"Indoco Remedies Limited
Q4 FY2019 Results Conference Call"

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Moderator: Ladies and gentlemen, good day and welcome to the Indoco Remedies Limited Q4 FY2019 Results Conference Call hosted by Nirmal Bang Institutional Equities Private Limited. 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 will now hand the conference over to Mr. Vishal Manchanda from Nirmal Bang Institutional Equities. Thank you and over to you Sir!

Vishal Manchanda: Good afternoon everyone. On behalf of Nirmal Bang Institutional Equities, I welcome you to Indoco Remedies Q4 FY2019 earnings call. I thank the Indoco management for giving us an opportunity to host the call. Today, we have with us the senior management of the company represented by Ms. Aditi Panandikar, Managing Director, Mr. Sundeep V. Bambolkar – Joint Managing Director, Mr. Mandar Borkar – Chief Financial Officer, Mr. Vilas V. Nagare – President - Corporate Affairs and M&A. I will now handover the conference to the Indoco Management!

Sundeep Bambolkar: Good evening all the participants. Let me begin with the business highlights. Financial highlights, the net revenues for the quarter were at Rs.245 Crores against Rs.259 Crores for the year. The net revenues were at Rs. 941 Crores as against Rs. 1017 Crores. While the EBITDA for the quarter is at Rs. 28.5 Crores compared to Rs. 49.5 Crores and for the year, the EBITDA is at Rs. 76.7 Crores compared to Rs. 134.9 Crores.

Now onto Domestic formulations business front, revenues for the quarter are at Rs.145 Crores as against Rs.151 Crores. For the year, the revenues are at Rs. 606 Crores as against Rs. 595 Crores. As per AWACS Indoco ranks 30th in the IPM with market share of 0.66% as on March 2019. For the Q4 FY2019, IPM growth is 9.9% whereas Indoco's growth is 12.5%. The company has shown good growth amongst the 21 to 30 rank corporates. As per HMRC, Indoco ranks 23rd with a prescription share of 0.86% as on February 2019 MAT basis.

Our secondary sales trend in the Q4 is quite encouraging which indicates a healthy and encouraging demand for our products in the market. During the quarter, the company launched one new product in subchronic category thereby taking the total new product launches to 10 during the year i.e., two in acute, five in sub chronic and three in chronic.

Now on the international formulation business front, during the quarter revenues were at Rs.71 Crores against Rs.88 Crores and for the year, the revenues were at Rs.233 Crores as against Rs.347 Crores.

Revenues from US business for the quarter were at Rs.11 Crores as against Rs.6 Crores and for the year, the revenues were at Rs.25 Crores as against Rs.40 Crores.

Revenues from the Europe business for the quarter were at Rs,28 Crores compared to Rs.47 Crores and for the year, the revenues were at Rs.106 Crores as against Rs.179 Crores.

Revenues from South Africa, and Australia and New Zealand business for the quarter were at Rs.8 Crores compared to Rs.12 Crores for the year and the revenues were at Rs.29 Crores as against Rs.56 Crores.

Revenues from emerging markets for the quarter were at Rs.24 Crores compared to Rs.23 Crores and for the year, the revenues were at Rs.73 Crores as against Rs.72 Crores.

Now on the regulatory front, US FDA inspections, the last inspection was held from January 17, 2019 to January 25, 2019 at Goa plant I, where the company received six observations. Status of the plant is OAI as per FDA communication dated March 13, 2019. Presently the company is in communication with the agency for submission of compliance response. For Goa plant II and III, the regulatory status was changed from OAI to VAI. EIR dated March 21, 2019 was received from FDA confirming withdrawal of the warning letter. As we talk today, there is a FDA inspection pre-approval supplement going on at plant II which will conclude on June 4, 2019.

UK MHRA inspections, the last inspection was held from May 21, 2019 to May 23, 2019 at Goa plant I and we await the inspection report as well as reinstatement of GMP certificate. With reference to the last inspection held from September 17, 2018 to September 21, 2018 at Goa plant II and Goa plant III, the inspection had concluded with no critical observations.

With reference to the last inspection held from October 16, 2018 to October 20, 2018 at Baddi plant I and Baddi plant III, the inspection concluded with no critical observations. GMP certification continues for Baddi plant I and Baddi III received the GMP certification from UK MHRA for the first time after its acquisition.

Now on the API business front, API business revenues during the quarter were at Rs.25 Crores compared to Rs.15 Crores. For the year, the revenues were at Rs.82 Crores as against Rs.61 Crores. The company has commissioned its new API facility at Patalganga in April 2019 and the commercial dispatches to domestic market have already begun. The company has also received the certificate of suitability CP from European Directorate of Quality Medicine (EDQM) paving the way to commence supplies to European markets. During the quarter, revenues from CRO and Analytical Services

Business were at Rs.4 Crores compared to Rs.5 Crores and for the year, the revenues were at Rs.19 Crores as against Rs.14 Crores.

That is all about the business highlights for the quarter and I now request the participants to put up their questions, thank you.

Moderator: Thank you very much Sir. Ladies and gentlemen, we will now begin the question and answer session. The first question from the line of Aditya Khemka from DSP Mutual Fund. Please go ahead.

Aditya Khemka: Good afternoon and thanks for the opportunity. The recent UK MHRA inspection on plant I, it has already been concluded as we speak?

Aditi Panandikar: Yes it has concluded. We had a three-day inspection from 21st to 23rd.

Aditya Khemka: Madam, how many observations did we get, how many critical, major or minor?

Aditi Panandikar: Zero critical, a couple of major.

Aditya Khemka: So in your understanding, there are a couple of major and how many minor observations?

Aditi Panandikar: I do not recall off my head, I was there in the inspection, but since the site is under IAG, the auditors will go back now with their recommendations and after that we will get the report. So we do not have any report in hand, but this was discussed in the closing.

Aditya Khemka: Then in your understanding estimation, will you get a complete compliance certificate or will it be restricted?

Aditi Panandikar: We should.

Aditya Khemka: Any timelines to that certification?

Aditi Panandikar: As per me, another two to three weeks, there is going to be back and forth communication on the majors, on the recommendations, on the IAG and after that we will just wait and see, probably in four weeks, we should be able to close this.

Aditya Khemka: Since you were there Mam, what were the two major observations or the couple of major observations?

Aditi Panandikar: I do not think I have liberty to discuss it yet, since the report is not in my hand, but both are of improvement measures of kind and that too related to some of the newer expectations from MHRA.

Aditya Khemka: Okay. This US revenue that we reported for the quarter at Rs.11 Crores and I think it has gone up from what we did last quarter Q3 FY2019 Rs.2.6 Crores, where is the delta in US supply coming from?

Sundeep Bambolkar: We have supplied tablets glimepiride and allopurinol, so that is more for solid dosages.

Aditya Khemka: Okay, so that is coming from plant I?

Aditi Panandikar: Yes.

Sundeep Bambolkar: So nothing being supplied from plant II or III yet?

Aditi Panandikar: No, not yet.

Aditya Khemka: If I can just ask on plant II and III, now the warning letter being lifted as you mentioned in your opening remarks, now what is our plan in terms of commercializing the already approved products and the potential approvals that we may get from plant II and III?

Sundeep Bambolkar: Glimepiride is already being supplied from II, three products will be supplied, three ophthalmic products we could start right away which we are already supplying prior to the warning letter.

Aditya Khemka: These are Trusopt, Cosopt and Vigamox?

Sundeep Bambolkar: Vigamox was not being supplied earlier, but it will commercialize now.

Aditya Khemka: So Trusopt, Cosopt and Vigamox are what you will supply immediately?

Sundeep Bambolkar: Yes.

Aditya Khemka: Any lead time to manufacturing that and launching that Sir?

Aditi Panandikar: Aditya we had some commitment to give FDA shipping studies etc., etc., because of the leakage issue on Latanoprost, most of those have been already done and submitted. So, that would have created a lag time before commercials would start. In addition to what Sundeep said, currently, I think you

might have heard, there is an inspection on in plant II and III right now, which is a prior approval supplement (PAS) inspection for some of the newer injectable filings. So we are hoping those would also get cleared then very quickly after that.

Aditya Khemka: Sure madam. Then the three products that we will be immediately launching in the near future, Vigamox, Trusopt and Cosopt, would Teva continue to sell these products for us or is there a new partner in place or are we going on our own?

Aditi Panandikar: It is under negotiation with Teva; no doubt that these products are really good, it is just that because of the long gap that we have had, we are looking at the quantities etc., and the pricing.

Sundeep Bambolkar: Things are being worked out.

Aditya Khemka: Okay but Teva is willing to supply the product market share quantity aside?

Sundeep Bambolkar: Yes.

Aditya Khemka: I have a few more questions Madam; I will get back in the queue.

Moderator: The next question is from the line of Nisar Bakhariya from Lucky Investments. Please go ahead.

Nisar Bakhariya: Good evening everyone. Madam I wanted to ask you that you mentioned that there is an existing US inspection going on relating to certain products, injectables; can you give us a rough indication as to what size or what sort of sales we can expect from these molecules if they go through?

Sundeep Bambolkar: Market size for the injectables is not very high; it is in the range of $20 million to $50 million per product.

Nisar Bakhariya: Right, it is for us I am asking Sir?

Sundeep Bambolkar: For us, I think, as we have always mentioned, you can take 10% market share.

Nisar Bakhariya: So should we expect $6 million to $8 million of sales from three to four molecules at least?

Sundeep Bambolkar: There is price erosion as well and after some time, yeah.

Nisar Bakhariya: Right, so whenever they scale up after one or two quarters, $6 million to $8 million we can expect from these three to four injectables, right?

Sundeep Bambolkar: Right, but two to three quarters at least.

Nisar Bakhariya: Two to three quarters, okay. Sir, can you also give us an update on some of these other molecules which we had, we had mentioned and disclosed on the call, Toprol XL and all of that, and we had to do some working and see if the batches can scale up and all that now, have we hived off those plans?

Aditi Panandikar: All that work is underway. Although in the past what we have been told is more for injectables. We are hoping that it might even cover plant III which has a solid…

Nisar Bakhariya: Madam now what is the way forward for our blockbuster molecule which we have in our portfolio?

Aditi Panandikar: See, most of the issues were really related to the plant and the regulatory issues that we had, especially in plant I and plant II. As you might have heard in Sundeep's narrative, we are having inspection after inspection in which we are clearing with no critical observation. In fact, both the sites have been every month having one or the other regulator with them. So, it is also a good confidence building for us that the issues had perceived, because all these regulators are actually you know they talk to each other now and it is now giving a good feel I believe to the regulators for not just the two sites but also the quality culture at Indoco per se. Once this is overcome, parallel we are working on hastening as far as possible (a) the approvals we can get from these sites and (b) whatever we can immediately commercialize.

Nisar Bakhariya: Madam, if everything goes well, let us assume that you know all the inspections go well and we can start ramping up production, after one year, I am not asking one to two quarters, but after one year, what sort of US sales we can see with normal products that we have which we can immediately scale up?

Aditi Panandikar: I think easily between Rs.100 and 120 Crores.

Nisar Bakhariya: Okay 100 to 120 Crores and these will be all at higher than gross level margins of the company?

Aditi Panandikar: Yes.

Nisar Bakhariya: Last question I have from my side Madam was that, what is the reason for this laggard performance in the domestic formulation business, not one or two quarters, but over the last one to two years?

Aditi Panandikar: Actually if you look at the quarter-on-quarter performance in domestic last year, I said this on the earlier calls, but I will repeat it anyway, year before last, we had this huge dip in sales in primaries because of the post GST and what we did in the current year which got over is while creating targets for domestic field staff, we actually added back those 45 days sales as a base. As a consequence, most people had targeted sales to do with 26% to 27% growth. This came at a time when the environment in the Indian pharma market itself slipped from a double digit growth to a lower single digit growth. That meant that majority of our field staff could not earn incentives and you actually see an impact of this in the primary sales not kicking off, the maximum impact of which we got in Q4. If you actually study the secondary sales for our company, which is there when you look at the AWACS data, you can see it, you can see that in the last two quarters in particular, we have actually started a very robust kind of a trend, so in Q3 we grew by 8% and in the Q4 we have grown by about 12.5%. So, secondary consumption, prescription generation is looking very good. The primaries got impacted because of certain internal things where the field staff motivation was a major factor.

Nisar Bakhariya: So, can we expect a 15% to 18% topline growth on domestic formulations from next year onwards Mam?

Aditi Panandikar: 15% is safer; I would not say 18% in this environment.

Nisar Bakhariya: Last question from my side is that, over the last two years we faced a lot of challenging times with US FDA and all of that, have we also filed incremental molecules for our pipeline going forward from FY2021-22 onwards or are we going to start focusing on that now considering that we have surpassed so many challenges?

Aditi Panandikar: We have already filed.

Sundeep Bambolkar: We have already filed. We have a target of 8 to 10 for the current year.

Nisar Bakhariya: So we have been filing consistently?

Sundeep Bambolkar: Yes.

Nisar Bakhariya: Is Teva willing to market most of these products because Teva itself is in a very difficult situation in the US, or will we have to find a new marketing partner for most of these molecules?

Aditi Panandikar: Not most, very few. Some molecules they are not interested in and on those, discussions are on.

Sundeep Bambolkar: These filings are not through Teva. Injectables are not through Teva.

Nisar Bakhariya: They are not through Teva?

Sundeep Bambolkar: No.

Nisar Bakhariya: So we have to find a marketing partner for them?

Sundeep Bambolkar: They are already partnered.

Nisar Bakhariya: Already partnered. Okay great. Thank you so much.

Moderator: Thank you. The next question is from the line of Aditya Khemka from DSP Mutual Fund. Please go ahead.

Aditya Khemka: Thanks for the followup. Madam on the balance sheet side, we have cross block which has gone up by if I am not mistaken by about Rs.50 to 60 Crores this year over last year and most of it is under WIP, can you point us as to what this expenditure pertains to?

Sundeep Bambolkar: I will let you know. We expanded the sterile facility. We completed the API plant expansion, so majorly these two were taken up. So part of that is shown as WIP.

Aditya Khemka: Okay and when you say sterile capacity, you mean Goa plant II?

Aditi Panandikar: Yeah additional line.

Sundeep Bambolkar: Additional two lines were brought in. One was purely for vials, that was from Romaco, Italy. The second from Rotta, Germany, that was for vial cum ampule.

Aditya Khemka: Okay, this particular quarter, Sundeep Sir, if you look at Q3 FY2019 versus Q4 FY2019, our gross margins seems to have improved despite lower contribution from the domestic business between the quarters. So, Q4 is lower contribution versus Q3 FY2019, but the gross margin in Q4 is higher than Q3 FY2019, so what exactly has changed in the gross margin front?

Sundeep Bambolkar: We have taken conscious decision to our price rise across the board for all our European products being supplied from Baddi and partly being supplied from Goa plant I. A few ophthalmics have

started to Europe which was from the Romaco line. So, with price rise, you will see the margins going up.

Aditya Khemka: In your reckoning, let us say if I forget FY2020 because FY2020 will be more of a transitionary year, some businesses will start in the middle of the year, and some businesses will start towards the end of the year. In FY2021, in your reckoning, what is the normalized EBITDA margin assuming your India business normalizes, your US supply is normalized, your European certificate is re-instated, where do you see your normalized EBITDA margin for FY2021?

Sundeep Bambolkar: We should do 18%, 18% plus.

Aditya Khemka: But 18% is what you were doing before these issues begun?

Sundeep Bambolkar: Yeah that will be the first year of stabilization, so I would like to be a little conservative.

Aditya Khemka: So 18% is what you are saying you should be able to do in FY2021 in terms of gross margins?

Sundeep Bambolkar: Yes.

Aditya Khemka: Sir, just help me understand the India dynamics a little better. I know Aditi Madam alluded to it, but again you know, if the primary feedstock is having problems and yet you are having secondary growth of 12%, 8%, and then therefore what you are trying to physically tell us is the inventory in the channel is shrinking, but there is a limit to which the inventory the channel carries right. So it does not carry more than 30 to 35 days of inventory anymore?

Aditi Panandikar: It is 31 right now for us.

Aditya Khemka: No Madam, my question is if the differential between your, this quarter for instance, the differential between your secondary and primary is about 16% right? So 12.5% is manageable?

Aditi Panandikar: Correct.

Aditya Khemka: So 16.5% of a quarter is almost 15 to 20 days of inventory. So does this mean that at the beginning of this quarter your inventory was at 46 to 47 days and it has come down to 31 by the end of the quarter? Because I remember last call you mentioned that your inventory was about 32, 33 days?

Aditi Panandikar: So what we are seeing, especially with acute portfolio is there are spikes in inventory build up but it is not sustaining to the level of 40 to 45 continuously. That is true, but what I meant initially when I discussed the primary performance or the primary sales versus secondary simply is that beginning this year, so you would see a lot of demand getting converted into orders in the first quarter this year.

Aditya Khemka: Just in terms of the field force Madam, how many MRs do we have today on the ground and how has this number evolved over the last 12 months?

Aditi Panandikar: We have around 2300 and with managers 2800. We have not increased this number at all, in fact serially we have been looking at difficult headquarters, headquarters we are not able to crack with the sale of 50,000 per month for continuously two years and then we have been scrapping them also. So there is a good amount of rationalization going on there. So you might have noted, I do not know in the MDA that is sent to you, the PHY has actually gone up to 2.3 averages, which used to be around 2.1.

Aditya Khemka: In your current portfolio, how much revenue comes from NLEM-covered products?

Aditi Panandikar: Around 9.8%

Aditya Khemka: In terms of your cost for the domestic formulation, you are obviously gets inputs from China where there is cost infused if I am not mistaken?

Aditi Panandikar: True, it has leveled off actually and that is also why you are seeing a better cost of goods.

Aditya Khemka: Cost of goods okay, but have you taken price increases in domestic in the non-covered portfolio?

Aditi Panandikar: We take whatever is allowed as per the price control order.

Aditya Khemka: But the price control order allows you 10% in the non-covered portfolio?

Aditi Panandikar: True. So we get it in sales, we do not take the hit at one time suddenly. So around 5% twice a year or something like that generally.

Aditya Khemka: So when the last 5% price was increase taken?

Aditi Panandikar: If you study our performance for the last year, you would see, in this quarter particularly, 4% price growth has come in and 4% volume growth has come in and the rest is new introduction and other things.

Aditya Khemka: That is the secondary data, but in your primary, when you say minus 4%, so 4% price increase you have realized, that means you volume, plus new introduction are actually resulting in minus 8%?

Vilas Nagare: 4% will be price rise, minus 3% volume, 1% new product, so overall it is 2%.

Aditya Khemka: You are talking about the full year Vilas Sir; I am talking about the Q4 because the price increase was taken close to the Q4?

Aditi Panandikar: No, no all of it does not come in Q4 alone.

Vilas Nagare: You take it on a yearly basis, across the year.

Aditya Khemka: Okay understood. This is the last question, going forward how much capex do you guys envisage for FY2020 and FY2021?

Vilas Nagare: Absolutely just normal capex, maintenance capex only. I think for the next three to four years we would not require any major capex.

Aditya Khemka: Sorry, I have one more then I will get back in the queue. On the Toprol XL CRL and the ophthalmic solution CRL, what is the timeline you guys are putting to get it to respond to FDA and potentially get approval?

Vilas Nagare: See the department for that sustained release product is absolutely ready, we have started optimization and trial, so scale up batches will be taken and three months stability data will be submitted, post which between 6 to 10 months, anybody's guess when we will get approval.

Aditya Khemka: So outer would be 10 months?

Aditi Panandikar: Yeah outer. The ophthalmics, most of the submissions we had to do largely to do with change in the container closure system as required by US FDA because of the ring retention and all those things, so for most products we have actually go ahead and done it even before, and because it is a part of our commitment to FDA, we cannot start a product without doing that. Most of it is done, now we just wait for the approvals to come in.

Aditya Khemka: This you are talking about the other ophthalmics, not the solution. So, from today, let us say Toprol XL to get approval in your estimate, it would be 10 months from today or 10 months after you submitted all the stability data?

Vilas Nagare: Post submission.

Aditya Khemka: Post submission, which means from today it would be 16 to 18 months, is that a fair estimate?

Vilas Nagare: Absolute outer limit.

Aditya Khemka: Absolute outer limit would be 16 to 18 months for Toprol and for the ophthalmic solution?

Vilas Nagare: It will be a little earlier, 12 months or so, 12 to 14 months.

Aditya Khemka: 12 to 14 months from today again?

Vilas Nagare: Yeah.

Aditya Khemka: Again I have a few more, but I will get back in queue. Thank you.

Moderator: Thank you. The next question is from the line of Rashmi Sancheti from Anand Rathi. Please go ahead.

Rashmi Sancheti: Thanks for the opportunity. Just want to know this time your other income seems to be very high during the quarter, does it include any one off or if you can give the breakup?

Mandar Borkar: Basically it does not include any one off; this is more of a some of the sundry balances write back, the interest and exchange related.

Rashmi Sancheti: Okay. Sir, on your domestic business, what is really impacting our performance in respiratory, gastro and anti-infective. I know that you have given some reasons for your laggard performance in the domestic business, but is it something related to you this particular therapy where you are losing market share?

Aditi Panandikar: Yeah, we are losing Rashmi, if you look at the performance of that category itself, in this year anti-infective and anti-cold product, anti-infectives have actually de-grown in units. So, it has been a very difficult year for the industry for our covered market for the antibiotic therapy. Among the top

four therapies we had, anti-infective, we definitely took a hit because of that and so have we taken in anti-cold.

Rashmi Sancheti: What about your major brand related to Cyclopam and Febrex Plus even if you see…?

Aditi Panandikar: So Febrex Plus is an anti-cold, that product and Oxipod have taken a hit last year.

Rashmi Sancheti: In case of Cyclopam?

Aditi Panandikar: Cyclopam is okay.

Rashmi Sancheti: But it is also like it is one of your major product and it also showing a flattish growth, right?

Aditi Panandikar: Yes.

Sundeep Bambolkar: No it is 6% growth last quarter.

Rashmi Sancheti: No I am saying at this quarter, it has shown a de-growth right?

Aditi Panandikar: Yeah.

Rashmi Sancheti: It is 7.7% degrowth.

Aditi Panandikar: Yeah.

Rashmi Sancheti: On export front, in US earlier this allopurinol used to be supplied from Goa III right?

Aditi Panandikar: Yes.

Rashmi Sancheti: So now since it has been shifted to Goa plant I?

Sundeep Bambolkar: No it is in III only.

Rashmi Sancheti: So it is in III only, so currently, you have already started supplying from Goa plant II and III or is it only III?

Aditi Panandikar: III we are supplying allopurinol.

Rashmi Sancheti: That is only one product which is supplying right, from Goa?

Aditi Panandikar: Yeah.

Rashmi Sancheti: From Goa I, how many products are you supplying to US?

Aditi Panandikar: Currently only one, Glimepiride.

Rashmi Sancheti: Okay and how many products are you supplying from Baddi III which is the new plant for Europe?

Sundeep Bambolkar: Not yet, we have just got the certificate.

Rashmi Sancheti: Any expectation like how much sales we can do it from this facility this particular year?

Aditi Panandikar: I cannot give you a number for this year, but the site is pretty large and at peak values we can go up to 500 Crores also from there actually.

Rashmi Sancheti: Okay that is the potential revenue from Baddi III?

Aditi Panandikar: Yes.

Rashmi Sancheti: Alright, and lastly on tax rate, if you can give your guidance like you know how much it would be?

Mandar Borkar: On normalized basis, we expect in the future it will be in the range of 20% to 25%.

Rashmi Sancheti: 20% to 25% okay and capex guidance?

Mandar Borkar: We just mentioned no capex.

Rashmi Sancheti: No Capex, so it would be roughly, if you say maintenance capex?

Aditi Panandikar: 40 to 50

Mandar Borkar: Yeah around Rs.40 to 50 Crores per year.

Rashmi Sancheti: Okay thank you. That is it from my side.

Moderator: Thank you. The next question is from the line of Aditya Khemka from DSP Mutual Fund. Please go ahead?

Aditya Khemka: Hi, just a last one for you guys. On the emerging market side, we have done pretty well in terms of at least the full year growth, but it seems that our Q4 and Q3 were heavier for emerging market sales in FY2019 versus the first two quarters, could you just remind me what was the problem in the first two quarters in losing market space?

Aditi Panandikar: See these are branded products and the sales are a factor of inventory carried at the site in those markets as well as now what is under **(inaudible) 33:05**. Also I had to tell you that initially when the MHRA issue started at plant I in particular, a lot of these markets were taking paper approvals because of the MHRA, so we had a certain setback where some of these authorities came down particularly markets like Ukraine where they actually came down and audited our sites again, and we had to clear them. So, like I mentioned earlier, actually plant I and plant II had one regulator inside every month for the whole year.

Aditya Khemka: Definitely rough patch Madam.

Aditi Panandikar: Taxing but huge learning experience.

Aditya Khemka: For sure and on plant I this US safety again classifying it as OAI recently while you expect MHRA to give you a full compliance certificate, and you know these evaluators do talk to themselves as you mentioned in your earlier remark, how would that pan out, I mean would not MHRA...?

Aditi Panandikar: I will just first clarify on the OAI itself. US FDA, our updates are underway to the response that is, you know the plan commitment with FDA is done and there are certain updates yet to go in response to those 483, so FDA at the end of 90 days has to give us status update. Since our EIR is not received and the inspection is not closed, they have concluded as OAI. Coming to MHRA, MHRA issues were very different and we were classified as restricted GMP with IAG, after six months they came and they found zero critical, after which they came again and now again they found zero critical. So their issues are very different and US issue actually from the OAI status they have not taken us out directly. Most of these regulators have in their mind a certain amount of time that is actually required for most of the issues to get cleared up to their expectations, but it does not change in anyway what we can or cannot do from that site for US.

Aditya Khemka: I understand. This is what I was actually trying to get. Okay Mam I wish you guys all the best.

Moderator: Thank you. The next question is from the line of Kunal Mehta from Vallum Capital. Please go ahead.

Kunal Mehta: Thank you for the opportunity. Madam I had two to three questions. Firstly, I wanted to understand the cost structure, if you look at the whole FY2019 versus FY2018, I wanted to understand the cost structure because you have an India business, also there are certain challenges with respect to growth, but it is a healthy business which is generating a good margin for you, but when I see it on an aggregate penal basis, we have a net loss of around Rs.9 Crores. So, what I am trying to understand is that is the cost structure in the US which you have build so high that assuming your Rs.650 Crores India business would be giving you at least Rs.120 Crores of EBITDA that whole needs to be re-invested into the ex-India business?

Aditi Panandikar: We have several sites, so we have three plants in Goa, we have two in Baddi and we have one in Waluj for formulations alone other than API. These sites have a huge cost base, especially when you are going through a phase like this, when there is no top line coming from them to cover cost. So what you are seeing exactly is that we have just had one site in Baddi going whole hog and the plant III in Goa that too one line giving us production and in lieu of that rather we have had all cost running all these sites and over and above that we have had the remediation cost also. So, all of that has actually impacted.

Kunal Mehta: So just drawing from it that, it is safe to understand considering the present cost structure, our breakeven points with the company as a whole is now revenue of at least Rs.1000 Crores for breakeven on the PBT levels, because over and above that only our business would be able to generate profits?

Aditi Panandikar: Right but as we do that, and as we do remediation, we are finding various avenues to increase efficiency. So, we would be able to improve it going further.

Kunal Mehta: So are there any opportunity to stream line this cost structure?

Aditi Panandikar: Yes.

Kunal Mehta: Okay. The second question I have is with respect to the Europe business. I appreciate that US is an important key geography for us and can you just throw some light on the Europe business, what are the prospects there and what was the revenue in the current year for the Europe business and how much do we see it in the next two years considering now that Baddi plant III has come on stream, so by Europe I mean UK, Germany and the other markets?

Sundeep Bambolkar: UK, Germany and the other markets put together could give us a business of about Rs.200 Crores for the year. That is the short-term target.

Kunal Mehta: The final question I had was just wanted to understand your view on the rest of the world business, I am sure the speakers before me asked the question about RoW markets, so the growth spending on in that market, especially in markets of Africa?

Sundeep Bambolkar: Africa, we are promoting our own brand. In the Eastern Africa, we have cost sharing, we have about 35 to 40 medical reps, those include the countries of Kenya, Tanzania, Zimbabwe, Zambia all those countries. In French West Africa, we have about 85 to 90 medical rep again promoting brand, so this business is going on well, good profitability and good business.

Kunal Mehta: We could at least have a low teen's growth expectation from this business, as you mean the lower base, would that be a fine assumption?

Sundeep Bambolkar: Yes, 15% plus.

Kunal Mehta: The final question I had was, just to give us a sense of the pipeline of the US business; can you just highlight a few key molecules which we as investors and analyst are supposed to track in the US business for your future launches?

Sundeep Bambolkar: Names of molecules, I would not be able to give you on the phone, on the conference call due to confidentiality reasons. We have an impressive pipeline. There are more than 18 ophthalmics; there are about 14 solid dosages and 6 injectables. All filed.

Kunal Mehta: You expect these to be at least commercialized I would say by FY2022, a major chunk of these to be commercialized?

Sundeep Bambolkar: Yeah, quite a number.

Kunal Mehta: Sure Sir. Thank you for the comment.

Moderator: Thank you. The next question is from the line of Rashmi Sancheti from Anand Rathi. Please go ahead.

Rashmi Sancheti: Yeah, thanks for the followup. Madam, you said that sales force as on to date 2300, can you give me the same figure for FY2018?

Aditi Panandikar: I think may be plus or minus 15, no change really, we had already downsized last year.

Rashmi Sancheti: FY2017?

Aditi Panandikar: We are not increasing any.

Rashmi Sancheti: And going ahead also it will be maintained at the same level?

Aditi Panandikar: Yeah, maintained at the same level. 2017 would have been about 100 more I think.

Rashmi Sancheti: What is happening on Aspen deal in Africa, you know how much sales have we booked. We had done lot many registrations also for that, so are we getting any approvals, like what is happening?

Aditi Panandikar: **(inaudible) 41:42** is one of the toughest regulators and it takes a very long time to get anything going from there. I think probably in the MDA that you got, you must have seen. In all our plants in Goa, we are having the SAPRAA audits and verifications going on right now. Again they have not come for 11 years, but because of what happened with the MHRA, they had to come down this time. So, quite frankly most of our businesses reg as well as some in emerging markets did get impacted this year because of the regulators perception of the company. I am hoping very much we are close to the end of the story now and we will be able to build from here.

Rashmi Sancheti: Earlier we were doing around Rs.20 Crores sort of number right through Aspen deal, so is it the same thing we are supplying now also, or is it like nothing?

Aditi Panandikar: It is less.

Rashmi Sancheti: Lastly on Trusopt and Cosopt, once we come back in the market, what kind of price erosion we will be seen from earlier, because earlier we were doing around 4 to 5 million dollars through this product?

Sundeep Bambolkar: They are already generic, I do not think there will be any further price erosion after we launch.

Rashmi Sancheti: Any major competitors or anyone who has come in those particular drugs?

Sundeep Bambolkar: Nothing appreciable. Aurobindo has I think, hardly

Rashmi Sancheti: Thank you Sir. That is it from my side.

Moderator: Thank you. The next question is from the line of Cyndrella Carvalho from Centrum Broking. Please go ahead.

Cyndrella Carvalho: Thanks for the opportunity. Aditi, I think things are much better from what you have spoken about, just wanted to try to understand the US, if we look at the US piece altogether, you have said that there are injectables, we would be launching Trusopt, Cosopt, again so like what is your thought process on the market as you know there will be some tie-up going to Teva, some on your own you are going to work out, or we have worked out marketing some tie-ups, how should we look at this stage?

Aditi Panandikar: At this stage we are not doing any front end of our own in US. With Teva, it was a little different because the ANDAs were in their name, so the other tie-ups which we talk of now are basically marketing arrangements. So it is Indoco's ANDA which will be marketed by our partner.

Cyndrella Carvalho: And that you are referring specifically for injectable ones?

Aditi Panandikar: Injectables as well as solid orals. So other than ophthalmics, we have not got into any such products which are filed in the name of the client or the customer.

Cyndrella Carvalho: The remaining ophthalmic pipeline also, which we have almost filed and now we are expecting approvals to come, so those will go via Teva tie-up or ….?

Aditi Panandikar: They were filed by Teva, most of them were filed by Teva, Teva has expressed interest to not want to continue with some of them and those are under negotiation right now, so we can get them back, but there are many which they continue with.

Cyndrella Carvalho: Some of them will continue with Teva and some of them you can go on your own via the marketing tie-up?

Aditi Panandikar: Correct.

Cyndrella Carvalho: So I said that we have said that around two to three more quarters are required for more products to come back from US perceptive. So, if we look at this FY2020 as such, I think all those opportunities would be more of second-half focused and in terms of even the European side I guess FY2021 would be much better wherein you could back our revenues to the earlier levels?

Aditi Panandikar: Yes, that is obviously true, but Europe should start rolling from the Q2 this year for sure, although I agree with you, FY2021 will be definitely better than this year.

Cyndrella Carvalho: Any outlook in terms of European filings, have we done something different, any other products which we can expect there?

Sundeep Bambolkar: Yeah, there are at least three to four products, but unlike US, you know Europe does not accept files unless the GMP is in place, so we are just waiting for this GMP certification of Goa plant I and once that is in place, we can file those. They are ready for filing.

Cyndrella Carvalho: In terms of Goa plant I, when was our last response sent to US FDA?

Aditi Panandikar: I think the last one was somewhere in April end or May first week.

Cyndrella Carvalho: And you said that there are some further responses which are pending?

Aditi Panandikar: Yes, so always with FDA, it is about shorter-term and a longer-term action plan.

Cyndrella Carvalho: When is the next going, any date in mind?

Aditi Panandikar: It is not uniform across all the observations, some observations probably we have already closed between us and FDA and some because we have to supply them with information data, so it must be dragging.

Cyndrella Carvalho: Aditi, just like how much would that be carrying cost in terms of fixed cost last year which would go out as we get some revenues out on stream, so what was like cost in FY2019 that you must be carrying on in P&L, any numbers that you can put?

Aditi Panandikar: Are you asking about the remediation cost?

Cyndrella Carvalho: Remediation as well as the fixed cost because most of our production…?

Aditi Panandikar: Actually, most of the plants in Goa, the fixed costs itself are running cost, because of the remediation per se we have not been able to shut them down just because we cannot manufacture if you know what I mean, so most of the remediation actions have got to do with manufacturing and quality and the regulator likes to see these departments running all the time, so we have to do validation batches, we have to do analytical validation, method validation, so we have seen a lot of cost, but we have not seen revenues, which is why I said going ahead as the sales come in, the cost structure need not stay like this and we could get some efficiency.

Cyndrella Carvalho: Any numbers there?

Aditi Panandikar: I will come back to you on it; I will not be able to give you exactly right now.

Cyndrella Carvalho: Okay thank you so much.

Moderator: Thank you. The next question is from the line of Kunal Mehta from Vallum Capital. Please go ahead.

Kunal Mehta: Just a single question Madam. Just wanted to understand as to which plant supply to which geography so, Goa plant I and Baddi III would supply to European markets and the Goa plant II and III would supply the US market, is there segregation that way?

Sundeep Bambolkar: Not really. Goa I is also supplying to US right now.

Kunal Mehta: Can Goa plant II and III supply to the European market?

Sundeep Bambolkar: They can.

Kunal Mehta: Are we mobilizing those plants or is there a reason?

Sundeep Bambolkar: Yes, supplies are going to Europe from plant III, Goa III.

Kunal Mehta: Understood Sir. Thank you.

Moderator: Thank you. Ladies and gentlemen as there are no further questions from the participants, I would now like to hand the conference over to the management for closing comments.

Sundeep Bambolkar: Thank you everybody for your active participation. Thanks a lot and have a nice evening. Thank you.

Moderator: Thank you very much Sir. Ladies and gentlemen, on behalf of Nirmal Bang Institutional Equities, that concludes this conference. Thank you for joining us. You may now disconnect your lines.