“Conference Call with the Management of Cadila Healthcare Limited”

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Moderator: Ladies and Gentlemen, Good Day and Welcome to the Conference Call with the Management of Cadila Healthcare. As a reminder, all participants' 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 for an operator by pressing '*' then '0' on your touchtone phone. Please note that this conference is being recorded. I would now like to turn the conference over to Mr. Vishal Gor – Head of Investor Relations. Thank you and over to you,

Vishal Gor: Good Evening to all of you. Thank you for joining this conference call which is organized to discuss the queries you might have on the warning letter received by us. We have with us today from the management team of Zydus Cadila, Mr. Pankaj Patel – our Chairman and Managing Director; Mr. Nitin Parekh – the Group Chief Financial Officer.

Before we proceed with the call, let me remind everyone that this discussion will contain certain forward-looking statements which include all matters that are not based on historical facts. By their nature, forward-looking statements involve risks and uncertainties because they relate to future events and depend on circumstances that may or may not occur in the future. There are several important risk factors that could cause material differences between the projected and actual outcomes. Therefore, such statements should not be taken as guarantees of future performance, including those relating to the strategies of the company, its future outlook and growth prospects.

Now, I would like to turn the call over to Mr. Pankaj Patel – our CMD. I would request all of you to restrict your number of questions to two initially and then wait in the queue for any further questions. You may also write to us for any other questions which remain unanswered. Over to Mr. Patel.

Pankaj Patel: Good Evening all. Welcome to this Conference Call. You would have read the intimation we have given to the stock exchanges about the warning letter which has been issued by the US FDA on the Moraiya Formulations facility and the Ahmedabad API facility. This warning letter has been issued pursuant to inspection of Moraiya facility in September '14 and API facility in December '14. Post the inspection US FDA had issued a few observations in Form 483 at both the sites. Moraiya facility has two points in the warning letter: One is specific to narrow therapeutic index products. Based on detail investigation, we have decided to reformulate the product and have currently discontinued manufacturing of the product. The other point in the warning letter is with respect to handling of the market complaints and investigation thereof. We have taken help of external consultants to revise the SOP and validate actual handling. The new SOP were evaluated during inspection at the other sites and the inspectors had expressed satisfaction over the revised SOP. The API facility at Ahmedabad Zyfine had issues with GMP and as a result we have taken necessary actions to correct people and processes and suspended activities there. While remediation work was going on, we had an

FDA inspection and certain observations obviously were observed. This site has not supplied directly or indirectly any API to US market. We had withdrawn all the drug master files from the site and also recently deregister the site with FDA. We continue to work on bringing the site to compliance and currently no commercial activity is taking place from this site. We are in process of preparing a comprehensive response to the warning letter which would be submitted to US FDA within the stipulated timeframe of 15-days. We would continue our efforts at improving systems and ensuring compliance of cGMP requirements. Along with the efforts of our internal team, we are already working with external consultants. Over the past year, we have significantly invested in quality with respect to equipment, manpower and systems and processes. We have involved subject matter experts to help us in this process. We are committed to aggressively and comprehensively work towards building a strong quality culture at all our sites.

Thank you. Over to the coordinator for Q&A.

Moderator: Thank you very much, sir. Ladies and Gentlemen, we will now begin with the Question-and-Answer Session. The first question is from the line of Ashish Rathi from Infina Finance. Please go ahead.

Ashish Rathi: Pankaj bhai, just wanted to check, as an investor, what has led to reoccurring the issues at the same facility in a time span of around 2-3-years? We had just come out of problems and warning letter situation in Moraiya facility. So somewhere the company and the management is failing to update practices up-to-date in the first learning itself is what my reading is. So this is discomforting because all the more US is the most important geography from growth perspective and Moraiya is the most important facility catering to its geography.

Pankaj Patel: First of all, there were no data integrity issue at the Moraiya site and what was basically said was about interpretation of the compliant whether FIR should be filed or not filed or whether there should be investigation with other batches and other products or not. So, this is one thing which was basically different than what was being practiced. It is worthwhile to note that we have several FDA inspections between last FDA warning letter and now. All these investigations were evaluated but nobody pointed out that. So it is basically the kind of new expectations which we missed out, as a result what we did as an organization is basically created a special group in the organization which basically reads all the published literature on the newer thinking at FDA, newer kind of observations made by inspectors at different sites, etc., and we are basically addressing this comprehensively at all our sites to make sure that they are evaluated and gap arrest is done, if there are gaps, they are corrected, if there are no gaps, of course, there is no issue. So, I think as a corrective step, we also have created this group which consist of several people who publishes regularly this thing and they are being monitored online to make sure. So, I think a lot of additional things have been done based on this learning that something which was okay yesterday, may not be right today and I think that

current Good Manufacturing Practices requirement has been added to the quality assurance function.

Ashish Rathi: Second question is just wanted to check if we did have OAI status on this facility at Moraiya, and if yes, when was that received?

Pankaj Patel: We never received any communication from FDA or the inspectors about OAI.

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

Abhishek Sharma: Sir, a couple of them; does the warning letter state anything about your remediation process in terms of what you have done ever since you received the observation letter?

Pankaj Patel: No specific things have been mentioned with respect to our remediation measures except what they have said is that they want a comprehensive report on all the investigation which we have done which we have to submit them as information, there is no specific mention about certain remediation information which we have provided to FDA on a regular basis. In fact, after the inspection, we have been submitting monthly updates to FDA with respect to whatever we have done and we have gone beyond the observations in terms of doing several new things. Just for your information, I would like to inform you that what we have done – all our laboratories are now (LIMs) Laboratory Information Management Compliant, so all plants have online recording of all the analysis which is being done at the plant. We have also included many of the IT-related software and hardware to make sure that all different analysis can be done more efficiently. The third thing is what we have done across the site is to basically create a kind of oversight function which would basically be continuously checking implementation of all the observations of other companies and other published FDA papers to see that whether we have gaps or no gaps. So, all these have been done and we have been keeping FDA informed about this. However, to my best knowledge, the FDA takes a call on inspection based on history not on the prospective thing done. So, that is what my understanding is. I think what has happened is basically based on the inspection and observations found during the inspection.

Abhishek Sharma: Could you just explain the last comment that you made – "FDA takes a call regarding inspection" I did not get it?

Pankaj Patel: The action which FDA will take on any inspection would be on historical data and not prospective data. That is my understanding. There are deficiencies, that is why we have 483, and that is the reason why we have received the warning letter.

Abhishek Sharma: But during the 14-months that have elapsed, you have completed your work around the observations which are raised and they may have been taken into consideration…?

Pankaj Patel: I do not have knowledge because there is no mention of that in the letter. We believe that we have taken action and if there are more to be done, we are willing to do it if FDA asks us additional work to be done. We would request FDA for an inspection to find out what we have done is sufficient or not.

Abhishek Sharma: So you would be submitting proposal to them and post that you would be doing further remediation I believe and then there would be a re-inspection. Do you expect this re-inspection to be a full-fledged one or would it only be related to the observations which have been raised at the warning letter?

Pankaj Patel: I am not sure about it. So hopefully there should be a full-fledged inspection is my opinion.

Moderator: Thank you. The next question is from the line of Surya Patra from PhillipCapital. Please go ahead.

Surya Patra: Sir, whether you have said ever what are the kind of revenue that you are generating from this Moraiya plant so far as US is concerned?

Pankaj Patel: Approximately 60% of the revenue of US is generated from Moraiya facility.

Surya Patra: Based on the kind of observation mentioned or things mentioned in the warning letter, you do not find any kind of major concerns about this revenue stream at least?

Pankaj Patel: That is what my interpretation is.

Surya Patra: About the warning letter points, you mentioned one is relating to SOPs and all that, the other point you talked about one neurotherapeutic index based product. What was the problem??

Pankaj Patel: We had a batch failure while manufacturing of the product, and as a result we have taken a correction action; however, after sometime the problem reoccurred. Though the earlier corrective actions were verified by a third-party expert, still it occurred, as a result we then finally decided to discontinue manufacturing and reformulate the product.

Surya Patra: So that product anyway is not there as of now?

Pankaj Patel: As of now we are not producing.

Surya Patra: Regards that API plant, you said sir, you identify the problem before only and you have taken action against people, against involved party and all that, what do you mean by that?

Pankaj Patel: What I was trying to explain to you was following: We had observed that there were some GMP violation at that facility. As a result of that, we had to take action against people; we took

action including the management at the plant. And then we basically started the remediation action and suspended all the activities there. While the remediation action was going on, the inspection occurred and obviously those things which were there were found. Subsequent to that, we withdrew all the Drug Master Files filed from that site and also we de-registered the site from the FDA register. We never had done any business from this site.

Surya Patra: So two things basically relating to this API plant; you said that you have withdrawn all the DMF in one hand and you are saying that you have disconnected the site from the US FDA, that is one; and second, you are saying that you are further walking on getting the plant compliant so far as US is concerned again?

Pankaj Patel: Yeah, ultimately we have a plant, so we have to make it compliant, so we will make it compliant, we will have third-party inspections done several times before we would basically decide whether to bring it to US or not. This is an oncology API manufacturing facility.

Surya Patra: Since it is Oncology plant, so whether it will have a kind of meaningful impact to your pipeline, that is…?

Pankaj Patel: No, because of the fact that we have second source available from other manufacturer.

Moderator: Thank you. The next question is from the line of Prakash Agarwal from Axis Capital. Please go ahead.

Prakash Agarwal: Just wanted to understand, sir, you mention that you have been sending monthly updates to the 483 observation that they have found. In the warning letter is there a mention of what is the comprehensive review that they have done until which part of your responses have been reviewed and from where that, if you can highlight that?

Pankaj Patel: Of course, we have to study this in detail, but apparently does not seem so.

Prakash Agarwal: Because there have been instances where there have been updates by the company and sir rightly said that it is largely coming from the historical precedences and not for the updates that we have sent. So just trying and understand have they mentioned that they have reviewed and analyzed your responses of early days till December-January and post that they have not responded or not have looked in detail of your monthly detail?

Pankaj Patel: I cannon specifically comment on this, we need to study the letter in detail.

Prakash Agarwal: Have they mentioned about having any third party audit or verifying products while we sent from this facility on an ongoing basis?

Pankaj Patel: No, they have not mentioned that.

Prakash Agarwal: For the Baddi, this was last inspected in May if I am not wrong. Any status there?

Pankaj Patel: We are getting product approval from the site.

Moderator: Thank you. The next question is from the line of Nimish Mehta from Research Delta Advisors. Please go ahead.

Nimish Mehta: Pankaj bhai, if you can just let us know where we are on the re-inspection request that we are or we were to send to the FDA? Secondly, generally speaking, after receiving the warning letter, what do you think would be the resolution timeline from here on?

Pankaj Patel: First of all, resolution timeline, it is very difficult to comment. We are going to send a comprehensive response to FDA and based on the response we would request FDA for re-inspection of the facility.

Nimish Mehta: Before the re-inspection, will you be doing any further remediation work now that we have the warning letter in hand or you simply do…?

Pankaj Patel: First of all, we are trying to understand the whole letter and I cannot say that today very conclusively that we have to do any additional work or not but if there is any additional work to be done, we will do it in a stipulated time and request for a thing.

Nimish Mehta: As of now we are not requesting for re-inspection, is that a fair understanding?

Pankaj Patel: It would be based on FDA warning letter. We will answer all the points raised by them. If we address all the issues, then we will ask for inspection or we will say that we will complete the additional work if required in such and such time and request for re-inspection.

Nimish Mehta: So resolution time any range…?

Pankaj Patel: I do not think I can comment on that at all because it is purely in FDA's hand, not in my hand.

Nimish Mehta: Observations that we had seen in last 483 where kind of four observations and within that there are some observations, how many of them would be now in the current letter?

Pankaj Patel: Current letter basically has two and it talks about narrow therapeutic index product, second is talking about compliant handling and compliant investigation.

Nimish Mehta: One related to quality of products like class recall are no more there in terms of the mention because I understand in the 483 there was a mention about some recalls and not handling that or is it the same you mention about compliant…?

Pankaj Patel: They are talking about compliant handling.

Moderator: Thank you. The next question is from the line of Rakesh Nayudu from Haitong Securities. Please go ahead.

Rakesh Nayudu: Given that substantial amount of remediation efforts seems to have gone into the Moraiya facility, what would be in your opinion a good estimate in terms of you asking US FDA to come and re-inspect the facility?

Pankaj Patel: I would not be able to give you answer specific to that question today. If you ask me this question after 10-days I would be able to specifically answer that question.

Rakesh Nayudu: Pankaj bhai was on TV and he had suggested that a few of your critical products, namely, Asacol HD and Toprol be safe. So could you elaborate in terms of how you see these opportunities unfolding? Especially, Asacol, if the final approval does not come through, how do you see the AG opportunity unfolding for Cadila in this product?

Pankaj Patel: We have a right for AG, that you are aware of. So if need be, we can always use the AG. Currently, we have not taken a view whether we should go for AG or look for approval. We believe that we have a dossier which is approvable and should get approved. The question would be only the compliance of the site. As a result, we have initiated action to also file from alternate site which will be filed in the next few months.

Rakesh Nayudu: Could you please tell me where have you referenced your dossier for HCQS?

Pankaj Patel: It has been approved for both Moraiya and Baddi site.

Moderator: Thank you. The next question is from the line of Saion Mukherjee from Nomura. Please go ahead.

Saion Mukherjee: Pankaj bhai, you mention about narrow therapeutic index products. When did you discontinue production of these products? How many of your future ANDAs would be having such profile?

Pankaj Patel: First of all, manufacturing of this product was discontinued about four months ago or so, so exactly I do not know the date. That is the only product which we have from this site which is a narrow therapeutic product…Warfarin.

Saion Mukherjee: This discontinuation, does it have a meaningful impact on revenues?

Pankaj Patel: No.

Saion Mukherjee: So since you have discontinued the product and not much of future pipeline is also related to narrow therapeutic index and the fact that you have implemented a new SOP, does it appear to you that typically we have seen a warning letter getting closed within a year's time given the nature of observation, will it be fair to assume?

Pankaj Patel: That would be our best effort I would say.

Moderator: Thank you. The next question is from the line of Jatin Kotian from Emkay Global. Please go ahead.

Jatin Kotian: I just wanted to know when was the last FDA inspection done for your other API manufacturing facilities?

Pankaj Patel: API facility Dabhasa was done in 2015 first half and Ankleshwar was done in late 2014 but I do not know exact date.

Jatin Kotian: Based on what has happened with Zyfine facility, do you think there could be a risk to the FDA coming and re-inspecting the other facilities simply because of the SOPs followed and so on, whatever with the problems…?

Pankaj Patel: Last year all our sites were inspected by FDA after they completed the Zyfine audit in the first three months and then all facilities were inspected.

Moderator: Thank you. The next question is from the line of Manoj Garg from Bank of America. Please go ahead.

Manoj Garg: Have we heard correctly that they have done the site transfer, you have already done with the 9 products?

Pankaj Patel: 9 products site transfer has already been done and got approval also and the others are in pipeline.

Manoj Garg: Typically, how much time it took from the day you initiate site transfer to the final approval of the products?

Pankaj Patel: It depends; some products do not require the Biostudy, then it can be done very quickly and some products where it requires Biostudy takes longer but usually one can say that it takes about 9-months to complete.

Manoj Garg: For some of our high value launches such as Toprol XL, Asacol HD and Prevacid ODT, have we already initiated site transfer for these products as well?

Pankaj Patel: Yes, we have initiated and we would be filing for approval to FDA in 2016 and typically these are all CB-30 filings.

Manoj Garg: So that means it will not require much bioequivalence or analytical studies?

Pankaj Patel: No, some of them will require bioequivalence studies, but we would basically be filing under CB-30, of course, they can convert into parts.

Manoj Garg: Post this Moraiya and Zyfine facility, since all our other plants are inspected and cleared by the FDA, so there is no mention of global quality network checking what we have seen in some of the other companies?

Pankaj Patel: No, we have not seen.

Moderator: Thank you. The next question is from the line of Rahul Sharma from Karvy Stock Broking. Please go ahead.

Rahul Sharma: Just wanted clarity on how many filings are yet pending from Moraiya which site transfer will be done over a period of probably 6-months odd?

Pankaj Patel: With respect to Moraiya site transfer, only about 4-products are required to be completed now from the lot which we have selected, #1. With respect to the filing, significant number of filing also is from the SEZ site and Baddi site. If you look at our total Oral Solid filing today with FDA, out of that almost 40% filings are from Moraiya and the balance are from the other sites. We expect that in the 2016 from other site based on the filing date and the progress made till date, we should be getting about 15 approval from Baddi and SEZ sites.

Rahul Sharma: Critical products – Prevacid, Toprol XL. Any other critical products which we are in the process of filing or we have got approval sir?

Pankaj Patel: We are in the process of filing these critical products from alternate site.

Moderator: Thank you. The next question is from the line of Nitin Gosar from Religare Invesco. Please go ahead.

Nitin Gosar: Just trying to understand the whole investigation process; I believe in the 483 it was mentioned that we have to expand or we did not expand the scope of investigation for whatever complaints we had received from the consumers. Now, we say that we have implemented the SOP. But does it mean that the scope of investigation which are needed to be expanded during those compliance, are they done or they are yet to be closed from your end?

Pankaj Patel: They have been already done for the past and also in future of course it is part of the SOP.

Moderator: Thank you. The next question is from the line of Monika Joshi from Bajaj Allianz Life Insurance. Please go ahead.

Monika Joshi: Just confirming; we have four formulation plants for the US currently, right, it is Moraiya, you have Baddi, you have a part of the SEZ and you have Nesher, is that correct?

Pankaj Patel: Correct, then we also have ALIDAC facility which is Injectable facility and which is also FDA approved and we have Ointments and Creams facility which is under approval, a separate site in Ahmedabad.

Monika Joshi: Now when we see what is supplying currently in the US, then it is fair to assume that it is five sites including the SEZ, correct?

Pankaj Patel: SEZ supplies have not started yet.

Monika Joshi: But you have an EIR at…?

Pankaj Patel: We have approval of the site. So we should be expecting product approval now.

Monika Joshi: Then I was just wondering, when you said 60% of your US revenues are from Moraiya, how that really works – are you including Hospira Oncology Injectable into this?

Pankaj Patel: No, it basically includes AG, Nesher and Baddi.

Monika Joshi: So you did about $300-310 million of sales in the first half. So according to you about $120 million is coming outside of Moraiya, annualize that is about $250 million of sales. I am wondering, Nesher was never that big and your AGs are also not that big. So where is this coming from – How does the 60%...?

Pankaj Patel: We can give you the breakup offline, I think Vishal can give you the detail, but this is what exactly numbers are.

Monika Joshi: That 60% of your FY15 US Formulations sales you are saying is from Moraiya?

Pankaj Patel: Supplied from Moraiya.

Monika Joshi: On the Oncology, the API unit also which is under warning letter, you have Oral and Injectable Oncology block on the SEZ. Any of these products filed from there for the APIs from Zyfine?

Pankaj Patel: There was one product which was there but I think we have also filed with this alternative Indian source.

Moderator: Thank you. The next question is from the line of Prashant Nair from Citi. Please go ahead.

Prashant Nair: I just had one clarification on your pipeline. You mention 40% of your filings are from Moraiya. Is that 40% of Oral Solid filings or overall?

Nitin D Parekh: Oral Solid filings about 28% and aggregate is about 40%, so all dosage forms put together.

Moderator: Thank you. The next question is a follow up question from the line of Prakash Agarwal from Axis Capital. Please go ahead.

Prakash Agarwal: Sir, you talked about 15 approvals that you are expecting from Baddi and SEZ. So what would have been our original plan supposing that warning letter has not come yet?

Pankaj Patel: Yes, then we would have got a large number of approvals from Moraiya as well and our approval would have been in the vicinity of 25-30.

Prakash Agarwal: It would be fair to assume that the products from Baddi and SEZ like what we are aware of the limited competition or niche products, so any of these you are expecting in these 15 or these are relatively smaller products?

Pankaj Patel: They are both mix of smaller and some important products. Similar number of approvals will also happen from the other sites.

Moderator: Thank you. The next question is from the line of Shobit Chaterjee from BNP Paribas. Please go ahead.

Shobit Chaterjee: I just wanted to know the nature of problem of the second one which is the one regarding handling of complaint because I have seen this quality control problems odd GMP issues. So, what is the kind of problem that exactly Moraiya facility has in this?

Pankaj Patel: This is not actually the facility related problem, this is related to the investigation of the complaints which we receive. So how do you analyze the complaint? Whether your analysis is say including previous batches and past batches also similar products which you are manufacturing or not. All those things should be part of the investigation. So that is not a comprehensive investigation which was being done. That is what exactly the observation is.

Shobit Chaterjee: So this actually might boil over to other facility as well because it is not specific to Moraiya if I understand it correctly or…?

Pankaj Patel: No, subsequently other facility have been inspected and the revised SOP were already in place at that time there, so the FDA inspectors as I mentioned earlier have expressed satisfaction with what we have done in those sites.

Shobit Chaterjee: We had already some approved filings after receiving the 483s and warning letter where again this issue of product specific compliant as well as the other issue of handling of complaint. So we had some approved filings from Moraiya right in the meantime before getting this warning letter?

Pankaj Patel: No, in last one year we have not received any approval from Moraiya.

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

Abhishek Sharma: In the aftermath of this warning letter, are you planning to appoint external consultants over and above what you already have as a part of your team?

Pankaj Patel: We already have external consultants helping us with respect to ensuring that whatever investigations we do for compliance are in line with FDA's requirement and that we have already been using it. So we do not intend to add any additional consultant.

Abhishek Sharma: To my earlier question, you said that you have done over and above what the first observation letter pointed out to which is essentially you have done lab automation and you have also invested in personnel, groups, etc., Have you kept US FDA up-to-date regarding these things that you have done over and above the observation letter?

Pankaj Patel: Yes, we did have 6-monthly meeting with FDA wherein we have personally went and presented FDA what we are doing additionally.

Abhishek Sharma: Was there any response that you could get out of them or …?

Pankaj Patel: Not really.

Moderator: Thank you. The next question is from the line of Sameer Baisiwala from Morgan Stanley. Please go ahead.

Sameer Baisiwala: Just to be clear; you said that 9 products have already been site switched. So these are the existing products of the market?

Pankaj Patel: Yeah, the existing products of the market which were produced at Moraiya have been shifted to other sites.

Sameer Baisiwala: How many of the high value products which are yet to be approved have you commenced the site switch?

Pankaj Patel: There are four important products for which we already have started the activity for site transfer and as I mention earlier in second half of next fiscal we will file them.

Sameer Baisiwala: I think you did mention Asacol HD is one such product, but if the AG triggers in July, then is there any point in trying to do that site switch?

Pankaj Patel: It is basically timeline and revenue issue, no. So we would basically take a comprehensive view based on timeline and how much revenue we gain or lose because of our action because when you do AG obviously the margins will be casualty.

Sameer Baisiwala: So is it possible that you launch AG in July and then if you get your own approval in say September-October, then you change the AG…?

Pankaj Patel: Not possible, one other option we can pick up.

Sameer Baisiwala: Then why you get into the site switch if you are not going to get it done before July?

Pankaj Patel: We would be but to file earlier, that is the reason why we think that there should not be a problem; however, we will take a review, we are reviewing continuously this and we will take appropriate action, we still have time.

Sameer Baisiwala: Out of 160 ANDAs pending approval, about 74 have been filed from Moraiya; of this 74, 4 is what you are aiming to site switch?

Pankaj Patel: You are right.

Sameer Baisiwala: Of the 45-50 ANDAs that you are targeting to file every year, how many would have been from Moraiya in next fiscal and does that get impacted or does that continue?

Pankaj Patel: Most of the filings are now happening from other sites and not from Moraiya. So we expect that a large number of filing will happen from other sites but some of the Injectable filings will happen from Moraiya because that is the site currently we have.

Sameer Baisiwala: Can that work continue despite the warning letter, do you have to now not…?

Pankaj Patel: There is no restriction on filing.

Moderator: Thank you. The next question is from the line of Ashish Thavkar from Asian Markets. Please go ahead.

Ashish Thavkar: Sir, do you feel that in the process of taking the remedial measures, you will have to take production cut?

Pankaj Patel: No.

Ashish Thavkar: On the Transdermals, since we have some filings from the Moraiya facility, are there any Transdermal products that we are planning to site transfer?

Pankaj Patel: Currently, we are not planning any site transfer of Transdermal products.

Ashish Thavkar: Earlier in the last call, we were confident that in the next one year we would be monetizing at least two Transdermals. So we stand by that comment or you feel …?

Pankaj Patel: It depends upon when Moraiya gets cleared because those both products are from Moraiya.

Moderator: Thank you. The next question is a follow up question from the line of Saion Mukherjee from Nomura. Please go ahead.

Saion Mukherjee: I just wanted to have some more granularity around Asacol HD. You mention that you would be filing soon I think in 2016 first half. There have been some challenges with regards to Biostudies, etc., What do you think would be the key hurdle for that particular product?

Pankaj Patel: We do not see the challenge in Biostudy. This is the reason why we want to file.

Saion Mukherjee: You also mentioned in your earlier remark that the product is approvable but for the site you have not received the approval. So does that in anyway give you more certainty getting an approval because you are the first-to-file here?

Pankaj Patel: Yeah, you are right.

Saion Mukherjee: So you would say that the challenge around Biostudy should not be a major hurdle. Is there a timeline for completing the biostudy for a product like Asacol HD?

Pankaj Patel: I think 6-weeks study. We are yet to commence the study.

Saion Mukherjee: So tentatively when do you expect — first quarter, second quarter — to file the product, if you can give some granularity on timings of that?

Pankaj Patel: First half is our target.

Moderator: Thank you. The next question is from the line of Surjeet Pal from Prabhudas Lilladher. Please go ahead.

Surjeet Pal: Could you please tell me what are the four products we have identified, have you mentioned?

Pankaj Patel: We have not mentioned the product names, but they are all important products, where we have some exclusive opportunity.

Surjeet Pal: What you have said is that you continue to file 40-50 ANDA in a year and Moraiya warning letter will not impact your planned filing, right?

Pankaj Patel: Yes.

Surjeet Pal: Your Transdermal Patches which I think the first approval was expected though not very great numbers in terms of site in 2016, so when do you think that could be delayed further?

Pankaj Patel: It depends upon when FDA clears the Moraiya facility. We should be getting approval after the approval of the site. So we cannot comment on that today because we have no clarity as far as when exactly we should be out of this warning letter for Moraiya.

Surjeet Pal: So will be your Injectables because that is also in the Moraiya plant?

Pankaj Patel: Yeah, we have an alternative site which is ready now and it is under validation. So, we would be basically doing site transfer of this product from this site to the new site which is being constructed at Baroda.

Surjeet Pal: Similar will be your Nasal?

Pankaj Patel: We do not intend to set up a second site for Nasal. So Nasal will remain at Moraiya.

Surjeet Pal: So that would also have been impacted by the delay?

Pankaj Patel: Yes.

Moderator: Thank you. The next is a follow up question from the line of Surya Patra from PhillipCapital. Please go ahead.

Surya Patra: Just a clarification; Zyfine facility I think it has a side-by-side Formulation manufacturing facility also?

Pankaj Patel: There is no Formulation facility at Zyfine site.

Surya Patra: So in Ahmedabad, one Formulation facility is there. That is not in the Zyfine site?

Pankaj Patel: No.

Surya Patra: Do you think the kind of the remediation action that you would be doing so because of that you will say kind of meaningful expense in the subsequent period?

Pankaj Patel: First of all, I explained to you; there is something not to do with the manufacturing activity or the quality activities, only about the investigation of the complaint, so you can understand that basically dedicated team appointed already in there. So we do not expect huge expenditure. Only thing is we will ensure that their investigations are thorough not only by us but also third-party so that always investigation are complete in nature from FDA's point of view.

Surya Patra: Even for the API plant because that is GMP related?

Pankaj Patel: As far as the API facility is concerned, we are not having any revenue from that site and that site is basically currently only working on creating a GMP facility. It would take some time because we would basically like to train the mindset of people at the site so that they learn the GMP well and do the right things and once we are convinced then we will go to FDA as far as that site is concerned.

Moderator: Thank you. The next question is a follow up question from the line of Rakesh Nayudu from Haitong Securities. Please go ahead.

Rakesh Nayudu: In the context of current situation, would you still maintain your 20% growth guidance from US for this year?

Pankaj Patel: First of all, it is too early for me to give you guidance, maybe another few weeks we should be able to tell you that what kind of growth we can expect from US market for 2016.

Rakesh Nayudu: Your Transdermal portfolio, would you want to link the approval of this product category with the resolution of Moraiya facility, I just wanted your comments in terms of nature of contentions that are being litigated for this portfolio or is it linked to the clearance of Moraiya facility?

Pankaj Patel: First of all, whatever we have filed from Moraiya facility those two products approval will be only after the Moraiya site is cleared. We also file the other products from SEZ Transdermal facility which will go on because that site is already inspected and approved. So we should be able to get approval for that product, currently I cannot give you timeline for that.

Rakesh Nayudu: Regarding litigation for Transdermal portfolio,

Pankaj Patel We can take this question offline. Today, we will focus on warning letter related questions.

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

Tushar Manudhane: Though the product has been discontinued, whatever existing in the US market has that been recalled or that is still in the market?

Pankaj Patel: None of the products were failing there. While manufacturing we found that one batch failed and that is the reason why we said that the product process is not consistent. That is why we have stopped. But there are no bad quality products supplied to US.

Tushar Manudhane: Specifically this Warfarin also, we have not recalled. Except this particular batch, which has been failed, other has been continued in the market?

Pankaj Patel: We have stopped manufacturing thereafter.

Tushar Manudhane: Before the batch getting failed, whatever was there in inventory…

Pankaj Patel: Supplied into US market.

Tushar Manudhane: This was not the point in the 483 in September 2014, right?

Pankaj Patel: No.

Tushar Manudhane: This was not in the observation then maybe the batch failed…

Pankaj Patel: Subsequently as a good compliance company, we have kept FDA informed about what we are doing with this product. So FDA has been kept abreast of whatever is happening.

Moderator: Thank you. The next question is from the line of Manoj Garg from Bank of America. Please go ahead.

Manoj Garg: Since you have already done nine site transfer from Moraiya and those products got approved. So were we expecting any warning letter at the Moraiya facility?

Pankaj Patel: It has been delayed so long. So we were not sure what will happen. It is very difficult for me to say that warning letter will happen or not happen. When you read the warning letter you will understand that why we thought that.

Manoj Garg: Like on Asacol HD, do we still believe that we are the only filer as of now and that is why we are probably taking the risk of doing our own filing instead of going maybe for an authorized generic route?

Pankaj Patel: Yes.

Manoj Garg: So that means even if like there will be a delay of 3-6-months launch we can still have a clear exclusivity of 2-3-years for that product?

Pankaj Patel: That is right.

Moderator: Thank you. The next question is from the line of Girish Bakhru from HSBC. Please go ahead.

Girish Bakhru: Just on the Lanzoprazole, just wanted to get your sense, what is holding approval for other peers?

Pankaj Patel: Others I do not know.

Girish Bakhru: But when you say four products from site transfer, which would be…?

Pankaj Patel: One of them is Lanzoprazole ODT it is important products.

Girish Bakhru: But there is no hurdle for you to get into the market again, right?

Pankaj Patel: First of all, we do not have approval today, so we were never in the market.

Girish Bakhru: No, I am asking for like Teva was in the market in 2010 and then of course Teva was first-to-file?

Pankaj Patel: They had to withdraw the product for certain reasons. We do not have those issues with us.

Girish Bakhru: So your non-approval per se does not block others to enter the market, right?

Pankaj Patel: Absolutely.

Girish Bakhru: On SEZ, there is no pending 483 observation letters?

Pankaj Patel: Enterprise Inspection Report has been already received. The site is approved, you can say, that is cleared by FDA. So we are awaiting for a product approval now on that site.

Girish Bakhru: Given that since 2015 there has been no approval but you expect there will be material approvals in 2016 from SEZ, right?

Pankaj Patel: Right.

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

Dhiresh Pathak: The API plant at Vadodara, when did we get the EIR?

Pankaj Patel: I do not have the date with me but we can give you the information.

Dhiresh Pathak: But we have the EIR?

Pankaj Patel: We will have to check and come back to you.

Dhiresh Pathak: When did we get the EIR for the SEZ?

Pankaj Patel: Received a few months back. Exact dates I do not have but Vishal can give you all those information.

Dhiresh Pathak: On Baddi, we are saying we are getting approvals, but I think we have only got like two or three approvals through the year. So is it natural to have expected just a few approvals from Baddi or…?

Pankaj Patel: Baddi, we have limited number of filings, more filings have happened from SEZ.

Dhiresh Pathak: Apart from Transdermals, what all facilities are there in the SEZ?

Pankaj Patel: Transdermal SEZ facility is a completely separate company known as Zydus Technologies. It is not part of Cadila Healthcare SEZ facility.

Dhiresh Pathak: Has that Transdermal facility also got the EIR inspection?

Pankaj Patel: Yeah, it has been inspected and EIR has been received, details Vishal can give you.

Moderator: Thank you. The next question is from the line of Gagan Thareja from Comgest India. Please go ahead.

Gagan Thareja: Sir, you indicated that prior to the warning letter you were anticipating approximately 30-odd approvals which you sort of split up and said 15-odd would probably be linked to Moraiya and 15-odd from the other facilities. That would be the number. Would it be fair to presume that the corresponding dollar value could be very different and Moraiya would probably be addressing a much larger chunk in dollar value?

Pankaj Patel: They would be similar except the ace product. If ace product would have been approved from Moraiya, obviously, they would have large dollar value, but other products would have similar values, the split would be like 50:50.

Gagan Thareja: Almost 14-15-months already have elapsed since you received between the 483 and the warning letter. Last time you were issued a warning letter on Moraiya, the time gap would not have been so much. Would then it be reasonable to conjecture the time period that would be required here on for addressing the warning letter could be relatively less than what we saw in the last instance?

Pankaj Patel: I wish that you are true but I cannot say about it because I have no idea exactly how much time it will take today. I think as time moves we will have more clarity but today we do not have any clarity how much time it will take.

Gagan Thareja: You indicated that post the inspection at Moraiya, you revised the SOPs and subsequently these were implemented at other plants and these other plants went through the inspections without any problems whatsoever. That being the case, would it not be again fair to conjecture that these revised SOPs since they are considered satisfactory for the other facilities they should logically be considered satisfactory for Moraiya as well, and then if that is the case why would the US FDA again mention this issue in the warning letter?

Pankaj Patel: That was the 483 observations.

Gagan Thareja: So you are saying that the subsequent actions that you have taken have not been taken into cognizance while issuing the…

Pankaj Patel: I am not saying that, I will not be able to answer this question at all because it is very difficult for what discussions and consideration goes in the FDA we do not know.

Moderator: Thank you. Ladies and Gentlemen, due to time constraints, that was the last question. I would now like to hand the conference over to Mr. Vishal Gor for closing remarks. Over to you.

Vishal Gor: Thank you for joining us in the conference call. If any of you have any questions which have remained unanswered, you can reach me for getting the answers.

Moderator: Thank you. Ladies and Gentlemen, on behalf of Cadila Healthcare Limited, that concludes this conference call. Thank you all for joining us and you may disconnect your lines now.