



“Wockhardt Limited’s Q1 FY-14 Earnings Conference  
Call”

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**MANAGEMENT**     **DR. MURTAZA KHORAKIWALA – MANAGING DIRECTOR,  
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**Moderator:** Ladies and gentlemen, good day and welcome to the Wockhardt Limited's Q1 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 at the end of today's presentation. Should you need 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 would now like to hand the conference over to Mr. V Suresh -- CFO Wockhardt Limited. Thank you and over to you sir.

**V Suresh** Hello everyone. I welcome you all to this investor call. As you know agenda for this evening will be a brief presentation by our M.D. – Dr. Murtaza Khorakiwala on recent events and also results for the first quarter and then this will be followed by a Q&A session. I now hand over to Dr. Murtaza Khorakiwala to run us through his presentation. Thank you.

**Dr. Murtaza Khorakiwala** Very good afternoon to all of you. At the outset let me thank you for being with us and participating in the investor call to share the recent events that have transpired at Wockhardt and also to share with you the financial result of the first quarter of 2013 and '14. If we go through the presentation on Slide 4 I will just give you a brief background for some of who are joining new. The organization that we have today we have direct operations as a business in countries like India, US and in Europe, and in the other countries we have indirect operations through various partners and alliances and distributors in the various Emerging Markets. As of today, we have 8,600 associates employed in 21 countries.

Going to Slide 5, to give you a sense of our manufacturing organization, we have 9 sites in India, of which we have 5 plants in Aurangabad, 2 in Daman, one in Ankleshwar, and we have 1 site each in UK, Ireland and in Chicago.

Slide 6, we have 3 research centers, India obviously is the one that has been there since the longest time and in the last 1-1/2-years we have also added a research center in US and UK.

Now I will just take you through some of the recent events that have happened at Wockhardt and which are the questions which had upper most of all our minds. Going to Slide 8, as you all know we had a US FDA inspection of our Waluj facility earlier this year and we were issued an import alert in May of 2013 and a warning letter subsequently. This facility has one solid unit facility and two injectable units. And these observations were mainly addressed for the need to include to increase the laboratory controls in our facility, enhancement of training programs and quality system and enhancement in facility maintenance. However, from the same plant, the US FDA continues to allow the import of Enalapril for the market. And also during the observations of the US FDA they recommended that we should take help of a third-party consultancy firm in GMP area to help us in taking the remediation actions necessary to achieve the GMP compliance.

Going to Slide 9, and as a result of that the following are some of the measures that we have adopted and initiated in this area. We have appointed Lachman who are a US-based GMP consultant based in US, and

in fact they have been now working with us over the last 1-1½ months and they have reviewed our facilities, have also suggested measures to improve our operations in various areas and they are working along with us to help meet our FDA requirements. Additionally, I think at an organizational level we have restructured the reporting of the quality organization which was initially reporting to R&D, now is directly reporting to the Managing Director, and this will increase the level of management oversight over quality operations.

We have also initiated various other steps which are required and necessary in terms of enhancing and harmonizing our quality systems for all the market, developing a dedicated training cell to ensure that there is an adequate training and application of knowledge by all the operators and people who are working on the shop floor. And also we have created a compliance cell that will provide an oversight of the various quality operations in the various facilities and we are also taking measures to improve laboratory controls. So as an organization I think we are using the help of the best consultants, we are identifying what are all the areas where the deficiencies are there and we are working together with Lachman Consultants to resolve these issues at the earliest.

Going to Slide 10, at the same facility Waluj, UK MHRA also had raised observations, and on July 10<sup>th</sup> they initiated a precautionary recall of 16 products for the UK market. These products that are supplied from our facility to UK are tested additionally by QP in UK before it is released in the market, and during the observations by UK they did not find any product related safety observations where the safety of the patient was compromised and therefore they have termed it as a precautionary recall and not as a product recall and there were no critical or major observations, but in view of the various findings general sense of GMP observations they had they thought it was prudent for them to do a precautionary recall and along with various measures that we are taking we will address the concerns also of UK MHRA as we go ahead.

Going to the next Slide 11, in addition to that over the last 2 to 3 weeks we have had an additional inspection by US FDA and UK MHRA on our Chikalthana facility, Shendra facility and Cephalosporin facility. Our Shendra plant which is mainly a liquid facility and is catering to the UK and the Irish market and even to the US market. There was an inspection by UK MHRA and there were no critical or major observations that were recorded, and the US FDA inspection of our Shendra facility is expected in the next few months. Cephalosporin plant was also inspected by the US FDA, there were some observations but by and large the audit was ended satisfactorily and we do not expect any major surprises in this area. Chikalthana plant was jointly inspected by US FDA and UK MHRA and they have raised observations. All these observations are being responded to by various measures that we are taking proactively to ensure that we adequately respond to these observations and along with appointment of various consultants who are supporting and helping us to respond to these various areas to improve the compliance level.

And also there is the issue of Spasmo-Proxyvon that has come up in the last few months. On 23<sup>rd</sup> of May there was a gazette notification by the Government of India where they suspended the manufacture and sale of DPN-based products and this was officially communicated to us on the 10<sup>th</sup> of June after which immediately we stopped manufacturing and selling the same and as a result of that currently the company has challenged the suspension in the first place of DPN by the government, the matter is currently in court and is being challenged by us and therefore it is subjudice, so I may not be able to share too much in detail, but the fact that the product was suspended and it was contributing around 150 crores to our India business.

Now coming to the first quarter financial results, we had a sale of 1,358 crores against 1,341 crores in the first quarter of last year, having a growth of 1% over the last year same period. Slide 15, as far as the EBITDA was concerned our EBITDA had a de-growth of 5% from 442 crores to 421 crores and this has been adjusted of 41 crores of R&D expenses for like-to-like comparison. As far as our PAT is concerned Slide 16 by and large remains flat, has gone down from 325 to 324 crores and again this is adjusted after R&D expenses. If we look at Slide 17 our R&D cost, because of the 1% growth of our top line, R&D expense as a percentage of sales has increased and for the current quarter it is at 7.7% of the sales.

To give you a brief highlight about each of our businesses, our US business grows at around 11% in INR terms and 7% in dollar terms. We have filed 4 ANDAs during this period and we have 50 ANDAs pending approval.

Slide 19, our UK operations have grown by 1% in pound terms and there is a slow growth in the UK market mainly because of Pinewood's UK portfolio showing a negative growth and we continue to be the 'Number Three' generic company in UK and 'Number Two' in the hospital segment .

As far as the Irish home market operations are concerned the entire market has shifted from a Branded Generic market to a Generic-Generic market, and as a result of which there has been a very significant price erosion of the product and therefore there is a decline, we have a de-growth of around 30% from €8 million to €5 million in the first quarter and we however continue to be the largest player in the Generic market with 27% market share.

Slide 20, Emerging Markets we have had a de-growth of 5% which includes India and the Emerging Markets outside other Emerging Markets. The India business has grown by 3% and the India business has been impacted to an extent because of some of the pricing issues related to NLEM and the strike by various retailers in certain parts of Maharashtra during May and June and the suspension of the DPN-based products. The ROW operations also had a decline of 28% and this was primarily because some of the orders that were there in the Russian market which were expected in Q1 got pushed to Q2 as a result of which this decline was there. So this is a very brief highlight about the financials for Q1 and some of the recent events that have transpired and I would be happy I think at this stage to open for any questions that you may have.

- Moderator** Thank you very much sir. We will now begin the question-and-answer session. The first question is from the line of Chirag Dagli from HDFC Mutual Fund. Please go ahead.
- Chirag Dagli** Two questions; first is on the US business if you look at the quarter-on-quarter US sales in US dollar terms about \$150-odd-million has become about \$125-odd-million. What explains this \$25-28million dip in the quarter-on-quarter US sales; this is June quarter versus the March quarter?
- Dr. Murtaza Khorakiwala** Yes I think this is mainly because of two reasons; one is that some of the pricing pressure that we are seeing in the US market on the products that we have which is approximately 10-15% pricing pressure we are seeing on the existing portfolio, part of the decline is related to that and obviously the early impact of the import alert of the products from the EoU facility there is an impact of that and obviously there is a seasonal aspect in Q4 of 2012-'13 with Q1 of '13-'14, there is a seasonal impact as the dying down of the winter season is there, some of the products which do well during that period of time, so there is a seasonal impact also that is there. But if you see as compared to the last year same period there is a growth of 7% on dollar terms and 11% on rupee terms.
- Chirag Dagli** Sir can you quantify the EoU impact? The corresponding number that we put out last time was \$100 million annual sales. I am just trying to get a sense of how much of the impact has already come through for this quarter?
- Dr. Murtaza Khorakiwala** In this quarter the impact is not very significant; the impact will come mainly in Q2, Q3 and Q4. For the current quarter that is for April, May and June there is not much of an impact because of the EoU import alert.
- Chirag Dagli** So this 125 run-rate could actually come down, okay. And sir second question was on Chikalthana, do we have 483 or are these just observations?
- Dr. Murtaza Khorakiwala** We have 483s and these 483s, some of them are more serious in nature and some of them are minor in nature. So what we have done is that we are reviewing all the responses, all the questions, observations that are there and we have to respond to the FDA in 15-days time so by next week we would be responding to them and Lachman is working along with us in going through all the observations and preparing a response for us. So we believe that after our response to these questions next week, after that we will get a sense of the scenario.
- Chirag Dagli** Is there an overlap of issues between what we saw at Waluj and at Chikalthana or are some of the issues common is what I am trying to understand?
- Dr. Murtaza Khorakiwala** There may be some issues which are the same but the Waluj inspection and the Waluj issues were of a very different order than the kind of observations which are there at L1 which are not of that level of gravity which were found at EoU but there may be some observations that could be common.

- Moderator:** Thank you. The next question is from the line of Prakash Agarwal from CIMB. Please go ahead.
- Prakash Agarwal** Just want to understand, you talked about pricing pressure in few of the products to the extent of 10 to 15%. Can you name the couple of bigger ones?
- Dr.Murtaza Khorakiwala** I do not have the specific product wise pricing detail but in some of the products we have seen some pricing pressure.I do not have the exact numbers product wise offhand.
- Prakash Agarwal:** This would include Toprol as well because the market share still remains healthy?
- Dr.Murtaza Khorakiwala** Yes, you are right, for Toprol we have maintained our market share in Q1 in spite of the competition. I don't have honestly specific product wise pricing detail.
- Prakash Agarwal:** Normally, you share the percentage of sales for Toprol. So would it be in the range of 14%?
- Dr.Murtaza Khorakiwala** It is the same around 14%.
- Prakash Agarwal** If you can give us a cash and the debt numbers and the question here is actually on the M&A, so do you look with an increasing cash pile would you go for an M&A given the little bit growth challenges we are seeing in our existing business?
- Tushar Mistry** The cash is around 1200 crores and the debt remains at around 2000 crores.
- Prakash Agarwal** So we are a net debt company of 800 crores?
- V Suresh** Yeah, that is right.
- Prakash Agarwal:** And question for the M&A possibility?
- Dr. Murtaza Khorakiwala** I think we are not closed to the idea of an M&A but we are not looking at M&A as a major driver for growth where we may look at M&A activity more from strategic point of view, technology point of view and looking at some niche areas but not as a driver for growth and not as a driver for consolidation but more strategically.
- Prakash Agarwal** Nothing as of now?
- Dr. Murtaza Khorakiwala** Nothing as of now but I am saying even from an approach point of view that is the approach.
- Prakash Agarwal** 98 crores to the total top line around 7.2% of R&D. Could you clarify that in the presentation I think you mentioned 7.7%?

- Tushar Mistry** 7.7 is including the CAPEX.
- Prakash Agarwal** So R&D number is 98 or is it more than that?
- Tushar Mistry** R&D is 98 revenue and 6 is CAPEX.
- Prakash Agarwal** On the R&D side?
- Tushar Mistry** On the R&D side, yeah.
- Moderator** Thank you. The next question is from the line of Bino Pathiparampil from IIFL. Please go ahead.
- Bino Pathiparampil:** Regarding US like you gave this number of \$100 million last year from Waluj facility, would you be able to give a number of what FY-'13 revenue was from Chikalhana facility?
- Dr. Murtaza Khorakiwala** FY-'13 last year revenue number from Chikalhana was \$230 million.
- Bino Pathiparampil:** Second, in the domestic market what happens to the Proxyvon product that were in the channel, have you seen some of that return and has that impacted your Q1 margins or we will see some impact of that in Q2?
- Dr. Murtaza Khorakiwala** No, there has been a marginal impact of the suspension of the DPN-based products but what are trying to do in Q2 is launch additional new products and formulations, and additionally we are launching 7 more products; some of them in the Pain segment and some of them in other segments. So we are trying to minimize as much as we can the impact of the loss of suspension of DPN.
- Bino Pathiparampil** Was there a specific impact related to product returns from the channel?
- Dr. Murtaza Khorakiwala** Yes there was.
- Bino Pathiparampil** How do you see the ground level situation regarding the implementation of new price control policy, have things stabilized and what kind of stable impact do you expect going forward?
- Dr. Murtaza Khorakiwala** No, I think the situation is yet very fluid and a lot of uncertainty is there in its own way because the court cases have been challenged whether one can have a new price in 45-days, it has been challenged by Cipla and Sun and now even we have joined in and the court has given that you have another 30-days to implement a new pricing policy. In addition to that other kind of cases where Sun has challenged the very formula that has been used in determining the prices. So there is a certain degree of uncertainty of how this will play out and what will happen, when it will happen, but given all that I think we have assessed what is the impact of the NLEM prices that the government has put up and what is the impact on that and the impact on that is to the extent of 20 crores on an annualized basis for us.

- Bino Pathiparampil** And finally one last question on UK, the full impact of product recall and import alert by the UK MHRA, is that reflected in 1Q number or should we assume there will be some more downside next quarter?
- Dr. Murtaza Khorakiwala** Full impact would not be visible in this quarter and there will be more additional impact maybe in the next quarter but I think what the UK business is also trying is to mitigate the risk of the precautionary recall of the product in UK by sourcing the product from other third-party suppliers to make it available in the UK market.
- Moderator:** Thank you. The next question is from the line of Anubhav Aggarwal from Credit Suisse. Please go ahead.
- Anubhav Agarwal:** Just two clarifications; one is your R&D spend this quarter was roughly about 100 crores. Once let us say our sales goes down for the balance of the year, how do you see R&D, would you sustain around 100 crores expenditure per quarter or would that come down?
- Dr. Murtaza Khorakiwala** No, we don't expect the current situation to have any impact on our R&D program and R&D plan and I think what we had planned and budgeted at the beginning of the year we would continue with that level of R&D activity and investment and there should not be any issue as far as funding and investment of that is concerned.
- Anubhav Agarwal** So 350 to 400 crores is the number we could look for this year?
- Dr. Murtaza Khorakiwala** We had indicated around that percentage to sales. So if the sales drop down by a little bit then accordingly that percentage may go up.
- Anubhav Agarwal:** Second, just a clarification on the Emerging Market business, you mentioned about Russia, I do not know how large is Russia business as a percentage of Emerging Market, basically just trying to ask that your Emerging Market drop by 28% if Russia orders were not impacted, ex-Russia how the business is done?
- Dr. Murtaza Khorakiwala** I think I do not have the detail with me right now
- Anubhav Agarwal:** But how large is Russia as part of the Emerging Market?
- Dr. Murtaza Khorakiwala** Russia business for us for the year 2013-'14 would contribute approximately I think around \$15million annualized.
- Moderator** Thank you. The next question is from the line of Shubhankar from SKS Capital and research. Please go ahead
- Shubhankar** One, sir, why is your finance cost down so sharply? And two, why is the tax rate of the quarter is low?



- Dr. Murtaza Khorakiwala** With regard to the interest cost I think you would have noticed that we have deleveraged ourselves over the last year or so and retired significantly in '12-'13 more than 1500 crore, and we have retired a large part of the debt last year, so as a result of which our interest cost is much lower this year.
- V Suresh** Taxation we continue to maintain guidance by 15%, the first quarter is about 10%, basically quarterly you can say a de-growth kind of thing but for the year we continue to maintain 15% as the tax guidance.
- Moderator** The next question is from the line of Purvi Shah from Dalal & Broacha. Please go ahead.
- Purvi Shah** My question was mainly that was it that only Chikalhana is where some 483s were raised or even at Waluj some observations have been there?
- Dr. Murtaza Khorakiwala** Waluj has happened then we have had an import alert and warning letter from Waluj and for Chikalhana we had an inspection in the last week of July where we had 483 observations and which we are currently preparing our response to, and we have to submit that response to FDA next week.
- Purvi Shah** No, the Waluj, the other units which were inspected, did we have some observations there as well or how is it?
- Dr. Murtaza Khorakiwala** Do you mean the Cephalosporin facility?
- Purvi Shah** Yes.
- Dr. Murtaza Khorakiwala** Yes, we had some observations, but we do not believe those are very critical in nature to warrant the kind of action we had at EoU facility and those can be responded adequately.
- Purvi Shah** The other question was regarding the inventory write-off mainly because of the ban that we have currently at the Waluj facility plus the UK imports as well as Dextropropoxyphene. So are there some write-off we have seen in this quarter or can we expect in the future quarters?
- V Suresh** We have already taken up in the Chennai High Court and as the matter is subjudice there is no write-off of the inventory of the DPN-related product.
- Moderator** The next question is from the line C. Srihari from P.C.S Securities. Please go ahead.
- C. Srihari** Firstly is L1 an exclusively Cephalosporin unit, and as regards Chikalhana could you please outline the key products being manufactured there? And the domestic branded operations on a like-to-like basis what would the growth have been?
- Dr. Murtaza Khorakiwala** The L1 facility is the facility that we have at Chikalhana and that is catering mainly to the US and the UK markets, and as I mentioned earlier it contributes around \$230 million to our sale and we had a joint

inspection of US FDA and UK in the last week of July which we are currently in the process of responding to and we will be submitting our responses by next week. Growth for Domestic business for the current quarter is 3%.

**C. Srihari** On a like-to-like basis?

**Dr. Murtaza Khorakiwala** It is on like-to-like basis 3%.

**C. Srihari** For the Chikalhana facility which are the key products out there?

**V Suresh** Toprol is one of the key products.

**C. Srihari** The second Waluj facility is that an exclusive Cephalosporin unit?

**Dr. Murtaza Khorakiwala** That is right.

**Moderator** The next question is from the line of Rahul Soni from Baljit Securities. Please go ahead.

**Rahul Soni** You said the US FDA and UK MHRA have observed 3 facilities, and as you said earlier that you are supposed to shift around 80% of the production to Shendra facility, which is a new facility, so what is the status of the same after this US FDA visit and when can we expect the response from US FDA regarding clarity on the same and when can we expect to starting shifting the production to this facility?

**Dr. Murtaza Khorakiwala** As we had said after our Waluj EoU inspection that we would be looking at transferring the products to alternative facilities and one of the alternative facilities was Chikalhana at Aurangabad and then we have at Shendra. The process has started but as you know during our transfer product, you have to take batches in the facility and then you have to put on a stability program for some time and then you file it, and so the whole process takes around 6 to 9 months before actually you can immediate the transfer, so that activity has started. We have started taking the batches. And with regard to the timeline, I think it all depends on how we respond to the US FDA, the queries that they have and the observations that they have and depending on our response and their comfort level on that, I think they will determine what kind of action and timelines it would take. So that is dependent on them. We would not really know how long it will take, but in terms of trying to mitigate the risk, I think what we are trying to do is have some of the business transfer to alternate facilities that would help in mitigate some of the risks.

**Rahul Soni** You said you will be sourcing products from third-parties for supply to Europe market. So what will be the impact on the margins due to the same?

**Dr. Murtaza Khorakiwala** No, it is not a very big amount, because Waluj itself was catering to only £5 or £8 million for UK and some of that will be now sourced from third party. On a total basis, I do not know really the impact, but it will not be very significant.

- Rahul Soni** As far as my understanding, Chikalhana is your largest revenue contributing facility?
- Dr. Murtaza Khorakiwala** That is right.
- Rahul Soni** For that we have received 483 observation?
- Dr. Murtaza Khorakiwala** That is right.
- Rahul Soni** R&D cost for the quarter, you said 7.7. So what was it in the same period last year?
- Dr. Murtaza Khorakiwala** I think we saw in the presentation it was 6.5% as a percentage of sales and the sale is by and large stagnant, 1% growth, so 1% more it is than what it was last time on 1,350 crores.
- Rahul Soni** What is your expectation for the current year for R&D cost?
- V Suresh** We have said that we will maintain more or less at this percentage and MD has also clarified that if the sales were to drop a little bit year ended, these percentage might go up in decimal.
- Rahul Soni** Is there any risk of this 483 observation followed by a warning letter?
- Dr. Murtaza Khorakiwala** I think we are trying to develop a comprehensive response with the help of a consultant to avoid having that situation and here we are doing it in a slightly more proactive way and trying to take all possible measures to prevent that kind of a situation occurring.
- Rahul Soni** When will we come to know about the outcome of this observation?
- Dr. Murtaza Khorakiwala** As I said we will respond to the regulator next week, and once we respond to them, I think then they take their own time to come back, sometimes they come back in week, sometimes they take months to come back, so that one really does not know how long they will take to come back.
- Moderator** The next question is from the line of Hardik from Motilal Oswal Securities Limited. Please go ahead.
- Hardik** Just wanted to ask one question on the pending ANDA approvals. We have about 50 ANDA pending approvals in the US.
- Dr. Murtaza Khorakiwala** That is right.
- Hardik** Can you give us a sense how many of these were filed from Chikalhana?
- Dr. Murtaza Khorakiwala** I will not know the information right now.
- Tushar Mistry** We will come back to you.

- Moderator** The next question is from the line of Aditya Khemka from Nomura. Please go ahead.
- Aditya Khemka** For the Chikalhana facility is a facility capable of manufacturing modified-released products, right. So I assume like 2 products; Lamotrigine, Lamictal XR also comes from the same facility, is that a correct assumption?
- Dr. Murtaza Khorakiwala** Lamotrigine XR, no, that is from the other facility, it is not from the same one.
- Aditya Khemka** Is it from Waluj?
- Dr. Murtaza Khorakiwala** Yes, it is from Waluj.
- Aditya Khemka** Do we have the capability of manufacturing XR products? The modified-release products in our other facilities like say the Punjab facility?
- Dr. Murtaza Khorakiwala** We have a capability in EoU, we have in L1 in Chikalhana and we are developing in Shendra and we can also develop in some of the other facilities that we have.
- Aditya Khemka** Lastly, I am looking at the sales data that IMS has released. So there is a considerable drop in the sales of Bromfed which is a Morton Grove product if I am not mistaken, month-over-month for the last 3, 4 months is that like seasonality or are we facing some competition in that space, what is the sense there?
- Dr. Murtaza Khorakiwala** I think it is more to do with seasonality, which is impacting the sales. From a competitive point of view there is no other competition that is there and it is mainly I think a seasonality impact.
- Moderator** The next question is from the line of Prakash Agarwal from CIMB. Please go ahead.
- Prakash Agarwal** Just wanted to recheck in terms of number of filings, we remain at 20 filings that is for the year?
- Dr. Murtaza Khorakiwala** Yes, we had 20 at the beginning of the year and I think we should be by and large around 15 or so we should be okay then.
- Prakash Agarwal** Any guidance on the approval front we can give?
- Dr. Murtaza Khorakiwala** Not very sure because the EoU approvals obviously will be held up till we get a green signal and the import alert is lifted. Other than that I think the rest of the activity remains alright.
- Prakash Agarwal** Earlier we had talked about \$100 million impact and a possible resolution in 6 to 9 months, anything you would like to revisit?

**Dr. Murtaza Khorakiwala** As I said other than the import alert on Waluj, nothing else definitely has happened in terms of any of the other facilities that could have had changed that outlook, and as far as Waluj is concerned we are responding to that and we are responding to the other things; the only other thing that has happened is there is a pricing pressure on some of the products in the US market. So that could be one area where they could have been an additional negative impact.

**Prakash Agarwal** Question was again on Waluj only, do we still retain that we can come back in 9 months either in terms of resolution or site transfers or we think as you said batches itself takes 6 to 9 months, so is it a fair assumption the whole thing gets back in 18 months plus?

**Dr. Murtaza Khorakiwala** If you are saying whether we will get the business back in 6 to 9 months, yes, I do not believe that we can get the full extent of the whole EoU business in 6 or 9 months back, but we would have been able to transfer those products to alternative sites and at least we would be able to then be in a position to get back the business, the full extent of how much we are able to get back and how long that will take I think that will only depend on the situation 6 to 9 months from now when we are able to achieve that site transfer.

**Prakash Agarwal** If I understand correctly, you expect approvals on site transfers starting in 6 to 9 months?

**Dr. Murtaza Khorakiwala** That is right.

**Prakash Agarwal** Lastly on the Comtan, Stalevo, we had some inventory, so what is the current inventory level there and have we tied up with Orion on the same for future approval and supply?

**Dr. Murtaza Khorakiwala** The current import alert that is there does not affect our Stalevo and Comtan sales because we were initially doing it from EoU but now we are doing it via Orion, so that business is not affected.

**Prakash Agarwal** So we are using the approval of the patent holder, is it?

**Dr. Murtaza Khorakiwala** Yes, that is right.

**Prakash Agarwal** So would that mean we are sharing profit with the patent holder?

**Management** No, commercial part of that agreement I have not got full details with me right now, but that was at the time when it was an AG that 6 months period, now it is no longer an AG. So obviously the same kind of commercial terms would not be valid.

**Prakash Agarwal** But what I want to understand is we are back in these two products from a full year sales perspective?

**Dr. Murtaza Khorakiwala** That is right.

- Prakash Agarwal** What is our market share currently if you can share?
- V Suresh** Not our policy, you can check up with IMS; IMS will give you that.
- Moderator** The next question is from the line of Nitin Gosar from Religare Invesco. Please go ahead.
- Nitin Gosar** Just wanted to check on Chikalhana facility since you are yet to reply on the 483 that have been raised. So can we continue our production at the facility or it will only happen once you get the final feedback from the US FDA?
- Dr. Murtaza Khorakiwala** Nothing has stopped in Chikalhana. It is as it has always been, production continues, sales continues, business continues. We have got observations which we will respond to next week and then depending on how long does FDA take to respond whether weeks or months, we will then come to know what is the situation.
- Moderator** The next question is from the line of Chirag Dagli from HDFC Mutual Fund. Please go ahead.
- Chirag Dagli** On Waluj, of the 6 odd observations in the warning letter, how many are related to the Oral Solids facility and how many are related to the Injectables?
- Dr. Murtaza Khorakiwala** Most of the observations are related to the Injectable facility which was not catering to the products being sold to the US and UK markets.
- Chirag Dagli** Taking that further, on Chikalhana, where there is a 483, given that this is an Oral Solids facility and so in general the processes should be similar to the Oral Solids facility at Waluj, what is the possibility of escalating to a warning letter in your assessment?
- Dr. Murtaza Khorakiwala** It is very difficult to say, but I personally feel that the probability is much lower than what it was in Waluj, and we are doing as much as we can from a corrective point of view, preventive point of view and proactive point of view and working with consultants well in advance to ensure that we do not get into that situation.
- Chirag Dagli** Just empirically if one were to look at some of your peers in the past and probably your consultants may have thrown some light on that, post a warning letter for it to again escalate to an import alert especially in the context of an Oral Solids facility, what are those things that probably will lead to an import alert vis-à-vis the Waluj experience that we have had?
- Dr. Murtaza Khorakiwala** Actually, it is very difficult to speculate on what may happen and could happen in Chikalhana and how the FDA perceives it and what FDA position they take, I can only share with you that at a broad level Chikalhana I think we are in a much better position than we were in Waluj, and with everything that we are doing, we hope that we do not end up with a warning letter or an import alert.

- Chirag Dagli** Where are these 4 filings that we have done in the fourth quarter from?
- Dr. Murtaza Khorakiwala** They are from other than Waluj.
- Chirag Dagli** So from Chikalthana included is it?
- Dr. Murtaza Khorakiwala** Yes.
- Chirag Dagli** Just to put things in context, you said there is some element of pricing pressure in Toprol, so Toprol was roughly about \$35 million a quarter in the third quarter of last year and then it moved down to \$30 odd million in the fourth quarter of last year. For this quarter it would be roughly about \$25 million, is this how the trajectory has broadly moved?
- Dr. Murtaza Khorakiwala** We do not give product wise revenue and information. But as I said the market share by and large remains the same and there is a pricing pressure of 5% to 10%.
- Chirag Dagli** 5% to 10% you mean for Toprol or was that 10% to 15% you meant for the entire portfolio?
- Dr. Murtaza Khorakiwala** In some of the products that we have seen that there is a pricing pressure.
- Moderator** The next question is from the line of C. Srihari from P.C.S Securities. Please go ahead.
- C. Srihari** I wanted to know that sale of domestic branded formulations revenue in the quarter?
- Dr. Murtaza Khorakiwala** Around 250 crores.
- Moderator** The next question is from the line of Rajat Budhiraja from Diamond Capital Advisors. Please go ahead.
- Rajat Budhiraja** Just want to understand in Chikalthana if you have any Injectables plant as well or it is all for the Oral Solids?
- Dr. Murtaza Khorakiwala** For the US and UK markets, Chikalthana facility is for the Solid facility.
- Rajat Budhiraja** And for the other markets including India?
- Dr. Murtaza Khorakiwala** In India we have a few products that we are making in Chikalthana which are Injectable.
- Rajat Budhiraja** Is it fair to assume that for the last inspection in Waluj, the US FDA team would have inspected the non-US FDA area of the plant as well in Chikalthana?
- Dr. Murtaza Khorakiwala** They inspected the entire facility.

- Rajat Budhiraja** And then just going back to one of the answers you said about the site transfer, could you just describe a little bit more about, will it be third-party sites or it will be some other sites of Wockhardt or what will be the impact on the margin if it is for the third-parties?
- Dr. Murtaza Khorakiwala** I think it is too early for us to come to that conclusion because we have just started that activity. We are looking at alternate sites at Wockhardt and it is very early to say any impact on top line and margin because this we will be able to have this transfer completed after 6 to 9 months and then we go back into the market and see what kind of business we can get back. So it is very much into the future and very difficult to give any kind of a reasonable estimate.
- Rajat Budhiraja** My last question just on Chikalthana, assuming this 483 you are working with the consultant and getting it resolved in the near term but let us say there is another import alert, will the timeline be again 6 to 9 months to transfer to a different site or will that be a different timeline given the solid production line post Injectables?
- Dr. Murtaza Khorakiwala** We have not assessed that for our Chikalthana facility as of now.
- Moderator** The next question is from an individual investor, Mr. Raj Mohan. Please go ahead.
- Raj Mohan** Though elaborately you explained about the Chikalthana situation, just wanted to understand, you mentioned production continues in Chikalthana, will the transfer from Waluj to Chikalthana be impeded by this FDA observation and delay the process of transfer?
- Dr. Murtaza Khorakiwala** Not unless we have any FDA-related action on Chikalthana, there is no reason why it should get affected.
- Raj Mohan** But based on your initial assessment of the situation you generally feel that this is a much more mellow situation right?
- Dr. Murtaza Khorakiwala** I feel it is not as serious as Waluj.
- Raj Mohan** Though you have mentioned about a comprehensive response to the current observation, was this response different triggered in the serious backdrop of the import alert and the appointment of consultants or would it have been a similar response had the import alert not happened and these being normal observations you would have responded in a normal fashion and now because of that import alert backdrop you are responding in a different fashion?
- Dr. Murtaza Khorakiwala** Yes, that is right. I think our response is for the Chikalthana is not a normal response that we would have responded in a normal course of time, but taking into consideration the context of the Waluj experience and various things that we would like to do in a proactive manner, we would respond in a way that we prevent any such kind of an action as much as we can.



- Moderator** The next question is from the line of Anirudh Mohta from Ginni Finance Limited. Please go ahead.
- Anirudh Mohta** I just wanted to know what is your outlook for your Irish business for rest of the year because as you said earlier there is a shift from the Branded- Generic to Generic-Generic?
- Dr. Murtaza Khorakiwala** Around two-thirds of our business is non-Irish market that is being exported from Ireland to outside which by and large we do not feel will be affected in anyway. The Irish part of the business which is one-third of the business has got significantly impacted and as you would have seen in the first quarter, there is a 30% degrowth of the Irish part of the Irish business which is one-third of the total Irish business and that kind of a pricing impact I think will continue because we have moved now from Branded Generic Pricing to Generic-Generic and that kind of a trend would continue. However, the impact of that is limited to one-third of the total Irish business.
- Anirudh Mohta** What is our field force right now?
- Dr. Murtaza Khorakiwala** We do not now have any sales force because it is no longer a branded business, we do not have the sales force meeting the doctors but we do have sales force meeting the trade and distribution channel.
- Moderator** The next question is from the line of Prakash Agarwal from CIMB. Please go ahead.
- Prakash Agarwal** Just wanted to reconfirm on this Shendra facility inspection, so US, any particular time you want to mention when you are expecting?
- Dr. Murtaza Khorakiwala** We have not got the date from them when they are coming, but we are expecting it in the next two to three months.
- Prakash Agarwal** Again on Europe, it is a sizable piece of the business 20, 25% and in the past you have commented that the margins are not too different from the company level a tad below, so with this Irish issues happening, would you say that your margins would have been dropped on Europe now?
- Dr. Murtaza Khorakiwala** I think the Irish would have a marginal impact on the margins, but on the whole I think if you see the margins, majority are from the UK business and will by and large not have a significant impact.
- Prakash Agarwal** Just taking from the last quarter's transcript that \$100 million you said because of pricing pressure, impact could have been higher, can you quantify that? And second one was on the margin side when earlier you had said that margins are expected to be around north of 30, so would you want revise that?
- Dr. Murtaza Khorakiwala** As I said it is a fluid situation and one does not know how it will exactly play out in the quarters to come and also what is the impact of Chikalthana on the whole scenario. So I foresee the impact to be more than what we had initially estimated because of pricing pressure an additional impact, but it is very difficult to quantify additionally what may be the impact.



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**Prakash Agarwal** So both with margins as well as revenue you are saying?

**Dr. Murtaza Khorakiwala** That is right but it will definitely be lower than earlier but difficult to give an estimate.

**Prakash Agarwal** Do I understand correctly that the ban for Spasmo-Proxyvon was at the fag end of the quarter, so the real impact would be the upcoming quarter?

**Dr. Murtaza Khorakiwala** That is right.

**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 Mr. V. Suresh for closing comments. Over to you sir.

**V. Suresh** Thanks for your participation in the call.

**Moderator** Thank you. On behalf of Wockhardt Limited that concludes this conference.