live webcast of this call and the transcript shall be made available on our website soon. All the discussion and analysis of 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. Erez Israeli – our COO; Mr. Saumen Chakraborty – our CFO; Mr. Anil Namboodiripad who heads the Proprietary Products business and the Investor Relations team. Please note that today's call is a copy righted material of Dr. Reddy's and cannot be rebroadcasted or attributed in press or media outlets without the company's expressed written consent.

Before I proceed with 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. So now I hand over the call to Mr. Saumen Chakraborty – our CFO. Over to you sir.

**Saumen Chakraborty:**

Thank you, Saunak. Greetings to everyone. I am pleased to inform that our financial performance for the current quarter shows an improvement on both year-on-year and sequential quarter basis.

Let me take you through the key financial highlights. For this section, all the amounts are translated into US dollar at the convenience translation rate of Rs. 72.54 which is the rate as of 28th September 2018.

Consolidated Revenues for the quarter are Rs. 3,798 crores that is \$524 million and grew 7% year on year and 2% on a sequential basis. Despite pricing pressure in some of our key products in US, arising out of incremental competition and the lack of contribution from gSuboxone, we were able to record marginal growth on the back of performance led by branded generic markets and a favorable currency environment.

Consolidated gross profit margin for the quarter is 55%, registering a sequential decline of 70 basis points. Normalizing the contribution from gSuboxone in Q1, there is a marginal increase which is backed by improved contribution from branded generics market and favorable currency after absorbing the impact of price erosion. Gross margin for Global generics and PSAI are at 59.3% and 28.1% respectively.

The SG&A spend for the quarter is Rs. 1,237 crores that is \$171 million with a sequential increase of 2% and year-on-year increase of 12%. Sequentially, after normalizing for the impact of forex related increases, salary increments and other inflation linked incremental spends, we were able to achieve reduction in the spends in line with the expectations.

R&D spend for the quarter is Rs. 412 crores that is \$57 million, which is largely at similar spend level compared to both year on year and sequential quarters. As a percentage to sale, it is 10.8% which is lower than the trend of last few quarters; however, the R&D spend in H2 is expected to increase and overall, it should be within the level as in the preceding year.

On the cost rationalization side, we feel good about the progress made to optimize our spend productivity and building higher cost consciousness across the organization. In line with our intention, during the quarter, we have concluded the sale of our antibiotic manufacturing facility in Bristol, USA. and select brand divestments. Further during October, we have entered into a definitive agreement towards divestment of our API manufacturing facility at Jeedimetla, Hyderabad. We believe, these efforts would help us in improving our asset utilizations and manage our cost structure better.

Other income includes gain of Rs. 46 crores on account of sale of rights relating to Cloderm brand, including its authorized generics and profit on sale of antibiotic manufacturing facility in Bristol, USA

The EBITDA for the quarter stands at Rs. 865 crores that is \$119 million which is around 22.8% of the revenue. The effective tax rate for the quarter is around 12.8%, but for the full year it is expected to be around 20%. EPS for the quarter is Rs. 30.31. Operating working capital normalized for the forex translation adjustment decreased

by around \$29 million during the quarter. We invested only \$19 million towards capital investment in this quarter. The free cash flow generated during this quarter was \$131 million, so our net debt equity ratio has improved to 0.26 as on 30<sup>th</sup> September, 2018 even after dividend payout during this quarter.

Foreign currency cash flow hedges for the next 6 months in the form of derivatives for US dollar are approximately \$240 million, largely hedged around the range of Rs. 67.4 to Rs. 71.4 to the dollar. In addition, we have balance sheet hedges of \$272 million. We also have foreign currency cash flow hedges of 1,010 million Rubles at the rate of Rs. 1.12 to the Rubles maturing over next 6 months.

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

**Erez Israeli:**

Thank you, Saumen. Greeting to all. Thank you for attending this earnings conference call. Let me begin with the current quarter performance highlight. It has been a good quarter for us with a strong all round performance across key businesses. At an overall level, we have seen recovery on sequential basis particularly across our branded generic markets and our operations. Please note that all references to numbers are in respective local currencies.

Our North America generic revenues for the quarter are at \$207 million, registered a sequential decline of about 13% and year-on-year decline of 6%. Adjusting for the sales of gSuboxone film in the first quarter, the sequential decline is in mid-single digit and is broadly in line with our expectations. During the quarter, we did not have a significant launch and the business continued to witness increased competitive price pressure across some of the key products including but not limited to metoprolol, decitabine, and palonosetron. Overall after normalizing the hit of such transition products, we have not witnessed major shift in price erosion trends relatively to earlier quarters and overall base business has been fairly steady.

Let me also provide the quick update on three key products; gSuboxone, gNuvaring and gCopaxone. On gSuboxone, the Court of Appeals for the Federal Circuit held its hearing on 4<sup>th</sup> of October and we await court's ruling in this matter. On gNuvaring, we had comprehensively responded to the agency. Agency has granted priority review status for this application. We continue to remain optimistic about potential approval and launch for this critical asset in the first half of calendar 2019. On gCopaxone, we have comprehensively responded to the agency on CRL for the DMF and also our ANDA. We continue to gear up towards potential approval and launch around the second half of calendar 2019. For both of the above products, there may be additional queries from the agency as part of response review process. We remain committed to actively engage with the agency to work towards faster conclusion.

Overall, new launches run rate has been fairly healthy and even within the month of October as of date, we have already launched four products. We expect the momentum to further accelerate to rest of the year with 10 to 15 launches lined up including some exciting limited competition opportunities.

Our Europe business recorded sales of Euro 23 million with a sequential decline of 7%. This decline is primarily on account of negative price erosion impact on few of our key products. We expect the performance in the second half of the fiscal year to improve on the back of new product launches and stabilization of supplies to the market.

Our Emerging Market business performance has been consistently improving, registering a strong year-on-year growth of 36% and sequential growth of 13%. The sequential growth is primarily on the back of improved volume offtake in our existing market and scale up in our new markets. Following the first quarter recovery in Russia, the team has done well in sustaining performance momentum in the second quarter. Overall, we remain optimistic towards delivering healthy double digit growth for this business in fiscal 2019.

Our India business revenue is Rs 686 crores with year-on-year growth of 8% and sequential growth of 13%. We are very excited with the traction witnessed in the launch of Hervycta, trastuzumab, a biosimilar of Roche's Herceptin in the domestic market. We are quite optimistic of growing our India business double digit for fiscal 2019. PSAI business revenues are \$87 million and have largely been in line with our expectations. As mentioned earlier, we continue to focus on reenergizing this legacy business and regain global leadership.

On the biologics side, recently you would have seen the press release by our partner, Fresenius Kabi, on our Pegfilgrastim biosimilar candidate meeting all the primary endpoints in two pivotal clinical studies. We are very happy with this positive development and we will continue to work closely with Fresenius Kabi towards eventual filing and approval in the US and Europe.

On our proprietary products business, we have been granted PDUFA date for DFN 02 in January 2019. Pre-launch preparations are ongoing and we expect to launch the product in Q1 FY20. 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 decline in volumes for Sernivo over the previous quarter, mainly due to a suboptimal coverage and seasonality in the category, however, with improved access from CVS Caremark coverage starting Q4 and changes to a corporate program, we should see volumes and net revenue grow consistently. Further, we divested Cloderm in Q2 with a view to optimize our steady product basket. As a result, increased salesforce focus on the other products should yield growth across the Derma portfolio. Progress on our key R&D program is on track.

On the two warning letters affected sites, currently the sterile injectable facility in Duvvada is undergoing inspection by the USFDA. Since the audit is ongoing, we will not be able to comment on it until the conclusion of this audit. On Srikakulam plant, as committed, we provided our response to the agency and as part of the review of the response, we have received certain follow-on queries which we plan to respond back within the coming month. We continue to engage actively with the agency to ensure concluding the issues at the earliest.

Please let me take a few minutes to provide you with a quick update on the company-wide strategy planning, we have been working on over the last couple of months. In the coming years, the company would focus on growing its profit derived from the 5 key spaces, namely US, India, Russia, China and API. For the US generics market, the key focus will be to leverage our improved cost structure, leverage the depth and the breadth of the portfolio with over 110 pending ANDAs accumulated over the years to significantly enhance the offering to customers. For India branded generic market, we plan to leverage our brand equity to further strengthen our existing brand and focus on new brands in selected therapeutic areas. For Russia, we plan to leverage our existing brands, work on the life cycle management and also build new brands in selected therapeutic areas including new therapeutic areas. For China, we plan to leverage our global portfolio to expand our presence in the market in light of the recent changes in the Chinese market. For our API business, we plan to leverage size capability, our cost structure in India and our access to intermediates to gain global leadership.

Businesses such as Biologics, Proprietary products, and Aurigene will continue to be driver for future growth. We will work on ways to ensure that they are financially self-sufficient over a period of time. Multiple initiatives are

being undertaken with a high focus on product launches, cost efficiency and superb execution to support growth across key businesses.

Having spend more than 6 months now in the organization, I feel really excited about the growth opportunities available for key businesses ahead of us. Good performance for the current quarter has been result of our ongoing efforts on profit growth as well as improving productivity levels. It is a journey and we will continue to build on it for a sustainable growth of the company and with it, I would like to open the floor for questions and answers.

- Aditya Khemka:** First question on the two plants; Duvvada and Srikakulam, so now that the inspection is undergoing on Duvvada and Srikakulam we have received follow-on queries, can you comment on how many ANDAs are dependent on the clearance of these two plants and how many are de-risked by transferring to other facilities?
- Saumen Chakraborty:** Exact number will be difficult to give straight away but it will be around say 15 to 20 we can expect over a period of time.
- Aditya Khemka:** So these 15 to 20 ANDAs out of the 110 which are pending approvals are from these plants, is that the correct assessment?
- Erez Israeli:** Yes, some of them we have risk mitigation and if we will be able to launch from this plant, naturally it will be better profitability as naturally it is our cost and we are not sharing the profit with others.
- Aditya Khemka:** Fair enough and secondly on the R&D spend, so can you comment on the split of the R&D spend between generics and non generic ventures like innovation, biosimilar, 505 (b)(2) etc.?
- Saumen Chakraborty:** Till date our ratio remains unchanged that means roughly 60% will be on API and generics and remaining 40% over Proprietary Products, biosimilar and Aurigene, in that order, even more on Proprietary products, then biosimilar and very less on Aurigene, but going forward, this ratio will change as I spoke earlier. So that 60% will come down and the other part will increase and that will happen in over a period of time, not as a step jump.
- Aditya Khemka:** And lastly if I may on the India business side, we have seen 8% year-over-year growth which seems to be quite good actually given the base of previous year, so what is the aspiration here, you think we will be able to grow consistently on a double digit basis in India, is that a fair argument?
- Saumen Chakraborty:** In terms of aspiration, yes, we will have to see every quarter how we are growing. Over the recent time, we are surging up in terms of our growth in line with the industry. So our aspiration will be to beat the industry, so let us hope, cannot commit.
- Prakash Agarwal:** My first question is on the launch guidance that has been given about 10 to 12 more over the last 6 months, did I hear that correct? And this is coming from the non affected facilities just wanted to check or we are assuming couple of facilities to come back operational?



- Erez Israeli:** This is unrelated to the facilities because we cannot commit yet when we will have it. Naturally, we hope that this will be cleared and then the numbers can increase.
- Prakash Agarwal:** So you are looking at 10 to 15 for the remaining 6 months and you already launched if I heard it right, 12, so total about 22, 25 for the year?
- Erez Israeli:** Just want to make sure what we said is that we launched in this quarter about 3 products. In October, we launched 4 and additional. 10 to 15 products remain till the end of this fiscal.
- Prakash Agarwal:** Understood, fair enough. Thank you for clarifying. Secondly you mentioned on the Suboxone case that its awaited, so just wanted to hear some what could be the possible scenarios here if you could help us on that?
- Erez Israeli:** There are actually two scenarios, one that we will win and one that we will lose. If we will win, naturally we will relaunch our product. If we lose, we will continue to be enjoined until there is a solution of the patent case.
- Prakash Agarwal:** So I was just trying to understand the competitive landscape actually. So if you win and continue to sell, if you can start selling again, can the competition, I mean the other guys settled and other in the race can also come in? I just wanted some color there please?
- Erez Israeli:** I cannot speculate on other people behavior because I don't know the nature of their agreements or disagreements with the innovator.
- Prakash Agarwal:** And lastly on the non core disposals that you have taken initiative, so just wanted to understand how much more is there in terms of creating a more profitable organization, I mean do we see this activities on an ongoing basis for the next 6 to 12 months or we are largely done?
- Erez Israeli:** In terms of manufacturing side, we are in a process of, let us call it a rationalization of our network. I do not expect in the near term additional activities; on the product and brands absolutely this will continue.
- Neha Manpuria:** First on, if I look at your SG&A spend adjusted for these things and employee, it does not seem to be showing too much improvement from the cost optimization that we are talking about. So you did mention in your opening comments that we have seen a decrease in cost. Could you give us some clarity on how much that has been and some number around what we are expecting out of cost saving over the next year?

**Saumen Chakraborty:** Yes, as we told during the last IR call that we actually have affected the increment during this quarter only, so this quarter we have got effect of the increment. So if we take into that and also because of the rupee depreciation, some of our manpower cost which will be there in overseas, so that costs goes up and if you normalize the impact of that and in the normal inflation-linked incremental spend, then the kind of reduction in the spends that we have is completely in line with our expectations.

**Neha Manpuria:** Do you have any sort of number, let us say x amount is what we are looking to save?

**Saumen Chakraborty:** No, we can't give further breakup or further guidance but all we can say is that we are continuing to focus on cost improvement and productivity improvement and we are seeing results of that. That you can see is reflected in our overall EBITDA margin.

**Neha Manpuria:** And sir, on the US business, we mentioned that we have over 100 products in the pipeline. Excluding the 3 products that we have discussed, what would be your estimate of meaningful products that we can expect from the pipeline over the next 2 to 3 years?

**Erez Israeli:** We are not giving guidance and it is also very hard to predict the value of the product because as we know well, product will go down in pricing 60% or 80% or 40% and also it is hard to predict market share, but let us say that in those 100 pending ANDAs, some are very exciting products and some that we will probably have exclusivity. So overall we feel that it is a very healthy portfolio.

**Neha Manpuria:** And one last question is on Russia. That business seems to be doing particularly well over the last two quarters. Is this improvement linked to the biosimilar tender and therefore could be lumpy or is this a sustained base of improvement that we should assume for the Russia business?

**Saumen Chakraborty:** Biosimilar will be lumpy because it will be based out of the tender outcome and also in Russia, there is a seasonal impact which happens and it all depends on when the winter sets in and that cannot be very predictable given the whole global climate. So to that extent, there is a little bit of unpredictability or some fluctuation but overall, based on new product launches and tractions in Russia market, we are seeing healthy performance in Russia, but beyond Russia, if you really look at overall emerging market in this particular quarter, whether it is China, whether it is Ukraine, specifically Romania because last year Romania could not do well because we had a supply constraint because we had that FTO2 problem and similarly some new market like Brazil and I think we have been performing quite well, so emerging market is performing well and we remain bullish and we will see how much we really deliver.

- Aishwarya Agarwal:** Sir, can you please help us when do we anticipate the court judgment on Suboxone, any timeline?
- Saumen Chakraborty:** The hearing happened on October 4 and judgment should be there within 90 days, so technically 90 days means 4th of January but we can expect anytime now onwards before that date.
- Aishwarya Agarwal:** And sir next is how you see the Nuvaring as well as Copaxone in the approval process and where are we and when we are anticipating the launch?
- Erez Israeli:** As I mentioned in my presentation, we already submitted all the required information and addressed the CRL that we got for both. Both of them are now on the normal regulatory review and we feel that we can launch, within the time that we discussed last time, which means that gNuvaring, we said is going to be in the first half of calendar 2019 and gCopaxone in the second half of calendar 2019.
- Anubhav Aggarwal:** One question is on PSAI segment. We have seen the sales increasing with the segment almost 11% sequentially. Question is how much was of this price driven and how was volume driven?
- Erez Israeli:** It is primarily volume driven.
- Anubhav Aggarwal:** So then what explains margins really shooting up for this segment sequentially from 22 to 28%. I understand the operating leverage but incrementally almost 85 to 90% of the sales has come as gross profits here?
- Erez Israeli:** It is a combination of product mix and also we have a nice cost efficiency products.
- Anubhav Aggarwal:** I am sorry, nice what?
- Saumen Chakraborty:** Some impact of currency also will be there Anubhav. It helps because primarily billings happen in dollar, but also it is the product mix which makes a lot of difference in PSAI margin.
- Erez Israeli:** And cost efficiency products.
- Anubhav Aggarwal:** Sir is this product mix that we benefit at this quarter? Is this the sustainable mix, so because if I look back, of course other than currency we have never done sustainably more than 25% gross margin here. So that is why I am asking that is this one-off benefits that you are seeing in the PSAI segment or this is new base for us?

**Saumen Chakraborty:** In PSAI, earlier also I have said there will be fluctuation. It is 28 has not been the highest, sometimes even we have done 30% in a quarter so it is so dependent in terms of the product mix and if there is say more development quantity then definitely it shoots up. So there are multiple factors. In this particular thing, there is an impact of currency as well, so depending on where the currency stabilizes and that will also have an impact on the margin. So sustainability cannot be assured but obviously always the attempt within the company will be to increase the margin as much as possible.

**Anubhav Aggarwal:** That's helpful Saumen, sir. One question is on R&D. You mentioned about R&D being almost similar to last year here, but directionally can you talk about roughly about fiscal 20 roughly? Can we think when you guys try to consider biologics and proprietary business living on their own? Can we think about R&D which is let us say 1700 to 1800 crores this year and last year; fiscal 20 can we bring it down to less than 1500 crores or what has happened?

**Saumen Chakraborty:** I will talk about next year in the next quarter.

**Anubhav Aggarwal:** I was not looking for quantitative number, but was just looking for let us say directionally that we guys need to increase our spend on specialties. You guys have talked about that earlier and you also mention that the 60% that you are spending on generic needs to come down going forward, right?

**Saumen Chakraborty:** I have not alluded to on absolute. Let us make a few points clear. R&D is our primary lever for future growth and we will never trade off that. We will continue to focus on R&D. Our activity level on R&D has not come down a bit, but we are trying to improve the R&D productivity, so that is why there will be sometime some advantage we will get in the overall spend without trading of anything on R&D. You are right, going forward, it could be more spend towards specialty and biosimilar side, to that extent, proportion of overall R&D can get skewed in favor of that compared to the generics and API. Having said that, we will continue even in the generics and API to spend wherever there are opportunities or potential which is available.

**Nimish Mehta:** Due to the facility divestment how much is the annual cost likely to come down and when it starts getting reflected in the numbers?

**Saumen Chakraborty:** We cannot give you a specific number at this point of time, but definitely it will bring down our overall cost, may be going forward next time onwards, we can give some flavor.

**Nimish Mehta:** And no ballpark outside is possible?

**Saumen Chakraborty:** Not at this point of time, we are in the midst, right? As you know, even in this quarter, specifically in October we have signed definitive agreement for our CTO-IV facility from Jeedimetla. So we are focusing on closing that agreement as well. So with all these things over, we will definitely by the time we prepare the business plan for next year. We will have a clear idea about what is the savings in our cost structure due to all the actions that we have taken during the year.

**Nimish Mehta:** The other thing I just wanted to know we have just entered second quarter, we ended the 180 day exclusivity on Aloxi, that is palonosetron. So just wanted to know are we likely to see sharp decline, I mean obviously after 180 day is, but what was the market share we attained during that 180 days, and what do you feel now likely to be the scenario of the competition after the 180 days?

**Saunak Savla:** Nimish on palonosetron, I think the market is already quite competitive and incrementally as of now, we don't have much visibility. We would not like to comment at this point in time, let us wait further, but I think at this point in time, it is quite competitive and to larger extent it incorporates a lot of players already in the market.

**Nimish Mehta:** What is the market share we attained in that 180 days that you can tell that will be helpful.

**Saumen Chakraborty:** By August, we had around 26% if I recall.

**Saunak Savla:** Yes, so it is around there, but may be on the specific, we will take it offline.

**Sameer Baisiwala:** Is it possible for you to spell out your plan for China and how much can this business grow when it is 3 to 4 years.

**Erez Israeli:** We don't want to share guidance. That we see a great opportunity as China is giving certain advantage for products which meet certain criteria. So if you meet those criteria and quality and speed, you can get access to hospital in a different way than used to be in the past and quite large number of our portfolio, around 65 to 70 products are meeting those criteria and naturally, part of them we hope we will bring that. So this is significant number over what we are selling in China right now.

**Sameer Baisiwala:** Any clue or anything that you can suggest that what do these 65 to 70 products and what sort of accessible market is it targeting? And second would you necessarily take this through your joint venture route or can you also do it 100% own entity?

**Erez Israeli:** I don't know exact market access, but these are fairly large molecules. In the sense of some will go to the joint venture and some will go with the partners depends on the

ability to access the market as the joint venture has certain therapeutic areas that are working on and other therapeutic areas, we will use other partners.

**Sameer Baisiwala:** Second question is on Duvvada ongoing audit and I know you can't speak too much but the broad question is, is this audit only going on for onco site or also for the non-onco site?

**Erez Israeli:** At this stage, I cannot comment of where the audit is. We will wait until it will conclude and see that.

**Sameer Baisiwala:** No worries, and just one final question, is it possible for you to update us on your anti-psoriasis oral compound which you had partnered with XenoPort?

**Anil Namboodiripad:** Yes, I can take that question. So you are referring to our product XP23829, which we had licensed from XenoPort for moderate to severe psoriasis. That product is currently in Phase IIb studies and the recruitment is going on right now. It is a blind study, so we cannot have the data until the study is complete. We expect the study to complete by the late Q4 FY19 or early Q1 FY20. At that point, we will make a decision about moving this product forward.

**Sameer Baisiwala:** And if you do move it forward, it would necessarily go through phase III?

**Anil Namboodiripad:** That is correct, it will have to go through phase III.

**Sameer Baisiwala:** Was it not already done phase II way back in September 2015, by the time when you in-licensed in March 2016?

**Anil Namboodiripad:** Yes, it is a little bit of technicality here. It had completed phase II but what we call phase IIa, in other words, there was a proof of concept that was established at that point in time and then we could directly have gone into phase III but that would mean we are taking on a lot more risk and significantly higher expenditure in terms of how we power the phase III study, so instead of the risks and higher expenditure, we felt it is prudent for us to do a phase IIb study, where we look at the dose response as well as the duration of the study so that we get clear signal to power phase III study which then would be significantly more de-risked as well as will be much cheaper.

**Sameer Baisiwala:** And it has taken you 2-1/2 years to almost 3 years by the time you have ended? Isn't that too long for phase IIb studies?

**Anil Namboodiripad:** No. That is just a nature of the R&D on the proprietary side so this is 6 month study so you have to follow up the patients for 6 months, so each patient has to go through, that

is the 400 patient study, 4 arms, 100 patients in each study and monitored for 6 months before the blind is broken.

**Sameer Baisiwala:** Yes. That is right. Sorry to persist on this. One final point from my side, so if you had in-licensed in March 2016 and if the study is going to get over by middle of 2019, it has been 3 years since the product has been with you and you took it after phase IIa and phase IIb has taken 3 years? Why is that so?

**Anil Namboodiripad:** There were a number of activities after we license the product so we had to meet with the FDA to get concurrence from them, so all of these take time to actually schedule a meeting with the FDA, put together a plan for both the phase IIb and phase III, get the concurrence and then after that to get the product going, manufacturing of clinical material and so on, that was the time.

**Saion Mukherjee:** Sir you have mentioned about the proprietary and biosimilar businesses being self sustaining over a period of time, I understand they are not at this point and we mention about increasing R&D spend. So in a way what you are saying is in the near term, there would be even more revenue and cost mismatches in these businesses. So there seems to be some kind of a contradiction here, if you can help us understand what is the timeline you are thinking in terms of both these businesses breaking even?

**Saumen Chakraborty:** We said, also we expect proprietary product to improve on the total revenue front, particularly now that DFN 02, the PDUFA date is in the quarter 4 of FY19, so we expect a launch in Q1 FY20 and that is a very significant product for proprietary product business. Although, it will take some time to ramp up but we expect that also to gain revenue and on the biologic side, as you know in India and emerging market, we have the pipeline and we are launching. For example, in India now we have launched trastuzumab and some of the emerging markets also will be followed up, so we expect the revenues also to come in as we are putting some more, like in biosimilar, it will be basically for the developed market that we need to take couple of products which we will do ourselves or we can even potentially sign up with a risk-reward kind of sharing with someone else to do that. So all these we will see and we will come back to you in terms of timeline by the time we finalize our plan and we will give you an indication, but the goal that has been set is that how these 2 business can get self-sufficient at the earliest possible without taking several years. So that is a complete planning exercise we will have to do and then get back to you.

**Saion Mukherjee:** Sir, is it possible to share biosimilar revenues overall India plus EM separately? Even approximate size of the business?

- Saumen Chakraborty:** Around 180 crores that we get in. Saunak, why don't you share?
- Saunak Savla:** It is roughly around you can take 90 odd crores a quarter so which kind of culminates to 350 odd crores of run rates between India and EM.
- Saion Mukherjee:** And approximate split was possible?
- Saunak Savla:** Split, maybe I will get back to you on this thing.
- Saion Mukherjee:** And just one last question on the EM where we are seeing good growth and I think you mentioned about a few markets, but the growth that you are seeing today, I don't know whether you consolidate the China numbers because you mentioned China also is doing well and just wanted to have a clarity on that and Brazil where I think you started operations. Last year, revenues are quite small, what is the uptake we can expect in the Brazil institution business?
- Saumen Chakraborty:** So first in China, we have 2 stream of revenue, one out of the joint venture which we do not consolidate in our financial reporting, only the profit comes, but there are some which is our direct and that gets reflected in the sales. In Brazil, even though we restarted the operation only last year, there has been considerable growth within a year and we hope to improve going forward with new launches, but apart from China and Brazil, as I indicated earlier, there have been other markets we have been doing well in emerging markets.
- Surya Patra:** Sir, I believe in the opening remarks, you talked something about the product rationalization in US, so whether that is a kind of continuing process or the sequential decline what we are seeing, what portion of that is because of that or how many product that we have curtailed? So any clarity on that would be useful?
- Erez Israeli:** The main impact is on few products that got competition from other players, so it is not across the board, it is , primarily on key products.
- Surya Patra:** So that means whether the base business is getting impacted by these effort in any meaningful manner?
- Erez Israeli:** It is meaningful to both products, yes.
- Surya Patra:** And just one clarification about whether the financials include any forex gain for the quarter?
- Saumen Chakraborty:** Absolutely yes.



**Surya Patra:** Can you please quantify that side because the financial income seems relatively a bit higher the quarter?

**Saumen Chakraborty:** So some part of the financial income will include hedge gain, but as we said we have divested the Cloderm brand as well as we have got the other income will reflect that. So in the finance income, some part will be the hedge gain and some will be the interest income that we will be getting.

**Surya Patra:** Okay, but you are not quantifying the forex gain or hedge gain?

**Saumen Chakraborty:** We are not specifically putting now.

**Surya Patra:** And just one more question, sir, whether any benefit your PSAI business has witnessed because of the Chinese supply disruption what it has been there since some time, so either in terms of the prices or in terms of the volume, anything that you have witnessed in the quarter?

**Erez Israeli:** We absolutely see no engagement with us because of the Chinese situation and we believe that strategically it is going to help us a lot.

**Shyam Srinivasan:** First is on the US generic market right now, did I get you right when you said if you adjust for Suboxone and take it out last quarter and this quarter, it was a single digit decline, is that what you said, I missed that.

**Erez Israeli:** Yes.

**Shyam Srinivasan:** So would that mean like an annual still low double digit kind of erosion in the environment because you seem to indicate price erosion in your press release at several points, so how are you seeing the market right now from a pricing stand point?

**Erez Israeli:** In general, it is stabilized, but when there is new approval that is hitting one of our products, then naturally we see the impact on that product. If the product is important, then naturally it impacts the overall basket. It is not so much from a price harmonization, it is more of a specific competition for a product.

**Shyam Srinivasan:** And you think the only way is like you what you alluded in terms of more product launches, like the 10 to 15 additional products is the only way one can actually grow the US business. It is 200 million right now quarterly and you foresee that you will be able to kind of grow this sequentially now through the end of the year?

- Erez Israeli:** We are not giving guidance, long time, for sure, we are planning to grow. When I was saying this it is primarily focused on growing the profit, so it is naturally launching products but also our cost structure and the ability to increase share in our product. So it is combination obviously.
- Shyam Srinivasan:** My second question is on Revlimid. I think we have had IPR challenges that we put in sometime around August if I recollect right, can you give us an update on what is happening on the Revlimid side, please?
- Saunak Savla:** Shyam, we can take this on offline basis.
- Kunal Dhamesha:** My first question pertains to growth in branded ROW business, so the growth has been solid, if I counted, it is approximately 25% growth year-on-year and our guidance is low double digit till last quarter, so where do we stand in terms of guidance for the remaining year or on a consolidated FY19? Is this the new base that we are seeing in this business?
- Erez Israeli:** I don't want to give any new guidance in this respect. Overall, we are still with 2 digits, I don't recall that we said lower, may be within, but I don't recall that we mentioned the exact amount.
- Kunal Dhamesha:** And just a kind of following up on previous participant's question. So you said the pricing pressure in general it has stabilized, so stabilized at what level, like mid-single digit, high-single digit in base business?
- Erez Israeli:** Stabilized is that whatever RFPs that we are selling with the similar prices, but naturally as you know well some of the customers are issuing new RFPs, so I cannot comment of what prices will be those new RFPs, but let us say, for whatever refill we do to most of the customers naturally we feel that these are the prices that we will continue to sell this product.
- Kunal Dhamesha:** And just a follow up. As you are continuing to see some rationalization from other players in the market, creating new opportunities for you?
- Erez Israeli:** Absolutely, it is there. Naturally I believe that there will continue rationalization in this market.
- Ranvir Singh:** Just one clarity that your product DFN 02 which was returned back to you, so just wanted to understand what is the status there? Are we going to outlicense it again or we will develop ourselves or how important it is for us?

**Anil Namboodiripad:** Yes, I will take that question. Actually, it is not DFN 02, it is DFA 02, topical antibacterial combination. So it is certainly very attractive product, requires phase III to be conducted by a partner and we are actively seeking other partners and we are getting some interest, so stay tuned.

**Ranvir Singh:** So how important is in terms of finances, if I talk about, so whether we are expecting some meaningful upfront or milestone payment out of this product?

**Anil Namboodiripad:** It is hard to predict, as you know with licensing deals, it depends on various factors, so it will be hard to predict what it would be but our expectation is to get, for any deal, it is not just for DFA 02, our expectation is to get an upfront payment and pre-commercialization milestones and then royalties. That is a standard ask for any of our products.

**Ranvir Singh:** And secondly our cost rationalization program, when we chose site to sell, what exactly is the criteria, like we see that Jeeditmetla API facility has been sold, so was that not profitable or when we rank this facilities in terms of contribution and then we scrap the bottom one, this is the way we do or what exactly modus operandi or point to consider before doing this rationalization?

**Erez Israeli:** So naturally we look at the products and the quantities that will be needed for the future, we look at the way to make them and we see whether we can condense them in few lines and do it with less people and we see which of the plants, their cost structure will not fit the new infrastructure that we need and this site was selected based on it.

**Ranvir Singh:** So this Jeeditmetla, we assume that was not contributed to our revenue or profit, right?

**Erez Israeli:** No, we sold products out of this site absolutely, but we feel that long-term, it did not give us what we needed from that place in the future.

**Ranvir Singh:** And the last if I may that in European market, you see that price erosion has been for quite some time, so where we see this going to stabilize for now?

**Erez Israeli:** Naturally, our baseline is relatively small at this stage and consistent of new product, so it is more of a product to product phase than anything and naturally most of the products is being sold as hospital tenders, so naturally it depends on the tender.

**Ranvir Singh:** We can see now this run rate getting stabilized going forward in subsequent quarter?

**Erez Israeli:**

We believe that two things, definitely we will have more products and we also suffer from an execution issue as we did not supply all the products that they could sell and we are absolutely working on changing that.

**End of call**