Sun Pharma Conference Call 10.30 hours, June 27, 2009



Corporate Participants:

Mr. Dilip Shanghvi Chairman and Managing Director, Sun Pharmaceutical Industries Limited.

Mr. Sudhir Valia Wholetime Director, Sun Pharmaceutical Industries Limited.



Moderator: Ladies and gentlemen good morning and welcome to the Sun Pharmaceuticals conference call. As a reminder, for the duration of this conference, all participants' lines will be in the listen-only mode. And there will be an opportunity for you to ask questions at the end of today's presentation. If you should need assistance during the conference call, please signal an operator by pressing * and then 0 on your touchtone phone. Please note that this conference is being recorded. At this time, I would like to hand the conference over to Mr. Uday Baldota of Sun Pharmaceuticals. Thank you, and over to you sir.

Uday Baldota: Thank you. Good morning and welcome to this conference call, I am Uday from Sun Pharma Investor Relations team. Today our hosts are Mr. Dilip Shanghvi, Chairman and Managing Director and Mr. Sudhir Valia, Wholetime Director. Just as a reminder, this call is being recorded and the replay of the call will be available till July 3rd, 2009. The call transcript will also be put up on our website soon. It will be appropriate for me to mention that the discussion today may include certain forward looking statements and this must be viewed in conjunction with the risk that our business faces. Also I would like to request all of you kindly send in queries that remain unanswered during today's call, to uday.baldota@sunpharma.com or mira.desai@sunpharma.com. I would now handover the call to Mr. Dilip Shanghvi.

Dilip Shanghvi: Good morning and thank you for joining the call.

Basically, the purpose of this call is to help address some of the queries that all of you have. This relates to the recent development at Michigan facilities of Caraco. On 25th June, FDA seized drugs manufactured by Caraco and its ingredients from their premises in Michigan. As per FDA this is on account of Caraco's continued failure to meet the FDA's cGMP requirements. Clearly this is another setback for Caraco's effort over the past one year to return to full cGMP compliance. In this one year, Caraco has undertaken several initiatives which it has routinely disclosed in its public filings. As it appears now, the result has clearly fallen short of FDA's expectations.

Looking back, revenue from manufactured products for Caraco in FY09 was US \$112 million while gross profit was US \$48 million. This includes revenue from all products manufactured at Detroit and also products manufactured by third parties for Caraco. As shared by Caraco, products manufactured by third parties for Caraco do not get impacted by this FDA action. Accordingly, it is possible that revenue from Detroit- manufactured products for Caraco which was less than US \$112 million in FY09, may stop until the facility becomes cGMP compliant. This will also be



reflected in Sun Pharma's performance and hence may necessitate a change in our sales growth guidance for FY10. We are reassessing this and will let you know of revision in sales growth guidance, if any.

Products distributed by Caraco for Sun Pharma, revenue for which was US \$225 million in FY09, will continue as usual. This is because Sun Pharma facilities remain in full compliance of FDA's cGMP requirements and are not affected. In fact, four of Sun facilities have been inspected in last six months without any significant 483 observation.

Caraco has disclosed that value of inventory seized by FDA is estimated at US \$15 to \$20 million. Also as per Caraco, their balance sheet provides them enough strength to go through this period of pain while continuing revenues will cover their estimated ongoing expenses.

Though getting to know the estimated timeline for resolution is of key interest to each of you, it is difficult for us to indicate anything specifically. As the largest shareholder we remain committed to working with Caraco and extend all help required towards protecting Sun Pharma's interest.

Without taking too much time, I would like to get into the interactive session. Before we start taking questions, it would be appropriate for me to remind that this is essentially a development related to Caraco, which is a publicly traded corporation. This often limits our ability to give very specific responses to some of your questions. With this I would like to leave this floor open for questions, thank you.

Moderator: Thank you sir. Ladies and gentlemen we will now begin with the question and answer session. Anyone who wishes to ask a question may press * and 1 on their touchtone telephone. If you wish to remove yourself from the question queue you may press * and 2. Participants are requested to use handsets while asking a question. The first question is from the line of Bino Pathiparampil from IIFL. Please go ahead.

Bino Pathiparampil: Hi, just had quick question about is it technically and legally feasible to move some of the products out of Caraco facility and then manufacture it in India or get it manufactured by somebody else in the US? I know it is too early for you to decide on those things, but this is more like a generic question is it technically and legally feasible, and how much time it might take?



Dilip Shanghvi: Our understanding is that it is feasible; however, we will have greater clarity once we start interacting with FDA for specific issues.

Bino Pathiparampil: Okay right. I missed exactly the point you said about the Caraco guidance, you said something about \$225 million revenue, could you just repeat that point?

Dilip Shanghvi: What I said is Caraco's last year manufactured product revenue was \$112 million, and for Caraco's distributed products for Sun Pharma, the revenue was \$225 million.

Bino Pathiparampil: Okay, that is it. Thank you very much.

Moderator: Thank you Mr. Pathiparampil. The next question is from the line of Abhay Shanbhag of Deutsche Bank. Please go ahead.

Abhay Shanbhag: Yes just two questions, 1) you indicated \$112 million comes from products manufactured at Detroit and third party, can you give a breakup of that, how much is Detroit and how much is third party?

Dilip Shanghvi: Caraco will need to share specific information related to third party and self - manufactured products.

Abhay Shanbhag: Okay. One last question sir, you know this plant has been having problems with the FDA. It started with 483, then a warning letter and product recalls. Is there anything really significant or are we seeing USFDA get a bit more jittery on the cGMP norms or have the cGMP norms been really tightened in the last one year?

Dilip Shanghvi: It is very difficult to answer a very generic question. I think our assessment is that FDA has become far more vigilant and is enforcing the existing law much more strictly after some of the issues which exposed US citizens to products that caused loss of life. And this is also the mandate of the current FDA Commissioner. What we see is that not only for manufacturing, but also for approval of new products, the emphasis on safety is becoming increasingly higher. And I think this is the focus for the FDA right now.

Abhay Shanbhag: Okay. And sir just a bit more clarification. How many times, in the last one year has this plant been inspected? I mean you had the 483, then the warning letter, then

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product recalls, and this one, and the letter talks about the May 2009 inspection, so was it just two times or was it more number of times that the FDA inspected the plant?

Dilip Shanghvi: I think Caraco would have disclosed the number of inspections in their filing. I do not exactly remember the number of times FDA would have inspected the facility.

Abhay Shanbhag: Okay fine. The Able Labs unit is not impacted, I mean the unit you acquired from Able Labs. So that would continue as normally right?

Dilip Shanghvi: Yes that is correct.

Abhay Shanbhag: So controlled substances are not impacted with this seizure?

Dilip Shanghvi: That is right.

Abhay Shanbhag: Okay, thank you sir.

Moderator: Thank you Mr. Shanbhag. The next question is from the line of Neelkanth Mishra of Credit Suisse. Please go ahead.

Neelkanth Mishra: Yes hi. I had two questions; one is the potential impact on the sales of distributed products. I understand that a lot of the sales happen as a sort of portfolio sales. Do you anticipate any impact on the customer response to this issue and the sales of distributed products in some way getting impacted; we have seen that some of your peers see sales declines even for products that were actually not put on import alert?

Dilip Shanghvi: It is difficult for us to respond because we have not seen the response as yet. We have to go through this before we can respond. My sense is that Sun sales will not be affected nor manufactured products. We may lose sales for a short period, in case if we lose, but we should be able to regain.

Neelkanth Mishra: Thank you and one last question. Unfortunately we are not able to interact regularly with Caraco management so apologies for posting the questions to you. The Veterans Administration Contract was apparently not renewed in the 4th Quarter last year as expressed in their 10K, our estimate is that it is about \$15 to \$20 million in sales.



1) Is that estimate correct? and 2) Did we see the drop in sales to the VA in the 4th Quarter or is the drop in sales expected from 1st Quarter onwards? That is the second question.

Dilip Shanghvi: I'm trying to understand the purpose of the question.

Neelkanth Mishra: Sir we are trying to estimate how much the sales dropped. We are trying to assess how bad this news is incrementally because it was perhaps acknowledged that the VA sales were to go away anyway. And if at all these issues do get resolved what kind of recovery can we expect?

Dilip Shanghvi: I think it is difficult for people to build a sales forecast based on the guidance which Caraco has shared with investors. I do not have specifics as to whether the sales in the last quarter were already impacted by the loss of VA sales or not. However, the sales in the last quarter for Caraco manufactured products were significantly lower than the overall previous quarter sales. They have sold significantly lower than \$30 to \$35 million which they used to sell quarterly.

Neelkanth Mishra: Okay. Thanks very much.

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

Sameer Baisiwala: Good morning everyone. Dilipbhai it has been a short period of time but did Caraco or yourselves have any chance to talk to your customers, any feedback from them?

Dilip Shanghvi: I am sure Caraco is actually interacting with each of their customers on an hourly basis and I think in any case they will continue to sell the distributed products. So that is exactly what I explained a few minutes back - that we do not have a sense yet as to whether or not our Sun product sales will be negatively impacted. Our sense is that it may not be, but even if it is, it should be recoverable within a short period. I also explained that in the last six months, four of Sun locations have been audited by the USFDA without any major 483. So there is no concern for the customers for Sun manufactured products.

Sameer Baisiwala: Okay. Sir it just looks a little counterintuitive, that the customer would make a distinction between products manufactured out of Detroit versus those being manufactured in India. What they would probably keep in mind is that, these are products being



sold from Caraco and Caraco is having FDA problems. It's a little general view, but probably the sensitivity involved in pharma products, this is what we have observed earlier. So I am just wondering, what is the basis of your confidence that Sun manufactured products will not be significantly impacted?

Dilip Shanghvi: As I explained, it is too early for us to take a definite view. However, what we have said is that we are withdrawing our guidance for this year and when we reissue our guidance that will factor in a more measured response to all the current issues.

Sameer Baisiwala: Okay. And Dilipbhai just the way forward, I am sure it is going to be a little iterative and FDA is going to tell us what to do, but do you think there is a good chance - FDA press release talks about a Court order and the Court is going to force companies to fall in compliance and stuff like that. So is this going to be Court intermediated process from here on?

Dilip Shanghvi: That is correct. I think the current seizure is under a Court order and the typical process as I understand after this happening is that we have to interact with the FDA, with external lawyers and try to work out a consent decree with the FDA. And the consent decree will have its own controls and restrictions on the process by which Caraco can come back into compliance, and once the company comes back into compliance, the consent decree is withdrawn.

Sameer Baisiwala: Okay, thank you very much.

Moderator: Thank you Mr. Baisiwala. The next question is from the line of Rajesh Vora of ICICI Securities. Please go ahead.

Rajesh Vora: Good morning gentlemen. Dilipbhai the written response by Caraco should have been done by 12th of June, within 30 days from 12th of May which is date of the last inspection by USFDA. What I am unable to understand is why FDA did not react after issuing a fresh 483 in the month of May and why it happened only a couple of days ago? Is there something that happened in between? Was it something to do with the written response? Could you throw some light on that?

Dilip Shanghvi: For me to guess why FDA did what it has done would be difficult. It would not be proper neither would it be accurate. The important issue for us to keep in mind is that the FDA's current thinking is that the firm is not operating under cGMP compliance. I think in the



context of what you have already said that if Caraco would have sent its written response, that feeling would have persisted even after the written response was submitted.

Rajesh Vora: Sure. And incrementally it is now almost a year since they inspected the facility, then it came to a warning letter and now it is a seizure. What is it that Caraco's team under Dan Movens and Sun Pharma team under your leadership, having done a great job all these years - is there something, which was under the control of the management both at Detroit and in Mumbai that you could have done, and that would have maybe not led to this sort of situation. Is there something that at our end was controllable, that at our end could have been done which would have changed things, or you think there is something that you plan to do very quickly to get out of this before it worsens.

Dilip Shanghvi: No, I think Rajesh it is important to keep in mind that all of us have a 20-20 vision post the event.

Rajesh Vora: Sure.

Dilip Shanghvi: So I think it is important for us to focus on the future and to try and do the right thing, so that we can continue to generate and create shareholder value. This specific instance has seen significant negative impact, - much larger short term impact for Caraco shareholders, and some relatively smaller impact for Sun shareholders. However, I have always maintained that as a company we always invest in short-term, medium-term and long-term growth potential and opportunity for the company. And I do not see anything which will significantly negatively impact our medium-term and long-term growth prospect. But as a company, we have always learned from every one of our failures and I think this will be an important learning for us.

Rajesh Vora: Sure. And you mentioned that you are withdrawing this guidance of 13% to 15% for Sun Pharma. Now considering that Caraco has shared, the impact of the inventory seized is only \$15 to \$20 million. That is a pretty small number relative to Sun Pharma's overall numbers. So is that something you will watch out for, how things pan out. Because you do not know and as you rightly mention about the future, we have to focus more and learn from the past. The biggest question in the minds of investors and all involved is, what can go worse from here. Is it injunction, is it ban, court driven delays, of course I am not trying to ask all that, but in that context though financially it looks like a very small number, but from a credibility view point Sun



Pharma is a serious player with a great pipeline. Does that bother you more qualitatively on the credibility and the reputation side than financial impact in the near term?

Dilip Shanghvi: No, as a company we have always given greater emphasis to credibility than money. So, to that extent this is a very large negative for us. However, there is a financial impact of this beyond the size of the inventory because this would also negatively impact the sales. So to that extent I think is the worst exposure.

Rajesh Vora: Sure. I think as you have done in the past you will come out of it, all the best and thank you very much for your time.

Moderator: Thank you Mr. Vora. The next question is from the line of Kartik Mehta from Daiwa Securities. Please go ahead.

Kartik Mehta: Hello, I want to know if there will be any change in the number of ANDAs that we are expecting to file in FY10 and what would trigger Sun Pharma to start manufacturing all of it in India and not manufacture anything at Detroit? Thanks.

Dilip Shanghvi: When we give the guidance for our overall performance this year we will also, if necessary, revise the guidance for number of ANDAs that we plan to file this year. The second issue is about the transfer of manufacturing site, and that decision we have not taken as yet. There are a large number of issues that we have to evaluate before we can decide and finalize where and which product to transfer. And transfer is not a very easy process, so it takes resources, time and effort. And sometimes those efforts may not be justified by the upside of transfer of products.

Kartik Mehta: Okay, thanks.

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

Saion Mukherjee: Yes hi, thanks for taking my question. Just wanted to understand the statement that Caraco made yesterday. Are you aware whether they have toned down their expenditure for R&D and SG&A for this year?



Dilip Shanghvi: We are not aware of any specific information that Caraco has shared about reducing their operating cost or investments in R&D. I am sure that at an appropriate point, once they address the immediate issues, they will give guidance, if necessary, if this will impact their R&D and filing efforts.

Saion Mukherjee: Okay. Going forward do you think such a change is likely? If you see, last year Caraco had made significant investments in capex and they had also indicated that going forward their cash R&D expense would also go up. Now given all these issues with the FDA, do you think there will be a change in stand there? You would possibly like to file more products out of India and carry out expansion here, than at Caraco?

Dilip Shanghvi: We have always believed that it is important for us to be present as a manufacturer in the US and that is the reason why we have acquired many manufacturing assets in the US. And this does not change our thinking.

Saion Mukherjee: Okay. And the last question is. Do you know whether there are risks for further product recalls?

Dilip Shanghvi: Caraco product recalls?

Saion Mukherjee: Yes.

Dilip Shanghvi: If I see the FDA release, then what they have said is that there is no health concern or safety concern for products which are already in the market. So if that is the stated position, I do not visualize them asking Caraco to recall the products.

Saion Mukherjee: Okay thanks a lot and all the best.

Moderator: Thank you Mr. Mukherjee. The next question is from the line of Prashant Nair from Citigroup. Please go ahead.

Prashant Nair: Good morning. A slightly longer term question. Would you be, post this issue, looking at any move to separate distribution of Sun products from Caraco just to avoid any potential negative fall-out? Is that an option at all?

Dilip Shanghvi: That is not an option that we have currently considered.



Prashant Nair: Okay. And second question is on the Veteran Administration contract. Were the products supplied under that contract wholly manufactured at Caraco or were they manufactured by third party?

Dilip Shanghvi: I think they were manufactured by Caraco.

Prashant Nair: Okay, thanks a lot.

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

Sonal Gupta: Good morning everyone. Just a couple of questions. Sir just wanted to understand, given the manufacturing facilities across all your plants, how unique do you think are the problems at Caraco or is there something that is not unique, and some problems can occur at other places as well, something similar to this?

Dilip Shanghvi: I think both Caraco and Sun are independent companies. Even though Sun is a large shareholder in Caraco but our operating process, our training, many of our systems may not be similar. Since we have been inspected four times in the last six months for pre-approval as well as GMP Audits, I do not visualize similar problems in the Sun facilities. Mr. Valia will have a better understanding.

Sudhir Valia: We do not see any major issues because in all the inspections we've had, we hardly have any 483 observations.

Sonal Gupta: Okay, a more generic question You were mentioning that as the USFDA becomes stricter and more enforcing of rules, how does it, for the industry and for yourself, increase the cost of compliance or do you think that there is not going to be a material increase, primarily on the manufacturing side, because of the higher benchmark in terms of cGMP compliance that the USFDA is setting?

Dilip Shanghvi: Right, it is a good question. We have not actually evaluated increased financial impact on account of increased compliance. However, our sense is that even though there maybe a short-term impact on compliance, over a period of time increased compliance leads to more efficient manufacturing process and reduced cost.

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Sonal Gupta: Okay sir. And finally, I don't know if its possible for you to answer this question, given that Caraco has been under the radar of the FDA for more than a year, over that one year period, where do you think Caraco has moved in terms of scale, from say 100%, where you would like to see it or where the FDA would like to see it and where is it currently, any thoughts on that?

Dilip Shanghvi: If I see what FDA has done, then it is far away from where FDA wants it to be. So, it has to come up to where FDA wants it to reach. And our observation is that it will need to improve significantly to meet the current expected requirements of the FDA.

Sonal Gupta: Okay sir, thank you very much.

Moderator: Thank you Mr. Gupta. The next question is from the line of Anmol Ganjoo from BNP Paribas. Please go ahead.

Anmol Ganjoo: Hi, I have a follow-up question. Of course with the benefit of 20-20 hind sight and given the vast difference in outcomes in the resolution of FDA related issues for Sun and Caraco facilities, what prevents us from exercising greater operational control on Caraco management and making sure that most of the process are identical to what are followed in Sun?

Dilip Shanghvi: There are regulatory issues from SEC. There is no FDA issue because SEC basically wants greater protection of minority interest and that means all the transactions between Sun and Caraco need to be on arm's length basis. So I do not think that it is feasible to treat Caraco as one more manufacturing location for Sun.

Anmol Ganjoo: Okay. And my second question is that the timeline, obviously the pitfalls, does it expedite in any way the search for US manufacturing assets, like what was done in case of Chattem Chemicals, or any other assets and therefore leverage balance sheet to address the issues that have been thrown up in the last one year?

Dilip Shanghvi: You mean ask whether we can transfer the products at Caraco to some other US facility, is that the question?

Anmol Ganjoo: A or Second, can we just expedite our search for bigger assets in the US geography in terms of giving you strength of product pipeline.

Dilip Shanghvi: Any acquisitions?

Anmol Ganjoo: Right.

Dilip Shanghvi: No, it is important for us to be cognizant of strengthening our capability rather

than becoming bigger. So I think with an ongoing issue of this size, it is important for us to work

towards addressing this issue and becoming stronger, rather than trying to be bigger. The answer

is that, this is a more important issue for our focus rather than to look at any important acquisition

right now.

Anmol Ganjoo: And the first question, in terms of transferring the manufacturing of products to

other facilities in the US in the medium term, is that a possibility, if not back to India?

Dilip Shanghvi: Yes it is possible. I think we have to evaluate because as I explained, every

transfer of product is more or less like filing a new product, so much effort is required, whether all

of that is justified by the upside of those products. So it has to be a product to product decision.

We also need to work with the FDA and get greater clarity whether after this seizure FDA will

consider transfer of product out of Caraco facility. So these are the issues that we do not know. I

think as time passes, we will have greater clarity.

Anmol Ganjoo: Okay and the last question pertains to reassessment of guidance, any timeline

you have in mind that we can look forward to.

Dilip Shanghvi: I think as soon as we will have this clarity, we will share the information with

you.

Anmol Ganjoo: Okay, thank you so much.

Moderator: Thank you Mr. Ganjoo. The next question is from the line of Ravi Agrawal from

Edelweiss, please go ahead.

Ravi Agrawal: Yes good morning and thanks for taking my question. I had just two questions.

One is on the inventory, if you see the inventory as of last year in Caraco is around \$79 million.

What I understand is \$15 to \$20 million of that inventory is currently seized. The question is, ex

the distributed products, what happens to the remaining inventory which is in Caraco. Is that

company going to do some sort of a write off on that inventory as well or it just stands in the

company.



Dilip Shanghvi: I think without understanding from the FDA as to what is the path forward, it is difficult to respond to your question. Because let us say that if Caraco is permitted to operate under restrictions and under control then most of this inventory would be used up, and would continue to be sold. So it is difficult for us to answer at this point of time.

Ravi Agrawal: Okay and my second questions is post whatever has happened on Thursday night, Friday morning, is there any chance that you are going to revise capex guidance as well?

Dilip Shanghvi: No.

Ravi Agrawal: Okay. Thank you.

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

Sameer Baisiwala: Sir if you just know, what are the number of months of inventory carried by our customers? Is it possible to disclose sir?

Dilip Shanghvi: Honestly I do not have the number. I know that Caraco keeps track of the inventory with customers but I do not have those numbers.

Sameer Baisiwala: Okay. And then just subsequent to all the discussion that we had on CPD just now, it may not be the best time to ask this question, but any thoughts on taking Caraco full 100%?

Dilip Shanghvi: I think you answered your question yourself - that this is possibly not the best time to ask this question.

Sameer Baisiwala: Okay, thank you.

Moderator: Thank you Mr. Baisiwala. The next follow up question is from the line of Abhay Shanbhag from Deutsche Bank. Please go ahead.

Abhay Shanbhag: Yes sir following up on Sameer's question. In the past we have found it a bit difficult to understand reasons for keeping Caraco listed in US, strategic or taxation. Now with so many issues facing Caraco is it not the right time to rethink the issue as to whether it should be



kept separate. You said, it has to be a separate company because of SEC regulations, so why not take it to 100%?

Dilip Shanghvi: Fine, I hear what you are saying and as I explained to Sameer just a minute back - this is not the best time to reflect on longer term issues.

Abhay Shanbhag: Right, but is there any strategic reason why it has still been separate. Over a period you have been increasing stake by transfer of ANDAs, but now that it is at 76%, is there any reason why you have kept it separate for a reasonably long period of time?

Dilip Shanghvi: Till this point of time we had explained that we have investment considerations whereby we should be able to recover our investment in four or five years. We were not able to meet that investment consideration in Caraco. So that was the historical reason and we have to see what happens going forward. But we were comfortable with a separate company and a set of minority shareholders. So this is not the time, I think our current focus is how to help Caraco come out of the current challenge.

Abhay Shanbhag: Yes, thank you sir.

Moderator: Thank you Mr. Shanbhag. The next question is a follow up question from the line of Neelkanth Mishra from Credit Suisse. Please go ahead.

Neelkanth Mishra: No, thanks. Sameer and Abhay have asked what I wanted to, thanks.

Moderator: Thank you Mr. Mishra. Ladies and gentlemen that was the last question of the day. I would now like to hand the floor back to Mr. Baldota for closing comments. Please go ahead.

Uday Baldota: Thank you everyone for joining the call. If you still have any balance questions, please feel free to get in touch with me or Mira, we would be happy to help you out, thank you.

Dilip Shanghvi: Thanks.

Moderator: Thank you Mr. Baldota, thank you gentlemen of the management. Ladies and gentlemen on behalf of Sun Pharmaceuticals that concludes this conference call. Thank you for joining us and you may now disconnect your lines.