

# Dr. Reddy's Laboratories Limited

## Q1 FY12

### Earnings Call Script

#### **Kedar Upadhye** *(Investor Relations)*

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Good morning and good evening to all. Welcome to the Dr. Reddy's earnings conference call for the quarter ended June 30, 2011, which is the first quarter of fiscal 2012. 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 the transcript shall be available on our website soon. The discussion and analysis in this call will be based on IFRS consolidated financials. To discuss the business performance and outlook, we have today G. V. Prasad, our Chief Executive Officer; Satish Reddy, our Chief Operating Officer; and Umang Vohra, our Chief Financial Officer. Please note that today's call is copyrighted material of Dr. Reddy's and cannot be rebroadcast or attributed in the 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 this conference call and webcast. After the end of the call, in case any additional clarification is required, please feel free to get in touch with Raghav, Milan or myself.

I would now like to turn the call over to Umang Vohra.

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## Umang Vohra (*Chief Financial Officer*)

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Thanks, Kedar. Good morning and good evening to everyone. I welcome you all on this call today. I will discuss the key financial highlights. For this section, all the figures are translated to U.S. dollars at a convenience rate of Rs 44.59 per U.S. dollar.

Our consolidated revenues in this quarter grew by 18% on year-on-year basis to \$444 million. Global Generics recorded revenues of \$323 million, strong growth of 21%. Pharmaceutical Services and Active Ingredients, which we will call PSAI in this call, grew revenues by 7% to \$108 million. Our gross profit margin for this quarter is at 53%, and the margins remained roughly the same, both at the segment and the overall level when compared to the previous year.

SG&A expenses, including amortization for the quarter, are at \$152 million, an increase of 23% over the previous year. This increase is attributable to the following factors: annual inflationary increase in manpower costs across business, the step-up in the OTC-related selling and marketing costs in Russia in line with our strategic intent to expand the OTC portfolio and the general overhead in the U.S. due to the recently acquired Bristol penicillin facility. R&D costs, at \$27 million for the quarter, show a planned increase of 21% over the previous year.

Included in our financials this time are, interest on bonus debentures of approximately \$3 million, which we believe is an indirect form of dividend to the shareholders and a one-time charge of \$3 million on account of a voluntary retirement scheme floated by the company. And adjusting for both of these factors, our adjusted EBITDA at \$97 million, represents 22% of sales and has registered growth of 27% over the same period in the previous year.

In this quarter, we made required shipments to the U.S. from India in anticipation of our launches. This has triggered a tax benefit in line with the IFRS-mandated treatment for unrealized profits on these stocks. The tax charge at the India entity's rate of 32% was more than offset by the tax credit of the U.S. entity's rate of 38%, resulting in a net credit for the inventory shipped out of India. Hence, the reported effective tax rate for the quarter is 4%. Adjusted for this benefit, it would have been 16%. On a full year basis, we expect the annualized effective tax rate to be around 21%, driven largely by olanzapine related exclusivities in quarter 3 and quarter 4. Adjusted profit after tax for the quarter, normalizing for the 16% tax rate is \$56 million and is at 13% of sales.

Key balance sheet highlights are as follows. Our operating working capital has increased marginally by \$20 million from the previous quarter. The increase in inventories in anticipation of new launches was partially offset by the release in receivables. Capital expenditure for the quarter is at \$41 million.

Foreign currency cash flow hedges in the form of derivatives and offsetting loans are at \$410 million as of date, hedged largely in the range of Rs. 45 to Rs. 47 a dollar. In addition to these, we have approximately \$236 million of balance sheet hedges of net receivables. Our current net debt is at \$414 million and the net-debt-to-equity is at 0.38.

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

## Satish Reddy *(Chief Operating Officer)*

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Thank you, Umang. This I think was somewhat of a mixed quarter for us. While North America and Russia-CIS markets demonstrated strong growth, India formulations was below our expectations, and the PSAI segment growth of 7% was in line with expectations. I'll now cover the business highlights for each of our key markets. Performance analysis is based on the respective local currencies.

Starting with North America Generics – we recorded impressive year-on-year growth of 51%, recording revenues of \$129 million and we are quite delighted with the continuing progress in our North America Generics business. Our key limited-competition products, tacrolimus and lansoprazole, continued their strong performance and sequential market share improvements. In this quarter, we had a benefit from the initial launch revenues of fexofenadine OTC. We now have 5 customers for this product, and the off-take is quite encouraging. Other key products in the portfolio, such as Omeprazole prescription and Omeprazole Magnesium OTC have also acquired an impressive increase in their market shares over the last one year. We have also begun invoicing from the newly acquired Bristol penicillin facility, with 4 SKU launches this quarter. We expect this business to scale up after the 3<sup>rd</sup> quarter with launches of some of the larger SKUs. During the quarter, we also launched 5 new products in our regular prescription portfolio. We have now got approval for OTC switch for fexo-pseudo combination product and launch preparations are underway. During the quarter we have filed 3 ANDAs, and cumulatively we now have 76 ANDAs pending approval with the U.S. FDA, of which 36 are Para IVs and 11 are first-to-files.

Moving on to India – Revenues for the quarter are at Rs. 2,936 million or \$66 million, which represents year-on-year growth of 6%. The performance in this quarter was below our expectations largely due to some pressures on our top brands. While we continue to get impacted by the price compression resulting from competitors' activities, it's less than what have seen of Q4 of the previous year. In the last one and half years, we also expanded and reorganized our field force deployment, for which we have yet to see the desired results. While we are not satisfied with the start to the year, we hope to recover the lost ground in the second half of the year. During the quarter, we have also launched 12 new products. Our recent launches of biosimilars are doing well, and our overall biosimilars portfolio, which is now 7% of India sales, has grown at an impressive rate of 69% over the previous year.

The Russia business continues its steady growth with revenues of \$56 million for the quarter and year-on-year growth of 23%. Our secondary sales growth of 17% for the Moving Annual Total of May 2011 is much higher than the industry growth of 6.5%. Our rank in Russia currently stands at

No. 13. This growth was largely driven by volume growth in our OTC products and key prescription products. The OTC segment represents almost 40% of the Russian market, and that's part of our strategic intent to increase our presence, we have been investing in brand promotional activities in the space. As a result of this, our OTC portfolio is now at 30% of the sales from about 25% about a year back.

Talking about Europe Generics – Revenues are at €28 million, which is decline of 11% over the previous year. Revenues from Germany for the quarter are at €19 million, which is decline of 17% and which is due to the continuing tender-based pricing pressures. In June we have commenced our supplies towards the recently awarded AOK tender. Despite winning a few high-volume products, we expect the margins to remain subdued due to low pricing. Revenues from the Rest of Europe grew marginally on the back of out-licensed products.

Moving now on to the PSAI business – Revenues for the quarter are at \$108 million, showing year-on-year growth of 8%. The Active Ingredients business grew very well on the back of new launches, but revenues from the Pharmaceutical Services declined sharply due to the temporary suspension of sales in our Mexico facility, post the import alert. However we expect to resume our supplies as one of our major product, which is Naproxen API, is exempt from this import alert. In our Active Ingredients segment, we are seeing good pipeline lock-ins around certain large molecules, and the business is expected to show higher growth. However, in the Pharmaceuticals Services segment, the outcomes are dependent on the progression of one or two partner's trials, which we may see by the year end. However, the business environment for this segment still remains challenging. During this quarter, we have filed 9 DMFs globally including two in North America, one in Europe and the rest in other markets. With this, the cumulative filings stand at 495 globally.

I now hand it over to Prasad for his discussion.

**GV Prasad** (*Chief Executive Officer*)

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Thank you Satish.

As Satish explained, this was a mixed quarter for us and we will continue to work on strengthening our market positions. I am however extremely happy with the progress in our North American Generics business. Apart from the impressive growth, we've also seen a number of positive developments recently, culminating in the approval of fondaparinux, which is being launched now after its long-awaited approval. The product will have a phased launch into the customer pipeline over the coming quarters. As you are aware, the development process for this product was quite complex and we would like to acknowledge the contribution of the entire development team and our technology partner Alchemia in this regard.

Similar to this product, our existing generics R&D effort is increasingly focused on complex molecules. We may not see a trend of high number of filings as earlier, but the complexity and market potential are expected to be much higher. As a result, our R&D costs are likely to move up in the coming years, not only on account of the more complex generics portfolio but also increased investments in proprietary products and biosimilars.

We also plan to launch another limited-competition product, fexofenadine pseudoephedrine higher strength in the OTC segment in the second quarter. We expect the second half of this year to have a higher growth and profits relative to the first half. This will be driven by olanzapine 20 mg under exclusivity and new SKU launches from our Bristol penicillin facility in the Augmentin and Amoxil range, ramp-up in the market shares of fondaparinux and the OTC launch of fexofenadine pseudoephedrine higher strength. While we derive the benefits of these positive developments, we also need to focus on some immediate challenges.

Apart from the sluggish growth in our India formulation business, another immediate priority for us is to resolve the issues raised in the warning letter by the US FDA on our Mexico facility. As indicated in the import alert, naproxen, which is our key product from this site, has been exempted. And we have sent our responses to the warning letter in end June and are working closely with the FDA to seek clarifications and resolve the issues, so that the import alert may be lifted.

With this, I would now like to open the call for question and answers.

## Q&A Session

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**Saion Mukherjee** I have a question on the domestic market because towards the mid of the last quarter, we were expecting that the growth will revive after a muted Q4. But that hasn't happened. So can you throw some more light, as to why the growth has been sluggish in India? What steps are we taking? And how do you see growth reviving from a 1 to 2 year perspective?

**Satish Reddy** Okay the growth has been disappointing, yes. We did indicate that things should improve from this financial year onwards, but quarter 1 results have not certainly reflected that, so we do express a sense of disappointment over that. So looking to the some of the reasons why and what do we expect going forward, if you look at this there is some initiatives we have undertaken about, say, 2 years back. One was field force expansion. We also wanted to redeploy some of the field force. But I think the deployment as well as the expansion have not yielded the sales increases that we expected it would, right, so that's one issue which needs to be still tackled. And we're still working on it, right, so that's one. As far as the other initiative goes, the expansion to rural markets, while it has started off well, there was a good scale-up in the previous year. There's been some issues with that in terms of field force attrition and things like that, which was somewhat beyond our control, right, but that's something we also had to anticipate. So I mean, these are two primary reasons we have seen, the first quarter was also hit with somewhat a lower growth in some of the top brands, so that's another issue. So these are broadly what I see as the issues for the first quarter compared to, say, what we anticipated in the previous quarter. Now while it's work-in progress in terms of trying to sort out the execution issues, I would expect that things to start looking up in the second half of the year, right, so this will be based on some of the interventions, which we have started plugging in early enough this quarter. But again, I would still like to see the performance of the second quarter. Once that improves, I would be able to comment more on that. I will be able to say with much more confidence on what happens in the second half, which I am sure, will definitely start recovering.

**Saion Mukherjee** And just one more question, have you seen an authorized generic in fonda yet?

- GV Prasad** Not yet, but we heard of a possible authorized generic.
- Manoj Garg** Have you seen any pricing pressure in the domestic market? Because for one of your products like rabeprazole, Pfizer has come out with almost little like 50% of your pricing. So do you see that MNCs coming out with a very aggressive pricing and it's affecting the overall pricing strategy in the Indian market?
- Satish Reddy** It's not just MNCs, I think, even among the Indian companies and overall if you see the industry itself there is intense pricing pressures happening to various products. So obviously, it does affect the market share, and that's something we all seen, yes.
- Manoj Garg** And have you also taken some like price corrections in rabeprazole?
- Satish Reddy** It is one of the leading products for us. We have not done anything.
- Manoj Garg** And what could be the adverse impact of nimesulide because there was some confusion in the market and, well, it might have impacted growth in the market.
- Satish Reddy** Nimesulide, I think from the time EMEA had put in some restrictions in the past, especially the issues on the pediatric suspension, which we had withdrawn quite some time back. I think the recent EMEA report also has clarified in terms of the benefits of nimesulide, except for chronic usage of that, which is something which we had already implemented quite some time in the past. But I think the whole activity, especially by competition, by also putting in false propaganda - in one case, actually we had successfully gone to court to restrain them. So this is something which has also seen de-growth in this molecule compared to the past. That's something we have definitely seen in this molecule.
- Perin Ali** What could be the depreciation and amortization impact because of the Bristol facility in the U.S. for this quarter?
- Umang Vohra** It'd be about \$1 million to \$1.5 million.

- Ranjit Kapadia** My question relates to the domestic market. If you can throw some light on the sales force? And how much of sales force was added in the last year? And any change in the guidance for FY 12?
- Satish Reddy** First of all we have not guided for FY 12, right?
- Ranjit Kapadia** Sorry FY13 of \$2.7 billion guidance, whether it has changed or that you are revising...
- Satish Reddy** That still remains. There's no change because of what you have seen, just because of the Indian market growth in the first quarter. That's no indication of any revision or any change. We still stick to the guidance, what we have indicated. In terms of the field force that you are asking, I think, last year, we added quite significantly to the field force, and it was about 500.
- Ranjit Kapadia** And what is the current strength now?
- Satish Reddy** The total will be about 3,800.
- Ranjit Kapadia** When do you feel that the full potential of this 500 people will be available to us?
- Satish Reddy** I think it's difficult to comment, saying that just because we added field force, overnight sales are going to increase. That's not what I was intending to say. So it is about field force which has been added in different marketing divisions and also the field force strategies that we employ and the execution that happens after that. So it's a combination of various things, which I said that, on execution, we have not performed up to expectations.
- Ranjit Kapadia** And what is the attrition rate in the field force currently?
- Kedar Upadhye** Across the division it varies but overall, it's about 25%.
- Hitesh Mahida** First thing is what will be sales contribution and how much is the cost of the new GSK facility, penicillin facility?
- Umang Vohra** The sales are about \$4 million, and the cost of the facility, because we haven't yet scaled up, is about \$5 million.

- Hitesh Mahida** And how much sort of peak sales, are you expecting from this?
- Umang Vohra** This will peak in quarter 3, and I think it could go at an average run rate of almost about \$8 million to \$10 million. But this is a seasonal product, so you will begin to see the variations between quarter 1 and quarter 3 at a full year average, and a good rate would be about \$5-million-odd per month.
- Hitesh Mahida** What's your view on the German pharma market? Even after we have started AOK supply do you expect sales growth this year?
- Satish Reddy** Sales will definitely not grow because we have already indicated in the last year itself that the price declines will continue for this year. So what you're seeing in the first quarter is generally the trend even for the rest of the year because the view on the market is that while AOK tender have good products with increasing volumes, as an outcome of that, because of the pricing pressures, that's why you see the decline.
- Hitesh Mahida** And what would be your market share in lansoprazole, tacrolimus, fexofenadine and omeprazole?
- Kedar Upadhye** We will share these numbers offline with you.
- Sushant Dalmia** Just one question in terms of the housekeeping, I suppose the \$3 million of the VRS has been in the SG&A costs. And interest on bonus-debentures is clubbed in the financial expenses. That would be right?
- Umang Vohra** I will just clarify: The VRS, it is split 70% in the manufacturing cost and 30% in the SG&A. And the interest is in the interest line, the bonus debenture interest is in finance income.
- Bino Pathiparampil** When you said that fonda will be launched in a phased manner over the quarters, can we go a little deeper into that? Why is it phased? And what is the time period in which you expect to achieve the best market share?
- G. V. Prasad** So part of the reason, this is going to be a slow phasing is because of the complexity of manufacturing of this product. So it involves nearly 60 steps of manufacturing, and hence, while we launch the product, I think we'll be able to fully exploit the market share of the product in about 3 months from now.

- Bino Pathiparampil** Just today, there was a FDA release that you got an approval for palonosetron hydrochloride...
- G. V. Prasad** It's a tentative approval.
- Bino Pathiparampil** Allegra – D 24. Did I hear that you said you already got the approval?
- Umang Vohra** Yes, we have received the approval. We are hoping to launch.
- Bino Pathiparampil** In the calculation of EBITDA, you have added back interest of about Rs. 22 crores in your press release, whereas the interest in your P&L is only about Rs. 4 crores or Rs. 5 crores. So what is the disconnect there?
- Kedar Upadhye** So, Bino, the interest in the P&L is actually the net finance expense, so that includes forex gain also. You can see the last page of the press release; it will give you all the components adding up to the EBITDA and finance expenses.
- Umang Vohra** Bino, we had 16 crores of forex gain this quarter.
- Bino Pathiparampil** So EBITDA number you have given out, includes that forex?
- Umang Vohra** That's right.
- Sonal Gupta** Just wanted to get a sense on; we are seeing a weak trend in terms of growth in our other CIS markets, other than Russia and also in the ROW markets. I think we are seeing it sort of weaker even over the last couple of quarters so, I just wanted to get a sense on what's happening there?
- Satish Reddy** Couple of markets had devaluation right. So Venezuela was one and also Belarus. We are talking about steep devaluation of the currency so, that's one impact of what has happened and that's the issue.
- Umang Vohra** Other than that I don't think there is too much that we are concerned about right now.
- Girish Bakhru** Just on fondaparinux, I wanted to understand, basically if there are different channels where fonda is probably more taken like it is probably a hospital based channel which takes the product more, just a little more colour on that.

- Umang Vohra** Fonda is split about 60% in hospitals and 40% in retail and wholesale.
- Girish Bakhru** The US launch is pretty much a priority right now but any update on the EU filing, where there is a stand right now.
- Umang Vohra** We are not providing an update on that as yet.
- Kedar Upadhye** Well the data exclusivity runs till next year Girish.
- Girish Bakhru** I understand data exclusivity is still 2012 but filing would of course be in preparation right.
- Umang Vohra** Yeah so we are not commenting on that right now but it is our plan to try to monetize fondaparinux as much as we can across the world.
- Girish Bakhru** Just wanted some more color on the US, it is of course pretty strong and the OTC launch has been there but how have been the launches in Lotrel higher strength and levocetirizine in some of the launches which were pretty recent, how has been the market share there and what is the colour on where the base sales might go to by the end of the year. I mean excluding some of the exclusive launches which may be coming in the latter half of the year.
- G. V. Prasad** So these products are highly competitive because of a very large number of players launching the product so, I don't think they form a significant portion of our sales.
- Abhay Shanbhag** Taking this question forward on fondaparinux, you said 60% is hospitals and 40% is wholesale retail. Right now in the press release, you were indicating that we would be targeting wholesale retail. Is that what you will start off right now, targeting 40% of the market?
- Umang Vohra** Yeah that's right.
- Abhay Shanbhag** And say in three months time you would then target a balance to the market. In terms of hospital distribution because you don't really have too many injectables in place so, what sort of market tie up you would have to take this product forward?

- Umang Vohra** So, this one is a little different from the rest of the products that sell in the hospitals so it doesn't require that kind of a special GPO type of an organization.
- Abhay Shanbhag** And what sort of market share can we presume by March-April of next year can we assume it at 30-35% market share build up over April, May, June next year or will it take longer to reach market shares like that?
- Umang Vohra** Abhay we are not commenting on that as yet.
- Abhay Shanbhag** The last one was on Russia. You indicated 30% is OTC now, how much is hospitals as a percentage of your Russia revenues?
- Umang Vohra** Less than 5% would be hospitals and we have plans to see what products we could pick and choose, to increase that portfolio and prepare it for the biosimilars and the other oncology products that we will be launching in the near future.
- Abhay Shanbhag** Any outlook on the Russian pricing, is there any transition, is there any expectation of any price change or structural change from the Russian market?
- Umang Vohra** We haven't heard anything in this quarter which is significantly different from the previous quarters. However, we will continue to maintain the stand that we don't see anything drastic happening in Russia, except that the long term trend of that market would be to probably correct a bit in terms of pricing.
- Ravi Agrawal** Just a question on the GSK penicillin facility. If I got Umang right, he was mentioning 5 million on a monthly basis as a regular trend?
- Umang Vohra** There are two things that are indicated, 5 million was the cost that we had in this quarter and the average sales that I mentioned on the subsequent question were 5 million per month.
- Ravi Agrawal** So, average sales on a steady state base can be around 5 million.

- Umang Vohra** Can be 5 million but it would spread between 2 million and 8 million depending on the season but the cost is 5 million roughly per quarter so, what we have shown in this quarter is 5 million cost.
- Ravi Agrawal** Just going on in the question on the penicillin facility. I do believe one of the reasons for acquiring the facility was also to take part in the tender businesses which come up in the US. Any thoughts you want to share, about whether it could actually see some upside in terms of revenues from tenders in that facility for this year.
- G. V. Prasad** I think we should go over to 60 million on an annualized basis. Let us see what upside comes.
- Ravi Agrawal** The second question was on the ROW markets and the growth of around 6%. When do we actually see the benefits from the GSK alliance from the emerging markets, actually begin to flow-in in terms of some of the numbers for ROW markets so, we had some sales coming from some markets last year.
- G. V. Prasad** Meaningful numbers post 2014.
- Anubhav Agarwal** I just want to understand the SG&A part slightly better. When you say for the Bristol facility the cost is \$5 million. Is that all the fixed cost which is included in SG&A?
- Umang Vohra** No SG&A has about \$2 million.
- Anubhav Agarwal** Okay, if we just look at SG&A sequentially excluding the amortization part, it has just increased by roughly around \$10 million. So \$2 million is for the Bristol facility. So, when you ramp up, let's say for the full year sales of \$60 million from the Bristol facility, what could the SG&A component look like?
- Umang Vohra** I don't think the SG&A will change too much.
- Anubhav Agarwal** It's fully factored in there. Should we consider this as true base to go forward for the SG&A part, or are there the some more costs other than factoring the normal increase in personnel cost every year.

- Kedar Upadhye** This could be considered as base except, where except the quarters where we might have to spend on OTC in Russia and other onetime expenses.
- Anubhav Agarwal** So, that incremental spend on the OTC in Russia would be for the future products but for the current products that you have in the market, the expense is very much there in the numbers would that be fair.
- Kedar Upadhye** Even for the existing products, the timing of various campaigns might be spread across various quarters.
- Anubhav Agarwal** Just to understand this slightly better, is the first quarter on a higher side or a much lower side in terms of OTC expense and for example if I look at SG&A number, it is 631 crores for this quarter excluding SG&A and the impact on VRS, what is an OTC expenditure part of this.
- Umang Vohra** We are not guiding to that level of granularity but if you were to look at maybe a quarter 3 or quarter 4 and our quarter 1, quarter 3 of last year, quarter 4 of last year and quarter 1 of this year, you will come to a rough average around the level that you are talking about.
- Anubhav Agarwal** The next question was just on the India business. You did mention about several products but on therapy basis can you just guide, which therapies are you facing the maximum pricing pressure? Is it like more within the acute side, is it like anti-infective or GI, can you help with that kind of slightly broader outlook?
- Umang Vohra** It is more on the acute and the cardio side.
- Anubhav Agarwal** Okay and not much of pressure on the anti-infective and GI so those.....
- Umang Vohra** So anti-infective doesn't really affect us too much because we don't have too big a portfolio on that.
- Anubhav Agarwal** Okay and just one more question on the gross margin on the PSAI segment, like sequentially they were down something from 27% to 24% level. Was it only the import alert because import alert essentially for you guys, came in at the fag end of the quarter right? What was the essential reason, was it just the problem on the service business?

- Umang Vohra** Yeah it was the service business problem and it was slightly higher input costs, which after the crude is corrected a bit, have began to even out.
- Anubhav Agarwal** Just a last question here on the tax rate, the true tax rates for this quarter is something like 17.5%?
- Umang Vohra** Well that's right 16% is a true tax rate for this quarter.
- Anubhav Agarwal** For the total business you have guided to 21% but for the base business its 16%, is it more representative number or something higher is a more representative number?
- Umang Vohra** 16% is the more representative for base case.
- Sameer Baisiwala** Can you update us on the two industrial accidents that had happened in December and then one after that in which we had two deaths each? Specifically, have regulators visited your Bolarum facility after that and could this culminate in to something more serious like a warning letter or import alert or something like that?
- G. V. Prasad** The accidents took place in our API facilities. One was a fire accident and another one was nitrogen caused asphyxiation in a confined space. In both these cases, investigations are going on. In one case, we have replied to a showcase notice, in another one the proceedings are going on. We expect some investigation and some regulatory action on this but nothing which should stop manufacturing or rather financial impact as such but there could be some action by the department.
- Sameer Baisiwala** Which department is it, a local authority or is it?
- G. V. Prasad** Local AP state authority. Director of Factories, which comes under the Ministry of Labour.
- Sameer Baisiwala** Okay but ever since then did you have regulators from foreign countries visiting in?
- G. V. Prasad** No this has no implication on foreign regulators. They have no jurisdiction on this.

- Sameer Baisiwala** Would FDA not at some point in time come over here and do inspection?
- G. V. Prasad** There is nothing to do with the quality of the product because there was an industrial accident involving people and equipments, so there was no product involvement.
- Sameer Baisiwala** Just update us on the Shreveport facility ramp up that you have mentioned on your previous call has that started or when should we expect that?
- G. V. Prasad** Part of the shift of manufacturing from here to there has slowed down because we have got additional business at Shreveport directly from our customers for some of the products that existed, when we purchased the facility and so hence you know the shift from India is slowing down. So the facility is fully utilized now and we are actually expanding the facility.
- Umang Vohra** Sameer, quarter 2 we should see some revenues on account of that.
- Sameer Baisiwala:** And I assume that you had a good fexo-plain OTC launch, has this been good enough to make up for what you have lost in the RX setting on a value basis?
- Kedar Upadhye** Yeah it would be Sameer, on a full year basis it could be.
- Sameer Baisiwala** Okay and just one final question on fonda pricing, is it something that is more or less in line with what happens with a one player market dynamics, plus authorized generic which is 20%, 30% erosion or is it something different than that.
- G. V. Prasad** We hope it will be like that.
- Nitin Agarwal** One is on the biosimilars front, you know even in the annual report we stressed quite a bit upon our capabilities in biosimilars and that being our medium term growth driver. So beyond the launches that you have done in India, how do you see the biosimilar road map really playing out for us over the next 2-3 years?
- G. V. Prasad** We have started registering the products in markets, which will allow us to register products on basis of the clinical trials we have done in India and some marginal additional trials. So that revenue, I think will become

significant by 2014 or so. But the real value unlocking will happen when the products are launched in the US and European markets. So for these, we have to do much bigger trials and our plan is to partner with somebody who has the expertise to do large scale clinical trials as well as detail and market the product in these geographies. So, in the meanwhile we are progressing the product and we had EMEA meetings. We have requested a meeting with the US FDA and the process of registering and doing the clinical trial will continue, we will not wait for a partner. But we believe that the full potential of the first few biosimilars from Dr. Reddy's portfolio will be unlocked only with a strong partner. So but you know these patents have to expire, we have to do the trials, we have to file. So they are a little bit away 2015-16 onwards.

**Nitin Agarwal** How material could the Rest of World opportunity is for you for these products?

**G. V. Prasad** I hate to put numbers but they will be significant.

**Nitin Agarwal** Okay and secondly in terms of India, how many new products in this biosimilars front you are looking to launch, we have already launched four, so how do you see that playing out in India per se.

**G. V. Prasad** I think we should launch another product by next 12 months and repeat that every 12 months.

**Nitin Agarwal** Okay and on the US business side we have got about \$129 million sales for the current quarter. So barring the launches that will come incrementally for the existing bunch of products, is it like a base that is pretty much safe to assume that?

**G. V. Prasad** Yeah pretty much safe to assume that is the base.

**Nitin Agarwal** And in terms of the pace of the market share addition, which is there on lanso and tacro and is it still significant upside left in terms of more market share gains or we are kind of maxing out on market share gains that you can have on these products.

**G. V. Prasad** Some products there is headroom left but not all.

- Nitin Agarwal**                    Lastly how many products are we looking to launch during the year going forward.
- G. V. Prasad**                    I think something like 10-12 products.
- Umang Vohra**                    Yeah about 10 in the US.
- Nitin Agarwal**                    And barring the 2 or 3 that we have talked about in terms of niche opportunity, all of them are going to be plain vanilla or they are going to be some interesting launches even in the ones that we have not really specifically mentioned.
- G. V. Prasad**                    I wish I could predict that with great accuracy because sometimes what we think is plain vanilla turns out to be big winner and sometimes what we think is big one, turns out to be a very competitive product. But I do think there is a significant possibility there.
- Saion Mukherjee**                Just one question on the Mexico facility and the impact of import alert, given that now we are allowed to market naproxen. What is overall yearly impact that you see because of the import alert?
- Satish Reddy**                    See roughly from the Mexico facility, we had a sale of on an average of about \$60 million a year. So you are looking at naproxen, which is half that and you know there are some other products also, that is the extent of the hit, if you should take it based on what you have just said.
- Saion Mukherjee**                Around \$30 millions.
- Satish Reddy**                    30 is full year by the way.
- Saion Mukherjee**                On the R&D cost, Prasad you mentioned about, you know increased or a step-up in R&D spent because of the complex filing of biosimilars and proprietary products. What is the level of R&D spend that we could expect. What is the level of step up that you are kind of looking at in absolute level?
- Satish Reddy**                    Yeah I think in the past we used to be around 6% of the sale. Even in the first quarter, we are roughly around that. I think what we have generally guided is that we should be about 7-7.5% of sales. That is what we expect it to be,

which is quite significant as a step up because by looking at sales increasing and then we are saying of a percentage and half increase on top of that.

**Saion Mukherjee** So basically you know if you are talking about 2.7 billion in FY13, so we could expect around 7% of that to be the R&D spends?

**Umang Vohra** That is right 7-7.5% Saion, on some of the biosimilars trials as well.

**Surjeet Pal** As you say, you will be targeting 40% of the fonda market in US, which is mainly retail and wholesale and 60% hospital and since it is an injectable product. So I was thinking, that since there is talk about AG and if AG is given to any established hospital generic guys like without mentioning any name, like those who are already available in US. Do you think that will have a dent on the potential revenue for your product?

**Umang Vohra** We don't think so for several reasons because like I mentioned before this is not a complete GPO type of a product and we are vertical on this product and we have the best cost position on it.

**Surjeet Pal** So you believe any established guy in the top three hospital distributors in US, if they get the AG it will not impact your potential as you know even in hospitals segment.

**Umang Vohra** See any AG will impact our potential revenue but we are quite confident of retaining relatively large market share over time.

**Surjeet Pal** Another point is that, as you were saying is that you are also putting money on proprietary technology through R&D expenditure and going by the kind of niche product as fonda has. Are you planning or do you have in your pipeline any similar carbohydrates synthesis based products which are pretty complex in nature and your team has done a fantastic job by scaling up of a successful doing. So do you have any product in pipeline or any expectation in say next two years time?

**Umang Vohra** We have products in our pipeline which are very complicated and require characterization like fonda required and we have got a nice emerging pipeline of that.

- Prakash Agarwal** Just one question on the gross margin side if you look at Q1 2012 and Q1 2011, not much of an improvement in spite of few large high value-high margin products being there for the last two-three quarters. So any particular reason or is it because of the lower domestic business growth which is again a high margin product for you.
- Kedar Upadhye** You know it is function of variety of factors. You know partly the cost of the new facility in US; you know that portion has come in the cost of goods sold, that is one factor. Secondly what you rightly mentioned is that, the proportion of India is a bit lower this quarter. So it is result of a number of several factors like this.
- Prakash Agarwal** And just going to Russia, I mean we all are aware of this Pharma 20/20 which is spread across 3-4 step functions, specially talking about 2013-2017 where it aims to replace 50% of the imported generic drugs with locally produced products. Is there a strategy which we have in terms of buying out a local body or setting up our own facility because what I understand is that, we are currently a marketing company in Russia?
- Satish Reddy** I mean we still have to wait to see how it actually plays out, it is not as simple as just stating that this is what the government wants to do and then it will just happen overnight . So there will be a lead time by the time it will happen and then I think each company will formulate its own strategy. So currently, we don't have any immediate plans to acquire anything local or any such thing. There are several options to it, which we are still evaluating. As things keep progressing, we will take a stance on that but there is no tearing hurry to get into any one of this concern.
- Prakash Agarwal** Okay and on the tax rate, I think I missed something what Umang said was 15% on an annualized basis or 21% given the olanzapine being on the second half.
- Umang Vohra** So let's say without olanzapine we are at 16% or with olanzapine we are at 21%.
- Prakash Agarwal** On a full year basis?

- Umang Vohra** That is right and that is why this quarter, what we normalized to 16.
- Prakash Agarwal** Okay so going forward, we would see a much higher tax rate than the annualized 16%.
- Umang Vohra** You would see higher than the 16 in the quarters where we have the exclusivity and around 16 in the quarters that we don't have.
- Prakash Agarwal** Perfect and any more colour you could give on Lipitor. I mean last we heard that you had a 30-month stay around May or something can you throw some more light there?
- Umang Vohra** We cannot comment on that right now. We choose not to comment on that please.
- Prakash Agarwal** But we are definitely there in that product, that is what I wanted to understand.
- Umang Vohra** Yes, we are on that product but I can't comment on the exact dynamics of it right now.
- Nimish Mehta** I actually missed the number that you mentioned from the penicillin facility. How much sales have you booked for this quarter if you can just repeat that.
- Kedar Upadhye** We have booked \$4 million.
- Ashwin Agarwal** Indian companies were very high in quality but recently we have seen many Indian companies in general getting FDA warnings, so have FDA regulations become more stringent?
- Satish Reddy** I would just say Ashwin that FDA scrutiny generally has increased for the past couple of years which was a stated intent. I don't think it targeted just at Indian companies, generally for all the companies it has happened. So we have seen multinational companies, we have seen large generic international companies, a lot of Indian companies with those issues.
- Ashwin Agarwal** Right one more observation I have seen, the time gap between a warning letter and an import alert has reduced significantly. Any reason that they

don't want companies to fill the pipeline in the US which you can market or what has been the reason?

**Satish Reddy** I mean I don't know particularly why that is; it is something that the regulator should answer.

**Chirag Talati** If you look at your annual report for FY11, then the DEPB credits and other related credits have gone up materially as a percentage of sales, almost doubled or more than doubled. How should we look at it going forward, if that goes down could we see it hurting your margins for say FY12 and FY13, how should we look at it?

**Umang Vohra** It should not impact the margins materially because I think the government will also announce a separate scheme or extend the DBK scheme with possibly a higher rate. So we don't expect too much of an impact on margins. However, the numbers that you are seeing in our annual report also is an outcome of what we sold in terms of Fexo-Pseudo into the market. So for the jump that you are seeing includes that.

**Chirag Talati** Okay fine and one question, could you update us on how the business has evolved for Promius Pharma as a whole and how do you see that going forward and some update on your terbinafine product for which you had phase three already enrolled?

**Umang Vohra** Though the terbinafine trials are ongoing, we have not got an early read kind of a methodology for that trial and we hope to receive data from that over the next one year. On proprietary products our business is approximately \$20 million in size and we are hoping to add more from our pipeline to take that higher as we go along.

**Chirag Talati** I mean you acquired Cloderm, so how should we see the potential of that product in terms of peak sales going forward.

**Umang Vohra** We aren't guiding to that as yet Chirag, we are not guiding by each product sale but the rationale for that acquisition was to enable us to be a little bit more critically sized on the Promius space.

**Chirag Talati** Yeah okay thanks that answer my question. Thank you.

- Vidhya Bharati** Yeah just on the margins, as you said from June onwards you have actually started supplying for the AOK tenders. How much was an erosion you are seeing going forward, or are the margins made this time sustainable what is your take on it sir?
- Kedar Upadhye** Vidhya, we don't want to comment on the specific margins related to the AOK tender but what we said is, for the overall Germany business that shows from the year-on-year price compression, we could see some margins dip. Although at an overall consolidated financials, we don't see there would be any noticeable impact.
- Vidhya Bharati** On the annual average figure, you said around 5 million for the GSK penicillin facility, does that include the one you told you will launch now from quarter 3, and does 60 million odd annual figure includes that?
- Kedar Upadhye** Yeah so it might be phased in the respective quarter in which the launch happens. So what we say is that the monthly range could vary and on an average basis it could settle down to about \$5 million or so, again this is a forward looking statement.
- Vidhya Bharati** Okay on the R&D focus, if you could just re-emphasize on your focused therapy areas you were looking at going forward because you said your filings are going to come down and it could be more on a complex product based filings, so if you could re-emphasize where you are focused right now?
- Kedar Upadhye** It will be from the US side, it will more dictated by the patent expiries and as of now we don't have any therapy bias in the portfolio. But from a complexity perspective you know we would like to increase the proportion of characterization led new products because that is where our strength lies.
- Vidhya Bharati** On the devaluation of currency which happened in RoW markets you mentioned are, you actually changing the strategy towards your hedging policy or will this impact flow through other quarters also how will that play out.
- Kedar Upadhye** To the specific markets in which we faced this devaluation challenge were Venezuela and Belarus and we don't believe a cost effective hedging solution

is available for these markets and given that devaluation has already happened, obviously the effect will flow through in the coming quarters.

**Vidhya Bharati** Okay thank you so much sir that is all from my side.

**Kedar Upadhye** We thank all for joining Dr. Reddy's Senior Management for the earnings conference call for Q1 FY12. In case you need any additional clarification, please feel free to get in touch with Raghav, Milan or myself. Thank you and good evening to all of you.

*Note: Necessary edits have been made in this document to correct for any factual inconsistencies.*