



## **Corporate Participants**

### **Dilip Shanghvi**

Managing Director, Sun Pharmaceutical Industries Ltd.

### **Sudhir Valia**

Whole time Director, Sun Pharmaceutical Industries Ltd.

### **Abhay Gandhi**

President, Sun Pharmaceutical Industries Ltd.



**Moderator:** Ladies and Gentlemen, Good Day and welcome to the Sun Pharmaceuticals Limited Q2 FY14 Earnings Conference Call. As a reminder for the duration of this conference, 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 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:** Good Morning to everybody and a warm welcome to our second quarter FY14 Earnings call. I am Nimish from the Sun Pharma Investor Relations team. We hope you received the Q2 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; Mr. Sudhir Valia – Wholetime Director; and Mr. Abhay Gandhi – President. Today, they will discuss performance highlights, update on strategy and respond to any questions that you may have. As is usual for the 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 up on our website shortly. The discussion today might include certain forward-looking statements, and this 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 any 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 earning call after announcement of financial results for the second quarter of 2013-14. Let me briefly update you on significant events during the quarter. In July 2013 Caraco received US FDA approval for generic Prandin. This followed the favorable ruling by the US Federal Circuit Court in June 2013. Given its first-to-file status Caraco is entitled to 180-day exclusivity. Caraco has already launched the product. We continue to enjoy the benefits of favorable pricing for 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 the discussions of Q2 performance.

**Sudhir Valia:** Thank you Mr. Shanghvi. Good morning to everyone and welcome all of you. Our Q2 financials are already with you.

Before we discuss the financials, let me highlight that the US dollar was at a higher rate this quarter as compared to same quarter 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.

Q2 net sales are at Rs.4192 crores an increase of 58% over last year. Material cost as a percentage of the net sales is 19%, almost similar to Q2 last year. Staff costs as a percentage of the net sales were at 13%, almost similar to Q2 last year. Other expenditure as a percentage of net sales is at 25%, in-line with Q2 last year.

As a result of the above, the EBITDA recorded in Q2 is Rs.1828 crores as compared to Rs.1168 crores for Q2 last year, a growth of about 57% which is in-line with revenue growth. EBITDA margins were at 44% for Q2 similar to that of Q2 last year.



Net profit for Q2 was Rs. 1362 crores registering a growth of 51% over recurring net profit of Rs 903 crores for Q2 of last year. On post-bonus basis, EPS is Rs.6.6, compared to adjusted EPS of Rs.4.4 that we had earned for Q2 last year. On a reported basis, net profit for Q2 was Rs. 1362 crores compared to Rs. 320 crores for Q2 last year. We had provided Rs. 584 crores in Q2 last year towards the generic Protonix litigation.

Now, we will discuss the half year performance. First half, net sales were at Rs.7674 crores an increase of 44% over first half year last year. Adjusted for the impact of one-time sales recorded in the domestic business in Q4FY12, which lowered Q1FY13 sales, the net sales for H1FY14 have grown by approximately 39% over first half last year.

Material cost, as a percentage of the net sales is 17% which is lower as compared to H1 last year primarily on account of better product-mix in Q1FY14. The staff costs for the first half is at 13.5% of the net sales which is in-line with that of H1 last year. Other expenditure was at 25.5% of the net sales, higher than that of the H1 last year.

As a result of the above the EBITDA for the first half is at Rs. 3359 crores a growth of 41% over the first half last year. EBITDA margins were at 44% for H1 compared to 45% for H1 last year. Recurring net profit is Rs. 2604 crores, a growth of 53% over that recorded in the first half of last year. The net profit after provision for generic Protonix is Rs. 86 crore compared to Rs.1115 crores for H1 last year. On a post-bonus basis, adjusted EPS is Rs.12.6, up from Rs.8.2 for the first half last year.

Taro recently posted Q2 FY14 sales of US\$ 205 million, up 28% from the corresponding quarter last year. Taro's Net profit for Q2 was US\$ 96 million up 47% over Q2 last year. It has recorded a slight increase in volumes for the quarter.

I will now hand over to Abhay Gandhi, who will share the performance of our Indian business.

**Abhay Gandhi:** Thank you Mr. Valia and good morning everybody. I will take you through our India Formulations business. Sales for Q2 were at Rs. 949 crores recording a growth of 17% over Q2 of last year. Sales for H1FY14 were at Rs. 1798 crores, up 29% over H1 of last year. If you adjust for the extra sales which we had done in Q4FY12, which in turn lowered Q1FY13 sales, then the adjusted sales growth for H1FY14 is 14% over H1 last year.

As per Sep-2013 AIOCD-AWACS report, Sun Pharma is ranked 2nd and holds 5.2% market share in the Rs.72,000 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.

Despite the implementation of the new pricing policy, we continue to find the Indian market as interesting and as competitive as ever. In this intensely competitive market, with new entrants coming into the market almost every quarter, we continue to look for innovative ways to differentiate our product portfolio, build customer trust and add prescription share.

With this I will hand over to Dilipbhai.



**Dilip Shanghvi:** Thank you Abhay. I will briefly touch upon the performance of our businesses across other segments as well as our overall performance in the US.

For Q2, our overall sales in the US were at US\$419 million, which is higher by almost 74%. This quarter includes revenue contribution from DUSA and URL which were not part of the company in Q2 last year. To that extent the numbers are not strictly comparable on YoY basis.

URL continues to perform well. However, we expect the performance to normalize in future. DUSA performance for the quarter was in-line with our expectations.

Formulation sales in the rest of the world market accounted for US\$79 million in Q2 registering a growth of 17% in dollar terms over Q2 last year. And excluding Taro's non-US sales, Sun's RoW sales for the quarter were up by 16% in dollar terms.

Our API business grew by 20% for the quarter. Most of the API we produce is used in-house, and the rest is sold to end users in the developed markets.

R&D expenditure for Q2 was Rs.223 crores at 5.3% of sales. For H1, R&D spend was Rs 428 crores at 5.6% of sales. This R&D spending enables development of future product pipeline including differentiated products.

In Q2, ANDAs for 10 products were filed, while we received 9 approvals from the US FDA. We now have 333 ANDAs approved for a total of 463 products filed with US FDA, and ANDAs for 130 products await approval. On a consolidated basis, we now have 789 patent filings with 506 granted patents.

Sun has become the sole supplier of generic Doxil to the US market given the manufacturing issues faced by the innovator. We have sufficient capacity to address the likely increase in demand for our product. At the same time, let me highlight that there may be other generic companies which are targeting this opportunity. A come-back by the innovator is also not ruled out.

Considering the performance recorded for H1FY14, we are enhancing our overall sales guidance for FY14. We expect our FY14 consolidated revenues to grow at 25% compared to our previous guidance of 18-20% growth. Our guidance is at constant exchange rate. The revised guidance takes in to account the performance achieved in H1FY14 as well the risks associated with increase in competition for some products.

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

**Moderator:** Thank you very much sir. Ladies and Gentlemen we will now begin the question-and-answer session. Our first question is from Prakash Agarwal of CIMB. Please go ahead.

**Prakash Agarwal:** I have three questions; one, on the US business if I look at the strong growth, on a sequential basis also there is a 15% growth but if I remove Taro and Prandin sales, I get flat to declining numbers. Could you explain something on this?



**Dilip Shanghvi:** I think we remain comfortable with the overall performance of our US business including our comfort on ability to grow across product range. I think on a quarter-on-quarter basis there would always be certain situations which are difficult to explain in terms of numbers.

**Prakash Agarwal:** If you can explain also the gross margin decline on a quarter-on-quarter basis because yearly it has been quite stable and healthy?

**Sudhir Valia:** The fluctuation happens due to product mix and the values so that implications will remain. It evens out over a period of time.

**Prakash Agarwal:** I am trying to understand could it be largely because of US or could it be because of higher growth in India business or...?

**Management:** Primarily US influence is more in this kind of things.

**Prakash Agarwal:** Sir, second question on Doxil, as you said, you are the sole supplier currently. Earlier my sense was J&J was promoting this product. So what is the future landscape, the generic competition, in my understanding would come in only in a year or two, but would you need to promote it, would you be able to take price hikes on this or what is the plan ahead?

**Dilip Shanghvi:** We are evaluating various options and I think it is a valid question as to what is our strategy because J&J was continuing to promote the product, so how do we find a way to communicate the message on both availability as well as the potential benefit to the patient of using this product. We are evaluating various options.

**Prakash Agarwal:** And lastly, on the India business, very strong growth vis-à-vis the industry and the peer group that we have seen so far. Are we doing something special here apart from the strong product portfolio? We have launches but launches I understand the regulator themselves have slowed down quite a bit, so what has led to this kind of growth?

**Abhay Gandhi:** A strong product basket apart, I think our continued focus on execution and our continued focus on building up our franchise and equity with our target customers is I think the main contributing factor.

**Prakash Agarwal:** No, but would you attribute it to some new product launches or price hikes or across growth and across sector.

**Abhay Gandhi:** In Q2 we had no product launch and any single product launch that we have in the India business cannot make a huge impact in the quarter anyway.

**Moderator:** Next question is from Manoj Garg of Merrill Lynch. Please go ahead.

**Manoj Garg:** I just would like to understand about Doxil further. While we are evaluating various strategy about the US market with regard to promotion and all, how do you see the landscape in other markets like Europe and emerging markets, and do we have any plan, are you also witnessing the similar kind of shortages in other markets for Doxil?



**Dilip Shanghvi:** I think it is a picture which is not clear yet, there are availabilities in many markets, but I think it is also important for us to keep in mind that we do not have a product approved in many geographies. So it is linked with our ability to register and get approval in many markets, so which is what I think is our focus.

**Manoj Garg:** So have we already started registering the products in some of the emerging markets and may be filed in the European market?

**Dilip Shanghvi:** That is what we have started is to start filing this product in many markets.

**Manoj Garg:** And the second question to Mr. Valia, if we look at on a sequential basis, ex-Taro, the gross margins have almost taken a hit of more than 700 bps despite better currency as well as Prandin sales in the quarter. So is there any one off which is there in the gross margin with regards on charge backs or provisions?

**Sudhir Valia:** There is nothing very specific to that but to the US business where this kind of things happen, one is related to the product, and this time actually even their volumes has gone up.

**Manoj Garg:** Volumes have gone up and margins have come down?

**Dilip Shanghvi:** I think our US product range has very different margins; some products have much better margins, some products have higher margins. So if we would have sold product with lower margin slightly more in this quarter it would have an impact on our overall cost of goods.

**Moderator:** Thank you. Our next question is from Girish Bakhru of HSBC. Please go ahead.

**Girish Bakhru:** Just following up on the margin side, just trying to clarify, is the entry of Mylan for Doxycycline impacting pricing in the product and that is how why the gross margin has declined, is that the reason?

**Dilip Shanghvi:** I think all of you are looking at only last quarter as a reference point for margin. I think you should look at margin over an extended period of time for the comparison, and if you do that I do not see a major difference. But on a product-on-product basis there will always be impact of new competition and that competition would be both in terms of price as well as in terms of lost market share.

**Uday Baldota:** I think my request is that Taro discloses cost of goods and does not disclose raw material cost, so to that extent I think people will need to ensure that they do a like-to-like comparison and they do not just do an arithmetical calculation.

**Girish Bakhru:** On the other Injectable side of the business in US just had a question, Testosterone injection is still not launched, any reason delay on that product?

**Dilip Shanghvi:** I think we launched the product beginning of this quarter.

**Girish Bakhru:** Just relating to that you also got approvals for Azithromycin injection, is that a significant opportunity you see and given that FDA is trying to probably work around resolution of many



drug shortages, and are there significant opportunities within these Injectable pipeline that could bump up US sales going ahead?

**Dilip Shanghvi:** Azithromycin I think is a fairly large volume but relatively low priced product. So that I do not think would have any significant impact. And I think US FDA continues to work for addressing drug shortages. And if we would have filed any one of the product which are in shortage then it may happen, we may get a little bit earlier approval so that we can work towards addressing the shortage. But I think that whatever we are expecting as new approval is there in our guidance.

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

**Sonal Gupta:** Just one was one of the Niaspan, you already have a tentative approval. So I just want to understand would you be able to launch on day-181 after 180-day exclusivity is over?

**Dilip Shanghvi:** I think we have some settlement which will ultimately determine when we will launch.

**Sonal Gupta:** And just in terms of the overall margins for the business, I understand there is fluctuation on a quarterly basis, but still at 44% EBITDA margin, Taro margins at 60%, so how do you see this overall margin trajectory? These are margins that of course they are being benefiting from various products, etc. but you would like to sustain them or do you see that longer term these can still be improved further?

**Dilip Shanghvi:** I think Sonal, three times in our commentary we highlighted risks with continued pricing. So that is our concern and that remains a concern that I do not want to have a situation where people expect that this is forever in terms of pricing. What we are comfortable and confident is that we will be able to continue to find ways to grow the business and grow the business profitably even if there are no major one-off opportunities. I think that is our focus as a management.

**Moderator:** Thank you. Our next question is from Sameer Baisiwala of Morgan Stanley. Please go ahead.

**Sameer Baisiwala:** I think FDA updated its website in the last week of October for Doxycycline drug shortages being resolved. Have we seen any impact of this and especially are you seeing any correction in prices on the back of this?

**Dilip Shanghvi:** I would not have product-to-product pricing familiarity and understanding, but clearly there would be a relationship to new supplies and proper supply with pricing impact of products.

**Sameer Baisiwala:** And second question is just to be very clear with the guidance. When you say constant currency terms what you are saying is the currency depreciation that happens average fiscal '13 or fiscal '14 is over and above this 25%, that is the way we should think about the guidance?

**Dilip Shanghvi:** That is correct. Actually at the beginning of the year we have indicated at what rate we are treating the currency, so all the turnover needs to be reflected on that value of dollar to rupee conversion. Also I think we need to clarify that the impact of the currency on inventory because we have inventory outside India which is held in dollars but the change in the dollar value against the Indian rupee is not reflected in P&L that is directly going into the balance sheet. So that is being done with a



view to unnecessarily avoid the fluctuation in profits of the company or the earnings. If we had, in this situation, a different policy I think our profits would have been significantly higher because between two quarters there was dollar appreciation.

**Sameer Baisiwala:** If I remember correctly this was a change that you had brought about in first quarter fiscal '13 and it remains so ever since then?

**Dilip Shanghvi:** Yes but I have seen some reports which possibly do not reflect the same level of understanding. So I do not want people to be under inconsistent understanding.

**Moderator:** Thank you. Our next question is from Nimesh Mehta of Research Delta. Please go ahead.

**Nimesh Mehta:** At what stage are we for the development of Lupron Depo injection for the US market?

**Dilip Shanghvi:** We do not generally indicate what we are doing for new products, we do not comment on products that we are either in the process of filing or have filed.

**Nimesh Mehta:** Secondly, if you can just comment on what is the reason for Doxycycline demand to be higher, besides the fact that there were shortages, but have we seen an increase in demand, is that something that we can take it for granted even not just because of the shortage but general demand?

**Dilip Shanghvi:** My understanding is that there is a reduction in the demand because the prices have gone up in many formularies. They are not approving usage of Doxycycline, so there is no increase in demand.

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

**Bino Pathiparampil:** One question on Taro. So have seen a major jump Q-o-Q in revenues as well as profitability in Taro, and the press release of Taro says that the volume increase has been minimal which again suggest further price increases. Would these price increases be on the same product that earlier resulted to upside over the last few quarters or is there a wider basket of products that is now seeing price appreciation?

**Dilip Shanghvi:** We would not be able to respond beyond what Taro has disclosed.

**Bino Pathiparampil:** In case of Doxil while you will not give any product specific information, in the way you book sales, is it fair to assume there is significant quarter-to-quarter difference in the level of Doxil sales? Across quarters, Doxil, since it has been an old product is it roughly the same every quarter or is there significant fluctuations in quantity of Doxil that could be sold in a quarter?

**Dilip Shanghvi:** Doxil I think last quarter there will not be any impact because I think there is still inventory of the innovator in the market till that time.

**Bino Pathiparampil:** FY14 base is very high base with all the price increases in Taro, Doxil, Doxycycline price increases in URL. So do you have some early thoughts on FY15 adjusted for the exceptional rupee depreciation or exceptional things you got in FY14? Still do we see reasonable growth potential in FY15?





**Dilip Shanghvi:** It is difficult to prepone the next year guidance. I think our focus always would be to find a way to grow the business.

**Bino Pathiparampil:** Let me put it this way, versus your confidence on FY14 at the same time in last year; do you have the same level of confidence on FY15 right now?

**Dilip Shanghvi:** I have enough to worry about today, so I do not want to start worrying about next year.

**Moderator:** Our next question is from Surya Patra of Phillip Capital. Please go ahead.

**Surya Patra:** One query on the Taro. Obviously, we have seen price hike in the recent quarter for possibly a basket of products which reported much better than expected numbers this quarter. But for the future can you provide some sort of visibility guide, what is the kind of pipeline that we would be having for Taro in terms of new launches or anything?

**Dilip Shanghvi:** I think they have given some guidance about the new product filing and a number of products which are awaiting approval. They have also indicated that last quarter there was an increase in the R&D spends. So my understanding is that their focus would be to find a way to improve productivity of research and file interesting products. That is why R&D costs will be going up.

**Surya Patra:** Even last quarter we had indicated that possibly the price of the products may not be sustainable for various US products. Despite that we have seen sort of a price increase for Taro basket. So will this be sustainable, what is your understanding on this?

**Dilip Shanghvi:** That is what we are repeatedly saying is that these are temporary market competition dynamics, so it will change.

**Surya Patra:** Just a last question. What is the kind of opportunity that we would be looking for the Nexium IV next year?

**Dilip Shanghvi:** It is a small product.

**Surya Patra:** Considering the size of the total opportunity you feel it is very small kind of opportunity or in terms of percentage wise of the total opportunity to be very minimal or how is it?

**Dilip Shanghvi:** Injectable Nexium is not a very large product. So generic for that also will not be a very large product.

**Moderator:** Our next question is from Chunky Shah of Credit Suisse. Please go ahead.

**Anubhav Aggarwal:** This is Anubhav here. Just a question on the inventory valuation which you talked about to an earlier question. My understanding was that you have changed your policy there instead of taking a quarter ending exchange rate; you are only taking quarter average rate. But is there a further change in the inventory valuation policy?

**Uday Baldota:** That is exactly what was mentioned, Anubhav



**Anubhav Aggarwal:** But let us say how do you treat inventory close which is lying at URL, Caraco and Taro, so any closing inventory there, let say in case of rupee depreciation, would gross margin reflect benefit of that at quarter closing rate?

**Sudhir Valia:** No, the unrealized inventory will not have a profit to book.

**Anubhav Aggarwal:** That's something we will take directly in the balance sheet?

**Sudhir Valia:** Correct.

**Anubhav Aggarwal:** Secondly, with respect to our hedging policy I see that in the balance sheet we are carrying about \$300 million hedges right now, and a large part of that seems to be long-term hedges. Can you quantify or can you explain what sort of long term hedges are we carrying and what exactly is Sun Pharma...?

**Sudhir Valia:** Primarily hedging is against advance sales which is we have done and some of the investments, not any other hedging.

**Dilip Shanghvi:** And also I think all the hedges are mark-to-market. So some of the anomaly that you see in the profitability would also be factoring in the mark-to-market impact of all these hedges.

**Anubhav Aggarwal:** The question was that your balance sheet indicates that you have been carrying hedges for more than 2 years now almost and the rate seems to be below 50 on those hedges.

**Sudhir Valia:** Sales continue, investment continues so the hedges required to protect that will continue.

**Moderator:** Thank you. Our next question is from Perin Ali of Edelweiss. Please go ahead.

**Perin Ali:** My question is on Indian market. There have been changes in the regulatory guidance on product approvals and clinical trials. How does it affect our business in terms of new launches in Indian market because I believe that the launches have slowed down a lot in the last year or so? How do we see these changes in regulation impacting our business?

**Abhay Gandhi:** It is common knowledge now that the regulatory process has become both far more time-consuming as well as resource-intensive in terms of the trials required and timelines and so on. So clearly we expected it will have an impact on the business.

**Perin Ali:** In terms of new product launches in India, how many products have we planned this year? Is it lower or higher than what we were anticipating earlier?

**Abhay Gandhi:** While we do not give numbers of products that we are filing or planning to file, we are confident we have a robust pipeline which will address our future needs. However, the time required for us to be able to register these products has significantly gone up than what it used to be in the past.

**Perin Ali:** Would it be possible to quantify the timeline? How much it has gone up in terms of months?

**Sudhir Valia:** It varies from product-to-product and people who investigate that.



**Abhay Gandhi:** I think the situation as far as the regulatory front is concerned is also not normalized. I do not think really anybody will be able to give you a sense of how long that would actually take now to register a product. Clearly, it has gone up significantly from what it used to be in the past. But if you ask me how many months or years, I may not be able to accurately quantify.

**Perin Ali:** This quarter growth has been very strong at 17%. So can I assume from that a larger part of that is because of increase in volumes of our existing products other than the new product contribution? And so when going forward when we look at the growth of business, how do we see a run rate of continuation of 17-18% which we are seeing in this quarter?

**Abhay Gandhi:** In a few calls earlier, I had said that with the price decrease in some of the products and the growth of the market in general, we will be able to grow volumes. The volume growth has been one of the major contributors for business growing quite robustly. How it will do in the future? Again, we have not really estimated, but we feel reasonably confident that we will continue to grow faster than the market.

**Moderator:** Our next question is from Nitin Agarwal of IDFC Securities. Please go ahead.

**Nitin Agarwal:** On the URL business, have we launched some of the discontinued products in this quarter?

**Dilip Shanghvi:** The typical timeline for reintroduction of product even if we are very aggressive would be anywhere between 6 months plus.

**Nitin Agarwal:** On a broader issue, we started out some time back, essentially the sporadic thing where because of shortages, manufacturers are going to take opportunities for price hikes across portfolio, this seems to becoming a little more widespread sort of a thing as shortages have increased across products. In general, have you ever seen some sort of push back now coming from formularies and from PBMs as this trend is sort of picking up a little bit of more momentum?

**Dilip Shanghvi:** I am not actually that closely connected to the overall market to be able to fully respond to your question, but I also see that because of shortages and risks the price increase is becoming kind of more widespread than what it used to be historically. So clearly, there would be some impact going forward.

**Moderator:** Thank you. Our next question is from Rahul Sharma of Karvy Stock Broking. Please go ahead.

**Rahul Sharma:** Just wanted a clarification on Zemplar. Probably FTF is due from Teva on October-13. So any guidelines on possibility of launch post that? And another thing is on Namenda where we have a settlement, probably January-15 launch, just wanted your comments?

**Dilip Shanghvi:** I think we are not first-to-file on Zemplar, we have a para-IV litigation. And Namenda, we are first-to-file, but it is a product on which there are many first-to-file. So we are not looking at both of these as major product opportunities.

**Rahul Sharma:** Any comment on Lunesta which could be probably after periodic exclusivity?



**Dilip Shanghvi:** Even that product I think there are many filers. So I do not see that becoming a very large product.

**Rahul Sharma:** Lastly, on the tax rates, what sort of tax rates you are looking at for the current year and going ahead FY15?

**Dilip Shanghvi:** We are not changing our guidance of tax rate that I gave last quarter.

**Moderator:** Our next question is from Ketan Gandhi of Gandhi Securities. Please go ahead.

**Ketan Gandhi:** This is regarding Doxil. How much time you see for the next competition to come in? And how many competitors in the next 3 years?

**Dilip Shanghvi:** I think you have expectations of capability from us which we do not have. Neither we know how many products are filed with the FDA, what is the quality of their filing, and what FDA is doing about it. So I do not think that we can respond on this at all.

**Moderator:** Our next question is from Chirag Dagli of HDFC Asset Management. Please go ahead.

**Chirag Dagli:** Two questions; first is on this inventory mark-to-market that you alluded to. This applies to Taro inventory as well, right?

**Sudhir Valia:** Yes.

**Chirag Dagli:** Secondly, on the US business we are now at almost \$400 million quarterly run rate. On this large base for us to grow profitably, do we see opportunities to grow profitably on this base on an overall basis for the US business?

**Dilip Shanghvi:** I think that is factored in our guidance for this year. As I have said that our focus always is to find ways to grow our business consistently over a period of time.

**Sudhir Valia:** But your concern is valid. As the base is increasing; it is more and more challenging for us to sustain the growth.

**Chirag Dagli:** And last question if I can squeeze, on the base business price erosion, ex of some of these big opportunities that we have seen in the past couple of years, is there any trend emerging there, is it getting any worse or better for us?

**Dilip Shanghvi:** I think generic business trend would always be that over a period of time prices will continue to fall and that will continue.

**Chirag Dagli:** There is no change in the trend per se?

**Dilip Shanghvi:** No, there is no change.

**Moderator:** Our next question is from Krishna Prasad of Kotak Securities. Please go ahead.



**Krishna Prasad:** My question is actually on the balance sheet. There has been a sharp increase in the short-term borrowing, if you could just probably throw some light on that?

**Sudhir Valia:** Actually there is no such borrowing except for the borrowing on account of the payment which we made to Pfizer.

**Krishna Prasad:** That was made during the current quarter?

**Sudhir Valia:** Yes, because we had all the money in the bank FD and that was earning more than what we were been able to get money in the market, barring that there is no borrowing.

**Krishna Prasad:** You had made a reference to formulary status. Is it now that formularies maybe looking at alternative to Doxycycline or how does this actually work, if you could probably just give a brief on that?

**Dilip Shanghvi:** It is difficult for me to respond. I only see that volumes are coming down for products on which there are significant price increases. I do not know how the system works so that the volumes come down.

**Krishna Prasad:** Finally, one last question, in the Indian market, have we seen any sort of impact on the confusion around Pioglitazone, is that now behind us or do you still see there is some concern with prescriptions for the product?

**Abhay Gandhi:** The products of all the companies are back in the market. Clearly because of all the controversy that has been created there is a drop in prescriptions in base erosion of the molecule and its combination that is clearly happening.

**Krishna Prasad:** So our growth is actually despite the impact on Pioglitazone?

**Abhay Gandhi:** That is correct.

**Moderator:** Our next question is from Saion Mukherjee of Nomura. Please go ahead.

**Saion Mukherjee:** Two questions; firstly, on this inventory gain or loss, sorry I missed that, so basically my understanding was that till fiscal '12 from the quarter starting to quarter end whatever gain was taken through the P&L, right, and from fiscal '13 onwards there has been a change wherein from the quarter starting to the average rate it is through the P&L and from average rate to the closing rate it is through the balance sheet, is my understanding correct?

**Uday Baldota:** Yes, I think that is right, Saion. Let us simplify this for everyone's benefit. At the closing rate, if I was to account for the closing stock to that extent and with the depreciating rupee, my material cost that appears in the P&L will be lower, and my profit will be higher. And this treatment we changed in first quarter of FY13 where we said that the material cost will actually go in with the average rate, and any change in the closing rate or impact of that will go directly to the balance sheet.

**Saion Mukherjee:** My second question is related to the R&D cost. When I look at the R&D cost overall that you have been reporting is around Rs.210 crores and Taro which I would assume is primarily into



topical R&D is doing around Rs.90 crores. So basically ex-Taro, our R&D spend has been around Rs.120-odd crores. Now do you see this go up significantly? We have seen other companies; we have seen numbers which have increased significantly in the recent past. So how do you think about R&D spend? And as a strategy do you think it is good to take risk by developing assets in-house or it would be better to look at acquiring certain capabilities inorganically, how do you think about building pipeline going forward for the US?

**Dilip Shanghvi:** I think our philosophy of investing in research since we went public has been an important contributor to our growth and we remain committed to continued investment in research for ensuring our future growth. Difficult for me to respond because I think, as we keep on working on complex products, some of the R&D cost also come from clinical trials or external costs, so that tends to be kind of lumpy. My understanding is our overall R&D expenses will remain within our guidance.

**Saion Mukherjee:** Particularly on Taro R&D, do you see enough effectiveness of Taro R&D at this stage, are you satisfied with the pace of filing that you are seeing there or there is scope for further improvement there?

**Dilip Shanghvi:** You want me to do performance appraisal on conference call?

**Saion Mukherjee:** No, basically the R&D spend if you look at Rs.90 crores at Taro and around Rs.118-odd crores this quarter ex-Taro, so I am just wondering whether the kind of R&D work done at Taro is the cost of filings on Derma products is that significantly higher...?

**Dilip Shanghvi:** I think the overall performance of Taro is in line with our expectation and that is not only for R&D, but overall all parts of business operations, manufacturing, quality and we are quite happy with the way the company is running.

**Moderator:** The next question is from Ranjit Kapadia of Centrum Broking. Please go ahead.

**Ranjit Kapadia:** My question relates to domestic market. We have seen that the companies have been suffering from trade-related issues. I just wanted to check with you how we have dealt with this?

**Abhay Gandhi:** The trade-related issues have been more issue-based and quite localized. So I think we have been able to address it on a case-to-case basis.

**Ranjit Kapadia:** Have we increased the margins for the wholesalers and the retailers?

**Abhay Gandhi:** No, there has been no change.

**Moderator:** The next question is from Manish Jain of Axis Holdings. Please go ahead.

**Manish Jain:** On the JV with Intrexon, when do you the first product entering the clinic in US?

**Dilip Shanghvi:** I think it is far, far away from clinic. It is a very new biology and there are a large number of basic biology issues that we have to understand better before we can even consider using it in US. So it will take time.



**Manish Jain:** And relating to clinical trial, actually in US I saw that multiple guys using Liposomal Doxorubicin as combos in their trials. So who supplies quantities to them?

**Dilip Shanghvi:** Today, I think if you see our product has now become the RLD, so they may be buying from the market and using. Till now I think Johnson & Johnson product was available. So it is difficult for me to respond.

**Manish Jain:** And the last thing in terms of Latanoprost and Timolol and Paclitaxel PICN in India launch, when do you see that?

**Dilip Shanghvi:** Both the products I think we have filed, we are awaiting approval.

**Moderator:** Our next question is from Krishnendu Saha of Quantum Mutual Fund. Please go ahead.

**Krishnendu Saha:** Just a simple question for understanding, this spin off from Sun Pharma Global FZE is because of what, because is there anything to do with Doxil filing or something like that?

**Uday Baldota:** No, it is not related to Doxil.

**Krishnendu Saha:** Because at one point of time I remember because healthcare professionals were addressed with urgency that there is a shortage. But what is the reason of spinning of this entity?

**Sudhir Valia:** It is a small rationalization.

**Krishnendu Saha:** One simple question is of the 336 products which are there in the US, how many of them are actually in the market right now, is there any figure to that?

**Dilip Shanghvi:** I do not see a very large number of un-marketed products for any reason other than attractiveness of product.

**Krishnendu Saha:** So mostly it will be on 330, 320 products still be in the market?

**Dilip Shanghvi:** I think slightly less than 300 because some products may not be large or attractive at the current price, so we may not be in the market.

**Moderator:** Our next question is from Sangam Iyer of Subhkam Ventures. Please go ahead.

**Sangam Iyer:** Just wanted to understand a little bit on the margin profile because earlier part of the call a lot of emphasis was actually been put on that. Could you give us some outlook as to how do we see the margins going forward?

**Dilip Shanghvi:** There are a large number of moving parts. It is difficult for us to guide in terms of specifics.

**Sangam Iyer:** Secondly, in terms of Taro, we have seen a good uptick primarily as they have mentioned because of volumes and also price hikes taken. So do we see that the current trend or the



run rate actually being the new base for Taro going forward or how do you see that, could you comment on?

**Sudhir Valia:** The US business is a very complex and very difficult and we have been all the time warning about sustaining the price, but we have been proved wrong so far.

**Moderator:** Thank you. Our next question is from Gagan Thareja of Comgest India. Please go ahead.

**Gagan Thareja:** You talked at length about the new combinations in the domestic market being delayed because of what the regulator is trying to do. From what I can understand the drug controller has also stipulated timeline for the state FDAs to produce safety and efficacy data on scores of combinations which are already in the market. So is it a possibility that combinations which are in the market might also be impacted due to some regulatory action in the coming year?

**Abhay Gandhi:** The timeline that has been given I think it is sufficient for us to protect most parts of our business and most of the key products.

**Dilip Shanghvi:** Also I think there is a new committee which has been appointed to look at combinations. So I think depending on how the committee's report is adopted would also influence this. We are not seeing a significant impact of this on our business.

**Gagan Thareja:** In general, do you see the impact coming on existing fixed dose combinations if some of them are found irrational, not specific to Sun, but as a market phenomenon?

**Sudhir Valia:** Anything irrational will get affected.

**Abhay Gandhi:** But I think in terms of our earlier filing and the products we have launched, we have taken due care that we have not launched irrational combinations. So to that extent, I think the quality of the filings that we have done and brought products into the market reflect that.

**Moderator:** Our next question is from Surjit Pal of Prabhudas Lilladher. Please go ahead.

**Surjit Pal:** I have two questions. One is that given the kind of EMEAs apprehension that there could be a situation of Doxil shortage in Europe; do you expect any kind of opportunity this year or next year in Europe for Doxil?

**Dilip Shanghvi:** Difficult for us to respond. I think these are regulatory issues and it is up to the regulator to take a decision. There is a guidance about approval of Liposomal Doxorubicin by the EMEA which is very different and much more complex than the US FDA guidance.

**Surjit Pal:** And related to that given that you have already Liposomal technology platform, are you trying for other products in US market on the similar platform of Liposomal product?

**Dilip Shanghvi:** We do not comment on future products. But I think idea for us would be to use our technological capability to develop first a range of products and then work towards improving the overall effectiveness of technology and develop new products.





**Surjit Pal:** Second one is on domestic. Given the recent news that government might be thinking to add the improved version of those DPCO-controlled drugs like say delayed or suspension products, do you think if those SKUs are included in the list of already controlled drugs how much impact could the industry would have further from the current level?

**Abhay Gandhi:** We have not quantified the total impact for the industry as such. There would be some impact on Sun clearly.

**Surjit Pal:** But will it be some significant amount or what do you think?

**Abhay Gandhi:** I think it is always good to remember that our India business is a highly balanced and diversified business in terms of number of products we have, or therapies we are present in, or the customer groups. An opportunity or let us say a risk on one product or a segment does not really hurt us to the extent that can make a very material impact.

**Moderator:** Thank you. Our next question is from of Parin Gala of Gandhi Securities. Please go ahead.

**Parin Gala:** My question is relating to Doxil. Would it be safe to infer that the sale of Doxil in the US in this quarter was lower? The inference is based on the fact that there has been a decline in royalty for SPARC for this quarter. What would be the reason if at all there was a decline in Doxil sales?

**Dilip Shanghvi:** I think we have to understand that whenever any product is in shortage, the behavior of customers would be very different than in case of normal supply. There would be a kind of situation where you will have lumpiness in sales. So you do not start looking at sales on a quarter-on-quarter basis. It is also not like India where it is a much more consistent business which is much more balanced and distributed.

**Parin Gala:** My second question if you can answer that, when can we see the first product launch from the Sun-Merck JV? What would be that product if you can share?

**Dilip Shanghvi:** I cannot share any JV-related information but I think we are quite excited and happy with the progress that we have made in the JV till date.

**Moderator:** Thank you. Our next question is a follow up from Sonal Gupta of UBS Securities. Please go ahead.

**Sonal Gupta:** Just on the ROW markets, could you give more granularity because ex of Taro this business is now more than \$200 million. So any key markets, etc. which are there, if you could give some more granularity there?

**Dilip Shanghvi:** You mean country specific information?

**Sonal Gupta:** Yeah.

**Dilip Shanghvi:** Our preference would be not to share any more detailed information than we are sharing at this point of time. And this is with a view to maintain a certain amount of business confidentiality and that has helped us till now.



**Sonal Gupta:** The other thing was on Liposomal Doxorubicin, you said that the EMEA guidance is more complex, but are you still pursuing an approval there, and do you see this as a meaningful market?

**Dilip Shanghvi:** Difficult for me to respond because I think logically we should be clearly pursuing registration in Europe because that is an interesting market. It was all a question of many things, in the sense availability of innovator for us to do comparative studies and a large number of issues that we have to find a way to solve before we can hope to get an approval.

**Moderator:** Our next question is a follow up from Sameer Baisiwala of Morgan Stanley. Please go ahead.

**Sameer Baisiwala:** Just wanted to check on Levetiracetam XR. After the adverse response letter by FDA what is the update on this one?

**Dilip Shanghvi:** I do not have an immediate response but I think we are working towards addressing the response. I think at a subsequent point may be you can get more information from Uday.

**Sameer Baisiwala:** Have we done the re-filing?

**Dilip Shanghvi:** You do not have to actually do re-filing. You just have to respond.

**Sameer Baisiwala:** Second question is on Levulan. Last disclosure that we had which was pre-acquisition of DUSA is that there were about 3105 devices which have been installed with the practitioners. So it is about a year or so down the line. Where does this number stand and how is DUSA value unlocking progressing?

**Dilip Shanghvi:** I think they had a historical rate of new users and that is continuing. Our effort would be to find a way to increase the number of additional users, how do we accelerate and also we see there is an opportunity for us to increase consumption per user. At a macro level I think Levulan is used only for around 6-7% of the overall actinic keratosis patients. So our effort would be to find a way to see how we can reach to a larger market share of the overall therapy.

**Sameer Baisiwala:** Just a final question. It is much being talked about outside the company but we do not have a very good understanding. It has been one and a half years since Mr. Israel Makov has been the Chairman of Sun. So is it possible to discuss what has been his role so far, and what are the expectations over next months and years ahead?

**Dilip Shanghvi:** I think he is adding significantly to our management processes and also helping us chart out a much more well-defined aggressive growth plan for the business going forward. I would expect him to be able to help us transition to a much more international and larger company in near future.

**Moderator:** Our next question is a follow up from Manish Jain of Axis Holdings. Please go ahead.

**Manish Jain:** In terms of Exenatide we were wanting to start clinical trials in the US, have we started them?



**Dilip Shanghvi:** I first of all do not know we have shared with anybody whether we are going to start clinical trial in the US. It is difficult for me to respond.

**Manish Jain:** Because it is a publicly available information on clinicaltrials.gov?

**Dilip Shanghvi:** Is Sun study already on US FDA site? I do not know.

**Manish Jain:** Yeah it is there already.

**Dilip Shanghvi:** I do not want to respond without fully being aware but what I know is that if we would have done something related to the filing we would be continuing to pursue that.

**Moderator:** Our next question is a follow up from Nimesh Mehta of Research Delta. Please go ahead.

**Nimesh Mehta:** Can you just elaborate a little bit on Levulan product in terms of the Phase-III clinical trials that we are conducting for upper extremities? When do we expect the data? And if positive how big this can be a market to address?

**Dilip Shanghvi:** There is no reason why data will not be a positive. So I think as I said in the beginning our focus is to find a way to increase the overall share of the procedure. So there are multiple strategies that we are pursuing with a view to improve that share and usage of Levulan in extremities is one of the components of that idea because there is a fairly meaningful market for this procedure.

**Nimesh Mehta:** Can you quantify that, how big can that be there as a market?

**Dilip Shanghvi:** I do not have the number, but I think it is around 10-15% of the total market.

**Nimesh Mehta:** So it can actually double from the 6-7% market share that we have?

**Dilip Shanghvi:** We have 5% of 85% of market. We will also have 5% of the 15% market. We are not tripling our market share. There is a reason why Levulan is not used. So we have to address all of those issues before it is used more frequently.

**Nimesh Mehta:** But when is the data expected, any time line that you can tell?

**Dilip Shanghvi:** No timelines.

**Nimesh Mehta:** Lastly, can you comment on the status of the Phase-2b trial of Novexatin, I mean the recent agreement with NovaBiotics when do you expect this to come in the market and how big size of the market would be?

**Dilip Shanghvi:** I think these are future and long-term projects and these timelines would be in years not in quarters. So difficult to respond at this time.

**Moderator:** Our next question is a follow up from Surya Patra of Phillip Capital. Please go ahead.



**Surya Patra:** Just one query. Is the Tetracycline a perfect alternate for this Doxycycline because when there was a supply constraint of Tetracycline the demand for Doxycycline increased?

**Dilip Shanghvi:** I think they are the drugs from the same class. So to that extent they would have some similarity but my understanding is that both Minocycline and Doxycycline have a much larger percentage of acne market compared to Tetracycline. I do not know for the other indications where Tetracycline is used whether Doxycycline is usable across all indications.

**Moderator:** Our next question is from Ajay Tyagi of PTI. Please go ahead.

**Ajay Tyagi:** What is the present status of your Mumbai laboratory for which DCGI has issued a notice to you?

**Dilip Shanghvi:** We continue to work with the...

**Ajay Tyagi:** Any timelines which you would suggest by that time the issue would be resolved?

**Dilip Shanghvi:** I think within next few weeks.

**Moderator:** Thank you. Ladies and gentlemen that was our last question. I now hand the floor back to Mr. Nimish Desai for closing comments.

**Nimish Desai:** Thank you everybody for taking time out to attend this call. In case any of your questions have remained unanswered I request them to please send it across to us. Thank you and have a good day.

**Moderator:** Thank you very much, members of the management. Ladies and gentlemen, on behalf of Sun Pharmaceuticals Limited that concludes this conference. Thank you for joining us, and you may now disconnect your lines.