Sun Pharma Q4 & FY 2013-14
Earnings Call Transcript
10:00 am May 30, 2014

Corporate Participants

Dilip Shanghvi
Managing Director, Sun Pharmaceutical Industries Ltd.

Sudhir Valia
Whole time Director, Sun Pharmaceutical Industries Ltd.

Moderator: Ladies and Gentlemen, Good Day and Welcome to the Sun Pharmaceuticals Q4 & Full Year FY14 Results Conference Call. As a reminder, all participants' lines will be in the listen-only mode. There will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal an operator by pressing '*' then '0' on your touchtone telephone. Please note that this conference is being recorded. I now hand the conference over to Mr. Nimish Desai. Thank you. And over to you sir.

Nimish Desai: Thank you. Good Morning everybody and a warm welcome to our 4th Quarter & Full Year FY14 Earnings Call. I am Nimish from the Sun Pharma investor relations team. We hope you have received the Q4 & FY14 financials and the press release that was sent out yesterday. These are also available on our website.

We have with us this morning Mr. Dilip Shanghvi – Managing Director and Mr. Sudhir Valia – Whole Time Director. Mr. Abhay Gandhi, the CEO of our India business is on leave and is unable to attend the call today. Today the team will discuss performance highlights, update on strategies and respond to any questions that you may have. As is usual, for ease of discussion we will look at the consolidated financials. Just as a reminder this call is being recorded and a replay will be available for the next few days. The call transcript will also be put on our website shortly.

The discussion today might include certain forward-looking statements and these must be viewed in conjunction with the risks that our business faces. You are requested to ask two questions in the initial round. If you have more questions you are requested to rejoin the queue. I also request all of you to kindly send in your questions that may remain unanswered today.

I will now hand over the call to Mr. Shanghvi.

Dilip Shanghvi: Welcome and thank you for joining us for this earnings call after the announcement of financial results for the 4th quarter and full year FY14. Let me briefly update you on significant events.

In April-2014, Sun Pharma proposed the acquisition of Ranbaxy in an all-stock deal valued at an Enterprise Value of about US$ 4 billion. The swap ratio has been fixed at 0.8 share of Sun Pharma for every 1 share of Ranbaxy. This highly complementary combination will lead to significant value creation opportunities and wealth for shareholders, driven by the strong positioning that the merged entity will

enjoy in the US, India and Emerging Markets. On a pro forma basis, for calendar year 2013, the combined entity's revenues are estimated at US$ 4.2 billion and EBITDA at US$ 1.2 billion. The merged entity will be able to generate synergy benefits of about US$ 250 million by the third year post closure of the deal. These would be driven mainly by a combination of revenue, procurement and supply chain synergies. The deal is subject to customary regulatory approvals and is expected to close by end of 2014.

In March 2014, we received an import alert from the US FDA for our cephalosporin facility located at Karkhadi. This import alert was issued by the US FDA as a follow up to the last inspection of the facility. We also received the warning letter related to this import alert subsequently in May-2014 identifying some potential data integrity issues. The language in the warning letter is in line with the language used in other similar cases.

In this process, we have learnt and have resolved to work on further strengthening our systems and controls. The company remains fully committed to compliance and has already initiated several corrective steps to address the observations made by the US FDA, not only at this site but also to strengthen our processes across the other sites. We remain confident and determined to come out of this as a stronger and better managed organization.

In FY14, we continue to enjoy the benefits of favorable pricing of certain generic products in the US. As indicated earlier, these benefits may not be long lasting.

I will now hand over to Mr. Valia for discussion of the Q4 & FY14 performance.

Sudhir Valia: Thank you Mr. Shanghvi. Good morning everyone and welcome to all of you. Our Q4 & FY14 financials are already with you. Before we discuss the financials, let me highlight that the US dollar was at a higher rate as compared to last year. The resulting growth in rupee-reported sales and profit on account of that may not be sustainable. As usual, we will look at key consolidated financials.

Q4 net sales are at Rs.4,044 crores an increase of 32% over last year. Material cost, staff costs and other expenditure as a percentage of the net sales are at 17%, 13% and 26% respectively, all lower than lower than Q4 last year.

As a result of the above, the EBITDA recorded in Q4 is Rs.1,786 crores as compared to Rs.1,260 crores for Q4 last year, a growth of about 42%. EBITDA margins were at 44% for Q4 compared to 41% for Q4 last year.

Net profit for Q4 was Rs. 1,587 crores registering a growth of 57% over net profit of Rs 1,012 crores for Q4 last year. On post-bonus basis, EPS is Rs.7.7, compared to EPS of Rs.4.9 that we had earned for Q4 last year.

Now, we will discuss the full year FY14 performance. Net sales were at Rs.16,004 crores an increase of 42% over the full year FY13. Adjusted for the impact of lower India sales in Q1FY13, the net sales for full year have grown by approximately 40% over FY13. On constant exchange rate, our revenue growth for FY14 was 31%.

Material cost, as a percentage of the net sales is 17% which is lower as compared to full year FY13 primarily on account of better product-mix. The staff costs for the full year is at 13% of the net sales which is slightly lower compared to FY13. Other expenditure was at 25% of the net sales, higher than that of the full year FY13.

As a result of the above the EBITDA for the full year is at Rs. 7,120 crores a growth of 45% over the full year FY13. EBITDA margins were at 45% for full year compared to 44% for FY13.

Recurring net profit is at Rs. 5,722 crores, a growth of 60% over FY13. The net profit after provision for generic Protonix is Rs. 3,204 crore compared to Rs. 2,983 crores for FY13. On a post-bonus basis, adjusted EPS is Rs.27.6, up from Rs.17.2 for the full year FY13.

Taro recently posted Q4 FY14 sales of US$ 187 million, up 13% from the corresponding quarter last year. For the full year, sales were US$ 759 million, up by 13% over full year last year. Taro's net profit for Q4 was US$ 90 million, up by 82% over Q4 last year. Net profit for full year FY14 was at US$ 360 million, up by 35% over the same period last year.

I will now hand over to Mr. Shanghvi, who will share the performance of our various businesses.

Dilip Shanghvi: Thank you Mr. Valia. I will first take you through our India formulation business.

For Q4, sale of branded prescription formulations in India was Rs. 947 crores, up by 21% from Q4 last year. For the full year FY14, sales were at Rs. 3,692 crores, higher by 25% over same period last year. Normalizing for lower sales in Q1FY13, adjusted growth was at 17% for full year FY14. This growth has been achieved despite the implementation of the new pricing policy and trade channel disruptions.

As per March-2014 AIOCD-AWACS report, Sun Pharma is ranked 2nd and holds 5.4% market share in the Rs.75,000 crores pharmaceutical market. The company continues to be ranked no. 1 based on share of prescriptions with 7 classes of specialists: psychiatrists, neurologists, cardiologists, ophthalmologists, orthopedicians, nephrologists and gastroenterologists.

We continue to find the Indian market as interesting as ever. In this intensely competitive market, we continue to look for innovative ways to differentiate our product portfolio, build customer trust and add prescription share.

Now I will briefly touch upon the performance of our businesses across other segments as well as our overall performance in the US.

For Q4, our overall sales in the US were at US$ 403 million, which is higher by almost 22%. For the full year FY14, sales were at US$ 1,620 million recording a growth of 43%.

For Q4, formulation sales in the rest of the world market were flat at US$ 72 million over Q4 last year. And excluding Taro's non-US sales, Sun's RoW sales for the quarter and full year were up by 9% and 16% respectively in dollar terms.

Our API business has strategic importance for vertical integration on key products. External sales of API reached Rs. 222 crores in Q4FY14, an increase of 31% over Q4 last year. For full year FY14, API sales were at Rs. 801 crore, a growth of 6% over FY13. The lower growth for FY14 is mainly on account of increased captive consumption.

R&D expenditure for Q4 was Rs.308 crores at 7.6% of sales. For full year, R&D spend was Rs. 1,042 crores at 6.5% of sales. This R&D spending enables development of future product pipeline including differentiated products.

In Q4, ANDAs for 10 products were filed, while we received 4 approvals from the US FDA. We now have 344 ANDAs approved for a total of 478 products filed with US FDA, and ANDAs for 134 products await approval. On a consolidated basis, we now have 573 patent filings with 346 granted patents.

For FY15, we expect our consolidated revenues to grow by 13-15%, R&D spend at 6-8% of revenues, 25 ANDA filings targeted in US and capex of Rs. 900 crores. The guidance takes in to account the higher base of FY14 as well as the risks associated with increase in competition for some products. Guidance is at constant exchange rate and excludes the impact of the proposed acquisition of Ranbaxy pending the deal closure.

With this I would like to leave the floor open for questions. Thank you.

Moderator: Thank you. We will now begin the question-and-answer session. The first question is from the line of Anubhav Aggarwal of Credit Suisse. Please go ahead.

Anubhav Aggarwal: One question on the notes-to-account you have in your release, where you have mentioned about deal with third-party for about US$400 million reimbursement. Some questions here; I could not understand why is this deal related to Protonix, and why is it not an independent deal?

Sudhir Valia: We have done this transaction to manage our cash flow and the debt in a better manner.

Anubhav Aggarwal: The question Mr. Valia is that, somehow probably I have still not understood that. This could have been absolutely independent deal where you supply to a third-party…

Sudhir Valia: It is always possible.

Anubhav Aggarwal: But why you have in your press release mentioned that in order to…

Sudhir Valia: We need the money to enhance our cash position since we have paid for the Protonix settlement.

Anubhav Aggarwal: There are two parts: does this money, all US$ 400 million come to you upfront?

Sudhir Valia: Yes, that is the arrangement.

Anubhav Aggarwal: So it comes to you. And if this deal was not there, would your FY15 guidance be any different?

Dilip Shanghvi: Our FY15 guidance would not have been different.

Anubhav Aggarwal: So the products that you are going to supply…

Dilip Shanghvi: It is only linked with our debt capacity. There are restrictions about automatic approval on how much we can invest. So to conserve our overall ability to raise debt for any future acquisition, this deal is structured in this way.

Anubhav Aggarwal: Mr. Shanghvi, a clarity here; this year are you going to supply any product to third-party? When you supply them, would this amount be booked in sales or there will not be any supply this year to the third-party under this arrangement?

Dilip Shanghvi: There will be supply and it will be captured in the sales.

Anubhav Aggarwal: That's exactly what I was asking when I asked the question that, if this deal was not there, would your guidance would have been any different?

Dilip Shanghvi: No, it will not have been higher than what we have guided.

Anubhav Aggarwal: So it is a negligible amount, you are saying that. And just last clarity on this question that, this deal is with an innovator company for a branded product or a generic product?

Sudhir Valia: Generic products.

Anubhav Aggarwal: This deal is with an innovator company?

Uday Baldota: It is a third party; let us not further characterize it.

Anubhav Aggarwal: Second question was on the India business. Let us say all companies are allowed to take price increase starting April. But when you ship the products in late of March, the last shipment for you would already have the benefit of the price increase or all of that price increase benefits will only from the primarily sales comes in the June quarter?

Dilip Shanghvi: Our overall guidance factors in the marginal impact of price changes in India business would be and which generally is not very high. Over the last 10 years, our historical average price increase has been around 2%.

Moderator: Thank you. The next question is from the line of Sameer Baisiwala of Morgan Stanley. Please go ahead.

Sameer Baisiwala: I understand that your FY14 presents a bit of a high base and little unusual circumstances, therefore your top line guidance for FY15 is 13% to 15%. But looking beyond that… and I am not asking for a longer-term quantitative guidance, but would FY15 be a sort of an adjustment year and thereafter you are going to resume the higher growth that you have always aspired for?

Dilip Shanghvi: We have to factor in additional stress on the system on account of effort involved for integrating Ranbaxy. Also I think the focus would be to find a way to revive the growth of the Ranbaxy business and which we feel reasonably comfortable looking at historical growth that Ranbaxy used to have previously.

Sameer Baisiwala: So beyond one year, that would be the additional factor that you would look for, but on a Sun standalone basis, things do not change?

Dilip Shanghvi: Once we integrate with Ranbaxy, there is no Sun standalone.

Sameer Baisiwala: The second question I have is related to capex and I think for the last couple of years and for FY15 you are again guiding Rs.900 crores and that has been a bit of a ballpark Rs.800-900 crores capex that you are doing. But the sales base has been increasing much faster. So the question here is that, how do you think about manufacturing in-house versus getting it done through third-party as you go forward? And second, as your growth aspirations remain high and base is much higher, would you not be required to ramp up the capex?

Sudhir Valia: The capacity which Ranbaxy has built is huge.

Dilip Shanghvi: So if we are able to bring those facilities back in compliance, which would be our focus, then to that extent, the need for expansion will be lower.

Moderator: Thank you. The next question is from the line of Girish Bakhru of HSBC Securities. Please go ahead.

Girish Bakhru: A question on Gleevec settlement, if you could clarify… when you launch in Feb'16, would you be the exclusive player along with the AG perhaps?

Dilip Shanghvi: Our agreement with Novartis precludes us from sharing additional information beyond that shared in the press release.

Girish Bakhru: But on the basis of the case that you did not get sued on the product and there may be many other filers who have not been sued, any color you have if they would have a leeway to enter, say, post your six months or would they be entering much later?

Dilip Shanghvi: I do not think we can share anything beyond what is shared in the press release.

Girish Bakhru: On Taro side, last quarter there was NDA pending approval and it does not show now. Has the product got approved? What has happened there?

Uday Baldota: We do not have this information ready with us. We will come back to you.

Girish Bakhru: Just related to that, Ovide lotion would not be the product that you in-license from Suven, that would not be the product that you have been referring to the NDA, right?

Dilip Shanghvi: No.

Girish Bakhru: Any color on the size of the Malathion lotion overall in the US market?

Dilip Shanghvi: It is not a very large product

Moderator: Thank you. The next question is from the line of Sonal Gupta of UBS Securities. Please go ahead.

Sonal Gupta: You recently announced the closure of the Caraco facility, which seems a bit strange given that it was almost coming back into compliance, you were ramping up products. So I just want to understand the thought process on why you chose to close down that facility out of so many options

that you had and what is the thought process going forward now, like you mentioned that eventually once Ranbaxy is merged, you will again have a lot of capacity? So what is the plan on in terms of on the manufacturing rationalization side, if any?

Dilip Shanghvi: We had significant more capacity in the US than what we needed over the next 3 years to 5 years. So we had to decide on one location which we needed to shut down. Then finally we decided that it will be the Detroit facility. Post closure of Ranbaxy transaction, we will do detailed internal manufacturing review to understand what would be our plans going forward.

Sonal Gupta: My second question is on again this third-party contract; can you just tell us what is the tenure of this contract?

Dilip Shanghvi: We have not disclosed the duration of the contract.

Sonal Gupta: The way it looks like it might impact your sales, but it will not probably help you too much on the EBITDA level. So in a sense, it will sort of a boost top line, whatever impact on margins is not very clear, right?

Sudhir Valia: Top line will go down; margin impact will not be there as we have made provision in the current year.

Sonal Gupta: But you are supplying, right, so you will book sales?

Sudhir Valia: The supply will reduce our top line, but since we have provided for it during the year, it will not impact the bottom line.

Moderator: Thank you. The next question is from the line of Aditya Khemka of Ambit Capital. Please go ahead.

Aditya Khemka: So in the 4Q, I was a little surprised to see improvement in gross margins on a consolidated level, seeing that Taro actually did not perform as well in 4Q as it did in 3Q and also some of your large niche products in US had incremental competition, Imitrex and ending of generic Prandin exclusivity. So could you help us understand what is driving this gross margin?

Dilip Shanghvi: It is essentially product mix.

Aditya Khemka: Sir, any of the new launches that you made in the US during the fourth quarter, which may be helping or is it the base business which is sort of helping the gross margins in that sense?

Dilip Shanghvi: Both; some of the new products as well as strengthening of our existing products.

Aditya Khemka: On the Ranbaxy acquisition side, our understanding on the legal requirements or the approval requirements, is it still where it was when you announced the acquisition that is 75% of the shareholders present and voting or has that understanding changed till now?

Dilip Shanghvi: I do not think there is any change in the law.

Aditya Khemka: Your tax rate in the fourth quarter was very low; 6% odd I guess. So what is the tax rate that we should be expecting for the next two years?

Dilip Shanghvi: It will be near to the FY14 tax rate or slightly higher than that.

Moderator: Thank you. The next question is from the line of Neha Manpuria of JPMorgan. Please go ahead.

Neha Manpuria: My first question is on the India business. Sir, the price act that we have taken in April for NLEM and non-NLEM, what is your stand on the margin discussion with the channel partners – has some of the price increase actually been used to offset the margin cut? The margin discussion with the channel partners, with the traders, so has there been any change in that?

Dilip Shanghvi: No.

Neha Manpuria: The other income has gone up significantly on a quarter-on-quarter basis. Is there some one-off amount in that number?

Dilip Shanghvi: It is higher mainly due to currency fluctuations.

Moderator: Thank you. The next question is from the line of Prakash Agarwal of CIMB. Please go ahead.

Prakash Agarwal: First question on the Doxil; if you could help us understand the present competitive scenario – are we still the sole player and what is our sense on J&J coming in that?

Dilip Shanghvi: J&J got approval for selling one batch and so they are still there in the market.

Prakash Agarwal: But very small?

Dilip Shanghvi: I would not know the size.

Prakash Agarwal: Just trying to understand Taro, if you look at the current quarter performance, you have always been guiding that the past performance would be unsustainable, given the fact there would have been price hikes. So would this be a normalized performance and we should look similar kind of growth going forward growth in margins?

Dilip Shanghvi: We cannot share any information beyond what Taro has shared with their investors. But our consolidated guidance factors in the overall performance of the company.

Prakash Agarwal: On the RoW business, we see you give rupee numbers as well as dollar numbers. So what is the percentage of billing in dollars and what is the right way of looking at it – should we look at dollars more or from the rupee side?

Dilip Shanghvi: Almost 95% of RoW business would be in dollar terms.

Prakash Agarwal: And the split in Taro sales in US and RoW?

Uday Baldota: You need to wait for Taro's disclosure.

Moderator: Thank you. The next question is from the line of Manoj Garg of DSP Merrill Lynch. Please go ahead.

Manoj Garg: This question is with regard to the recent warning letter, which has been updated by FDA where they have indicated that the observation may result into the delay in the product approvals from other plants. So just want to understand like how do you see… it is going to impact your approvals from other facilities, because of this warning letter?

Dilip Shanghvi: It is difficult for me to respond, but if we look at what has happened after the import ban, we have received approvals. After the warning letter, we have not received any approval. But our consultants advise us that this warning letter is specific to the plant. So we have to wait till we get an approval somewhere to have complete clarity.

Manoj Garg: Second thing is while you have given the guidance for the top line, and in the past you have indicated about some of the price hikes, which may not be sustainable in future. So just want to understand about your outlook on the margins – do we see the margins to be sustaining at the current level or there could be some consolidation which may happen on this side?

Dilip Shanghvi: Generally, we prefer not to give guidance about margin. Our effort always would be to find a way to sustain the margin, but clearly, if some of the high margin products come under increased competition, we may see some erosion in terms of margin.

Moderator: Thank you. The next question is from Bino Pathiparampil of IIFL. Please go ahead.

Bino Pathiparampil: If I understood correctly, the provision related to this US$400 million deal is taken in the current year, is all of that appearing in 4Q or is it spread across? Regarding this discounted supply of products worth US$400 million in future to a third-party, I believe what I heard is that you have taken a provision related to that discounted pricing in the current year?

Sudhir Valia: Yes, it is correct.

Bino Pathiparampil: The entire provision, is it appearing in the 4Q P&L, or is it spread across several quarters?

Uday Baldota: It is spread across quarters.

Bino Pathiparampil: It would be coming in the other expenses line item?

Uday Baldota: Yes.

Moderator: Thank you. The next question is from the line of Manish Jain of SageOne Investment Advisors. Please go ahead.

Manish Jain: Merck got an approval for Doxil as Caspria in a lot of markets outside US. Is Sun supplying this to Merck?

Dilip Shanghvi: Yes.

Moderator: Thank you. The next question is from Chirag Dagli of HDFC Mutual Fund. Please go ahead.

Chirag Dagli: If I look at the press release, we have indicated a recurring PAT number of Rs.5,722 crores and if I compare that with our PBT before exceptional items, the effective tax rate on a normalized basis comes to about 21%. While you are guiding to a smaller number, going forward, will this be 21% or will it be lower?

Uday Baldota: I think we will need to take this offline. I am unable to understand this 21% computation.

Chirag Dagli: On the 2% gap in the R&D spend guidance, amounts to on an absolute basis to almost Rs.350-odd-crores. If you can give some flavor of what is happening at the R&D front, where we have uncertainty around projects worth Rs.350-odd-crores, 2 percentage, why this variation is what I am trying to understand?

Dilip Shanghvi: I think our guidance for R&D spending was 6% to 8% of revenues and we closed the year at 6.5%. So it is not significantly different from what we had guided. R&D projects move at their own speed even if we want them to move much faster.

Chirag Dagli: But these uncertainties is coming from clinical trials that we might have to do or is it about increasing number of projects that will get you?

Dilip Shanghvi: Both, I think there are costs associated with various aspects of development phase and clinical trial would be a large amount of that cost, but there will be other costs also. So if the project moves fast, then that money will be spent this year. If it moves a little bit slow, then it will be spent next year.

Chirag Dagli: Are Doxil sales on a quarter-on-quarter basis very volatile, as in very different?

Dilip Shanghvi: We do not give out product specific information on quarter-on-quarter basis, but in the US where you have large customers; there would be certain amount of inconsistency on quarter-on-quarter basis. Our India business will be much more consistent because we have large number of small customers.

Moderator: Thank you. The next question is from the line of Meeta Shetty of HDFC Securities.

Meeta Shetty: Just on the tax front, I actually missed the number that you shared for FY15 & FY16?

Uday Baldota: We did not share a particular number; we just said it will be broadly in the range but slightly higher than the FY14 number.

Meeta Shetty: So it will be in the range of 17%, 18% is what I can draw?

Uday Baldota: I think what we said is broadly in the range where we are but slightly higher than the current year.

Moderator: Thank you. The next question is from the line of Nimish Mehta of Research Delta Advisors. Please go ahead.

Nimish Mehta: Can you update us on the likelihood of Doxil launch in Europe, when are we expecting this? And in general, the Europe business, some color, now that we have a portfolio of products which are high value in the US market, how are we looking at launching of all of those products in the European markets?

Dilip Shanghvi: We are not able to give any guidance about European launch of Liposomal Doxorubicin. Europe business also is not a very large part of our overall business. We are not guiding specifically for European business. Once I think that this comes to a certain size, we will give you separate information related to that business.

Nimish Mehta: How big would be the Doxil market in Europe?

Dilip Shanghvi: My understanding is that, for Johnson & Johnson, it used to be in the region of US$200 to US$250 million.

Nimish Mehta: A couple of quarters back you mentioned that you are in the process of filing Lupron Depot in the US market. So how have we moved there, and what can you…?

Dilip Shanghvi: We will not be able to give you product specific filing plans.

Moderator: Thank you. The next question is from the line of Saion Mukherjee of Nomura. Please go ahead.

Saion Mukherjee: Two questions; Firstly, it would be great if you can share some thought on customer consolidation and the pricing environment in the US, what you are seeing and how you think it would play out?

Dilip Shanghvi: I think ultimately between 3 or 4 customers, more than 80% of the business will get consolidated. So it would reduce our ability to negotiate in terms of price as a manufacturer. It should affect more or less all the manufacturers to some extent.

Saion Mukherjee: But have you already seen some impact of that yet?

Dilip Shanghvi: I am not actually very directly involved with this, but I am sure there would have been some impact and that would have been felt in our performance.

Saion Mukherjee: Regarding the R&D and the US filing, we had I think 29 filings this year, 20 plus last year, now you have guided for 25. So you think this 20--25 kind of filing is something which we would continue to see let us say over the next three years? I am just trying to look at the opportunity in slightly longer term, how are you thinking about the organic part of the US business given the base that we have currently?

Dilip Shanghvi: We remain very excited about the US business and opportunities that the business provides. The filings are a function of our capability to file. Our effort would be to strengthen our capacity to file more products.

Saion Mukherjee: In terms of opportunities, you think there is enough opportunity to pursue in the US in terms of addressing something like 20-25 kind of filings every year?

Dilip Shanghvi: Yes.

Moderator: Thank you. The next question is from the line of Anubhav Aggarwal of Credit Suisse. Please go ahead

Anubhav Aggarwal: One question on the Karkhadi plant. Can you confirm, Mr. Shanghvi that the systems that you have there are very materially different from the other plants? For example, in one of the observations, FDA pointed out its inability to track deletion activity. Would your systems at Halol or the other plants be materially different than this?

Dilip Shanghvi: Yes, Halol and all would have more advanced systems. We would still have certain standalone analytical equipment which is not integrated with the central system. So, we are now looking at how to resolve that, so that we can ensure, through systems and processes, that there are no potential data integrity possibilities.

Anubhav Aggarwal: A general question related to this Karkhadi observation only is that there was observation related to performing unofficial testing. Now, is this a change at FDA practice? FDA always had the same stance towards this and only recently they have started pointing out of performing unofficial testing by the Indian companies or let us say by the generic companies. The question is basically that was the guidelines from FDA always the same and now they are strictly implementing it that more companies they are trying to mention about the practice of this unofficial testing?

Dilip Shanghvi: My understanding is that there is no change in the FDA expectation, this was always there.

Anubhav Aggarwal: Because the question was the last time your Karkhadi plant was inspected it was absolutely clean, no 483s and now so many observations, so that is why I was…

Dilip Shanghvi: I think you have to understand that any audit is a function of the observations at that point of time and of the systems which were audited. So a clean inspection does not mean that you will never get any observation in future. So I think FDA is working with various organizations so that it is able to develop a more comprehensive understanding of the quality and systems in a plant on an online constant basis rather than looking at it at a point of time when the plant is being inspected.

Anubhav Aggarwal: Last question is on Doxil, with J&J now back into the market, do you expect that the market may expand in terms of prescription or value now?

Dilip Shanghvi: It depends on what kind of effort they put behind the product and what is the competitive scenario in the approved indication.

Anubhav Aggarwal: But so far, with them back for about three months now, you have not seen anything materially different?

Dilip Shanghvi: No we have not seen anything.

Moderator: Thank you. The next question is from the line of Dheeresh Pathak of Goldman Sachs. Please go ahead.

Dheeresh Pathak: Just trying to understand this third-party agreement a little better. As per my understanding we had a total liability of about US$550 million, of which in FY13 we have provided for US$106 million and in Q1 of FY14 you had provided for the balance. To a question of the earlier participant you had said that this is shown in other expenses over the last three or four quarters, but this was shown as an exceptional item in Q1 of FY14 and now that once you already provided for it, it should not impact our P&L in the coming year. Can you just explain how the accounting has worked and how it will work in FY15 for this?

Uday Baldota: Let us connect offline and we will help you understand.

Dheeresh Pathak: Other question is on the US sales, which is basically manufactured in India, that is your plants in Halol and Dadra, when were they last inspected?

Dilip Shanghvi: I do not have a date, but they would have been inspected less than 2 years back, because both the plants are in compliance. Typically if a plant goes beyond 2 years for an inspection, it may need to be inspected again.

Dheeresh Pathak: Is it possible for you to share what percentage of US revenues comes from these two plants?

Dilip Shanghvi: No, it is not possible.

Moderator: Thank you. The next question is from Sonal Gupta of UBS Securities. Please go ahead.

Sonal Gupta: How many products have you filed for the year?

Dilip Shanghvi: That is there in the press release.

Sonal Gupta: It says 10 for the quarter; it does not say what is for the year.

Nimish Desai: We filed 27 products in the year.

Sonal Gupta: Just again coming back to this warning letter, it says that you need to have a comprehensive valuation of your global manufacturing operations and potentially hiring a consultant. Are you doing something on that regard?

Dilip Shanghvi: Yes.

Sonal Gupta: On the generic landscape, like you mentioned that there will be three or four customers who will sort of have 80% of the business. So how do you see this playing out – does this impact the smaller players more and it will be more of a big to big, something which Teva used to talk about some 4-5 years back or do you think for each product there can still be multi-source, so there is still room for even in a single product of 8-10 players to be there in the market or do you think the market will be there only for 5-6 players?

Dilip Shanghvi: It is difficult to anticipate and respond. But even though you may have one customer representing 20-25% of market, you also need to have manufacturers who are capable of supplying that much volume. So if you have 5% of the market, you can have a single source, but if you have 25% of market, you will require 3-4 sources to ensure continuity of supply. So, simple consolidation of customers will not dramatically change the scenario, because consumption needs to be met and there has to be capacity to meet the market.

Moderator: Thank you. The next question is from the line of Chirag Talati of Espirito Santo. Please go ahead.

Chirag Talati : This one pertains to Doxil again; if I look at the data by units, it seems that the market has actually expanded to levels higher than what we had seen before the shortages actually occurred. Can you give us a directional sense of how the Doxil market has actually evolved in terms of total unit sizes?

Dilip Shanghvi: My understanding is that when Doxil was in shortage, some of the hospitals would have changed their treatment protocol because of non-availability of Doxil. Now that the product became available, they would have reverted back to their original protocol of using Doxil and not something else. But we do not promote this product and hence would not have direct understanding of how customers and institutes are behaving.

Chirag Talati : But the IMS data does show that since the past one year, the amount of units sold have been on a 12-month basis higher than what we had seen pre-shortage levels?

Dilip Shanghvi: Which is what I am saying is that some of the institutes who would have changed the protocol because of non-availability would have now changed back to use of Doxil or Liposomal Doxorubicin, now that it is available.

Chirag Talati : In another words, there is no more significant expansion that can potentially take place now for the market?

Dilip Shanghvi: I am not visualizing a dramatic increase in market.

Moderator: Thank you. The next question is from the line of Manish Jain of SageOne Investment Advisors. Please go ahead.

Manish Jain: Just extending the consolidation on the US Generic side from the customer side, a natural transition which we see would be to have your own sales team and your own products. When would you envision Sun to have its own sales team?

Dilip Shanghvi: We should have products which we can promote.

Manish Jain: So that is what exactly the question was that given that Ranbaxy and other kind of…

Dilip Shanghvi: I think we should have products to justify promotion, because the reimbursement scenario is changing, the cost of marketing is increasing. So ultimately it becomes an economic decision-making process.

Moderator: Thank you. The next question is a follow-up from Saion Mukherjee of Nomura. Please go ahead.

Saion Mukherjee: Some product specific question; on Decitabine, what is the kind of traction you were expecting and what is the level of traction you have currently?

Dilip Shanghvi: We do not give product specific response but I think we have a slightly different product. So I do not expect this to be a very large product.

Saion Mukherjee: On Gleevec, we have not seen many litigations there. So just from the difficulty perspective, would you consider this to be one of those difficult to overcome product given the crystal patent?

Dilip Shanghvi: It would have similar level of complexity and difficulty. So it is not dramatically more difficult.

Saion Mukherjee: So you think post the exclusivity period we would see a fair bit of competition here?

Dilip Shanghvi: Yes.

Moderator: Thank you. The next question is from Chirag Dagli of HDFC Mutual Fund. Please go ahead.

Chirag Dagli: On the Karkhadi warning letter, from here on is there like a to-do-list that the FDA has given for our India-based facilities, there are things that we need to revert to them on our processes on the India-based facilities?

Dilip Shanghvi: No, I think the process works in a way in which you have to respond to the warning letter within the stipulated time. And they will study the response and from our point of view we will hopefully be able to satisfy their expectation. That would be our effort.

Chirag Dagli: But our response is restricted to Karkhadi only, is it sir?

Sudhir Valia: Naturally

Dilip Shanghvi: We can only respond to the warning letter.

Chirag Dagli: So these same issues they will look for when they come next time around at the other plants?

Sudhir Valia: Possibly.

Dilip Shanghvi: That is the global policy of FDA is that they now look at observations and comments that they have given in the past inspection whether you have improved and implemented that in the other locations or not.

Moderator: Thank you. The next question is a follow up from Prakash Agarwal of CIMB. Please go ahead.

Prakash Agarwal: A question on the India business; we saw fairly higher growth versus what we have seen in the past, at least 300 bps higher. Any specific product launches or any specific attribute you would like to share, and if you could split it by volume, price and new products?

Dilip Shanghvi: Nothing dramatically different.

Prakash Agarwal: If you could share with respect to volume, price and new products?

Dilip Shanghvi: There were no major new products during the year. Approximately 1.5-2% of our India sales come from new products.

Prakash Agarwal: So it would be largely the volume growth?

Dilip Shanghvi: Yes.

Prakash Agarwal: What we have seen in this quarter, which is much higher growth than what we have done. So this kind of growth is what is sustainable?

Uday Baldota: I do not think we should look at quarter growth, look at the annual growth number which is at 17%.

Prakash Agarwal: A follow-up on the Doxil again. Just looking at the last quarter, would it be fair that the market would have expanded in the last quarter?

Dilip Shanghvi: I explained to you that in oncology business you cannot actually track on a quarter-on-quarter, because there you have large customers. If they purchase at the end of one quarter that will change the picture, it will be difficult to correlate usage with sales.

Moderator: Thank you. The next question is from Bhagwan Choudhary of IndiaNivesh. Please go ahead.

Bhagwan Choudhary: Just one question on this warning letter again, is it possible that this warning letter can trigger the inspection for the other facilities of the Sun Pharma?

Dilip Shanghvi: I think so, because it would have raised a certain amount of concern with FDA about the quality of systems and processes in other locations.

Bhagwan Choudhary: Secondly, one question on the SPARC side. Is it possible to know the kind of the revenue contribution to SPARC, means from the royalty and others, what are the revenue sources, means how can we look on that side?

Nimish Desai: On this call, we will not take questions related to SPARC.

Moderator: Thank you. The next question is a follow up from Sameer Baisiwala of Morgan Stanley. Please go ahead.

Sameer Baisiwala: Just wanted to understand your thoughts on the RoW market. I think now we finished fiscal FY14 at US$316 million, up about 13% in dollar terms. So how do you see this build out in RoW going forward, and could there be years where there is a step jump in the overall base?

Dilip Shanghvi: That would be the focus. We want to focus on strengthening our business in RoW.

Sameer Baisiwala: What are the key challenges to take it from US$300 million to US$500 million to US$700 million rather than kind of at some teen growth?

Dilip Shanghvi: One would be achieving critical mass in some of the interesting markets and how do we get it. So I think one advantage of the Ranbaxy transaction is that we will significantly strengthen our business in the RoW market, and it will come closer to maybe US$800 million to US$900 million. Then the challenge would be how we find a way to grow the business faster with a much more comprehensive product basket. For that we might have to do some kind of bolt-on acquisitions in some of the geographies.

Sameer Baisiwala: Is it possible to share what is the total number of product filings that we have done across RoW markets?

Dilip Shanghvi: Market-by-market details are very difficult to give on the phone, because we file in more than maybe 35 countries.

Moderator: Thank you. The next question is from Parth Shah of ICICI Bank. Please go ahead.

Parth Shah: Sir, you mentioned that favorable pricing regime in the US market may not be long lasting. So just wanted to understand from an industry point of view, what would be the reasons for that, only competition or…?

Dilip Shanghvi: Generally competition.

Parth Shah: From the Karkhadi plant, just wanted to know the sales amount which will be impacted because of US alert?

Sudhir Valia: Less than 1%.

Moderator: Thank you. The next question is from Nimish Mehta of Research Delta Advisors. Please go ahead.

Nimish Mehta: Can you throw some light on the performance of DUSA? We were expecting some data on upper extremities on Levulan PDT. So where are we there? And has the data come in?

Dilip Shanghvi: They continue to develop other usage of the product. My understanding is that the indication has not been expanded as yet.

Nimish Mehta: But have we given up on the Phase III trials on the upper extremities, is that no more ongoing?

Dilip Shanghvi: I think there are ongoing studies.

Nimish Mehta: When can we expect any data there?

Dilip Shanghvi: I do not honestly have immediate answer, but I do not expect any additional implications.

Nimish Mehta: Just to understand better about DUSA, has the sales been increasing or how is it performing overall?

Dilip Shanghvi: We do not actually break down and give product specific information for the US. But I think we are happy with the overall performance of the business and I think we should be able to meet our financial benchmarks.

Nimish Mehta: You are talking about DUSA or overall US?

Dilip Shanghvi: DUSA.

Moderator: Thank you. The next question is from Ajay Tyagi of PTI. Please go ahead.

Ajay Tyagi: I just wanted to know that once the acquisition of Ranbaxy is complete, how do you propose to tackle the FDA issues which Ranbaxy has?

Dilip Shanghvi: We have to understand the FDA concerns and work to address all of those concerns by strengthening the capability of the organization to meet the FDA expectation on a consistent basis.

Ajay Tyagi: Regarding the facilities of Ranbaxy, overall, you gave the guidance to the steps that you will be taking, but any ideas when you think those issues could be resolved?

Dilip Shanghvi: Without getting a detailed understanding of all the issues, it is difficult to respond at this point of time.

Moderator: Thank you. Ladies and Gentlemen, due to time constraints, that was our last question. I now hand the floor back to Mr. Nimish Desai for closing comments.

Nimish Desai: Thank you everybody for being there on the call and if any of your questions have remained unanswered, please send them over. Thank you and have a good day.

Moderator: Thank you. On behalf of Sun Pharmaceuticals that concludes this conference. Thank you for joining us and you may now disconnect your lines.