



“Wockhardt Limited Q3FY15 Earnings Conference Call”

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Moderator: Ladies and Gentlemen, Good Day and Welcome to the Wockhardt Limited Q3FY15 Earning Conference Call. We have with us on the call today, Dr. Habil Khorakiwala – Chairman; Dr. Murtaza Khorakiwala – Managing Director; Mr. Manas Datta – Chief Financial Officer. 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 touch tone phone. Please note that this conference is being recorded. I would now like to hand the conference over to Mr. Manas Datta – CFO of Wockhardt Limited. Thank you. And over to you Mr. Datta.

Manas Datta: Thank you. Good Morning, Ladies and Gentlemen. I am Manas Datta, I am the CFO of the company. A Very Warm Welcome to our Q3FY15 Conference Call. Today, we have with us Dr. Murtaza Khorakiwala – our Managing Director and Dr. Habil Khorakiwala who is our Chairman; our Chairman will be present in this conference call but will be available for Q&A session. We will start our meeting with Dr. Murtaza Khorakiwala’s presentation on the financial performance of the company for the Q3FY15. Thank you very much, and over to you, Dr. Khorakiwala.

Dr. Murtaza Khorakiwala: A Very Good Morning to all of you. I am very happy to be here for presenting Wockhardt performance in the third quarter of the financial year 2014 & 15. I think we start off with basically a brief introduction of the organization: If we see our global operations, we are a global company, we have direct operations in India, UK, Ireland, France, USA and Mexico and via our alliances and partners, we are present in the rest of the world markets also, all put together as an organization we have 8,600 associates and we have people in 21 countries. Looking at our manufacturing organization, we have 12 locations globally, out of which we have 9 sites in India, 1 in UK, 1 in Ireland and 1 in Chicago, and of the 9 sites in India we have 5 in Aurangabad, 2 in Daman, 1 in Ankleshwar and 1 in Baddi. As we have been mentioning earlier, we have over the years established 3 R&D centers; our primary R&D center headquarter is in India, we have also established 1 in USA and UK.

I will go first to the financial results of the company for the quarter that is Slide #10. So for the quarter we had a sale of Rs.1,382 crores, which is a growth of 12% over the quarter of last year. On EBITDA front, we had EBITDA of Rs.463 crores against last year’s same quarter EBITDA of Rs.241 crores, which represents a growth of 92% over last year. As far as PAT is concerned, our PAT for the quarter was Rs.347 crores against last year Rs.304 crores, which is a growth of 14%.

Coming to the nine-month results of the current year, our sale was Rs.3,321 crores against Rs.3,792 crores last year, which is a decline of about 10% in sale. On EBITDA basis, against Rs.858 crores last year we are this year at Rs.608 crores for the nine months which is a decline of 20%. On PAT basis, against last year’s Rs.766 crores we achieved Rs.371 crores which is a

decline of 52%. If you look at our R&D cost spend, for the last three quarters we have been spending Rs.114 crores and this quarter our spend was Rs.122 crores and as a percentage of sale earlier last two quarters we were at 11.7%, 12.2% and for current quarter we are at 8.9%. And for a period of nine months our R&D spend is Rs.340 crores, which is approximately 10.6% of our sale. Our US business which was at \$304 million last year, this year at \$132 million for the nine months which is a decline of 55% in rupee terms and 57% in dollar terms. Our UK operation which was £81 million last year, this year for the nine months period we are at £109 million which is a growth of 30% in pound terms and 41% in rupee terms. Irish operations which is primarily the operations in the Irish market, against €17 million last year this year we are at €15 million which is approximately 10% decline over nine-month period. In Emerging Markets against sale of Rs.214 crores last year we had Rs.246 crores and the growth is about 18% for the quarter and 17% for the nine-month period. The India business out of that has grown by 15% in this quarter and 17% in nine months. For the India business we have launched 40 products in the nine months period and 7 new products in the last quarter. Similarly, ROW businesses also done well and has grown by 28% in the quarter and 15% in this nine months period.

To give you an update on some of the regulatory aspects of the company, I am happy to share with you that we have had our L1 facility which is Chikalthana facility which has been inspected by UK MHRA over the last couple of years we have received a letter saying that our facility is not in a state of non-compliance. That means we are able to product the products in Chikalthana facility for the UK market. The second positive development we had was our Morton Grove facility in US which was inspected earlier part of this year. And in terms of our responses to the 483 we have got they have been found satisfactory from US FDA and operations continue as they were before as normal. Additionally, Wockhardt has offered all office manufacturing facilities to the FDA for an inspection and including our new facility which is Shendra.

Thank you very much for being with us today and hearing the presentation. I would now like to invite any questions that you may have and I would also request our Chairman Dr. Habil Khorakiwala to have the opportunity to interact with you during this session.

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 Sir, if you could give more details on the higher rupee sales this quarter?

Dr. Habil Khorakiwala: In the UK we had a great opportunity to do our product for one company which has resulted in a significant improvement in the performance for the quarter and to some extent this opportunity will continue in the next couple of quarters, may not be at the same extent but to a very significant extent. So, that will be there, and after that, we expect that whatever I can

respond to way forward questions since it was there, since we have offered all our facilities for inspection USFDA, especially, Chikalthana L1 and also Shendra which is our new facility and it is last 2, 3 months we have offered them and we expect inspection anytime and we believe that we should be able to resolve that issue to the satisfaction to the FDA because it has already been resolved as far as UK MHRA is concerned, and we believe that we should be able to begin business of US operations on some of these facilities hopefully, in the second half of the financial year '15-16.

Dheeresh Pathak But coming back to the UK, if you could just provide the nature of this opportunity, is it Contract Manufacturing for some other players, is it some tender that is available for a few quarters?

Dr. Habil Khorakiwala: It is Contract Manufacturing facility for some other player because the very unique nature of the product where they were the only supplier in the world and we have been manufacturing for a while, so we were able to negotiate of our better rate for the contract and that is likely to continue for next 2 quarters, and it will not be to the same extent as the current quarter but at a reduced level it will continue for the next 2 quarters.

Dheeresh Pathak Can you also just update and sort of refresh the US cumulative filings and pending?

Dr. Murtaza Khorakiwala US, we have filed so far in 9 months 13 ANDA and I think over more than 60 odd ANDAs are pending. The other positive about this is that US FDA has continued to review our pending ANDAs on a continuous basis. So, we do expect once we normalize our operations, we should be able to receive additional approvals of the pending ANDAs in a relatively short period of time.

Moderator Thank you. We have next question from the line of Anupam Agarwal from Credit Suisse. Please go ahead.

Anupam Agarwal Just on that ANDA question, last presentation in the September quarter, the release carried that you had 75 pending ANDAs. Just wanted to understand how many of them will be Para-IV, just a rough number will be useful, half, more than half?

Dr. Habil Khorakiwala: I honestly do not have exact number on Para-IV but broadly, I could tell you that most of our filing are basically technology-driven filing with NDDAs or other related issues or sterile. So, pure generic filings are relatively less, and our approach on Para-IV filing has been that we consistently deal and negotiate and resolve issue with the innovator. So, some of the Para-IV filing has been legally sorted out with the innovator for clear understanding.

Anupam Agarwal Just a sub question on that now, assuming that you come in second half FY'16 if you got to manufacture and if approvals start coming, have you done a very-very broad analysis and this is I am asking very broad; out of the 75 by that time do you think that this 10%, 20% of them

would have anyways become economically unviable to launch just because of a delay that you had?

Dr. Habil Khorakiwala: Let me put it to you differently because our idea basically is to issue manufacturing of the current products and then deal with it. We have not fully assessed unavailability of it, but from what we understand is the unavailability would be very limited or hardly anything. Probably what will happen is suppose the potential we were expecting may be a little lower for some of the products than our original internal forecast.

Moderator Thank you. Next question is from the line of Gopal Madnani from Arjavam Advisors. Please go ahead.

Gopal Madnani First question is that you said you would get some of the revenues that you got from UK sustainable for the next two quarters. Can I understand that most of it is sustainable for the next 2 quarters or a large part is not sustainable for the next 2 quarters?

Dr. Habil Khorakiwala: There are two stream of revenue – one is our normal business, in fact that will show a growth in the next coming quarters. The new opportunities which we have had will continue for next quarter but at a reduced level.

Gopal Madnani So, significantly reduced or just somewhat reduced because it has contributed a large part of your bottom line this quarter, Rs.400 crores extra compared to last quarter in sales and your EBITDA and net profit also went up by similar amount actually?

Dr. Habil Khorakiwala: So, what we would say that whatever opportunity which we had in quarter will be split up in the next two quarters broadly speaking.

Gopal Madnani Second question that I had was regarding this US FDA approvals. It seems that UK issue is broadly resolved. It seems to me that US FDA decides whenever it feels like to come and inspect facilities. Is there no timeline that they have to give you after you have actually invited them or did they could just come anytime they feel like?

Dr. Habil Khorakiwala: That I cannot answer the question on behalf of FDA but from the past practice and from whatever we know is we offer them some time in November our facilities and we did expect that they should be coming at the beginning of the current year. So, we have no idea as of today when they would be coming. Since we have invited, we are in a readiness position whether they come without notice or with notice. So, it is not an issue with us basically.

Gopal Madnani One more question also on the consultants that you all had hired for this entire remediation process namely Lachman Consultants. Would you actually be engaging this which is on an ongoing basis to make sure that your plants are always in compliance and not going to face this issue again?

- Dr. Habil Khorakiwala:** I must say that we have used Lachman initially and StepChange subsequently as our consultant. StepChange continues to remain in that position as of today. But what we have used ultimately as an organization you have to develop your robust system and that should be there and that is what we have done, the whole approach and system we have developed in the manner like for example, we have computerized entire quality system as far as HPLC is concerned in which we are in the process of all aspects of quality system computerizing. Second, we have brought about competency in the organization with new leadership at the right level. Thirdly, we have provided extensive training to all our staff both in quality and manufacturing for compliance, and that is what is reflected when MHRA visited us on the third time in 18 months of these compliance were in place. So ultimately, the organization has to be in a readiness and competent to handle this issue on an ongoing basis.
- Gopal Madnani** My last question is regarding debt-equity ratios at this point in time. I know that your net debt is almost zero now from what I can understand, but can I say that you will even go below that and try to move towards being a debt-free company?
- Dr. Habil Khorakiwala** I think the numbers are with you and you are right our net debt is 0.18% to be exact today and I think our objective is basically should remain all the time liquid. So, depending on our performance as far as cash is concerned, we carry a current cash of more than Rs.1,000 crores. We will remain always liquid with the cash in hand, but our net debt obviously based on our profitability and our cash flow, and you are absolutely right, that within reasonable period of time it may come down. We also have our CAPEX expenditure in the current year and the forthcoming year also. So, collectively, we believe that we would be liquid in terms of cash availability and we would be in a more or less current situation of the debt-equity ratio.
- Moderator** Thank you. We have next question from the line of Pritesh Chheda from Emkay Global Financial Services. Please go ahead.
- Pritesh Chheda** If you could just dwell a little bit more on the filings and what potential those filings have?
- Dr. Habil Khorakiwala:** That is a tough question because we do not generally give guidance on those parameters but I think I could simply tell you this that all our filings are looking at significant opportunities in a competitive sense in the market, and the very fact that we file this year also about 13 and we will file before end of the year some 3 or 4 more. So, that will reflect going forward for the next 2, 3 years, we have a very healthy pipeline of the products which will be coming out.
- Pritesh Chheda** And just digressing the Q3 number, so, barring the UK ops part which has this exceptional number, should we consider at least the other business lines are kind of base business lines for us or base business numbers for us?
- Dr. Murtaza Khorakiwala** Yes, I think that would be correct and going forward as we move ahead, there will be further consolidation and strength and growth of the base business partly, as a result of the resolution

of some of the regulatory issues and partly because of the new products that we would introduce during the coming quarters which would result in a more positive growth.

Pritesh Chheda Last just want to understand, on the UK business side, you said that there is significant part of the number which we saw in Q3 might continue. Can you quantify what part or what extent is it a (+/-5%, 10%) number which will not continue, if you could quantify that part?

Dr. Murtaza Khorakiwala I think the question has been asked earlier and we have responded adequately to the extent we could as of now.

Moderator: Thank you. The next question is from the line of Nishith Sanghvi from CIMB. Please go ahead.

Nishith Sanghvi: We are doing around \$46-\$50 million kind of run rate from this quarter for the US. From 2HFY16 we plan to see additional uptick. So how many product launches are we expecting there post some sort of resolution?

Dr. Habil Khorakiwala: The products which are under alert, obviously we would start introducing those products obviously on a priority basis with the value creation potential. So, we believe that significant part of value creation even though the product number may be small, will take place during the second half of the year.

Nishith Sanghvi: So basically that would be one part and probably we have seen that there have been some large products that maybe coming for launches like Abilify, Nexium, Namenda, I feel that we will also be participating in this opportunity?

Dr. Habil Khorakiwala: Yes, as soon as we receive approval, we will immediately participate in those opportunities.

Nishith Sanghvi: Probably we are not sharing what are the sustainable base business margins for this quarter, but probably on a steady state basis, looking at FY17 where we will be seeing and selling of our US business and on a steady state UK business, what kind of margin levels can we achieve traditionally we had been doing 30% EBITDA, so FY17 if I have to look at what can be the potential do you see here?

Dr. Habil Khorakiwala: I believe basically business model and the product mix are not going to significantly change, and the EBITDA margin would be more or less maintained what was earlier, the only factor which one has to probably take into consideration that our R&D spend as a percentage or as a totality will go up by '17, as we have been working on a number of products where there are clinicals involved, both for pharmaceutical products as well as the drug discovery area. But it may not be very different in terms of percentage of sales in FY17 than what you are seeing today.

Nishith Sanghvi: So sir, how much proportion of R&D going towards drug discovery, if you can...?

Dr. Murtaza Khorakiwala: The current period it is not very significant, but I think from next year and onwards, I would not be able to tell you exact number at this point, but it will be something like about 20% to 25% of our R&D spend in the next couple of years.

Moderator: Thank you. We have next question from the line of Kumar Saurabh from Macquarie, please go ahead.

Kumar Saurabh: Just wanted to know an idea around the filings that we have made in the last two years, what proportion of the filings has gone from Shendra?

Dr. Habil Khorakiwala: Majority of filings has gone from Shendra what we have done in the current year and the previous year, literally all of the current year filing has gone from Shendra, and even the previous year, majority of the filing has gone from Shendra, so we have hardly filed one or two after the initial alert we received from existing facility, and Shendra has all the facility of steriles, solid dosage form, and the liquids and we are doing some filing from our Morton Grove facility also.

Kumar Saurabh: Is it fair to assume 35-40% of your 60 odd ANDA spending approval would be from Shendra, Morton Grove like ex-Chikalthana and Waluj?

Dr. Habil Khorakiwala: Yes.

Kumar Saurabh: Second point around the alternative filing. So, the products that were there in the market and assuming a fact that suppose Chikalthana and Waluj do not come on stream in FY16, are there any other third-party sites or potentially even Shendra where you try to ship some of your critical products?

Dr. Habil Khorakiwala: We have done that and that process is continuing anyway as our Plan-B.

Kumar Saurabh: In terms of sequence of events of potential inspection, of course, we can make a wild guess out here, is it fair to assume that Shendra being the new facility could be the one that gets inspected first from US FDA?

Dr. Habil Khorakiwala: That is very, very difficult question honestly to answer. FDA once they start visiting our facility, they might visit all our facilities within a short period of time. That is what we expect, because they will need to have a comprehensive view of the organization also and that is our readiness, because we have more or less the same approach, same system across all the facilities.

Kumar Saurabh: UK MHRA has approved both Shendra and Chikalthana now. So as we speak these two facilities we can supply into UK?

- Dr. Habil Khorakiwala:** That is correct. In Shendra they have only visited our liquid facility, because that is the only product we have offered for the UK, so MHRA has not visited our sterile and solid facility because we have no product to offer to them.
- Kumar Saurabh:** As we speak today, your largest facility in terms of capacity would be the Shendra facility or still L1?
- Dr. Habil Khorakiwala:** For historical products our main facility continues to remain Chikalthana L1.
- Kumar Saurabh:** But in terms of capacity like Shendra quite a large facility now the way you...?
- Dr. Habil Khorakiwala:** By the time we get the product and manufacture, and everything, so in the next two to three years, the Shendra would become the largest facility.
- Moderator:** The next question is from the line of Anubhav Agarwal from Credit Suisse. Please go ahead.
- Anubhav Agarwal:** A couple of questions; one, your comment on UK MHRA clearance Chikalthana facility. What I see on the web site is they have commented on 16th of January that what they have allowed is initially they allowed some critical APIs continued to be manufactured by Wockhardt and Wockhardt sent them a notice that they do not want to manufacture or they are seizing supply of this critical APIs and they say that reinspection by European authorities will be required in order to let Wockhardt supply to European market from Chikalthana facility in future. So anything has happened after 16th of January?
- Dr. Habil Khorakiwala:** Just let me clarify the situation, that the Chikalthana L1 for UK we had one small product, API manufactured, where we have a very small facility. Our principal facility in Chikalthana is pharmaceutical solid dosage form facility. So looking from a overall business perspective we have decided to discontinue manufacturing for UK and European market the L1 facility API, and therefore what you are referring to is referring to that API facility and we have no intention to issue that facility for UK supplies. As far as our pharmaceutical facility which is a main facility we have been discussing has been given the clear GMP certification by the MHRA.
- Anubhav Agarwal:** Second was on the Morton Grove facility. When FDA cleared it did they came for reinspection or just from the responsive from 483 they gave a clean chit there?
- Dr. Habil Khorakiwala:** Monthly periodic three to four updates we have given from time to time, and we had a new leadership in quality function even in Morton Grove six months back, and then we had one-on-one meeting with US FDA, and we appraised them of the developments and everything which we have done, and they wanted some more clarification and so on and so forth, but they very clearly indicated to us that there are no further actions they are intending to take on and they are more or less satisfied, but what could it result into is they might come for reinspection in near future, which we do not know whether they will come or not but it is possible that they

may come during the current year inspection because the last inspection was anyway six to nine months old. This is only 483, we did not had a warning letter or alert or anything, as you know that.

Anubhav Agarwal: You have not got any approval from Morton Grove post that right?

Dr. Murtaza Khorakiwala: No, this took place very recently, and we do not have any pending approval, which is reaching an approval stage, because we just started filing during 2014 itself to FDA, so they are not even due for approval.

Moderator: Thank you. We have the next question from the line of C Srihari from PCS Securities, please go ahead.

C Srihari: Regarding the UK product, could you please tell us what is the kind of volume growth you saw in this quarter and what is the outlook going forward?

Dr. Murtaza Khorakiwala: I believe that specifically I may not be able to respond to that but we can always get some more information, but if I look at the base business outside the Contract Manufacturing opportunities, I think because of the regulatory issues which have dogged us earlier, some of the products where the approvals we had, we have not been able to market, so there has been a slight degrowth of the base business because of the regulatory issues, but now that the Chikalthana facility has been allowed to manufacture products for UK, for the next year we expect to return back to growth for even the base business.

Dr. Habil Khorakiwala: Additionally we are continuing to supply to UK from our two facilities in Daman basically.

C. Srihari: I meant about this particular product that you are talking about...?

Dr. Habil Khorakiwala: I had answered this question earlier by saying that the business which we have received around Rs.300 odd crores current quarter of this special opportunity, the similar opportunity we will have in the next two quarters, not every quarter, collectively opportunity would be there,

C. Srihari: I wanted to know what is the kind of volume growth you saw?

Dr. Habil Khorakiwala: This is the contract manufacturing, we did not have an idea on the volume growth here.

C. Srihari: Is it more like a campaign business which will lapse after the next two quarters?

Dr. Habil Khorakiwala: No, it may not continue after the next two quarters, and probably by the time we will have our regular growth of our product coming in with full supplies going to the UK, and also a lot of filings we have done. So we expect to have some approvals coming in the next 6 months significantly, and that will provide healthy growth for our UK operations.

- C. Srihari:** Regarding your Insulin, Glargine business, can you throw some light on that?
- Dr. Murtaza Khorakiwala:** I think as we have discussed earlier, our Biosimilar products is a core area for us, we are highly committed to that in terms of manufacturing and also in marketing, over the years the Insulin and Glargine have got approved in various markets all around the world and I think that business is moving ahead and it is continuing strongly, and we also are working on developing further new products. So I think that is on course, and we are moving ahead, we are expanding globally, and that seems to be all right.
- C. Srihari:** Can you please share some numbers, I mean, what is the kind of revenues you might have posted between these two products?
- Dr. Murtaza Khorakiwala:** I do not have it readily available right now, we can come to it later.
- C. Srihari:** Between the two, Glargine has relatively fewer approvals. Is that expected to pick up?
- Dr. Murtaza Khorakiwala:** That is right, because we introduced Glargine a few years back whereas Insulin has been in the market for almost 10 years now, so obviously the regulatory filings which have been done and are in process, will consolidate and we will have more and more markets opening up for Glargine also.
- Moderator:** Thank you. We have next question from the line of Chirag Dagli from HDFC. Please go ahead.
- Chirag Dagli:** Last time we had indicated that we are ready for inspection at Chikalthana but not at Waluj by the FDA. Has that status changed?
- Dr. Habil Khorakiwala:** We have already informed FDA and offered all our facilities for inspection including Waluj.
- Chirag Dagli:** So that is a change in the last say six months?
- Dr. Habil Khorakiwala:** Yes.
- Chirag Dagli:** If I understand correctly, there were some repeat observations at Morton Grove, observations that were similar to what happened at Waluj as well as Chikalthana. So I just wanted to know your thoughts on what view the FDA has taken on some of those points?
- Dr. Habil Khorakiwala:** As I mentioned to you earlier, we have resolved all issues as far as Morton Grove is concerned with the US FDA.
- Chirag Dagli:** Is there some follow through that you need to do basis which or conditional...?
- Dr. Habil Khorakiwala:** We had given certain commitment and time schedule of compliance, all these aspects, and we have been giving a regular feedback to FDA on those fronts with proper documentation and

other things, and we are on schedule and we have completed the complete remedial action which we had committed to FDA. Consequent to that they are satisfied with our approach and response in terms of remedial action and that has been resolved satisfactory to FDAs requirement.

Chirag Dagli: So now there is nothing conditional in the EIR that we have received on Morton Grove?

Dr. Habil Khorakiwala: Yes, you are right.

Chirag Dagli: Both India as well as the European business, even excluding this Rs.300 crores opportunity that we have, have grown reasonably well in the third quarter. Any specifics here that you want to share with us in UK for example or Europe as a whole even excluding this Rs.300 crores and India has also grown 15% odd, what is happening there and are there any price hikes that we have taken in UK or new products, anything at all ...?

Dr. Murtaza Khorakiwala: Let me start off by India, I think what we have done is significantly we have strengthened our India operations and the focus on the business over the last one to one and a half year, and as a business I think we are doing reasonably well, we are growing faster than the industry and the various measures which we have taken in terms of sales and marketing and specifically introduction of some of the new products during this period has been well received in the market and we see that the business maintaining that momentum even in the coming period going forward.

Dr. Habil Khorakiwala: As far as the UK business is concerned I think more or less it is on track excepting some disruption which took place, because of our facilities at Chikalthana, and once they are resuming we expect that our UK business coming forward base business should show a double-digit growth.

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

Dheeresh Pathak: Sir, on the MHRA clearance for L1, when was the inspection that led to this clearance?

Dr. Habil Khorakiwala: I think we had an inspection sometime 6 months back and we received communication sometime in December or so.

Dheeresh Pathak: This was if I remember correctly joint inspection by FDA and MHRA that had led to the withdrawal of...?

Dr. Habil Khorakiwala: No, there were three inspections by MHRA in last 18 months; the first one was a joint inspection, and the next subsequent inspection was only by MHRA. But I must share that FDA and MHRA both have communicated to us that they are sharing information of details of the inspection to each other, so that is what they have informed us very specifically, they will be

sharing information so MHRA inspection have taken place and whatever the observation they have had, is available with FDA.

- Dheeresh Pathak:** The Waluj facility is still has a withdrawal GMP certification from MHRA, right?
- Dr. Habil Khorakiwala:** We have not yet offered there for inspection because we hardly had much of a business. So there our strategy basically is to get the US FDA first there.
- Dheeresh Pathak:** The Contract Manufacturing product for UK business this quarter that is being made out of the Daman facility or some UK facility
- Dr. Habil Khorakiwala:** This is being manufactured in UK.
- Dheeresh Pathak:** Manufactured in UK for UK market?
- Dr. Habil Khorakiwala:** Yes.
- Moderator:** Thank you. The next question is from the line of Manoj Garg from DSP Merrill Lynch. Please go ahead.
- Manoj Garg:** Just would like to understand, out of the 60 pending ANDAs which we have in the US, how many of them are vertically integrated?
- Dr. Habil Khorakiwala:** Normally what happens is, we do not as a method of approach manufacture our own API for our ANDA, we do it only in the case where there is a strategic reason to do that. Either the product is not available or the supply limitations are there, in those cases only we manufacture our API, and generally we file in a year about six to eight DMF for our own ANDAs, so that will give you some idea of our own, so our strategic advantage is coming for API out of the scarcity of availability of API.
- Manoj Garg:** In your opening remarks since you have indicated that in the past two years there was import alert from the facility but FDA continued with their ANDA applications review. So is it fair to assume that as and when these plants get cleared, probably you can have bunch of approvals coming at the same time?
- Dr. Habil Khorakiwala:** Yes, it is quite possible that we might receive in rapid succession some of the pending approvals.
- Manoj Garg:** One from a qualitatively perspective, would it be possible for you to share like in terms of out of the 60 applications, how many could be in the area of sustained release or in a differentiated or complex segments and how many could be of meet to kind of products?

- Dr. Habil Khorakiwala:** Generally speaking you could say more than 80% of pending ANDA would be a differentiated product, and that is our basic strategy of filing ANDAs.
- Manoj Garg:** Looking at this Biosimilar Insulin, since we do have both Glargine as well as RH Insulin, do we have any plan or have we initially talk towards European clinical trial for these products?
- Dr. Habil Khorakiwala:** Let me put it to you this way, that as far as our Biosimilar is concerned, we would like to go to the developed markets both UK and USA, and we would be initiating clinical trials during '15-16, but we see because of the various issues especially in the European market we would be able to enter much earlier, but because in the US market because of this Para, ANDA, the device related issue, even after filing we will have 30 months period before we can enter. So that I think you are aware of it. So the US would be a little delayed by a couple of years compared to entry into the Insulin, Glargine and other Biosimilar market.
- Manoj Garg:** And the strategy out here would be to go alone or probably you would look for some partners out there?
- Dr. Habil Khorakiwala:** As far as US is concerned we will do it ourselves. As far as EU is concerned, we have not yet taken a call, because nearer the approval stage, we will evaluate the benefit, but wherever we have physical presence today that we will do it ourselves anyway.
- Manoj Garg:** So Europe you do believe that probably you may come in the market maybe down the line in the next one or two years?
- Dr. Habil Khorakiwala:** No, I do not think it will be two years, but at least two plus years you can say.
- Moderator:** Thank you. The next question is from the line of Praful Bohra from Religare. Please go ahead.
- Praful Bohra:** Just a clarification on the UK business. The number that we have reported this quarter does it also include any sort of a licensing income?
- Dr. Murtaza Khorakiwala:** Not really.
- Praful Bohra:** Secondly, would it be fair to assume that the margin that we have reported is it largely driven by the UK business?
- Dr. Murtaza Khorakiwala:** Yes, that is a fair assumption.
- Moderator:** Thank you. The next question is from the line of Rahul Soni from Baljit Securities, please go ahead.
- Rahul Soni:** Top line and EBITDA margin performance is largely to do this 300 special income from the UK market, correct?

- Dr. Habil Khorakiwala:** Significantly you are correct on that, yes.
- Rahul Soni:** This is sustainable for the next two quarters as you said before?
- Dr. Habil Khorakiwala:** No, I did explain to you that whatever business we have got this quarter; 50% of the business has come this quarter, the balance 50% will come in next quarter.
- Rahul Soni:** UK MHRA has lifted the ban on your Chikalthana in January 2015. So, what kind of additional revenue are you expecting towards the lifting of the ban in March quarter and next June quarter?
- Dr. Habil Khorakiwala:** We will resume supplies during the current quarter, but I think one would see during the coming year, we will be back with our base businesses and double-digit in UK.
- Rahul Soni:** So it will take next 3-4 quarters to normalize the business?
- Dr. Habil Khorakiwala:** No, I did not say that, what I said that after this quarter '15-16 begins, we will see a double digit growth coming in '15-16, we will be normalizing by beginning of the next financial year.
- Moderator:** Thank you. The next question is from the line of S Vishwanathan from Unify Capital, please go ahead.
- S Vishwanathan:** Like to have the CAPEX that you have planned for FY16?
- Dr. Habil Khorakiwala:** Our approximate CAPEX is about Rs.300 crores for FY16.
- S Vishwanathan:** Are we planning for any inorganic acquisition in the coming year either domestic or ...?
- Dr. Habil Khorakiwala:** Our clear answer is no.
- S Vishwanathan:** Are you looking to hive off your India business by any chance?
- Dr. Habil Khorakiwala:** Same answer; clear answer is no.
- Moderator:** Thank you. The next question is from the line of Naresh Suthar from SBI Life Insurance, please go ahead.
- Naresh Suthar:** A small clarification on Morton Grove facility. Have we received formal EIR on the facility or we are telling only based on the communication we had with them?
- Dr. Murtaza Khorakiwala:** As far as my understanding goes, I think we have received communication from them, which says that they are satisfied with our responses of 483 and our operations continue as it was in a normal way.

Moderator: The next question is from the line of Pulkit Agarwal from Karma Capital Management. Please go ahead.

Pulkit Agarwal: Just one or two small questions: What percentage of our revenue in India is under price control?

Dr. Murtaza Khorakiwala: I think not a very significant amount; less than 20% would be under price control.

Pulkit Agarwal: What kind of volume gains have we witnessed in the past on that...

Dr. Habil Khorakiwala: I think broadly speaking, we have been growing as you have seen current year 17% to 18%, which is a little higher than industry growth, and our internal strategy is a combination of existing products and new product introduction to maintain growth rates higher than the normal industry growth for the year.

Pulkit Agarwal: So 17% is the total growth in the India portfolio, right?

Dr. Habil Khorakiwala: Yes, that is what we have this 9 months 17% growth.

Pulkit Agarwal: What would be the volume growth in that and what would be the price?

Dr. Habil Khorakiwala: We do not measure ourselves by unit growth and volume growth primarily because it is a multi-product approach and we focus really on value growth and profitability of the business.

Moderator: Thank you. Ladies and Gentlemen, due to time constraint that was the last question, I would now like to hand over the floor to the management for their closing remarks. Over to you, sir.

Dr. Habil Khorakiwala: I just would like to basically mention that I think overall way forward as a company we are quite positive about what we have done so far, and we believe that the major issue which is hampering our performance in the last couple of years, we do hope that in the coming financial year we should be able to resolve those vis-à-vis all regulatory bodies and then we should be going back to normalcy of our business. We have fairly robust portfolio on R&D. Our commitment in spite of tough times we have had last two years, we have continued to invest into future for the organization and invest in R&D, and our investments in R&D has not gone down, in fact in absolute numbers also, it has gone up, as a percentage of sales it has gone up significantly, and that is what we continue, because the future of the organization depends on how well we invest not only in research but identify the right kind of opportunity in a market competitive sense, and I think that is what we will continue to do as an organization. Thank you very much, pleasure talking to all of you, and responding to all your queries.

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