



**“Wockhardt Conference Call to discuss
US FDA Report on Waluj Facility”**

24th May 2013



SPEAKER: Habil Khorakiwala, Chairman

Moderator: Good day, ladies and gentlemen. Thank you for standing by and welcome to the Wockhardt Conference Call to discuss the US FDA import alert on Waluj facility. For the duration of the presentation, all participants line will be in a listening-only mode. And we will have a “Q&A” session after the presentation. I would like to now hand over the conference to Abhishek Singhal, Analyst from Macquarie Capital Securities. Thank you and over to you, Sir.

Abhishek Singhal: Welcome all. We have with us the Senior Management of Wockhardt represented by the Chairman Mr. Khorakiwala. We will start this call with brief opening remarks from the management, after which the floor will be open for interactive question and answer session. Over to you, Sir.

Habil Khorakiwala: A very good afternoon to all of you. I have already communicated briefly to the media and I will repeat that communication that we have received yesterday from US FDA import alert for one of our facilities at Waluj which is near Aurangabad which primarily manufactures injectables, which was visited by FDA and we have received in late March 483. And in that same compound which separates this injectable manufacturing unit if you see, is also our solid dosage facility. And the location being the same, the entire products of the facility are under the alert.

On the last year sales basis, downward impact on our sales in USA on an annualised basis is about \$100 million. So that is the situation. And the remedial approach, we are undertaking are the following. One, we are on a very fast track basis appointing US consultant who would be helping us in bringing this facility in compliance in a month or two months maximum. And the 483 dealt with primarily some of the GMP violation because we have two manufacturing facilities. One facility, which was manufacturing for US FDA injectable products, and in fact, it was visited last year. And generic Zometa, we wanted approval and there was a minor issue. So we requested actually FDA to come and visit that facility. But we also have another facility, which was primarily meant for products, not for USA. But we have one of the products filed in that area. And that is where they observed non-compliance of GMP in terms of SOP non-compliance and other areas, which we are in the process of correcting.

Now, we have given a clear reply to FDA within 15 days as required by law of the corrective measure in the timelines we proposed in terms of correction; and with the consultants coming in and visiting this facility and helping us out in terms of bringing to compliance as soon as possible.

Simultaneously, in addition to that, we had filed for injectables of four products in our new facility, which we are creating at Shendra. And which anyway, US FDA is inspecting sometime in July, late July, early August which they have informed us. And with that nearly, once we receive in the next 6-8 months, the approval of the new facility, 80 % of the injection volume could be restored.

Amongst the solid dosage form, there are two approaches we are following. We are working with our consultants to segregate these two facilities because in this visit, US FDA has not even visited our tablets facility. And we have a compliance letter from US FDA as early as August 2012 after their visit last year to this facility. So we are making efforts to see that facility comes out of the import alert.

Simultaneously, we are also taking a number of products, which constitute about 80% of the value of solid dosage form into our other approved facilities in India at Aurangabad and other places. So I think, this is briefly the general statement I would like to make. And then I would invite questions and I will respond to that.

Moderator:

With this, we are going to start with the “Q&A” interactive session. So I would request all the attendees and the participants, if you wish to ask any question, kindly press “0” and “1” on your telephone keypad and wait for your name to be announced. I would request all the attendees and the participants, if you wish to ask any question, kindly press “0” and “1” on your telephone keypad, please. The first question is from Jigar Walia from OHM Group. The line has been unmuted, you can go ahead and ask your questions, please.

Jigar Walia:

Sir, you have given a certain timeline for resolution of the issues, but looking at the past experience that we have had recently, say for like Aurobindo, for Claris, can you give some examples wherein you may be a little more confident that the timeline should be less than others?

Habil Khorakiwala:

See, two issues are there. One issue is finding a solution to our existing facility and our effort is to do it as fast as practical and possible. Second issue is that 80% of the products in terms of value, we are in a process of having an alternate site. And this will happen in 8 to 9 months’ time because these are absolutely different sites; one is an approved site, another is under approval site, you can call it. So that is our strategy. So that is what I can tell you. In the worst-case scenario, we might not

have an immediate answer in 8 to 9 months for about 20% of our lost business.

Jigar Walia:

Sir, thank you.

Moderator:

Thank you, Mr. Walia. The next question is from Mr. Subrajeet from Nomura. The line has been unmuted, you can go ahead and ask your questions, please.

Subrajeet:

Thanks a lot, sir, for taking my question. Sir, can you please name what are the products among the solid – which forms were manufactured at your Waluj facility?

Habil Khorakiwala:

I can tell you our major product like Metoprolol and the Fluticasone and other things are not manufactured there. The collective value of this business in injectable is around \$24-25 million and about \$75 million or so is solid dosage form. There are the number of products, but relatively each one of them has a smaller value proposition.

Subrajeet:

Sir, is it true that generics of Stalevo, Comtan, and Geodon are manufactured at your Waluj facility?

Habil Khorakiwala:

See, LEC and Entacapone we had authorised generic and we are going to source it from that outside sources. In addition, as far as LEC concerned, we have more than 8 months inventory lying with us also. So all these products, also generally, we have 3 to 6 months inventory lying with us in United States. So the impact on an annualised basis as I have mentioned will be 100 million. But already two months have gone and some inventories are lying with us. So the remaining period impact would be there as a worst-case scenario.

Subrajeet:

Okay. Thanks a lot, sir.

Habil Khorakiwala:

Yeah, thank you.

Moderator:

Thank you so much, Mr. Subrajeet. Before we move on to the next questions, I would like to repeat once again to all the attendees, if you wish to ask any question, kindly press “0” and “1” on your telephone keypad, please. The next question is from Mr. Prakash Agarwal from CIMB. The line has been unmuted; you can go ahead and ask your questions, please.

Prakash Agarwal:

Yeah, good afternoon. Sir, just a question here; you expect this 80% of the sales to come back by site transfers. But just one question here, I mean, how easy is to get market share post you withdraw products from the market because if I correctly understand like Geodon, you were fifth player in the whole

product and then you could end up with 10% market share. So with products like Comtan, Stalevo where you are an AG, you have good market share, but when you pull out from the market, is it easy to get market share back?

Habil Khorakiwala:

I think it is a very good question. As far as the Entacapone and LEC are concerned, today we would be buying it from the original manufacturer. So those products will not come in the picture. But you are making a reasonably valid point. If you lose market share as the worst scenario, to gain back market also would be a challenging situation. So we may lose out because of that dynamics also partly in the market.

Prakash Agarwal:

Okay. And what is the usual distributors' reaction. I understand you must be dealing with the CVS Walgreens of the world. And when you have this import alert, given that you said you have good inventory of 8-month inventory, does it impact the distributors' response to this?

Habil Khorakiwala:

Honestly, it is rather too early because it is only one day, which has gone between. And we are in a process of discussing with the distributors and we are communicating it depending on the various products. So to respond to you is that the products at the distributor where we are not affected, we don't believe there will be any impact whatsoever.

Now, whenever the products are affected that is where we are in discussion and we are sharing very transparently with them to what is our level of inventory and what are the issues. So we are trying to work out with them, the approach and see that – we will definitely have an impact as far as the products, which are not available. But we are doing everything possible to see that it does not have any collateral damage.

Prakash Agarwal:

Okay. And lastly, if I can add one more, you talked about that 483 observation was more on the quality front. So looking at some history, I mean, you went through that CDR and you had R&D expenditure fallen down to 3 to 4% and CapEx had come down to Rs. 1.5 to 2 billion vis-à-vis if I see the industry practice that is pretty high compared to us. So would you like to comment there?

Habil Khorakiwala:

No, I don't believe that any of those elements have contributed to that because we have about 8 to 10 manufacturing facilities, which are approved by the FDA. Most of our productions are done even in India. Even in Aurangabad area there are two. Then we have another two in India. Then we have Morton Grove and others. So in fact, we have modernised our facility

and invested in CapEx as and when it was required. So I don't think it is a fallout of that.

Prakash Agarwal: So you don't see a spike in CapEx per se going forward?

Habil Khorakiwala: No, we have a plan as we communicated. CapEx is about 250-300 crores for the current year and that will remain.

Prakash Agarwal: Understood. And consultant cost, from that field it seems like...

Habil Khorakiwala: Yeah, but those are relatively marginal, \$1-2 million.

Prakash Agarwal: Okay, thanks. I will join back the queue.

Moderator: Thank you so much. The next question is from Prashant Poddar from Invesco, Hong Kong. The line has been unmuted; you can go ahead and ask your questions, please.

Prashant Poddar: Thank you, sir, for taking my questions. Sir, first question is related to this import alert itself. Generally, as we believe the process of these regulatory things is like this you get 483s and then you get a warning letter and then you get an import alert. What do you think really made FDA issue an import alert right away rather than issuing a warning letter first?

Habil Khorakiwala: I honestly have no idea. But from what I do understand, if there is a warning alert it comes rather quickly after the inspection. And warning letter of course follows.

Prashant Poddar: Okay. I think either there is a lack of understanding from my side or it hasn't been communicated. But what was the nature of the problem because of which this import alert was issued?

Habil Khorakiwala: As I mentioned to you that 483 highlighted some of the GMP compliance issue as far as following SOPs and various other areas which resulted into this because there were two, three critical observations and collectively FDA took this decision.

Prashant Poddar: And from this facility, were we supplying to United States?

Habil Khorakiwala: Yes. That is why the import alert is there.

Prashant Poddar: Okay. Sir, the second question is related to the incremental approvals. Do you think that the incremental approvals for products filed from other facilities could also get impacted because of this issue?

- Habil Khorakiwala:** We don't believe so. This doesn't happen even in the past with anybody. So when there is an import alert, it gets restricted to that facility itself because other facilities are approved. See, currently as of current year position, we have more than 45 pending ANDAs. Obviously, out of that, half of them has been filed from this facility and the other half is filed from other facilities. So they are not affected at all. And out of this facility, what is filed from here, at least 12 products we had just recently filed. So anyway, we would have received approval after two years for those products.
- Prashant Poddar:** Okay. So in terms of approvals from other facilities, you are saying that should not ideally slow down going by past experience?
- Habil Khorakiwala:** Yeah, it should not be affected. It should be done on the merit of the case, we believe.
- Prashant Poddar:** Okay. And in terms of sales from your other facilities or let us say, inspection of other facility, the other major facility was inspected last, when?
- Habil Khorakiwala:** See, we have a facility in L1 that is in Aurangabad that is getting inspected again in July-August this year. It was two years back and the FDA has already informed that they are coming for inspection. We have created a new facility Shendra that is – Last year, we communicated to FDA and filed the products. So they are also coming around the same time to inspect these two facilities.
- Prashant Poddar:** Okay. Sir, going back to the old point again, generally a company of your size and the size in United States would be very focused on the manufacturing practices because FDA is very concerned about these things. So this lack of preparation at that facility or lack of following a guidelines for that facility, so was it related to that facility not being managed by the facility head really or would you often have to look at other facility?
- Habil Khorakiwala:** No, I will explain to you. There are two injectable facility we have in Waluj where this alert is there, and one of the facilities was manufacturing products which were supplied in USA. And that is where the generic Zometa approval delay was coming from FDA. And we invited FDA to come and visit the facility and clear the product. Then we also had another facility which primarily was dealing with a non-US operation, injectable sterile, but we had one product filed going out of that because of a technology reason. And that is where FDA inspected the facility and found the issues. And that is where our team was

probably not fully ready for following SOPs and other compliance and that is what they observed.

Prashant Poddar: Okay. So it was on your invitation that this facility was being inspected actually?

Habil Khorakiwala: Absolutely. And they did a very expedited inspection because we requested in mid March and they came within two weeks and inspected the facility. It was on our invitation actually.

Prashant Poddar: Okay. Now, going to just the analysis of the products that you would have expected to receive approvals for this year, for FY14. How much of the incremental growth can get impacted because of just this facility late approvals?

Habil Khorakiwala: We would not receive new approvals from this facility during the year.

Prashant Poddar: No, but my question is on the new approvals from other facilities. How much can they contribute in terms of incremental revenues if you were to let us assume, get nothing from this facility?

Habil Khorakiwala: See, these timelines we do not have it in our hand. Sometime we project, we get it now and FDA takes three months, six months, nine months time. So for me to comment to you— very difficult— how much new approval we will receive from other facility and when we will receive?

Prashant Poddar: Okay, one last question. Sir, on other products in the US market, could that also get impacted because of the fact that one of your facilities have been put on import alert? Does it affect the brand which they generate for your partners?

Habil Khorakiwala: Possibility would be that FDA may come and visit our other facility. And it is subject to what happens in that facility. As an example, after our injectable facility, we have a clinical research organisation in Aurangabad area, not at Waluj, another location, which we had been doing our clinical trials there. So FDA inspector had come in and visited that facility sometime in April actually. And that facility came out quite alright. We received a couple of two minor 483 on that.

Prashant Poddar: Okay, alright. Sir, thank you very much.

Habil Khorakiwala: Okay. Thank you for your question.

Moderator: Thank you so much. Before we move on to further questions, I would like to repeat, attendees, if you wish to ask any question,

kindly press “0” and “1” on your telephone keypad and kindly restrict your questions as we have a long queue. Thank you so much. The next question is from Mr. Kartik Mehta from Sushil Finance. The line has been unmuted; you can go ahead and ask your questions, please.

Kartik Mehta: Thank you for taking my question. Sir, just correct my understanding if I am wrong. For the injectable, you said that your sales would be impacted to the extent you replaced the sales by the new facility. One is at Aurangabad where your inspection is going to happen in the month of July and also, from another facility at Shendra. Correct?

Habil Khorakiwala: No. Injectable, the new facility is only at Shendra. And we have filed products already from – that is the second alternative source because we didn’t have the capacity in this facility. And the Shendra is a very large facility. So we had filed it last year itself as the second source. So once the Shendra gets inspected and cleared, we will have those products available. That is what I have mentioned.

Kartik Mehta: Okay. So that would be done by when, July?

Habil Khorakiwala: July-August, they are coming. Normally, they take few months; three, four, five months before they give you a clearance.

Kartik Mehta: So that facility would be able to compensate the complete volume, which is, supposed to be lost from this?

Habil Khorakiwala: It will have the 80% of value wise, the products available on that space. That is what it is as of today.

Kartik Mehta: And in the case of Aurangabad, how is it going to play the role? Is it for solid or what?

Habil Khorakiwala: No. For solid, I suggested two approaches. One is we would be requesting FDA that import alert for solids may be removed because that facility was never visited by FDA in the recent inspection. And they had visited their solid facility last year itself. And we have received the compliance letter from them from August 2012. So our effort would be there to do it. I cannot say whether we will succeed or not. So that is one option. Second option is that we would be developing a second source from an approved facility, which is in Aurangabad because this facility is located in Waluj, which is near Aurangabad. And with that, we will have about eight to nine months’ time, roughly 80% of value wise production moved there. So there are two strategies for solid.

- Kartik Mehta:** Right. So in summary, for solid worst-case could be 8 to 9 months delay. And for the injectable, if you get the approval by August, you can immediately start supplying now.
- Habil Khorakiwala:** No, I don't think we will get approval. We are going to have an inspection in August and after that FDA takes 4-5 months. So in both cases, you are looking at the same time horizon.
- Kartik Mehta:** So in that case, sir, any calculation you have made for the costing side like your fixed cost would be the same. So what would be the impact on the margin?
- Habil Khorakiwala:** You are right that some of the fixed cost will remain unchanged. And there would be some loss of revenue because of this. But we would be getting revenue growth in normal course anywhere from 90% of our operation. But there may be an impact of 2% or soon our margin.
- Kartik Mehta:** Okay. And sir, one last question. I was just thinking that this kind of inspection comes and if there is an alert, we have a big revenue loss to the extent of let's 100 million dollar. And then, we are finding a remedy of sourcing some consultant who is extremely expert into the field. So just before end of the US FDA visit, we just pay \$1 or \$2 million and get it inspected and it is a kind of insurance we buy ahead of any risk, you know?
- Habil Khorakiwala:** Yes, I understand what you are saying.
- Kartik Mehta:** Because company like us having such a big risk – Now, we are paying \$1 or \$2 million to get remedy. Why can't we do it earlier and get the insurance? At least we are a little bit more sure compared to without having...
- Habil Khorakiwala:** Thank you for your suggestion.
- Kartik Mehta:** Okay, thanks.
- Moderator:** Thank you so much. The next question is from Ms. Monica Joshi from Avendus Securities. The line has been unmuted; Ms. Joshi, you can go ahead and ask your question.
- Monica Joshi:** Hi, thank you, good afternoon. I just wanted to understand the context of the 8 months of inventory. Are you talking about inventory? Is it currently in the market? Is that right?
- Habil Khorakiwala:** No, no, some of them, not all the products. Some of the products, we have a large inventory of 6 to 8 months, not all the products.

- Monica Joshi:** Sure. But this inventory is where? Is it already on...?
- Habil Khorakiwala:** With us.
- Monica Joshi:** Okay. So if I understand it correctly, if you have an import alert, you are not allowed to really export into the US. So you are having an inventory for...?
- Habil Khorakiwala:** That is correct. These are the inventory lying in US.
- Monica Joshi:** So you can sell them?
- Habil Khorakiwala:** Yeah, of course, we can sell.
- Monica Joshi:** Okay. Second understanding, I pretty much didn't get this timeline right. So you are saying 8 to 9 months is what you are expecting 80% of the value of your solid dosage business which is \$75 million hopefully to be transferred to other sites which I believe are two sites, is that correct?
- Habil Khorakiwala:** Yes, correct.
- Monica Joshi:** Sir, just wanted to get your feel. Is this not an aggressive kind of target because we do not believe site transfers really happen this fast or is this some assurance that you are getting from your conversations with the FDA that it gives you this kind of comfort?
- Habil Khorakiwala:** We have evaluated this from our technical people and operational people. And we believe it is possible to do that because we have to take those batches for three months stability and then CB-30 is available. So these are the timelines we believe we could meet.
- Monica Joshi:** Okay. Well, just lastly on your other plants in Aurangabad the two existing plants, so one of them is coming up for re-inspection. I believe that is a third unit, right? When does that come up for inspection?
- Habil Khorakiwala:** The Aurangabad plant, they are coming for inspection in July-August.
- Monica Joshi:** There are three plants in Aurangabad, is that correct?
- Habil Khorakiwala:** Yes. Aurangabad area, we have four facilities, two in Waluj, one in Aurangabad and one in Shendra. So in Aurangabad area, we have four facilities. Out of that, Shendra is a new facility,

which is coming for inspection as I mentioned earlier in July-August. Our Aurangabad facility which is the older facility, FDA has already informed us that they are coming for inspection and it is a normal inspection after two years. Around the same time they are coming for inspection.

Monica Joshi: Great. Got it. Thank you so much, sir.

Moderator: Thank you so much, Ms. Joshi. The next question is from Mr. Bino from IIFL. The line has been unmuted. You can go ahead and ask your question.

Bino: Hi. Thanks for taking my question. Most of my questions are answered, couple of follow-ups. Just following up from the earlier questions, again this Chikalhana facility, is that the older facility that you think will be inspected in July-August?

Habil Khorakiwala: That is correct.

Bino: Okay. And what is the possibility of having to go through individual filings once again, you know, as and when the facility gets back to compliance?

Habil Khorakiwala: You know, our solid dosage facility has not been inspected during its inspection. And none of the products which we are supplying to USA specifically any product has the GMP violation. It was the second facility which was mainly meant for non-US operation where there were some GMP violations. So our problem in this situation is slightly different that none of the products supplied in USA specifically has been identified for GMP violation. It was the facility, which was identified for GMP violation.

Bino: Right, right. And, sir, the problems the FDA found with quality or manufacturing process, was it related to some common operations that catered to all the sub-units within the plant, like, say common quality assurance department or common inventory management department or something like that?

Habil Khorakiwala: See, I can tell you as far as solid dosage are concerned, we have an independent facility with its own quality function. As far as the injectable facility both the facilities which we have, we have a single quality team there.

Bino: Sure.

Habil Khorakiwala: So we have two quality teams, one for injectable and one for solid dosage. So they are independent with independent relation.

- Bino:** Okay. And finally if I could ask one unrelated question over this redemption of certain preference shares recently. What led to that?
- Habil Khorakiwala:** Sorry? I don't get your question.
- Bino:** There was some redemption of certain preference shares which was announced recently on the stock exchange which was originally supposed to be...
- Habil Khorakiwala:** Yeah. This is about State Bank of India had taken it for CDR scheme. One of the options of preference share, so there were two options. One was encashment and another one was the preference share. So at the time of our exit, they decided that they would like to take the option of encashment rather than the preference share and that is why the reduction took place.
- Bino:** So now you have exited completely the CDR?
- Habil Khorakiwala:** Yes. We have exited the CDR because CDR committee has already accepted about two months back exiting. We have paid back all the banks, all their outstanding loans and I think we are in a formal process of getting officially our assets released from the banks.
- Bino:** Great. Thank you. I will join back the queue.
- Moderator:** Thank you so much. The next question is from Mr. Jesal Shah from JM Financials. The line has been unmuted. You can go ahead and ask your questions, please.
- Jesal:** Yeah, thank you for taking my question. If you can just give some idea about all your manufacturing facilities, particularly, the two oral solid facilities at Aurangabad, what are the capacities that you have and how many products are really pending approvals from these two?
- Habil Khorakiwala:** See, we have one facility in Waluj and one facility in Aurangabad. In addition, we have a facility in Morton Grove in USA. And we have our new facility coming up in Shendra which has both sterile and liquids and solids. So as I mentioned earlier that out of pending ANDAs, 50% of these ANDAs are from location other than this Waluj facility, which is under this FDA, alert – 50% of them.
- Jesal:** Right. You know, in terms of capacities, let's say, how big will be that Waluj versus the one at Chikalthana?

- Habil Khorakiwala:** I think they are equal size facility we have both in Waluj and Chikalthana facility.
- Jesal:** Right. And what's the existing utilization at Chikalthana?
- Habil Khorakiwala:** We have a capacity at Chikalthana, which will take more products. That we have already evaluated.
- Jesal:** Right. And of the products which are pending at Chikalthana, how many do you expect to get approvals within the next two years?
- Habil Khorakiwala:** See, we have about 40 odd products, which are pending approvals. About half of them are sitting in EOU. And out of other half, maybe 50-60% product because recent filing of about 12 of them is from the EOU facility, which we said we will get it after two years. So we should be getting out of the remaining 24 applications at least 60% to 70% of that coming out of other facility.
- Jesal:** And, sir, just the last one. Do you have a number incomes of what is the, you know, either the adjustable market size or in the past you've stated that half of your products are complex? So would you say that more of these complex products were really from the Chikalthana facility versus Waluj?
- Habil Khorakiwala:** See, in value terms, so, obviously, more complex products are coming from Chikalthana facility. And I would not be able to comment on it, but at both those locations we have the facilities to make complex products.
- Jesal:** Right. Okay. Thank you.
- Habil Khorakiwala:** Yeah, thank you.
- Moderator:** Thank you so much. The next question is from Mr. Anubhav Agarwal from Credit Suisse. The line has been unmuted. You can go ahead and ask your questions, please.
- Anubhav Agarwal:** Yes. Thank you. One question is on the impact that you said, sir, about \$100 million, just a clarity that, is that adjusted for the inventory you have in the US or is it unadjusted number?
- Habil Khorakiwala:** No, this \$100 million is based on our last year's 12-13's actual sale. So we believe that as a worst-case scenario. It will be 100 million. And we are doing other measures and I discussed earlier in earlier calls to mitigate part of that.

Anubhav Agarwal: Okay. And the second question is on the 483 observation that you got because of which you got the import alert on this facility, the nature of those observation was that more related to the process which are followed only in the injectable plants? Basically, I am trying to ask that would your processes be very different across the injectable or a solid dosage facility?

Habil Khorakiwala: No, I think the issue was compliance, not the process. And, obviously, for a sterile facility you have a very different approach of manufacturing than when you have for a solid dosage facility.

Anubhav Agarwal: Sir, can you slightly elaborate here when you say just compliance actually I am not able to understand the gravity of the situation here?

Habil Khorakiwala: In what? Because it's a bit technical for me also to go beyond what I said, you know, like SOPs and operating procedures, which are there, and being not followed and there were more than one instance where they found this happening. Because, you know, the other facility was there and it was being supplying the products for non-US. It was in WHO compliance, but somehow it was not meeting the stringent standard one follows for USFDA facility for a sterile product. So that was the whole issue there.

Anubhav Agarwal: Okay. Thanks, sir. It's helpful. I will join at the queue.

Moderator: Thank you so much. The next question is from Mr. Nikunj Doshi from Bay Capital. The line has been unmuted. You can go ahead and ask your question, Mr. Doshi.

Nikunj Doshi: Yeah. Thanks. Mr. Khorakiwala, just wanted to know will you be required to call back any of the products because of this warning from US, means, whatever inventory lying there? Would you be required to recall those products or write off any amount because of that?

Habil Khorakiwala: We do not believe that there would be any recall of the product taking place. As I mentioned earlier, the GMP compliance issues were there. There were products meant for non-US markets, A, B, even though we had the approvals for one of the products which we are not manufacturing for USA that was there. So none of the products manufactured for USA specifically had a compliance issue.

Nikunj Doshi: Okay. So there will not be any kind of write offs on account of inventory or something?

- Habil Khorakiwala:** We do not envisage that because of recall or anything.
- Nikunj Doshi:** Okay, thank you very much.
- Moderator:** Thank you so much, Mr. Doshi. The next question is from Mr. K.C. Suri from Span Capital. The line has been unmuted. You can go ahead and ask your questions, please.
- K.C. Suri:** Yes. Sir, I mean, you said that the 75 million is the oral solid dosage and which wasn't really inspected, how soon is your next interaction with the FDA with regards to this import alert and you can have a segregation, I mean, of course, the transfer of 80% values in other alternative?
- Habil Khorakiwala:** I honestly cannot say the timeline vis-à-vis USFDA what will take place, but we would be going to USFDA on the subject within 4 to 6 weeks.
- K.C. Suri:** 4 to 6 weeks. And there would be another 4 to 6 weeks to arrive at our decision in this.
- Habil Khorakiwala:** I can't comment on the USFDA timeline nor their response.
- K.C. Suri:** Okay. And just in case, I mean, if you go to USFDA, hypothetically, you go to them and whatever time it takes and they segregate the OSD facility from the injectable on the import alert, so you would be able to ship immediately from the OSD facility?
- Habil Khorakiwala:** Yeah, if import alert is removed, we can activate once again that facility and manufacture the product and supply.
- K.C. Suri:** Right. Right, Sir. And, sir, you spoke about the two products Entacapone and the other name. I didn't get the other name for which you said you had an 8-month inventories, right?
- Habil Khorakiwala:** Yeah. 6 to 8 months inventory we have for LEC. And this Entacapone and LEC both these products we are sourcing from the innovator as a part of authorized generic.
- K.C. Suri:** Right. Okay, fine. Thank you and all the best.
- Moderator:** Thank you so much. And we will take the last two questions for today's call. And the next question is from Mr. Shri Hari from BCS Securities. The line has been unmuted. You can go ahead and ask you questions, please. Mr. Hari, your line has been unmuted. You can go ahead and ask your questions, from BCS Securities. Moving on to the next question from Mr. Abhishek

Kulkarni. He is an individual investor. The line has been unmuted. You can go ahead and ask your questions, sir.

Abhishek Kulkarni: Hello, Mr. Khorakiwala.

Habil Khorakiwala: Hello. How are you Abhishek?

Habil Khorakiwala: Good, good. Sir, first of all I am pretty sure that company is going to come out of this considering the past experience and the resilience shown by it. So I just want to know if the profit impact from this import alert considering that the revenue of 90% can still grow in FY14-15, so can we maintain the PAT level what we achieved in FY13?

Habil Khorakiwala: What are you saying can we maintain FY13-14 the PAT level of 12-13. Is this your question?

Abhishek Kulkarni: Yes, sir, because 90% of the revenue can still grow.

Habil Khorakiwala: Normally, we do not give the guidance for the future, but our effort is to see that, in fact, overall as a company. Because it's only 24 hours we came to know these things and this is what I have the information at the moment. So, obviously, as a company we will be responding to see that this aspect has as minimum impact as possible on our performance during 13-14.

Abhishek Kulkarni: Okay, sir. Thanks a lot.

Habil Khorakiwala: Thank you.

Moderator: Thank you so much. The next question is from Mr. Ranbir Singh from Share Khan. The line has been unmuted. You can go ahead and take your questions, sir.

Ranbir Singh: Yeah. Thanks for taking my question. Just one thing that one million you mentioned, that injectable part is 20-25 million, solid dosage 20-25, is that what you are saying the loss of revenue I'm talking?

Habil Khorakiwala: Sorry. I didn't get your question. Could you come again?

Ranbir Singh: Yeah. 100 million revenue that would be affected for import alert; out of that 100, I believe that 20 to 25 million is from injectable side and so rest of it is from solid dosage. Is that correct?

Habil Khorakiwala: Yeah, that is correct.

Ranbir Singh: Okay. And, sir, 50% of pending ANDA which we would not be able to get approval during the period for which the resolution is not coming, so have you evaluated what would be the value of those products?

Habil Khorakiwala: We are not able to do at the moment evaluation because ultimately the valuation of product depends on when we get approval and what is the competitive dynamic at that point in time. So even if you do internally it becomes very speculative in that nature. So I don't think I will be able to comment on that information.

Ranbir Singh: Okay. And in terms of margin, I believe the injectable generally has a better margin. So we should take in that proportion or do you have to say anything on margin also?

Habil Khorakiwala: No, I think our margins are good for all our products as they are more or less as a group identical.

Ranbir Singh: Okay. Okay, that's it from my side. Thank you, sir.

Moderator: Thank you so much. The last question of today's session would be from Mr. Jigar Walia from OHM Group. The line has been unmuted. You can go ahead and ask your question. So Mr. Walia has got disconnected. So we will take the last question in the queue would be from Mr. Bhagwan Choudhary from India Nivesh. The line has been unmuted. You can go ahead and ask your questions, please.

Bhagwan Choudhary: Hi. Thanks for taking my question.

Moderator: Sorry, sir. We cannot hear you. Can you please come closer?

Bhagwan Choudhary: Yeah. Is it audible now?

Moderator: That's right.

Bhagwan Choudhary: Yeah. Thanks for taking my question. Just want to understand that you are saying that earlier we were having some observation on the injectable part, then now it leads to the import alert to the entire unit. And when we are going to resolve it you are saying that first we will resolve this oral solid dosage product and then we will look after other injectable side. Is that right?

Habil Khorakiwala: Yeah, let me just clarify to you the import alert is in the whole compound where we have number of manufacturing facilities, that is for the whole alert. Within that compound we have two injectable facilities and a solid dosage facility also. So in the

last inspection the inspector visited the injectable facilities and they had not visited solid dosage facility. So our effort is I have mentioned earlier is to take up with USFDA this facility had been visited by them last year and we will be segregating this compound into two compounds and say they are different compounds now and request them to do it. Now what will be the response of FDA when they will do it, well, that is the effort we will be making towards doing that.

Bhagwan Choudhary: Okay. And in between we want to transfer our oral solid dosage one to the other facility also.

Habil Khorakiwala: Sorry?

Bhagwan Choudhary: In between of that, we are planning to transfer our oral solid dosage one to the other unit also.

Habil Khorakiwala: Yeah, that will take about – That we are doing it anyway. It will take 8-9 months to complete the process.

Bhagwan Choudhary: Okay, okay. That I understood. Thank you.

Moderator: Thank you so much. With this, we are going to end the Q&A session for today. I would like to hand it over back to Dr. Habil for any final comments or remarks.

Habil Khorakiwala: I would like to thank all of you for taking interest in Wockhardt. And I hope that I have been able to respond to the issues of USFDA alert, which has happened. And we have tried to give as much information as we have; we have shared all of that with you. Anyway our corporate results are going to be announced on Monday. And we would be having a normal investor call on Tuesday for the year and the quarter results, which will be announced at 11 o'clock. Thank you very much once again. And if you have any more issues on our corporate results and other things, Dr. Murtaza would be there. Dr. Murtaza Khorakiwala who is the Managing Director, he would be available and respond to all your issues on that front. Thank you very much.

Abhishek Singhal: Thank you very much, sir.

Moderator: Thank you attendees for joining in. With this, we conclude the conference call for today. Wish you all a great day ahead.