Dr. Reddy's Laboratories Limited
Q2 FY 2015
Earnings Call Transcript

Kedar Upadhye

Good Morning and Good Evening to all of you and thank you for joining us today for Dr. Reddy's Earnings Call for the Second Quarter of Fiscal 2015. 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 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. Please note that today's call is copyrighted material of Dr. Reddy's and cannot be rebroadcast or attributed in press or media outlet without the company's expressed written consent.

Before we proceed with the call, I would like to remind everyone that the Safe Harbor language contained in today's press release also pertains to the conference call and the webcast. After the end of the call, in case any additional clarifications are required, please feel free to get in touch with the Investor Relations team.

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

Saumen Chakraborty

Thank you, Kedar. Greetings to Everyone.

Let me begin with the key financial highlights. For this section, all the amounts are translated to US dollars at a convenience translation rate of Rs.61.92, which is the rate as on 30th September 2014.

Consolidated revenues for the quarter are at Rs.3,588 crores or $579 million. We registered year-on-year growth of 7%. Revenues from our Global Generics segment are at $466 million and grew by 9% year-on-year. This growth was led by branded business in India and Emerging Markets. We experienced a bit of currency volatility for Russian Rouble and Ukrainian Hryvnia during the quarter and the adverse impact on revenues because of this movement is approximately 2% of overall revenues. US Generics business experienced changing customer dynamics, coupled with slowdown in the new product approval. Revenues from our PSAI segment are at $103 million. While flat on a year-on-year basis, sales improved sequentially with improved margins. Consolidated gross profit margin for the quarter is 58.5% and expanded year-on-year by 50 basis points. Corresponding gross margin for Global Generics and PSAI are 65.6% and 26.8% respectively.

SG&A expenses, including amortization, for the quarter are $172 million, an increase of 10% year-on-year. This increase in absolute terms is largely attributable to normal salary increments, manpower hirings and other sales & marketing spend. Sequentially the SG&A expense remained flat.

R&D expenses for the quarter are at $66 million, representing 11.5% to revenues versus 9.0% in the corresponding quarter of the previous year. R&D spend is in line with our planned scale up in activity.

EBITDA for the quarter is at $141 million, 24% to the revenues. Adjusted for the one-time litigation settlement income of $6.75 million recorded in the last year and higher R&D spend this year, the EBITDA percentage to sales is similar as that of last year.

Tax rate for this quarter is 17.2%; however, full year effective tax rate is expected to be in the range of 21-22% as guided earlier.

Key balance sheet highlights are as follow: Our net operating working capital increased by $36 million during this quarter. This is partly due to build up of stock for forthcoming launches in North America Generics and PSAI and an increase in receivables in line with agreed credit period.

Capital expenditure for the quarter was at $32 million. Our net debt-to-equity ratio is at 0.10. Foreign currency cash flow hedges for the next 18 months in the form of derivatives and loans are approximately at $610 million, largely hedged around Rs.59-61 to a dollar. In addition, we have balance sheet hedges of $524 million. We also have foreign currency cash flow hedges of Rouble 840 million at the rate of Rs.1.70 to a ruble, maturing over next six 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.

While we are reporting single-digit growth on an overall basis, performance reflects several sustainable growth trends in our key markets, partly offset by the impact of some externalities. Our India business performance has become relatively more predictable than the past and in this quarter delivered healthy double-digit growth. Emerging markets business was able to maintain trajectory as we sustained supply to Venezuelan market which helped offset macro issues in Russia and Ukraine. Due to the absence of major approvals during this quarter, US Generics recorded single-digit growth. At the same time, injectable line of business in US is clocking its expected run rate. For PSAI business, while performance is flat for this quarter, we expect a relatively stronger second half.

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

Revenue from North America Generics for the quarter was $235 million and grew by 7% year-on-year. As mentioned earlier, we did not receive any new approval during the quarter. However, going forward, we expect the number of launches for which our supply chain is adequately geared. As you would have read, we launched sirolimus in the market yesterday. Parallelly, IMS data shows good progress on the market shares for several key molecules such as metoprolol, divalproex, and atorvastatin. Sequential decline in sales is attributable to the usual price erosions in base business, full quarter impact of channel consolidation and changes in the buying pattern between Q1 and Q2.

India Formulations business posted its all-time highest revenues of Rs. 480 crores and grew 14% year-on-year on the base of higher pre-NPPP prices of previous year. This growth is largely volume-led and represents improved portfolio mix and healthy share expansion, especially for major products covered under the NLEM list. The team continues to target portfolio expansion by introducing differentiated products and address existing unmet medical needs.

On the emerging markets front, Russia revenue was $68 million for the quarter and remained flat in local currency terms on year-on-year basis considering a higher base of previous year. Current geopolitical situation in Russia and Ukraine has started to impact the healthcare sector. In this background, we continue to outperform the market in volume and value terms. YTD August 2014 growth, in constant currency, as reported by IMS, was 13.3% Vs the market growth of 12%. In volume terms, our growth was 4% Vs market decline of 1.4%. OTC continues to be an important lever for Russian business. For the same period, as per IMS, our OTC operations grew by 20% Vs the market growth of 12% (in constant currency).

From the other Emerging Market geographies, Venezuela continues to deliver superior growth both on volumes and price realizations. It is turning out to be a high potential market for us, providing substantial upsides while the possible currency devaluation headwind continues.

PSAI sales performance is flat year-on-year; however, the product mix has improved, which is reflected in improved gross margins. A number of initiatives have been taken to achieve the twin objectives of sales growth and healthy margins. The filings have picked up for API business. Orders for the Custom Services business are also seeing an uptick. With this improving trend, I feel business is poised to deliver a relatively stronger second half performance.

You would have noticed the increase in R&D spend that we are reporting for the last 2 quarters. It is a conscious decision and signifies our efforts to strengthen the portfolio across Complex Generics, Proprietary Products and Biosimilar businesses. We are continuing the journey of building a rich and differentiated generic pipeline through the globalized R&D platform. During the first half, we filed 11 ANDAs in US; most of these are high-quality filings and are characterized by technical complexity, which helps us target limited competition opportunity at the time of launch. We have also been able to diversify our filings across dosage forms and enhance estimated potential value for our filing. Parallelly, for the Proprietary Products business, several assets are in the late stage registration trial. The portfolio of assets both in Dermatology and Neurology is quite robust. In Dermatology, our assets are targeting the indications of steroid-responsive dermatoses, acne, rosacea and actinic keratosis, while in neurology, it is primarily migraine. We are targeting our first NDA filing by the end of this fiscal year.

In the Biosimilars portfolio, we have spoken about IND filings of rituximab and Peg GCSF earlier. The Phase-I global trials for both these molecules are on track.

Balaji Prasad Firstly, on the US congressional investigation have you responded to the question on price hikes? And if so, what is the gist of your responses?

Saumen Chakraborty Yes, we have responded. Basically, out of these 2 products, pravastatin is what we are not marketing and the other one divalproex ER, we did not take any price increase during the period referred to in their queries.

Balaji Prasad Did you drive or initiate the price increases in either of these products or were you...?

Saumen Chakraborty No.

Balaji Prasad What will be next steps be that we need to take?

Saumen Chakraborty We have responded to the query. Now if there is any further query, we will look at that.

Balaji Prasad Secondly, on Russia, can you explain to us the nature of your distribution arrangements, and also what percentage of your Russian sales in local currency?

Saumen Chakraborty Russian sales are in local currency only.

Balaji Prasad 100%?

Saumen Chakraborty Yes. In Russia, there are a few number of distributors as mainly the market is quite consolidated. We have 10 to 20 distributors.

Balaji Prasad I remember you also used to have portion of sales being booked in US dollars couple of years ago. That is not the case anymore?

Kedar Upadhye That is not the case. Now we have a subsidiary from which we sell entire sales is in the Russian Roubles only.

Balaji Prasad You said you expect to file the first NDA in Q1. So I presume this is the intranasal sumatriptan that you have spoken about. What stage of the trial this is in and the response that you are seeing and how confident are you?

Abhijit Mukherjee We are not specifically talking of the asset, but yes, before the end of the financial year, the first filing will go through. So naturally, the product is in late Phase-III.

Balaji Prasad The expected timeline of approval would be on 12 months from your date of filing?

Abhijit Mukherjee Normally, thats the way NDAs are approved.

Saion Mukherjee Can you share for the key RoW markets, including Venezuela, how big is that market opportunity for you? What are the dynamics in that market - in terms of your market share, how many products you are selling and how should we think about sustainability of the business going forward?

Abhijit Mukherjee From the time social unrest broke out in Venezuela, the market has been volatile and there are lot of players who have not been able to keep up the supplies in the market. Our traction in terms of prescriptions and our credibility with the doctors is already high and then this opportunity came up, which we seized it well. We had taken decision to stock up the market in advance. The current run rate is very very healthy. A large part of the RoW growth which you see has come from the Venezuelan market. It is a very significant market right now for us. The biggest headwind which could come in is devaluation. Given that oil basket is weak currently and considering it's a high oil-dependent country, so this could happen. So far, so good, we are gaining ranks rapidly and it is an important market.

Saion Mukherjee In the US market, You have seen a sequential decline. Is the impact of additional competition in decitabine, fully in the numbers now in the second quarter?

Abhijit Mukherjee The competition as you know came in sometime in the second quarter, so it is not fully factored in. Overall we are doing okay. There is still some amount of innovator share which was left in the generic market as you may recall. Hence not fully factored in, but we are not very far either.

Saion Mukherjee How do you see the second half in terms of new launches when compared to the first half?

Abhijit Mukherjee We are more optimistic about the second half. Some of the launches are in public domain now. gDiovan launched by Ranbaxy and we have also got a tentative approval. For Rapamune, we are the first to launch, because the SKU which was launched earlier was only 5% of the market value. You will surely see competition as the authorized generic has just come in and we might see one more. The rest, I would not be able to comment on, but we are cautiously optimistic. There is slowness in approval from FDA and I gather it is for other people as well. If that picks up, then it will be better.

Neha Manpuria On the PSAI margin that we saw in the quarter, you did mention improvement in product mix. Is this a one quarter sort of improvement because of probably more

development revenue coming into the quarter and should probably taper off or with the improvement in revenue, you could see these margins improve further?

Abhijit Mukherjee We are doing some structural changes in terms of improving the gross margins essentially through reducing very low margin products and looking at costs. To answer the question, there are some structural changes being attempted in the right direction. We are also looking at extending the definition of the business to deals which encompass what we call "API Plus", this is mostly for the emerging markets where we can look at the dossiers as well for the complex APIs, which may not be very value-accretive as pure API business, which is still beginning to happen. So all in all, we are moving in a direction with a design.

Neha Manpuria It would be fair to say that margins could improve from these levels, even if some of these one-off revenues which have come this quarter go off? Basically what I want to highlight is if there is a sustainable margin improvement.

Abhijit Mukherjee Any structural change may see a little bit of movement either way. The attempt is going in a right direction with design.

Neha Manpuria On the US business, you mentioned channel consolidation as one of the factors which impacted the quarter-on-quarter decline and the change in buying pattern. First, what is a rough estimate and impact from channel consolidation in terms of pricing erosion? What was this change in buying pattern that you saw from first quarter to second quarter? Could throw some light on that please?

Abhijit Mukherjee Without giving you exact figures, this has been one of the brutal years of price erosion as the channel consolidation has been heavy in US. The impact largely has gone through now, not much left but it has been quite heavy. Partly, we have been able to counter a part of it through some market share increase through the product which is available in public domain, but it has been quite heavy. Launches have been weak, so that is the other factor which has added to Q2 performance.

Surajit Pal Can you throw some light on the filings you have done, the 11 ANDAs as well as the portfolio you were developing in terms of injectables other than what you have said already?

Abhijit Mukherjee The quality of the pipeline is changing, we messaged it earlier as well. A few years back we were primarily an oral solids company. Just to give you a broad feel of it, of the current pending approval list ~40% are non-oral solids. Of those being filed this year ~50% are non-oral solids. These are largely injectables, topicals, patches and

soft gels. Of those in development is going to go up to almost 60% non-oral solids. That is how it is moving, which has its flip side as well in terms of higher R&D costs. Also because of the increased amount of external partnering. This partnering is not just off-the-shelf buy. We do a certain part of it with a partner, some of it we put in ourselves while we fund it entirely. As a result the R&D costs are pushed up. Nowadays complex products call for in-patient trials more and more and some of them also need some efficacy clinics as well, as mandated by FDA, that's pushing up the R&D costs.

Surajit Pal It looks like you were going to be pretty big in Derma space, particularly in older Dermal products where competition is very less and price rise opportunity has opened a pretty big area for you?

Abhijit Mukherjee Yes, we are looking at topicals and we started filing as well. We are not looking at only price rise products. We are looking at clinic-based products where upfront investment is a little high and the entry barriers are a little higher.

Surajit Pal The 40 million deficit in terms of sequential revenue in US revenue. Without taking any particular number, do you believe that the major part of this has been attributed to Dacogen?

Kedar Upadhye We would not be able to go product-by-product. To an earlier question we answered that it is largely because of the erosion in base portfolio and customer consolidation.

Surajit Pal Do you have any major product launch in the US this year?

Abhijit Mukherjee In public domain is only Valsartan where there is a fixed date. The rest are not in public domain.

Sonal Gupta While the step up in the R&D spend is in line with your expectations, it is still around 11.5%.How do you see this developing going forward? Currently, you have 2 proprietary products in the clinics, a couple of Phase-I trials for Biosimilar, correct me if I am wrong. So how does that sort of really change? So next year, how many do you intend to have in the clinic? And if you could sort of give a sense of, what sort of step up do you see further in terms of percentage terms in R&D from current levels, say in the next 12 to 18 months?

Saumen Chakraborty This particular quarter it has become 11.5% because we had a muted growth in the top line. Otherwise, we expect R&D to be between 10% and 11%. Going forward, we do not really anticipate any change in this number.

Sonal Gupta Currently you have 2 in the clinics and Proprietary Products. Next year, do you intend to have more in the clinics and that will push this up much further or how does this work? Or do you think that the run rate on Proprietary Products in terms of clinical spend will remain at similar levels?

Saumen Chakraborty We have factored in all our existing plans, and that is how we phased our R&D. So as you have seen, it has gone up from a range of 6% -7% of sales to 10% -11% within a span of 1 year. We have factored in all these things which were to happen in Proprietary Products and Biosimilars. Having said that, as we said earlier, our ratio of R&D spend across Global Generics and API to Biosimilars and Proprietary Products remains at 60 to 40.

Sonal Gupta Could you give us some visibility in terms of what clinical end points do you need to achieve and what probability do you see to these. Typical probability as a rule of thumb and given that the payer environment in the US has got much tougher, what sort of realistic targets are you expecting out of this? What gives you a lot of confidence on some of these 505(b)(2) sort of products?

Saumen Chakraborty You will have to wait for the R&D day that we are going to have, so that you can put all these questions to our Head of Proprietary Products and he can fill these questions.

Sonal Gupta Anything in terms of ex-Copaxone for next year, how do you think about your US business growth? I am leaving out Copaxone depending on how the regulator looks at it. Do you think you will be able to still grow next year ex-Copaxone on a current base?

Abhijit Mukherjee We think so. Irrespective of the uncertainties of Copaxone. Your guess is as good as mine. While there is no bad news as yet, but other than that also we have reasonably robust year next year.

Sonal Gupta So you do expect some other complex launches to come through next year?

Abhijit Mukherjee That is what I am saying.

Anubhav Aggarwal You won the litigation on Propofol. When do you expect to get approval from FDA on this product, in the sense is it within one year or it could even take longer?

Abhijit Mukherjee The litigation is not through fully, so I would not be able to answer this question.

Anubhav Aggarwal On Sirolimus, you mentioned that you expect one more player. Is that Actavis who had exclusivity on this strength, they have exclusivity forfeited or what is the status with them or is there second player expected to be Actavis?

Abhijit Mukherjee So as per FDA rules, as you know, unless the FDA has forfeited, the other players cannot come in. Probably that answers your question.

Anubhav Aggarwal Do you expect this scenario of 1 or 2 players to sustain for almost a good amount of time, say about a year or could be low competition could be for much shorter position?

Abhijit Mukherjee That is again a difficult question. I wish I knew, but this is not a plain vanilla product really. So your guess is as good as mine.

Anubhav Aggarwal Abhijit, just one more clarity on Nexium settlement that you have done with the channel. Actually, I am very confused with that case, because first, only a few players, Dr. Reddy's, Teva and Ranbaxy from several participants were sued in that case. By settling with the channel, you certainly get benefit that you are absolved of all the potential liabilities. But what is the flip side, what do you lose out by settling with the channel, because this option was always there, you could have settled much earlier as well if there was no flip side?

Abhijit Mukherjee No, no. Settlement happens only when both sides agree, but the point is that throughout, we were very confident of our legal position and we are glad that it is validated through a settlement with no financial impact to us. So the flip side you are talking about, there is no flip side. That is because largely, our legal position was strong and we all through maintained that.

Anubhav Aggarwal Your opportunity from Nexium front, whatever it was before settlement that remains as it is even post the settlement is done?

Abhijit Mukherjee These are completely different things. This is completely a different legal case to the opportunity. I would not comment on opportunity, but at least I can tell you that they are two completely different things.

Anubhav Aggarwal What is the status update on Fondaparinux in Europe? The last update you gave was that you were expecting by end of this fiscal, you would have some update on Fondaparinux in Europe application?

Abhijit Mukherjee Our first filing ran into some different views from European agency and we are in the process of filing again. It is a very-very competitive market particularly in terms of

pricing. So it is a high top line, relatively low margin, we would not calculate that actually. It is not very highly impactful as far as the whole company's bottom line is concerned.

Prakash Agarwal My question relates to our understanding on the GDUFA transition by USFDA. We have clearly seen for yourself and other industry players where the approvals have slowed down. Now we are stepping into the next quarter, which is October to December. Have we started receiving CRLs and hence do we have better visibility of approvals in the second half?

Abhijit Mukherjee We just got one approval as we already told you. Probably your information is better than ours, because you are talking to everyone. We just stepped into the next quarter, it is too early and difficult to say. We stay optimistic.

Prakash Agarwal Any lead through on the GDUFA transition both in terms of filing and approval guidance?

Abhijit Mukherjee FDA is not providing a lot of guidance. Whether there is a distinct improvement, which is perceivable, the answer is no. At the same time, it is very early in the next quarter. Let us see, somewhere this has to move up or step up in terms of speed.

Prakash Agarwal The second question relates to our portfolio – one in Biosimilars and second in Proprietary. First on Biosimilar, I mean, apart from the MABs and the GCSF, are we targeting other segments in the Biosimilar space?

Abhijit Mukherjee There are only a few assets in the Merck deal. However in the pipeline, yes, that continues. The larger cost implications are from the products, which are more or less known and in public domain. There are many of them we have launched in India. So the current expenses are on those products. The early development and the other MAbs, etc., are in progress actually.

Prakash Agarwal We would be looking at the other pieces of the portfolio in Biosimilars?

Abhijit Mukherjee In due course of time.

Prakash Agarwal On the Proprietary, sir, what is the portfolio that we are looking at? Earlier you had mentioned that 15 products with a peak sales potential of $30 million to $300 million. Has there been any progress there?

Kedar Upadhye We will talk about it on R&D day.

Prakash Agarwal On Copaxone, what is our current understanding in terms of the first-to-file getting approval and our monetization?

Abhijit Mukherjee Not much changed from the last communication which we had. The rest of it you are reading in public domain, a lot of things are happening. The questions raised in court by the innovator, the view, etc., Apart from what you see in the public domain not much from our side. The file keeps moving.

Girish Bakhru On US again, just trying to get a sense of how the second half would be. With Sirolimus giving a good traction, would you say the combination of certain recent approvals like Xopenex, Sirolimus second half would be definitely better than what first half has been at $500 million?

Abhijit Mukherjee There are two caveats I would like to put there; one is we do not know about the large injectable assets, whether there is any further approval coming in; the second thing is the base level. If you are talking of comparison, last year Q3, these injectable assets were in full flow versus what they are right now. Some approvals would come in the second half, so we expect better than Q2 for sure.

Saumen Chakraborty H2 better than H1.

Abhijit Mukherjee Overall, Q1 was pretty good, but let us see. With 50% of the Generics business coming from North America, that is about 80% of the company, some of the questions which I know as little as you know - can change things.

Girish Bakhru But, just on the market, why Xopenex? Is it a material market you think that there are only 4 approvals and probably less would come in time, how interesting will it pan out?

Abhijit Mukherjee Levalbuterol is the 2 AGs, 3 generic players, we are the sixth one, small launch for us, partnered and nothing of significance.

Girish Bakhru Just again a clarity on one product in US, how do you see Gleevec? I know the case is pretty fresh for you and with Sun settling for February ‘16, does it give you a window to launch in August or it could be further delayed?

Abhijit Mukherjee It is in discussion at the moment and litigation.

Girish Bakhru So you would say that your litigation outcome will essentially decide your launch, right?

Abhijit Mukherjee Yeah, unless we are able to converge.

Girish Bakhru On Habitrol, actually I did not really get what is the current sales of the product. Just judging by the overall market, where I see nicotine replacement market actually has been declining steadily and a lot of these new e-cigarettes and all things are catching up, how interesting do you see is this asset?

Abhijit Mukherjee You can put a factor of 0.45 to IMS, which brings it in the range of $60 million odd top line. There is potential because e-cigarettes have gone into some controversies as well. These products have been moved from behind the counter to in front of the counter. Having said that, this is a combination of store brand and to a lesser extent a full-fledged brand. We already have an OTC business, we have connectivity with the OTC channels and we will see where it goes.

Manoj Garg In continuation to the previous question, do we expect similar kind of deals more in the pipeline going forward? Wanted to understand the overall thought process behind this deal with Novartis?

Abhijit Mukherjee As you know, GSK Consumer Care and Novartis Consumer Care merged and FTC mandates divestiture of some assets, so this came up. As you know, that primary asset is Nicoderm. We were one of the bidders and we went through. It is still to be cleared through the FTC process. While we are going ahead and we have closed the deal, but the process with FTC is yet to be completed. To that extent, it is not 100% complete.

Manoj Garg Do we expect some more similar kind of deals in the OTC segment going forward?

Abhijit Mukherjee Yes, like any other company, we are on the lookout opportunistically. Unless it falls in our areas of focus, we would be choosy. A lot is happening in the emerging markets as well in various types of assets, etc.

Manoj Garg Are you sharing the financial details, like how much we are paying for these assets and all?

Kedar Upadhye Not at this stage

Manoj Garg Abhijit, in the past, we kept saying that incrementally we are filing 10 to 15 products because our focus is basically more on the quality pipeline. However, in the last 2-3 quarters, we have started seeing ramp up in the filing itself and even in the first half, you filed around 11 ANDAs. Do we expect now that going forward probably we will have this filing run rate of around 20, 25 products annually?

Saumen Chakraborty Actually, what we earlier said about 10 to 15 was in terms of number of launches. So, of course, your filing will have to be higher, then, you have to get approval and then launch.

Abhijit Mukherjee We should be better than last year. In US we filed 12 last year. This year will not be 25 or something as you are saying, but somewhere close to 18.

Manoj Garg What is the long-term aspiration in terms of the margin guidance? From the current level of 23%, 24%, where do we see the margin over the next 2 or 3 years?

Saumen Chakraborty We expect it to be approximately 25%.

Sameer Baisiwala Checking on the Nexium settlement with the channel, if you had a strong case, you would have won the court case, no? Why did you have to settle with the channel and then cooperate with them, which I understand would be against AstraZeneca, Ranbaxy and Teva?

Abhijit Mukherjee No, basically, we have given our depositions, we stand by our depositions and we will repeat our depositions. This is our view and our facts which we have with us. Your question was if you have a strong case, why not keep fighting? The US legal costs are pretty high. If you have an opportunity to come out with no financial impact, and we do not ever do a lot, so we have chosen to come out.

Sameer Baisiwala On this point, would your settlement be any different from that of Teva? Both are supposed to be 181 days, if I remember correctly? Would this then, be too different from Ranbaxy? It would all be addressing the same patents before and after, which you are coming. So wouldn't the three companies more or less be in the same boat, at least you and Teva?

Abhijit Mukherjee Firstly, I would not have the details of what Teva has or anyone else has. You would know better than me that I am not going to share anything about our settlements.

Sameer Baisiwala Looks like the Proprietary pipeline is not too far away. Maybe getting approved in 2016 sometime. How are you thinking about the marketing and sales front end for this?

Abhijit Mukherjee So we are there in US, as you know, Sameer, already with a front-end sales force.

Sameer Baisiwala Especially for Neurology and Derms?

Abhijit Mukherjee Neurology and Derm. These assets, as we have said in the past, are not NCEs. These are unmet needs designed around properly and then taken through to a logic and a full-fledged clinic. The front end is not a very large concern for us because I think the company is familiar with creating value. The important thing is how the filings and approvals go through.

Sameer Baisiwala Would these be brands and you would be required to market it to the doctors?

Abhijit Mukherjee Yes, of course.

Sameer Baisiwala On Habitrol, is it a matured product and has a steady cash flow or are there ways to unlock value in this?

Abhijit Mukherjee The first is right, but this is only the patch, and as you know, there are other smoking cessation products in the market and we do not have that portfolio altogether. There are ways to in-license some of the other things like lozenges and a few other things. So the portfolio can be also completed. The larger part is the patch and it is not going to give a large value first, but there is some growth there and there is some growth in the channel in terms of increase in presence in the channel a little bit more.

Surya Patra In the Russia business, in the first quarter, we have seen a constant currency growth of around 18%, and second quarter we are seeing flattish number. So what kind of full year growth visibility one should have for that region?

Kedar Upadhye We have been, over the years, demonstrating healthy double-digit growth for Russia. We will not give you specific number guidance for the market.

Surya Patra Yes, but qualitatively, can you give some sense because we are seeing multiple concerns around that market. Can we maintain the growth momentum there despite the geopolitical issues continuing and all that?

Abhijit Mukherjee Growth momentum would be there, but we are more concerned about the currency movement actually. The sanctions will have an impact on out-of-pocket purchasing and all that. So that is a little bit unknown, but otherwise, operation wise, we feel very-very confident to sort of moving ahead of the rest.

Surya Patra Is it possible to share the size of the OTC business in US and the kind of performance that they are doing? What is the kind of growth that they have reported in the first half?

Kedar Upadhye Annualized OTC business in US is around $120-130 million at the current scale.

Surya Patra Is it again possible for you disclose what are the kind of budget that you have earmarked for your clinical trial for this Biosimilar assets in the US market?

Saumen Chakraborty I already mentioned the ratio between Global Generics - API vis-à-vis Proprietary Products and Biosimilars. Between Proprietary Products, Biosimilars maybe at the moment, Proprietary Products is having a little bit higher spend than total Biosimilars, but the detailed further breakup we will not be able to divulge.

Chirag Talati First question relates to the migraine product. We have seen that the FDA has come out with a possibility of the guidance being revised for the triptans product category as a whole. Do you think that can have an impact on your filing timelines or on your end points or will you be required to do additional trials?

Abhijit Mukherjee Specifically, we are not saying anything about any asset, we are saying one NDA filing being targeted before end of the fiscal. For specific guidances and questions, Saumen mentioned that there will soon be an opportunity, some time earlier part of next year for the R&D Day to ask these questions directly. Overall, the journey is progressing at least on track at the moment.

Chirag Talati How did you go about selecting the therapies for Proprietary Products, why Neurology? It has not been one of the core strengths for Dr. Reddy's. It is a market that is highly competitive, you are competing against Zolmitriptan, an established brands with no field force, no additional products. What was the rationale behind going into some these Proprietary Products or Therapy areas per se?

Saumen Chakraborty The basic thing was to look at where there is a need, which is currently not met properly or sufficiently. Where there is enough opportunity. Based on that, we have chosen specific areas and it is a very limited number of specific areas that we are focused on and within that we specifically picked up the product where we can focus. More questions on that again I would like you to just wait some more time and you will get an opportunity on the R&D Day.

Chirag Talati I guess the point I am coming to is I want to understand the capital allocation policy that goes behind some of these decisions because to me it seems that you seem to be diluting your focus by going into many therapy areas with limited number of assets. What I am trying to understand is could you have done better by filing a fewer more of these Complex Generics instead of going into a Neurology area?

Saumen Chakraborty The capital allocation decision that we are taking will be across the BU. Within the BU, definitely, we are not curbing our Complex Generics submissions at all from the

point of view of being able to allocate capital. If we were at trading off, then your questions could have been more valid, we are not doing that.

Abhijit Mukherjee The journey did not start 6 months back. The journey is on for quite a few years. We have invested into this for several years. So why should one pull the plug off having come so near? Moreover we are quite focused, two therapies, not a very large doctor base in both these therapies. We have unmet needs in these identified. So why not?

Aditya Khemka Firstly, sir, on the PSAI segment, we saw in the first quarter SEC filing disclosure that maintained that among the top 10 products you had Capecitabine there as a big product, which was contributing more, and there appears to be some rationalization on the lower margin products of escitalopram and naproxen. To understand the second quarter result for PSAI better, is it still this one large product, which is contributing materially to be sequential growth between 1Q and 2Q '15?

Abhijit Mukherjee As I mentioned, there is the conscious structural change also contributing. Any business will have some large products, some are some smaller products, overall, directionally, we are moving in a specific direction with a design. More than that, I do not want to go deeper into it. We will move in to acceptable gross margin and things were much slower earlier, so we are unlikely to see the slow margin.

Aditya Khemka Sir, I appreciate that, but my concern is that in first quarter of FY '15, almost 20% of your PSAI revenues came from one product, right? And if this is the only product which has grown like sequentially from 1Q to 2Q then it might be currently contributing anywhere between 27%, 30% and this is a product which is under exclusivity in the US market. So once this product goes off exclusivity, it faces competition and price erosion. Is it that we are coming back to the sort of sluggish margins that we have seen in the past in the PSAI segment?

Saumen Chakraborty Maybe we can just give a one line clarification that you can expect H2 performance to be better than H1 in PSAI and with that we leave it there.

Aditya Khemka My second question is on the North American Generics business. We have seen $35-odd million sort of decline sequentially and as you mentioned, most of this impact seems to be that of channel consolidation and price erosion. If I just take it on a percentage basis, then you are talking about roughly more than 6%, 7% sort of a price erosion sequentially between 1Q and 2Q, is my assessment correct?

Abhijit Mukherjee Yes, it is probably more than 7% actually. So what else could be where one could lose base business? Yes, there are some launches of products. Again, basically leads to

price erosion. If you take between channel consolidation and new launches, probably, the impact of channel consolidation would be about 70%.

Aditya Khemka I saw the presentation and we saw some market shares being maintained in the United States again between May and August of this year and there is significant price erosion obviously in many of those products as we just discussed. It is about hanging onto market share despite price erosion in the Generic segment, but in the PSAI segment, we appear to be going in the opposite direction where we are letting go of market share for better margins. Is there a difference in the dynamics of the two business that leads us to believe that it is better to hold onto the Generic business despite high price erosion and in PSAI, it is better to let go of a low margin business and look at higher margin products?

Abhijit Mukherjee These decisions are dynamic and dependent on what status the business is in. It is not that we continue to lose market share and give up share in PSAI or it is not also true that we continue to hold on and let things erode. These are very dynamic. For PSAI especially is a bit of a correction, which is being done. As far as Generics business is concerned, again, it is very-very case specific, does not have to be that every time one has to hold onto market share, but that is certainly not the way to operate in North American market.

Saumen Chakraborty Rather I will put it this way that the market share expansion has actually offset some of the price erosion.

Ranjit Kapadia My question relates to the European market. You have seen a negative growth rate in both PSAI and Global Generics business. I just wanted to know what is the management's thought process for the turnaround of both these businesses in Europe?

Abhijit Mukherjee For PSAI, the Europe business is defined as where we sell but not where it goes eventually. Depending on the customers and all that, there are some changes, although the large part of it was a downturn of new Generics business, some of the customers are becoming more and more aggressive. On the pure Generics side, probably after a long time Q-o-Q we are flat. We have been always been saying that we are trying to look at the product mix. With this flatness and new products coming in we hope that at least on the bottom line, it is going to get better certainly in the second half. Having said that, as you know, it is probably only about 5% of the total Generics Europe business.

Ranjit Kapadia No, 4% business.

Abhijit Mukherjee 4%, yes, it is a small business. So I do not know how much more detail you would like to have on that.

Ranjit Kapadia Both the businesses are 4%, that makes a total 8% in the European market. If it is de-growing by almost 29%, it is a matter of concern.

Abhijit Mukherjee So it cannot continue to do so. It has happened. So going ahead, we will have to see where it goes from here.

Kedar Upadhye Thank you all, for joining Dr. Reddy's Senior Management for the Q2 Fiscal '15 Earnings Call. In case of additional clarifications, please get in touch with the Investor Relations team. Thank you and good day.