"Wockhardt Limited's Q2 FY-2014 Earnings Conference Call"

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Moderator: Ladies and gentlemen, good day and welcome to the Wockhardt Limited's Q2 FY-14 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 any assistance during this conference, please signal an operator by pressing '*' and then '0' on your touchtone phone. Please note that this conference is being recorded. I now hand the conference over to Mr. Tushar Mistry -- GM, Investor Relations and Corporate Affairs, Wockhardt Limited. Thank you. And over to you, Mr. Mistry.

Tushar Mistry: Good evening, everyone. I welcome you all to this earnings call for Q2 FY-14. We have today with us our Managing Director Dr. Murtaza Khorakiwala; and our CFO Mr. V. Suresh. We will begin with a short presentation by Dr. Murtaza on the recent events and the results for Q2 FY-14 which will be followed by the Q&A session. I now hand over to Dr. Murtaza for the presentation.

Dr. Murtaza Khorakiwala: Very good afternoon to all of you and I welcome you to the 'Investor Presentation' for the second quarter 2013-14. I would start by giving a very brief introduction to the organization as we always do. Slide #4, we have Direct operations in India, UK, Ireland, France, USA and Mexico, and Indirect operations in the rest of the emerging markets. As of today, we have 8,600 associates employed in 21 countries. From a manufacturing point of view we have 12 manufacturing locations globally, 9 sites in India and 3 sites outside India in UK, Ireland and Chicago in US. We have three research centers in US, UK and India.

What I thought is that before we go into the financial highlights of the quarter I could give you an update on some of the recent events that have occurred over the quarter and what is the status of those events and some of the impact that is there on the organization. Going to the next Slide #10 for the second quarter as an organization we have had 11 regulatory inspections in the last 12 weeks and these have been with the US and UK regulatory agencies. For H1 we have had 12 inspections. Out of 11 inspections in the second quarter 8 inspections have had positive outcome and 2 inspections have had a negative outcome that is L1 for UK and Kadaiya for UK and one result is awaited that is L1 for US. So as you see it has been a quarter in which we have been subjected to a large number of regulatory inspections. Our quality and manufacturing organizations have been occupied in one inspection after another and as we go now into Q3 I will give you an update on some of the other aspects.

On Slide #12, regarding our Waluj facility that is the EoU facility which was the first facility to have a import alert and then warning letter from US and similarly UK. Remediation measures have started. A baseline assessment of the GMP issues have been conducted by Lachman who is our consultant over there. We have also enrolled Lachman for training and the corporate training in manufacturing and quality functions is being done by them and that activity has been completed. We have restructured the quality organization. We have strengthened the leadership. We have a new head of quality, and at senior levels we are

reinforcing and strengthening the function also at various sites and at various certain functions and quality that we are getting a senior leadership to man that.

An update on our Chikalthana facility, this was jointly inspected by US FDA and UK MHRA in July. US FDA has had 483 observations and we have responded to them. They have not come back either way on our response. So response is still awaited. UK MHRA to whom we have responded to have come back and they have given us restricted GMP certificate allowing us to manufacture 10 critical products while for the remaining they have withdrawn the GMP certificate, and for which we will have to address the issues and reapply for an inspection to get a full compliance. From a value point of view the UK business from L1 is approximately £12 million, of which £9 million is affected by the restricted GMP certificate and 5 of the products which are non-critical, there has been a drug alert by the UK agency. The UK agency has also reiterated that there is no evidence of risk to patient safety. And from a product safety point of view there are no issues. These are mainly related to GMP issues and process issues where the processess that are being followed are not GMP compliant. Our Kadaiya facility which is in Daman was inspected by UK MHRA in September where we have also been issued a restricted GMP certificate allowing us to manufacture critical products. We have not got a formal response of the list of the critical products at what its value is. Therefore, we are not able to at this point of time give an indication of business impact as a result of this regulatory action. The Bhimpore facility has been inspected by UK again in September and it has been completed satisfactorily with few non-critical observations. Some of the other facilities that have been inspected. Shendra facility was inspected by UK MHRA and that has had a satisfactory outcome. Waluj Cephalosporin facility was inspected again by US FDA and that has had a satisfactory outcome. Baddi facility was inspected both by US FDA and UK, again satisfactory outcome. Going to Slide #16, our UK facility also was inspected by UK MHRA and US FDA in July and September respectively and has had a satisfactory outcome. So this is a brief recap of the various regulatory inspections that we have had over the last quarter and what their outcome is. To give a sense of clarity and a sense of status update on where we stand in terms of regulatory status.

The second aspect which is an event that has happened during the quarter is the suspension of DPN by the Ministry of Health which was notified in May and the result of which is there in the second quarter. As an organization we are contesting the suspension. Currently, the matter is subjudice and is in court.

Coming to the results of the second quarter on Slide #20, our sales for the period is Rs.1,197 crores which is a decline of 11% compared to the second quarter of last year.

Slide #21 our EBITDA is Rs.196 crores compared to Rs.517 crores in last year which is a decline of 62%. And adjusted PAT is at Rs.138 crores compared to Rs.435 crores of the previous year's same quarter which is a decline of 68%. Our R&D expenditure has marginally increased in absolute terms compared to last quarter but in terms of percentage to sale, because of a decline in sale today it is at 10.2% to sales.

Coming to the H1 results of the current period, our sales stand for H1 at Rs.2,555 crores which is a decline of 5% over last year. Slide #26, our EBITDA is at Rs.617 crores for the H1 which is a decline of 36% compared to last year. Our adjusted PAT is at Rs.462 crores which is a decline of 39%.

If we look on Slide #28 our balance sheet, some of the other key financial highlights are the following: Our net debt-to-equity which was 0.36 at the beginning of the year is now at 0.21. Our free cash flow before CAPEX is over Rs.700 crores for H1. Our capital expenditure for H1 is approximately Rs.200 crores and R&D expenses as I mentioned is at 10.2% of our sales.

Coming to some of the business highlights, US business has been significantly impacted as a result of the import alert. Our business which was at $118 million last year for the second quarter this year is at $87 million and 26% degrowth in dollar terms, 19% in rupee terms. During the period we had filed 3 ANDAs. 53 ANDAs are pending approval as of today.

Slide #31 EU operations, our UK operation against same period last year in pound terms is at £25.8m compared to £26.3m. In rupee terms it is at Rs.239 crores compared to Rs.228 crores which is a growth of 5% during the quarter. UK sales have been impacted due to reversals on product recall. We had 1 new launch in UK in the quarter and 4 launches in H1 and we are the #3 generic company in UK and continue to be #2 in the Hospital segment.

Coming to Ireland, one of the fundamental issues that has happened in the domestic Irish market, it has moved from a Branded Generic market to a Generic Generic market and prices of the products have significantly collapsed, and as a result of which we see that Ireland declined by 37%, is at €4.2 million compared to €7.6 and at Rs.34 crores Vs Rs.53 crores.

Coming to our next slide, Emerging Markets including India, we are at Rs.344 crores compared to Rs.371 crores last year which is a degrowth of 7% for the quarter and degrowth of 6% for H1 of which the India business has degrown by 2% for the quarter and 1% for H1 and this has been impacted on two counts. One is the suspension of Dextropropoxyphene and the second is due to the new prices by NLEM and DPCO, this has also impacted our sales.

During the second quarter we have launched 13 new products and 2 new divisions have been launched for the Indian market. Our emerging market sales have also declined during this period by 21% in the quarter, 24% in the half year, mainly on account of supply constraints in manufacturing because of increased quality oversight as a result of which supply issues have led to degrowth. Thank you very much for your attention and I think at this point of time I can open it up for a Q&A session and I would be happy to provide further clarity on questions that you may have.

Moderator: Thank you very much sir. We will now begin the question-and-answer session. First question is from the line of Jigar Walia from OHM Group. Please go ahead.

Jigar Walia: Sir, first question. Can you quantify the one-off impact in terms of the adjustments which were there in the quarter from the distributors? And also in terms of some remediation caused or the one-off cost which would be there? And some comment on the expense line, how much should be one-off, how much should be the recurring inflation?

Dr. Murtaza Khorakiwala: Let me share with you some of the ongoing increase in the cost as a result of the various consultants and remediation activities that we are planning as well as impact on the top line. If I look at our top line it has got impacted by approximately $10 million on account of recall of products from the UK as well as contractual obligations with various distributors and customers in the US for the products from our EoU facility. If I look at it on the expenses side there is additional impact of another Rs.40 crores which is as a result of 3 or 4 major factors. One is additional expenses in remediation correction of various GMP issues involving the consultants. Second is one-off stock write-off of inventory that has been there. Third is additional expenses of air freight that has incurred and some of the other legal expenses. So to sum it up I would say that top line impact has been there for approximately Rs.60 crores, EBITDA impact of around Rs.80-90 crores, half of it would be kind of a recurring expense and half of it would be a one-time expense.

Jigar Walia: Sir another question I have had is if you can comment on Comptan and Stalevo in terms of volumes and our profitability under the new arrangement Vs when we are selling it on our own?

Dr. Murtaza Khorakiwala: So as per our earlier communication we are sourcing the products from our supplier, the innovator and we have continued to do so. The sales have been impacted for that primarily on the basis of their own supply constraints, as a result of which there has been an impact of 20-30% for those two particular products, but the arrangement continues and they are hoping to resolve their issues by end of the current calendar year or early next year, following which normal supply should resume.

Jigar Walia: Has there been any discussions with any of our US distributors, particularly post all these inspections and the regulatory issues?

Dr. Murtaza Khorakiwala: Yes, discussions are always ongoing, and in a normal course of business I think on all areas discussions would be ongoing.

Moderator: The next question is from the line of Bino Pathiparampil from IIFL. Please go ahead.

Bino Pathiparampil: A couple of questions. If I look at your US run rate it was about $140-150 million just before the import alert in the Waluj facility, and if I recall the Waluj facility as you said was contributing about $100 million to the US revenue. So even if I take a quarterly $25 million out and even adjust for the $10 million that you say is because of contractual obligation still the $84 million of this quarter seems to be something seems to be completely missing there. So what are we missing there? Where is this sudden decline in revenue that has come in from?

Dr. Murtaza Khorakiwala: As I explained to you some of these are one-time impact, in addition to that there are a couple of other impacts. One is the additional impact on LEC and Entacapone for the quarter. Additionally, there has been some collateral impact on the products also from our L1 facility to the tune of approximately 15-20% of that L1 facility business. And the third element is the one-off impact which I mentioned.

Bino Pathiparampil: What is the status of Toprol now, have you seen significant reduction in revenues from Toprol over the last couple of quarters?

Dr. Murtaza Khorakiwala: Broadly, if you see our Toprol sale, there is a decrease in terms of value but in terms of volume our market share has been maintained.

Bino Pathiparampil: So it is mainly because of price erosion in the market and not because of collateral damage.

Dr. Murtaza Khorakiwala: That is right for Metoprolol.

Bino Pathiparampil: In terms of looking forward from here assuming there is no import alert that comes from US on Chikalthana facility, you said about Rs.90-crore impact on EBITDA of which half is one-time. So if I add about Rs.45 crore to the EBITDA of this quarter is that the kind of EBITDA run rate that we are looking at?

Dr. Murtaza Khorakiwala: What has not been factored in that EBITDA is the L1 impact of UK which has got restricted GMP certificate in which 10 products have been allowed and the remaining are not allowed. So on an annualized basis that impact is £9 million, so for that second half that would be an impact of around £4-5 million. And second part of it is we do not know what is the impact of our Kadaiya facility which has also got restricted GMP certificate from UK; we are awaiting a formal feedback from them on which are the products which are going to be allowed and what is the business impact of that. As of now we do not have information on that.

Bino Pathiparampil: Is that a formulation facility as well?

Dr. Murtaza Khorakiwala: That is right.

Moderator: Thank you. The next question is from the line of Kunal Sabnis from VEC Investments. Please go ahead.

Kunal Sabnis: Just wanted to understand that with factoring this one-off impact in the EBITDA margin your EBITDA margin would be still above 20-odd percent. If Chikalthana goes into import alert what drop in EBITDA margin are you looking at?

Dr. Murtaza Khorakiwala: We do not really know what may be the impact and when that impact would come, whether it will come in Q3, Q4 or it may come later but the total value of L1 facility for US for the quarter was approximately $40 million.

Kunal Sabnis: And you also mentioned about 15-20% revenue from L1 is affected. Can you elaborate on that bit?

Dr. Murtaza Khorakiwala: Of the total value that we had from L1 we had seen that there is about 20% reduction in our business from L1 compared to the earlier quarter and that is on account of some of the products where we have lost customers and some of them where there has been price erosion.

Kunal Sabnis: And in terms of the remedial expenses for Waluj and Chikalthana as well, is there any kind of analysis you have done in terms of what could be the entire quantum which will have to be expended to get these facilities up to the mark?

Dr. Murtaza Khorakiwala: It is very difficult to say because at this point of time we have engaged the consultants. One does not know how long they will be there and how long it will take to correct all the issues and have a re-inspection, so it is very difficult to quantify at this point of time what may be the impact.

Kunal Sabnis: And out of the 53 ANDAs pending approval, which plants would these be filed from?

Dr. Murtaza Khorakiwala: It is a combination of all our plants which is Waluj and Chikalthana and Shendra which we have and cephalosporin. All put together we have 53 and out of the 53, 43 are from Waluj and Chikalthana, and 30 of these have been filed either in the last year or in the current year.

Kunal Sabnis: Have you already started trying to move the production and filing of these products from other plants especially for the products which were filed from Waluj?

Dr. Murtaza Khorakiwala: Yes, we have already started that activity. We are in the process of filing them from Shendra, and in Shendra we have one small facility for oral solid and we are expanding that to a larger facility. So we will be transferring some of these products to our Shendra facility and some to an alternate site outside. These activities have started and they are ongoing.

Moderator: The next question is from the line of Jigar Walia from OHM Group. Please go ahead.

Jigar Walia: Sir if you can let know what are the scheduled repayments for foreign debt, your debt particularly which are coming up in the coming two quarters, and would we be repaying those and reducing our debt as we are doing or would they be refinancing sort of a thing?

Dr. Murtaza Khorakiwala: Suresh will answer that.

V. Suresh: We have roughly around Rs.220 crores at the current exchange rate which will be coming up in the second half of the year and we plan to meet our obligations, we are not looking for any refinancing because our cash position is very comfortable.

Jigar Walia: So we would be using our dollar cash for repaying these debts?

V. Suresh: That is right.

Jigar Walia: And sir one question just to understand you shortly mentioned that you are expanding the oral capacity at Shendra, and similarly are we really looking a setting up of new plant anywhere irrespective of Chikalthana given that it may help in terms of growth as well as security in terms of any regulatory action? That apart irrespectively so that whatever cash flows that we have can go towards CAPEX.

Dr. Murtaza Khorakiwala: As I mentioned we are expanding both Waluj and L1 solid dosage form facilities which primarily has been impacted and that is what we are expanding our solid dosage capacity in Shendra and creating a capacity that would not only take care of the product transfer volume, in case we do not get certificate in due course then it can be from Shendra. So not only we are creating capacity for the product transfer but the new filings that we are doing in the US market and UK market we are filing from Shendra. So we are creating a very large facility in Shendra that would take care of existing volumes from Waluj as well as new products that we are planning to file.

Jigar Walia: Sir what would be the CAPEX that we would be incurring for this expansion?

Dr. Murtaza Khorakiwala: For the first half we have had CAPEX of around Rs.200 crores and we expect by the end of the year to have additional CAPEX of around Rs.150 crores.

Jigar Walia: Sir if I can ask you a very broader question, given the FDA and the UK regulatory action that we have seen of late not on our company but overall for many other companies in the sector, I understand it is more a function of the US FDA regulator expanding its bandwidth rather than incrementally the companies becoming more complacent. So it is more a function of that is what I would probably guess. In that light if they have really expanded their bandwidth, is it fair to assume that any corrective measure also should take up an appropriately less time given that now they have the bandwidth to probably take up more quicker inspections and stuff?

Dr. Murtaza Khorakiwala: I honestly do not know whether I could have an opinion on that. They have had a significant backlog because of the shutdown of the government. So, it is very difficult to say what kind of responses and how fast they would respond in situations. I would not be able to have an estimate on that.

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

Anubhav Agarwal: I just had one question. From the Waluj facility for the product transfers of the existing products, is there any requirement from the FDA which needs to be fulfilled before you can initiate the product transfer to one of your facilities in Shendra or any other third-party outside facility?

Dr. Murtaza Khorakiwala: Yes, there are normal protocols that are there, SOPs protocols that are there, obviously the facility has to have a GMP certificate and the normal protocols that are there for product transfer, they have to be fulfilled, there has to be validation batches, so the normal activity has to be done and facility has to have a GMP certificate.

Anubhav Agarwal: My question was more at the product level, let us say for your existing products you do not have to, let us say, prove validity because the products have been found good, it is only the GMP side…

Dr. Murtaza Khorakiwala: Yes, you are right, as of now observations have been on processes and GMP practices, and there has not been any questions raised on product safety. So we do not anticipate any such issues to be there, since these are more GMP-related and process-related issues.

Anubhav Agarwal: So when is the inspection of Shendra oral solid scheduled?

Dr. Murtaza Khorakiwala: We were initially expecting inspection in October as per the earlier intimation, but apparently that has got delayed, maybe on account of the government shutdown. We are going to ask for a re-inspection and we have not got any date on that so far.

Anubhav Agarwal: Getting a clarification here, once let us say inspection is done and that is good, you can immediately start the product transfer from the Waluj site?

Management: That is right.

Moderator: The next question is from the line of Rakesh Jhunjhunwala from Rare Enterprises. Please go ahead.

Rakesh Jhunjhunwala: My question is you have got various regulatory problems in various plants. Can we have plant wise what are the problems, what are the products, and how are you going to resolve, and what timelines you have, you made any charts for that.

Dr. Murtaza Khorakiwala: As I mentioned to you in one of the earlier slides, we have 11 inspections that we have had over the last quarter, almost every week we have had an inspection, and each inspection lasts for week, so a very significant part of quality and manufacturing organization has been involved in that. I can give you a list of the inspections that we have had and what has been the outcome of that. Chikalthana facility was inspected by UK and the result of which is that we have got a restricted GMP certificate, 10 out of 22 products are allowed to be sold and manufactured, business impact is £9 million on an annualized basis, and around £4-5 million for the second half, facility was inspected by US FDA. We have responded to their queries and we are doing a regular update on the corrective actions that we are taking and providing that. We have not got any response from the US FDA, so response is awaited from US FDA. For our Waluj facility, which is under import alert, we have involved external consultant Lachman, who has done a baseline assessment, and we have begun working on a corrective remediation plan which would address all the GMP related issues that have been raised by the regulatory

agency, and once we have completed that activity we would again request for reinspection of the facility by UK and US.

Rakesh Jhunjhunwala: Do you think all this to resolve will take another 15 months?

Dr. Murtaza Khorakiwala: In terms of our corrective and remediation plans, it should take approximately 6 months I feel from the information that I have today. And once that is done, then we apply for re-inspection, and then it depends on the regulatory agencies, they will come here, they will visit. So probably the entire process would take upwards of a year from now. It could be earlier than that, it could take longer than that, situation is very uncertain, it is very difficult to predict actually at this point of time. But I think the whole organization has been involved in working on it on emergency basis to put things right. We have got various consultants who are helping us. We have two consultants that are working for us; one is for EoU facility and one is for L1. We are hopeful that with all the actions that we are taking and also there are regular updates that we are providing to FDA and MHRA. We can hope for earlier resolution.

Rakesh Jhunjhunwala: But today this Waluj facility on which the import alert is there the remediation plan is fully in progress. And once it is complete, we will give, we are ready, and then we will ask FDA for a re-inspection.

Dr. Murtaza Khorakiwala: Yeah, that is right.

Rakesh Jhunjhunwala: Same about Chikalthana?

Dr. Murtaza Khorakiwala: Chikalthana, as far as US is concerned, we have provided a response, and they have not taken any action as of now.

Rakesh Jhunjhunwala: We are able to export from Chikalthana at the moment?

Dr. Murtaza Khorakiwala: Yes, from Chikalthana we are exporting to the US market. For the UK market we can export 10 out of the 22 products that are registered from there, which has an annualized value of £3 million.

Rakesh Jhunjhunwala: No. 2 update on recent Spasmo-Proxyvon.

Dr. Murtaza Khorakiwala: Spasmo-Proxyvon is a product that we have in the Indian market, it is a pain killer, and it contributes about Rs.180 crores of our sales in the Indian market. This was suspended by the Ministry of Health in May, and the impact of that has been about Rs.30 crores in Q2. But we have a follow-up strategy where we have introduced another product. So we hope that some part of the business we can transition to the new product. We have introduced the product in late August/early September. So I would expect to see some impact in Q3 and bigger impact of the new product in Q4.

Rakesh Jhunjhunwala: What about your Shendra facility, that US FDA has not done?

Dr. Murtaza Khorakiwala: Shendra has been inspected by UK and Ireland, and they found it be okay. US FDA inspection is awaited, as I mentioned we were expecting an inspection in October, but it did not happen. So, we have asked for another inspection. They have to come back to us on the dates for that.

Rakesh Jhunjhunwala: This is a new facility, Shendra?

Dr. Murtaza Khorakiwala: That is right.

Rakesh Jhunjhunwala: So then we can transfer some products to Shendra?

Dr. Murtaza Khorakiwala: That is right.

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

Bino Pathiparampil: Could you please elaborate a bit more on the supply constraints on emerging markets, why is it happening and has it got anything to do with the US FDA, UK MHRA action?

Dr. Murtaza Khorakiwala: Yes, I think as a result of the various requirements in terms of quality and extra precaution that has to be taken in manufacturing, and additional oversight of various operations that are there, and also quality testing. So it is taking additional, more time to manufacture the products. From a productivity point of view there is a lower productivity because of the various technical issues that are there, manufacturing and as a result of the various further additional steps and precautions that one has to take. So a result of which there are some supply constraints that we have had in Q2. I believe that as we move along I think that should get aligned in Q3 and Q4, and that should fall into place.

Bino Pathiparampil: EM being serviced mostly from Waluj and Chikalthana, or some other plants?

Dr. Murtaza Khorakiwala: EM is being serviced from our all the facilities, from our EoU facility as well as from our Baddi facility, and Baddi facility has been inspected by both UK and US in this period. So for two weeks the facility was under inspection.

Moderator: The next question is from the line of Rajat Budhiraja from Banyan Capital. Please go ahead.

Rajat Budhiraja: According to the best of my knowledge UK MHRA and US FDA have come to the inspection at the same time and that is in coordination with each other, am I right?

Dr. Murtaza Khorakiwala: For some of the facilities, they have come together, in fact at one point of time; there were 9 inspectors from UK, US, and Ireland all at the same time in various facilities. So, there was a coordinated inspection and on Friday we were informed that they are coming on Monday, so it was a surprise inspection, and subsequently we have had inspections of our Daman facilities and Baddi facilities, which have been individual inspections by the different regulatory

authorities. In our Daman it has been inspected by UK, and Baddi we had US and UK, but it was done independently and was not done jointly.

Rajat Budhiraja: And in the case of Chikalthana, was it …?

Dr. Murtaza Khorakiwala: Chikalthana, was a joint inspection and all the three agencies were there at one point of time.

Rajat Budhiraja: That means the observations raised by all of these authorities were same?

Dr. Murtaza Khorakiwala: No, each agency gives their own observations, but obviously they are discussing amongst themselves and they are sharing information, and quite a few of them are the same, and some of them are different, related to different products that are in there in their respective markets.

Rajat Budhiraja: Because I have seen the 10-page document which is there after the article in the news, and more of the issues were related to processes, that there were some issues?

Dr. Murtaza Khorakiwala: Yes, that is right.

Rajat Budhiraja: The issues which were serious according to you were given by all of these authorities?

Dr. Murtaza Khorakiwala: Yes, that is right.

Rajat Budhiraja: And the response what you have given to UK MHRA, should we assume that the same response has been given to US FDA for the serious issues?

Dr. Murtaza Khorakiwala: As far as the questions by and large have been the same the response has been the same response, because that is the corrective action that we have taken the response that we have. So, as long as the same questions, we would have the same response.

Rajat Budhiraja: Now when you have received a response from UK MHRA, so you would have a fair idea that, which were the main issues that were mainly in front of UK MHRA, and is it possible or have you taken any preempt measure by sending additional response to US FDA or is it possible or not, I am not sure on that?

Dr. Murtaza Khorakiwala: Yes, we are doing whatever we can to prevent any negative action on L1 and we are doing a number of things proactively. Among them some of them are, we have additional manufacturing oversight by consultants in our L1 facility, which means that third-party independent consultants are overseeing the operations in Chikalthana which will give additional comfort to US FDA in terms of there being an independent third-party oversight of operations. Additionally, we have done a training program with Lachman where we have trained 200 managers over the last month or so, on various GMP practices, and corporate training is an important part of the remediation and corrective action that organization has to take. To ensure that our managers are adequately trained in GMP, so they have been trained and they have got a certification of the training. Additionally, what we are doing for L1 is that

as we are providing a very regular update to US on the various improvements and the various steps that we have taken and we are trying to do this on a regular basis, we are doing this every three to four weeks we are providing a regular update to them, so we have done that to give them a sense of what we have accomplished in the last one month and what our plan is for the next one month to give them a visibility of our progress as well as the direction that we are taking going forward. So, these are some of the things that we are doing in terms of corrective measures as well as for L1 proactively to ensure that we do not have any negative action from US.

Rajat Budhiraja: Basically I am asking when you send a response, then on one day you get import alert or warning letter or just a letter, or is this a two-way discussion over a period of say one or two months when you are communicating on a constant direct basis with US FDA?

Dr. Murtaza Khorakiwala: I think US FDA has various options of what they would like to do, and they can choose to communicate in a written way, they can choose to give directly a warning letter, they can choose directly to go into import alert, so there are various ways by which they can take action. As of now we have given a response to the 483 observation, and in addition to that we are giving regular updates to them on various positive steps that we are taking in L1 facility. Very difficult to say what the US response is, but as of now there is no response to our communication we have given them.

Rajat Budhiraja: For how many months of inventory do you have for Toprol currently?

Dr. Murtaza Khorakiwala: I think it is around 2.5-3 months.

Rajat Budhiraja: And in the last quarter was there any revenue from the inventory of any product from Waluj facility?

Dr. Murtaza Khorakiwala: Marginal, I would say not anything substantive.

Moderator: Thank you. The next question is from the line Bhavesh & Vipul from Aricon. Please go ahead.

Participant: One first question, in case there is an import alert on Chikalthana facility by US FDA, does the company have any Plan-B? When the Waluj facility was having import alert, the company was planning to ship the products to Chikalthana. And the second question is who are the consultants have been appointed and what is the scope of these consultants, and is the scope of work restricted to only Chikalthana and Waluj facility or to other facilities as well?

Dr. Murtaza Khorakiwala: The first question you had was what if something happens to L1. Yes, in our product transfer plan that we have, where we are transferring products to Shendra facility and alternate sites, there are some products that we have looked at from L1 also, which are part of that list and be a part of that product transfer plan. Second question you had was on consultants. As I mentioned to you we have engaged Lachman Consultant for EoU facility, and for corporate training where they are doing training of our technical team manufactured quality, regulatory,

R&D. In addition to that we have another consultant that we have engaged in for L1 operation for oversight.

Participant: So going by the inspections that have been happening, would it not be advisable to have consultants for all your facilities?

Dr. Murtaza Khorakiwala: As I said in earlier part of the presentation, we have had 11 facility inspections from regulatory authorities, and 8 have been a positive outcome, so there is absolutely no issue that the regulatory agencies have had with the operations over there, the GMP practices or the products. So there is absolutely no need to take any action on that. And the negative outcomes, we obviously are working on. But the point that I think you are trying to make is that, and what we are doing is that whatever is the observations that we are having in the affected facilities, and wherever learning from those observations is applicable to other facilities. So we are doing our system wide corrective action to other facilities also where it may be applicable based on whatever observations are there. So we are applying the learning and applying some of the positive measures and corrective measures to other facilities also.

Participant: So when can we expect response from US FDA for Chikalthana?

Dr. Murtaza Khorakiwala: I do not know when they will come back.

Moderator: The next question is from the line of VP Rajesh from Visa Investment Partners. Please go ahead.

VP Rajesh: My first one is just trying to understand the whole situation. You have import alert at Waluj, and Chikalthana, you may or may not get import alert. If we go back for the last fiscal year, what is the total revenue out of that which is at risk, some of that is already, in case of Waluj is suspended, but let us say if Chikalthana also there is an import alert?

Dr. Murtaza Khorakiwala: As I mentioned of our existing in Q2 of our current revenue that we have, approximately $40 million is from L1, so that would be the negative impact if something happens to L1. The EoU impact has already been factored in and the Q2 reflects the EoU impact. So in addition to that if something happens to L1 at a current run rate level it is approximately $40 million for L1 for US. Two other factors, which have not been factored in the current quarter, but which will have an impact going forward; one is our Kadaiya facility where we have a restrictive GMP certificate, we have not been informed officially of the impact of that in terms of our business, which are the products that we would be, which are critical products and we would be allowed to continue selling in the UK market and additional impact of the L1 facility for UK which would be around £4-5 million for the second half of the year from L1.

VP Rajesh: In addition, if I heard correctly, in the earlier part of the call, Shendra is yet to be inspected by the US FDA, is that correct?

Dr. Murtaza Khorakiwala: That is right.

VP Rajesh: And given the shifts you are making from Waluj to Shendra and from Chikalthana to Shendra what is the expected revenue from Shendra facility in the next couple of quarters for the rest of the year?

Dr. Murtaza Khorakiwala: There will not be any business from Shendra for at least minimum 1-1.5 years because we will get an inspection of the facility, we have to do a product transfer, and after product transfer the FDA takes approximately 6-9 months for approval of the product. So this is not something that will happen in the short term, it is something more that will happen in the medium term.

VP Rajesh: And then apart from these two facilities, Waluj and Chikalthana, how much revenue is going to the US from your Daman facility and the Baddi facility?

Dr. Murtaza Khorakiwala: Daman facility, there is no business for US market, Baddi facility, I think annualized business is $3 million.

VP Rajesh: Are there any other facilities in India from which you have let us say more than 5 million of revenues to the US market?

Dr. Murtaza Khorakiwala: There are no other facilities that have more than 5 million. We have Cephalosporin facility, but it is less than $5 million.

VP Rajesh: So just going back to Chikalthana for a minute, given the action that has been taken by the UK regulatory agency, it is natural for us to assume that the US inspectors would have a similar point of view and therefore the risk of getting an import alert is quite high and I understand you have been communicating, but it sounds like it has been a one-way communication, you have not been hearing back from them. What is the opinion of your consultant, or your assessment of the situation in terms of whether there is a likelihood now less or more of getting an import alert or getting a warning letter, I know it is a tough question, but I would just like to hear what is the assessment of your consultant on all this?

Dr. Murtaza Khorakiwala: I think none of us know what will really happen. We are hopeful, I think with everything that we are doing in terms of taking whatever the necessary steps that the FDA expects us to take in such a situation because after the observations the FDA expects you to do certain things, so we are doing all those things and we are taking corrective action. And I think with that we are hopeful that it happens, but it is very difficult to say what point of view or perspective FDA takes on this and how long it will take, it is really we cannot give you guidance on that.

VP Rajesh: My last question is, in terms of the quality and production organization, can you describe what are the specific changes have you made so that these kind of issues do not happen in the future.

Dr. Murtaza Khorakiwala: Yes, one, what we have done is, we have got a new leadership as a quality head at a senior vice president level, so we have a quality leadership, new head of quality. Second is, one level below him, we have strengthened the quality organization and inducted people at senior level and strengthened the entire leadership team of quality at a corporate quality level as well as we

are strengthening the quality organization at every site and facility where we are looking for people with the right set of capabilities. We are also looking at the quality operations people in the QC laboratories as well as in the operational part in strengthening. One part is the quality, strengthening the quality team. Second is, we have put in a system, which is on the computer, where all the quality testing that is there, gets recorded on the network, and as a result of that it is visible and it is apparent, and there is an audit trail that is available, and that would ensure that transparency and ensure accountability of all testing that is done in the laboratory, so that is another thing that we have done. Third thing, what we are doing is in these kinds of situations whether the people have the right set of capabilities, their understanding of various processes in GMP. So training is another important element in terms of the understanding of GMP and the expectations of US FDA and UK of the quality systems. So we have engaged in a corporate wide training program with the help of a consultant in GMP training, and we have had various training programs where 200 of our managers have been trained, and obviously this would then develop into a training schedule and system where the rest down the line people and workers would obviously get trained also, so that is the third thing that we are doing. And in general I think there is also strengthening in manufacturing organization at various levels down at operational level, and at site level also we are also looking at strengthening leadership over there.

Moderator: Thank you. Ladies and gentlemen, due to time constraints no further questions can be taken. I would now like to hand the floor back to the management for closing comments.

Dr. Murtaza Khorakiwala: Yes, thank you very much for being part of the investor call for the second quarter. We will provide you a regular update on the situation and the events as they unfold. And I conclude and wish you a very happy Diwali celebration during the coming week, and wish you all the best. Thank you.

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