"Wockhardt Limited Q1FY16 Earnings Conference Call"

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Moderator: Ladies and Gentlemen, Good Day and Welcome to the Wockhardt Limited Q1 FY-'16 Earning Conference Call. As a reminder, all participant lines will be in the listen-only mode and there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal an operator by pressing '*' 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. Manas Datta — Chief Financial Officer, Wockhardt Limited. Thank you and over to you sir.

Manas Datta: Thank you. Good afternoon ladies and gentlemen. This is Manas Datta and Welcome to our First Q1 2016 Results. Today, we have with us Dr. Murtaza Khorakiwala — our Managing Director who will give us a Presentation on the Financial Performance of the company for the Q1 2016, it will be followed by a Q&A Session where our Chairman — Dr. Habil Khorakiwala will also join in. Thank you very much once again for joining in. I will hand it over now to Dr. Khorakiwala. Thank you.

Dr. Murtaza Khorakiwala: Thank you, Manas and Very Good Afternoon to all of you. Welcome to our Investor Conference of Q1 2015 and '16. I will be starting off with a short presentation that provides the highlights of our performance for the current quarter.

Going on to Slide #4, globally, as an organization, we have basically Direct Operations in India, UK, Ireland, and USA and over the last few years, we have set up our office in Mexico. Additionally, through our various partners and distribution partners and channel partners we are present in a large number of emerging markets which are shown in 'green'. We have a large multi-ethnic force covering almost 21 different nationalities.

On Slide #5 we have presentation of our manufacturing organizations globally — we have 9 facilities in India, we have in Aurangabad 5 plants, in Daman 2 plants, Ankleshwar 1 plant, Baddi 1 plant and globally we have facilities in UK, Ireland and Chicago.

Slide #6 going on to our Research part of the organization; we have 3 R&D centers worldwide. Our largest center and global headquarters for R&D is in India, additionally, over the last 2-years we have established centers in US and UK.

Moving on to the Business Update on Slide #8, I would first start with a brief regulatory update: The US FDA has inspected a one facility in Himachal… Baddi facility that we have in July and we have not received any 483 from this inspection and that has been cleared. Additionally, the US FDA had inspected the Waluj facility during the quarter where we had minor observations which we have responded to. The company continues its ongoing efforts in terms of compliance and in terms of the remediation for our other two facilities which is Chikalthana and Waluj and is continuing to make good progress on the same. These observations as the FDA visits have been noticed and the regulatory agencies have noted the progress the company is moving towards full compliance.

As far as the UK regulatory agencies our concerned I think the Daman facility has always resumed normal supplies last year itself, additionally in this year our Chikalthana facility also has got a UK fully compliant certificate and we are going to start resuming supplies from our UK facility from our Chikalthana facility to the UK market.

As far as our research operations or research activities are concerned, we have received over the last 6 to 9-months three QIDP approval which is a fast track approval for New Chemical Entities which we are developing. By and large as an organization we are in the New Chemical Entity space we are focused in the Anti-Infective space and three of our molecules have received QIDP status and we received one in the last quarter that was WCK 4873, and earlier two of our molecules that is WCK 771 and WCK 2349 had also received QIDP status. So in total we have three molecules under QIDP and we are the only Indian company to have received QIDP status for NCE Molecules.

During the quarter, we got an additional approval for an ANDA which we had filed from MGP that is our Morton Grove facility in the US which is Oxycodone and basically that is for management of pain in opioid tolerant patients.

During the quarter we have also filed 54 additional patents and received 26 patent approvals and that takes our cumulative patents granted to 367 and cumulative filings of patents to 2,322.

Moving on to the Financial Results of Slide #10, if you see our sales performance for the quarter we have ended the quarter at Rs.1141 crores versus Rs.991 crores last year same quarter, which is a growth of 15%.

Slide #11 shows our EBITDA, we have grown from Rs.63 crores of last year to Rs.167 crores this year which shows a growth of 165%.

Slide #12 shows our PAT which ended the quarter at Rs.114 crores versus last year's Rs.20 crores a growth of 470%.

Coming on to our Research Activity and Research Expense, so over the years as you would have seen that our investment in research has gone up and from financial year 2012 when our investment in research was Rs.248 crores till the last year our investment was Rs.515 crores which was about 11.5% to sale and for the current quarter our investment in research is Rs.152 crores which is 13.3% as a percentage to our top line.

Our US business which today for the current quarter contributes 20% of the total revenue had a sale of $36 million or Rs.227 crores compared to last year's Rs.287 crores or $48 million. We filed 5 ANDAs during the quarter and we have received 1 approval which I mentioned earlier Oxycodone, and as of now we have 73 ANDAs that are pending approval.

Our UK operation for the current quarter we had a sale of Rs.368 crores or £37 million and that is a growth of 55% over the last year. We had 1 new filing and 1 new product launched during the quarter.

Our Ireland business we ended the quarter at a sale of €6 million compared to €5 million of last year, which is a 4% growth in Euro terms but 11% degrowth in Rupee terms.

Going on to Slide #16, our India and Emerging Markets, the India business which was Rs.295 crores in last year same quarter is at Rs.375 crores, which is a growth of 27% and during the quarter we have launched 24 new products. The emerging markets which was Rs.66 crores last year same quarter is at Rs.97 crores and has a growth of 47%.

That concludes the presentation part of the update and at this stage I would like to open the call for any Q&A that you may have and we would be happy to answer. Thank you very much.

Moderator: Thank you very much, sir. Ladies and Gentlemen, we will now begin the question-and-answer session. We have first question from the line of Dheeresh Pathak from Goldman Sachs. Please go ahead.

Dheeresh Pathak: The product Oxycodone that you talked about, what is the size of the molecule? I think we have approval for Solution form, right?

Dr. Murtaza Khorakiwala: Yeah, it is not a very large product, of couple of million dollars for the year.

Dheeresh Pathak: Do you also have filings from that facility for the tablets and the extended release?

Dr. Murtaza Khorakiwala: No, the Morton Grove facility is mainly for Liquids and Solutions.

Dr. Habil Khorakiwala: Chicago facility is for Liquids and we are also establishing Solid Dosage form, and it is not our practice actually to announce the product which is under development.

Dheeresh Pathak: Second question, if you can talk about what led to the strong growth in India and Emerging Markets?

Dr. Murtaza Khorakiwala: So I think over the last few years where we have been working on the India business and it is doing well we had a good performance last year and even this year we will have a good performance on the India business. We have good established brands which have a good equity in the market and I think growth is being driven from that as well as we are launching a large number of new products and some of the new opportunities that are there in the market we are leveraging that capitalizing on that. So on the whole India business is doing well. And going forward I think emerging market is also an area where some of the new products which we are filing in emerging markets and as and when that gets approval growth and business will come from there also.

Dheeresh Pathak: If you can give some guidance in terms of when do we expect Waluj and Chikalthana for US market to be in compliance?

Dr. Habil Khorakiwala: As Dr. Murtaza mentioned earlier to you that we had US FDA inspection to 4 of our Dosage Forms facility in last 4 to 5-months, I think some of the approach FDA is taking is they are taking our facility quite seriously, we are in ongoing discussion in a dialogue with them through communication on a regular basis and it is very difficult to predict when it will happen but we are very positive and hopeful that some of our facilities could get reasonably early approval.

Moderator: Thank you. The next question is from the line of Shannon D'Souza, individual investor. Please go ahead.

Shannon D'Souza: In the previous quarters, we receive some Contract Manufacturing from UK. Has that come up in this quarter's results or is it completely operational outside of that?

Dr. Murtaza Khorakiwala: Yes, we have got some business from the Contract Manufacturing opportunity in UK, so that has resulted in a gain for this quarter which will continue for next quarter and I think after that that part of the opportunity will get normalized and normal business will maintain. And also as I mentioned the Chikalthana facility which got earlier had a GMP compliance from UK regulator, so product supplies from that will resume from the next quarter. So that will start our regular business to UK from India also.

Shannon D'Souza: Can you quantify what that regular business from Chikalthana will add going forward in the second half of the year?

Dr. Murtaza Khorakiwala: I think when we will get back it will start gradually and slowly because obviously I think one has to get back into the market and gain back the market share. But, on a full basis I think before the restriction was there this facility contributed to between I think £10-15 million of business for the UK markets from this facility.

Shannon D'Souza: Just one more question in terms of US. There was some conversation last quarter that we have some third-party manufacturing or there will be some shifting to other facilities to supply to the US. Has that happened or has that come up in this quarter, is that something that we are looking into going forward?

Dr. Murtaza Khorakiwala: The activity of the 3rd party sourcing we have started and the products business has not accrued in the current quarter, but from next quarter onwards some of the sourcing from the 3rd party will start for the US business.

Moderator: Thank you. The next question is from the line of Farhana Lambe from NVS Brokerage. Please go ahead.

Farhana Lambe: Sir, I wanted to know about the other income in this quarter. Will that sustain in the next quarter?

Dr. Manas Datta: Other income which you are referring is predominantly on our surplus funds investment. So it comprises of the investment income globally in the various subsidiaries as well as the India operation where money is kept into surplus liquid funds, funds means the FDR and all. So those are coming as a regular part of the other income. It will sustain to some extent, yes, till the time that the cash flow remains in the same manner, so it will continue to be.

Abhishek: This is Abhishek from Macquarie. I had a quick question, is there any potential guidance that you would like to give for this financial year in terms of revenue, grown 15% first quarter despite miniscule contribution in the US. So, is there any visibility you would have that in a scenario where we do not get our facilities up and running for the US market this financial year? Will we be able to deliver this kind of a top line growth for the full year?

Dr. Habil Khorakiwala: Abhishek, what you see in this quarter is a baseline business minimum we are getting from the US. So there is nothing down slide we see in a current level of activity for coming quarter. The only exception one has to make a note that we had a one-time income in UK in the first quarter which will accrue in the second quarter. That has to be adjusted in the future projection in case as you asked the question nothing happens at the FDA level. But, India business is very robust, UK business by itself will do very well in the second half as we get into normalcy there and emerging markets is doing well.

Abhishek: So no specific number that you would want to highlight right now in terms of guidance from top line?

Dr. Habil Khorakiwala: We do not give guidance generally.

Abhishek: In terms of margin profile, like the gross margins are around 65% or so, in a scenario where the UK goes off, historically, you maintain pretty decent gross margin. Is this the kind of level we should anticipate you will be able to sustain even without UK?

Dr. Habil Khorakiwala: More or less, yes, a few percentage you take it here and there.

Moderator: Thank you. The next question is from the line of Shradha Patil from Wealth Managers. Please go ahead.

Shradha Patil: I just wanted to know what is the reason for the sharp improvement in the margins because gross margin along with other expenses have improved sharply, so which part of the business is the reason for this?

Dr. Habil Khorakiwala: When you compare with the last year you see a sharp increase but if you compare with the previous quarter it is in line with our gross margin, and that is as we mentioned earlier that we had a one-time business coming out of our UK operation for last 2-3 quarters and that is what

is reflecting in the higher gross margin this quarter. Once this is over our gross margin may slightly come down but it will not have a very significant impact.

Shradha Patil: So, out of the margins, how much would be the contribution from this one-time CRAM, any color on that?

Dr. Habil Khorakiwala: The color I think we do not have those numbers in front of us. So why do you not contact us separately? Finance can help you to give you some numbers on that.

Moderator: Thank you. The next question is from the line of C. Shrihari from PCS Securities. Please go ahead.

C. Shrihari: As regards India and emerging markets, I wanted to know a little about your new product launches, what are the growth prospects, if you could share some guidance for the two regions?

Dr. Murtaza Khorakiwala: As I mentioned a bit earlier, our India business we have grown by more than 20% and we expect to continue that going forward and the way we look at it is our existing brands which are there and we identify ways by which we can continue the growth momentum in that either through new brand extensions and life cycle management of the brand and further taking that brand forward. Additionally also, we look at new business opportunities for the market and I think we look at all therapeutic areas like Diabetes, Dermatology and other areas where we are not present and like for the current quarter we had 24 products that we launched in the first quarter and with the new product launches that also creates its own growth momentum going forward. So I think the India team has got a robust plan and we expect to have a strong growth coming from the Indian market in the future also. Similarly, emerging market, we have our office in Mexico which we have opened up last year and through that we intend to drive our LATAM strategy, we have in emerging markets in Africa and also in Russia and in South East Asia. So these are the emerging markets the four blocks that we basically have. And with the insulin and the analogs that we have which is a one driver for growth we have and some of the brands which are there from India that are there as well as the US portfolio and UK portfolio which all put together create a very robust product portfolio for emerging markets and we expect to drive that in these four major areas in the emerging markets.

C. Shrihari: For this quarter you had a growth of 47% in emerging markets. What is the kind of growth we can forecast – (+25%)?

Dr. Murtaza Khorakiwala: Yeah, I think that should be reasonable.

C. Shrihari: Regarding the 27% growth that you had, is it possible to split in terms of volume realization and new launches?

Dr. Murtaza Khorakiwala: Yeah, we would have the micro details, but I do not have it right now in front of me, we can provide it to you later separately.

C. Shrihari: Is it possible that it was driven by new launches or let us say line extensions?

Dr. Murtaza Khorakiwala: As I said it is a combination of three or four factors; one is our existing brands which are there that is a large base that we have so that drives growth to a large extent and then the new products that we launch which are either brand extensions of existing brands or the new products itself that we have. So we have actually multiple strategies for growth and all of them I think put together they have effect and that is what you see in the performance I think in the India business.

C. Shrihari: Can you highlight a few of your new launches, anything promising out there?

Dr. Murtaza Khorakiwala: I do not have I think too many details on that I can discuss or maybe we can provide that to you separately, if you want product wise or brand wise I think that details are available with us, IMS also has information about that.

Moderator: Thank you. The next question is from the line of Gaurav Maheshwari from Unilazer Ventures. Please go ahead.

Gaurav Maheshwari: Can you give us the number for the UK business which are the Contract Manufacturing part for this quarter?

Dr. Habil Khorakiwala: I think what you have is your overall number and I must say that if you are looking at our UK business by and large existing business is more or less flat because last year we had a restricted supply and that will be resumed, but we will not be able to provide you specific details of this business.

Gaurav Maheshwari: Secondly, just a clarification on the plants. So, Waluj and Chikalthana, all the FDA audits are over, right, is that the right understanding and basically you are just awaiting your reply from the US FDA?

Dr. Habil Khorakiwala: That is correct.

Gaurav Maheshwari: You would have responded to all the 483s for both the plants, right?

Dr. Habil Khorakiwala: Out of four plants they have visited there was no 483 in one, the other three had some 483, two of them we have already responded and at Chikalthana L1, we will be responding in a next couple of weeks.

Moderator: Thank you. The next question is from the line of Gopal Madnani from Arjawam Advisors. Please go ahead.

Gopal Madnani: I had a question on this Recall business which we have got into because of solving the USFDA problem historically. So is that over and done with and all the costs associated with that are already factored in?

Dr. Habil Khorakiwala: This I believe you are referring to Recall we did in April, we withdrew all our products yeah. I think we are over and done with it and whatever goods we received in the quarter I think that has been accounted for it is adjusted.

Gopal Madnani: The second question was on the Shendra plant. Is there any progress on USFDA inspection on that plant?

Dr. Habil Khorakiwala: We are ready for inspection for Shendra for quite some time, but we have no information from FDA when they are visiting us and we sincerely hope they would visit us soon enough.

Gopal Madnani: Once the Shendra gets approval let us assume you immediately start shipping to the US some of the new products or will that take a longer time to set up?

Dr. Habil Khorakiwala: No, once they visit the facility then they have to approve the product. So the facility automatically do not trigger the approval of product or supplies. But, that is the first step necessary. But, then what happens a lot of filing is pending with them and one can reasonably hope to receive approval in relatively short period of time.

Moderator: Thank you. The next question is from the line of Saurabh Kumar from Macquarie Securities. Please go ahead.

Saurabh Kumar: You had earlier alluded to the fact that there has been some transfer of products to third-party sites. So, in a scenario because it has almost been 2-2.5-years plus, even if we do not get Shendra on track, are we right in our assumption that potentially some approval from third-party site which you would have possibly transferred, we could start seeing that in FY16 or second half of FY16?

Dr. Habil Khorakiwala: Yes.

Saurabh Kumar: How many could that be sir like are there some material products which we were earlier shipping through into the US from Chikalthana and Waluj which we could possibly get back on track from the third-party transfer?

Dr. Murtaza Khorakiwala: There would be, yes, some material product but it will not be Metoprolol which I could clarify which was a very significant product, but some other product will be there.

Saurabh Kumar: We should anticipate sometime towards second half of this financial year some approval also from the third-party site?

Dr. Habil Khorakiwala: That is correct.

Moderator: Thank you. The next question is from the line of Abhishek Sharma from India Infoline. Please go ahead.

Abhishek Sharma: I just wanted some color on the break-through designation. So, you have three products which have achieved that status. Has the status lend them more attractive towards licensing prospects and if so, then are you in process of finding suitable partners who can take the development program forward?

Dr. Habil Khorakiwala: Yeah, this is three products where we receive this breakthrough, that is QIPD status for anti-infective program. Our immediate goal is basically to continue development work and we are not actively seeking any licensing opportunities at this point in time.

Abhishek Sharma: But these would typically need to go through the full gamut of the clinical development program or would that be an abbreviated sort of a thing given the fact they have achieved the breakthrough status?

Dr. Habil Khorakiwala: It depends on product-to-product. In some cases we believe that it would be an abbreviated program definitely and in some cases also it is a reduced program, not abbreviated where generally you require two full studies for an indication. Now, in a breakthrough status, the FDA accepts one full study for one indication but they need two full studies. In fact with the same two full studies it is the one indication you can get approval for two indications.

Abhishek Sharma: I believe it is a very difficult status to achieve. Have there been some in-bound enquiries regarding people who want to partner with you on this?

Dr. Habil Khorakiwala: I have already answered that we are not actively seeking any licensing arrangements.

Moderator: Thank you. The next question is from the line of Tushar Manudhane from India Nivesh Securities. Please go ahead.

Tushar Manudhane: Sir, just would like to know the number of MRs for Domestic Formulations market currently and how many we plan to increase for FY16 or '17?

Dr. Murtaza Khorakiwala: So for the current year we have about 3,000 people in the field and there has not been a very significant increase in manpower… may be about 5% over last year. So that is what the level of field force we have.

Tushar Manudhane: Any plans to increase further or this is the level we will keep it for?

Dr. Murtaza Khorakiwala: No, I think our strategy is basically to improve productivity and improve the quality of the prescription depth and that is what we try to focus on, obviously, as the new products are there, new therapies are there, in normal course, normal kind of expansion will be there, but our primary focus is to drive growth to improvement in productivity.

Moderator: Thank you. We have a follow up question from the line of Shradha Patil from Wealth Managers. Please go ahead.

Shradha Patil: I just wanted to know what is the market for Oxycodone?

Dr. Murtaza Khorakiwala: I mentioned earlier that we expect a couple of million may be sales on an annualized basis.

Shradha Patil: But the product size of the market?

Dr. Murtaza Khorakiwala: I do not have those details with me right now.

Shradha Patil: When is this genericized?

Dr. Murtaza Khorakiwala: I do not have the details right now.

Shradha Patil: You have a pipeline of 73 ANDAs. So I just wanted to know that out of these products, how many products must have already become Generic for it may not be the first time opportunity for you?

Dr. Habil Khorakiwala: Most of our products which are pending some of them would certainly be already genericized and we may not be first, but there are a number of products where we would be in a HTM status or even FTF status.

Shradha Patil: So there are a meaningful number of products?

Dr. Habil Khorakiwala: Yes.

Shradha Patil: Which are the therapies in which these products are awaited?

Dr. Habil Khorakiwala: I do not think we do too much tracking product wise, we look at the size of the product and the opportunity and competitive portions, that is how we generally take our product position in a Generic space.

Shradha Patil: So, should it be that the therapies will be with how you have been launching before all the USFDA problems?

Dr. Murtaza Khorakiwala: What we are trying to say is that the therapy does not drive our decision for launching a product. I think basically there are a lot of factors in terms business opportunity, market opportunity, product, patent expiry, differentiation, innovation, technology. Those are the aspects that we really look at in terms of portfolio selection and then introducing the product in the market.

Shradha Patil: So there can be something from Dermatology as well or something else?

Dr. Habil Khorakiwala: We are not in Dermatology space.

Moderator: Thank you. The next question is from the line of Dheeresh Pathak from Goldman Sachs. Please go ahead.

Dheeresh Pathak: Sir, earlier to a question you said that Chikalthana 483, we are yet to reply. But 483 was received in the month of March if I am correct, right? So, why is it taking so long to reply?

Dr. Habil Khorakiwala: No-no, there are two issues; first, we gave immediate reply within 15-days as required, and the second response what we are talking is all 483 response will go in next couple of weeks where all the issues they have raised where we would state that we have complied with all of that. So it would be a completion report we would be submitting in next 2-weeks.

Dheeresh Pathak: Post the initial reply, there have been another …?

Dr. Habil Khorakiwala: No-no, there were 483, they have raised 7 or 8 issues, to that we replied that these are the corrective action we will be taking. My second reply will say that we have completed those corrective actions.

Dheeresh Pathak: Just a follow-up to your remedial action that you are taking?

Dr. Habil Khorakiwala: It is a follow up to original question also confirming that all corrective actions have been complied with fully.

Dheeresh Pathak: So post that you expect them to come for a further reinspection or do you expect approval without reinspection?

Dr. Habil Khorakiwala: I do not think we will be able to comment on that.

Dheeresh Pathak: US business has declined from around $45 million to $35-36 million. So, is this run rate a more sustainable run rate or you expect it to go back to what you were doing in the Q4?

Dr. Habil Khorakiwala: You could take that the current run rate is a minimum run rate we will have.

Dheeresh Pathak: Any particular product where we have seen some erosion?

Dr. Habil Khorakiwala: As I mentioned earlier that some of the products where we have filed through a 3rd party we have received one or two approvals and some more may come, so those will be introduced in second half of the year.

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

Jigar Walia: A few queries: First is continuing on the L1 that we will be submitting the completion report shortly. In Q2, since we read news about some large product recalls, I understand it would be more pertaining…

Dr. Habil Khorakiwala: We have not recalled anything recently. Our only recall has been in the April where we have recalled all our products. However, we have to submit to FDA every month actually the goods we receive from the trade. What is getting recorded in the newspaper every month is a number of units which has come back and we give this report to the FDA and that has been quoted. So, it is not a recall we are doing every month. It is only one recall we did in April and what you hear is month-to-month actually goods coming back to us…

Jigar Walia: Any write-off related to it that we should expect in Q2 results or there would not be much of it?

Dr. Habil Khorakiwala: We believe that a significant part of recall has already occurred in Q1.

Jigar Walia: A next question is of the five filings that we have done, how many of them would be from the MGP plant?

Dr. Habil Khorakiwala: None of them is from MGP.

Moderator: Thank you. The next question is from the line of C. Shrihari from PCS Securities. Please go ahead.

C. Shrihari: I would like to know the share of Insulin and Biosimilars in both Indian sales and emerging markets sales and what has been the growth for the quarter?

Dr. Murtaza Khorakiwala: I do not have the exact details of the same available right now. So, I think I can come back to you maybe later.

C. Shrihari: On Insulins business front, what has been the growth for the current quarter in that segment?

Dr. Murtaza Khorakiwala: I do not have that detail with me right now. We can come back maybe to you later.

Moderator: Thank you. As there are no further questions from the participants, I would now like to hand over the floor back to Mr. Manas Datta for his closing comments. Over to you, sir.

Manas Datta: Thank you very much, every participant. This was nice speaking to you. So thank you once again for participating into investors call for Q1FY16. Whatever information we could not provide it to you, you can call us up separately, and we will provide those information.

Moderator: Thank you very much, sir. Ladies and Gentlemen, on behalf of Wockhardt Limited, that concludes this conference call. Thank you for joining us and you may now disconnect your lines.