“Lupin Limited Q3 FY19 Earnings Conference Call”

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Moderator: Ladies and gentlemen, good day and welcome to the Lupin Limited Q3 FY'19 Earnings Conference Call. 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 an operator by pressing '*' then '0' on your touchtone phone. Please note that this conference is being recorded. I now hand the conference over to Lupin Management. Thank you and over to you.

Dr. Kamal K. Sharma: Hello, good afternoon, everyone. It is my pleasure to introduce you to the team around with me here; I have Vinita, Nilesh, Naresh Gupta, Rajiv Pillai, Arvind and Mr. Sunil Makharia to take up your questions.

To begin with I just like to say that this is the quarter where we did see operational improvement in the performance both in the top line and in the bottom line. You would have noticed that there has been a growth sequentially and corresponding quarter of 12%. Even if you take out the one-time licensing income, it is about 7%. Likewise, the EBITDA adjusted for the forex and the one-time income, increased by about 3%. So that is a broad outline. I also understand that the business is getting more stabilized.

But to walk you through the details I now request Rajiv to take it through the Financials and thereafter we will open the lines for Questions-and-Answers.

Rajiv Pillai: Thank you, Dr Sharma. Good afternoon, friends. I am pleased to take you through this quarter's performance. Our sales for the quarter were Rs.4,377 crores, which grew 12.5% sequentially and 12.2% YoY. Excluding AbbVie, our growth has been around 7.1% sequentially and equally around 7% YoY. This growth has been secular across most of the geographies; North America grew at around 13.5%, APAC grew very strongly with Japan growing around 12%, similarly LATAM also did very well. As far as our Institutional and API business, they also grew fairly well. Sequentially, India has been flattish and EMEA has shown slight de-growth. Our gross margins for the quarter came in at 63.4% and this was lower than the previous quarter, but adjusted for AbbVie licensing income and forex, it would be normalized around 63%. The EBITDA margin for the quarter came at around 18.2% as compared to 20% in Q2FY19. Like Dr. Sharma alluded to, adjusted for the forex volatility and the one-time licensing income received from AbbVie for the MALT1 licensing deal, the sequential operational growth has been around 3%. Forex losses have been across lines and stood at around Rs.157 crores versus Rs.213 crores gain which was there in the previous quarter. So adjusting for both the forex volatility across quarters and the one-off that we see across the quarters, we see an operational EBITDA improvement of 3%. R&D came in at Rs.426 crores and this, as we committed, would be around 9.5% - 10% of the sales, and we will continue to maintain the same clip. We did see fair amount of cost containment measure and operating leverage. That is all from my side on the operational highlights. And now we would open the floor for questions.

Moderator: Thank you very much. Ladies and gentlemen, we will now begin the question-and-answer session. The first question is from the line of Saion Mukherjee from Nomura. Please go ahead.

Saion Mukherjee: My question is can you share the sales for the US branded business and Solosec particularly for this quarter?

Rajiv Pillai: We normally do not give segmental growth for branded business, but I can say that it is flat compared to the previous quarter, so that has been around US$ 8 mn for the branded products

Nilesh Gupta: So the total sales for the US was US$ 193 mn and US$ 8 mn of that was branded.

Saion Mukherjee: So you mentioned Solosec at US$ 3 mn I think in the previous quarter. So how much will that be this quarter?

Vinita Gupta: Around the same level. The previous quarter, had the stocking, we basically recognize the inventory that we had put out in the trade at the time of the launch. So there is a little bit of that two quarters phasing that we recognize in Q2. So in Q3 you are seeing the actual revenues pretty much aligned with the scrip demand generation.

Saion Mukherjee: Vinita, just one question, the IMS data show some dip in prescription. Is it a true reflection of what you see in the market and what is your view the way the prescriptions have ramped up so far?

Vinita Gupta: Actually, the dip in the prescription was primarily to do with the holiday. If you look at the scrip growth in November and December actually scripts ramped up very nicely and peaking at 1,500 scrips a week, so December was on an average 1,500 scrips a week, and then the dip we saw was the Christmas week and the New Year week. As we look at the scrips right now, they are already trending in the right direction. I think in a week's time we will be back at the pre-holiday level and then growth from there obviously may just show you how promotion sensitive the product is in holiday season.

Moderator: Thank you. The next question is from the line of Neha Manpuria from JP Morgan. Please go ahead.

Neha Manpuria: Vinita, we have done a very strong growth in the Generic business in this quarter versus the last quarter. But if we were to look at the margins, margins have pretty much stayed flat, adjusted for the one-offs that you called out in the opening remarks. So why the improvement in the Generic business that we are seeing reflected in margins?

Vinita Gupta: Actually, the margin both last quarter as well as this quarter was significantly impacted by forex with the gain in the last quarter and really a loss this quarter.

Rajiv Pillai: So in terms of business mix, we had a flattish sequential growth as far as India is concerned. India being relatively lower, contributed to the margin mix change. So while we had an offset in terms of increased margin from US, the business mix impact of India reduced the salience.

Nilesh Gupta: The main thing was for forex and the rest of it was the business mix.

Neha Manpuria: How much was the forex in the quarter if you could just…?

Nilesh Gupta: 1.5% of the margin change in the gross profit line.

Neha Manpuria: My second question is on the outlook, we have a good launch calendar, we have already launched I am assuming Levothyroxine, we have Ranexa. As we look into FY20 we have a couple of good launches. So how should we look at the generic business particularly going into FY20?

Vinita Gupta: Base business is very solid. If you look at what we delivered in Q3, majority of that was all of the base business in line products, we really did not have any material new launches. Now with Ranexa in our portfolio, we are launching it in the next couple of weeks. Levothyroxine will be launched later in this quarter in March. So very little of Levothyroxine sales in this quarter, but next quarter onwards and the next full year, we should have the full impact of Levothyroxine sales actually ramping up as we get approval against the other two RLDs on the bioequivalence. So on the generic side of the business, of course, Ranexa is exclusive for a short period of time. After that we expect Levothyroxine to fuel the generic business growth, and then later in the year we also expect ProAir to get approved hopefully. Once we get ProAir approved, we expect to launch it later in the year. Really the generic business has turned the corner this past quarter and with the near-term growth drivers, along with other smaller launches - we are looking at 20 launches next year, we should be able to grow the Generic business.

Neha Manpuria: ProAir would be close to the fourth quarter in FY'20?

Vinita Gupta: Yes.

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

Tushar Manudhane: Just with respect to the observations at Mandideep, just would like to understand tentative timeline to implement the remediation measures with respect to observations?

Nilesh Gupta: We have obviously responded to the 483s, we have sent a follow-on update as well. There are certain actions that we are committed to. The timeline for that broadly is the end of March. By the end of March, we will have addressed most of the observations. As you would have seen there was an observation on training. That is the only one that will go on for more prolonged period of time. But I think we have addressed most, and the balance we will address by March.

Tushar Manudhane: So this training-related issue, will that affect if at all any product approval?

Nilesh Gupta: So, we have no products pending approval from Mandideep as you know. That is the older Cephalosporin site. There is really nothing pending from there.

Tushar Manudhane: Secondly, just on the Solosec, there have been reviews in terms of the taste being too bitter and lingering for longer time. Does that by any chance impact the prescription rate or being a much better treatment it offsets that lack of taste?

Vinita Gupta: Actually, we have not got any adverse events or feedback on the product taste. The only adverse event that we heard of was when people crunched into the granules, which they were not supposed to do, they took it with granola and therefore could taste the drug. But otherwise if it has taken as per label, you should not really be able to taste the bitterness of the product. The feedback that we have got is on the product was very strong, it is rock solid, the physicians like it, patients are being treated, so both from an efficacy standpoint as well as the taste standpoint we have not really heard any negative feedback.

Tushar Manudhane: Levothyroxine capacity by any chance is constrained?

Nilesh Gupta: We have actually set up dedicated capacity for Levothyroxine. We have a good amount of capacity. As we have talked before, there will be a slower ramp up to this product. We were not even sure if we would launch it, till it was bioequivalent to all the other RLDs, but now we feel good about being able to launch and get some market share. As we get approval for the other RLDs, that is when it comes into full swing. It is a very sticky product. So the ramp up will be slower, but obviously the product will stay for longer as well, but we have good capacities.

Moderator: Thank you. The next question is from the line of Anubhav from Credit Suisse. Please go ahead.

Anubhav Aggarwal: Vinita, just on US sales, is there any large stocking in this quarter like Tamiflu have we stocked little higher, because US sales ramp up is very strong on a generic side?

Vinita Gupta: Yes, it was really hardcore performance of the generic team, Anubhav. Nothing to do with stocking. I wish we had some stocking for the flu season. Unfortunately, the flu season has been very light through December. It has picked up only in the last couple of weeks. So we have seen some pick up in products like also Oseltamivir. Majority of the growth was on our top-10 products, older products like Lisinopril and combinations, Cefdinir, so some flu season products, Cefaxetil. It was really a matter of leveraging our supply chain. Our team really worked hard at picking up share in the older products as some folks left the market.

Anubhav Aggarwal: So you are basically saying this is the new base for us, is that like because it is a sharp increase in a quarter. That is why I was wondering? Is this the new base? Of course, adjusted for Tamiflu.

Let us say we think about Q1 when Tamiflu seasonality is gone. Adjusted for that, you are saying this is very much volume here to stay with us?

Vinita Gupta: It is a solid base. We do not have any one-off.

Anubhav Aggarwal: Just a second question on Solosec. In one of the presentations, you did recently mention that the repeat prescribers was roughly about 52%. So just wanted to check that what are the top one or two reasons, why the remaining 48% are not prescribing for the same?

Vinita Gupta: It is just a matter of really getting used to writing the product which takes time, the physicians that have used it and are writing it and getting the patients to use the product obviously are seeing results and therefore encouraged. I think one of the challenges that we noticed in the last couple of months was availability of the product at the right pharmacies. What happens is if a physician has written the prescription and the patient does not get it, because it's not available at the pharmacy, the prescription gets substituted and the physician gets put off. Likewise, in some cases, we saw a challenge on pricing. We have very good managed care coverage but still in the early launch phase in the first six months its 40 in some territories. So in cases where patients do not get good coverage, you will see a switch of the scrip. So, we have also seen a delta in the number of scrips that actually were generated versus the ones dispensed. So there were a lot more scrips written compared to the scrips that were dispensed and our team is working hard to ensure the pull-through from the physicians' offices to the pharmacies and payers to ensure that the product gets dispensed. We have not heard any negative feedback on the product, we have not heard physician's say that they gave the product to the patients and it did not work or anything of that sort. The feedback has been very positive. Our team is really working hard on ensuring that the physicians continue to write the prescriptions and the prescriptions actually get dispensed.

Anubhav Aggarwal : Just one clarity, why would this availability of product at pharmacy be issue, I mean, this may be a challenge in the first quarter when we launch but now, we are almost seven months plus?

Vinita Gupta: So, that was in the first quarter, it is not at this point. At this point the only issue that we have heard of is really pricing, again to do with coverage in particular territory versus what it will cost a patient and therefore concern on pricing. Also that we have addressed in the last couple of months with additional savings coupon for patients that have a high copay.

Anubhav Aggarwal: Initially when we launched it was US$ 25 to a patient. Now what does the patient pay for it?

Vinita Gupta: It is still US$ 25.

Anubhav Aggarwal: So, what is additional here?

Vinita Gupta: It was changed to US$ 25 actually.

Nilesh Gupta: There is no further change, the same change that we made.

Vinita Gupta: That is the change we made back in November.

Moderator: Thank you. The next question is from the line of Nitin Agarwal from IDFC Securities. Please go ahead.

Nitin Agarwal: Vinita, on Solosec, based upon the experience in the first 6, 7 months, do we remain comfortable with the US$ 180 - 200 mn number that we talked about as a potential peak for the product?

Vinita Gupta: We have a long way to go obviously but the initial trend has been very encouraging. The fact that product has been well received by the physicians and the physicians have been willing to write it. The challenge that we saw in the initial quarter more to do with the availability of the drug, in the second quarter adjusting the price, we have seen the results of the changes that we made in the last couple of months. So it is obviously a very positive trend, I wish it was further along. But at this point, we are still expecting it to get to that 15-20% peak share and working towards it.

Nitin Agarwal: In terms of market share, at what stage in terms of timelines, would you see inflection point in these prescriptions in your own assessment?

Vinita Gupta: We are hoping in the next couple of months and quarters. Already compared to Q2, our scrips have more than doubled obviously, gone to the 1,500 level from the 700-800 level. We would really like to get as fast as possible to the 5,000 and 10,000 level but we are working towards it.

Nitin Agarwal: Secondly, in your assessment what is the addressable market for ProAir – do you see it as being a product which is going to be substitutable across the molecule class or your target audience going to be essentially the user of the ProAir brand per se?

Vinita Gupta: We always felt that a generic would compete across all the brands- ProAir, Ventolin as well as Proventil, and we still see that as the market that we are going to address.

Nitin Agarwal: What could be the challenge to that assumption?

Vinita Gupta: At this point, actually we should be able to gel in the next few months how the market behaves. We have two AGs as you know, GSK launched AG to Ventolin and Teva launched the AG to ProAir. We believe that each of them is going after the entire market. But in the next couple of months we will be able to confirm for sure. We certainly think of it as one Albuterol market. We hope that the fact that these companies have launched an AG at a reasonable price expands the market.

Nitin Agarwal: On this Mandideep issue that was raised earlier, we had a recall recently which was I think classified as a class-1 recall and that sort of combined with the observations. Does it create any issues for the facility?

Nilesh Gupta: I do not think so on the count of the classification of the recall itself. We have unfortunately had Class-1 recall even from other sites and that did not escalate action in itself. In fact, we tried to push hard to justify on why this should not be a Class-1. In reality, this does not go to the consumer, it is used in hospitals or in clinics at best, but eventually that is the FDA's decision. So they made the decision on the classification. But I do not think that escalates in itself.

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

Mehul Sheth: One question related to your forex loss. Can you quantify the number?

Rajiv Pillai: I had mentioned that at the outset; about Rs.157 crores across all the lines.

Mehul Sheth: One question related to US business. How do you see a competitive scenario in Levothyroxine because there are similar competing brands as well?

Vinita Gupta: There are a few brands and then you also have a couple of generics. We still see it as a limited competition product/market, where the generic companies like ourselves have proven that our product is bioequivalent to three RLDs. So we should be able to participate in the entire market for all the brands.

Mehul Sheth: What would be the tax rate for say FY20 and FY21?

Rajiv Pillai: Currently, what we saw around 48% for the quarter is not reflective. So if you look at the various regimes across where we are having operations, our cash tax rates are in the range of 28-29%. From an accounting perspective, the rates would range around 35%+. So, it will be closer to 40% for the end of the year from an accounting perspective. Cash tax would be around 28-29%. As our international subsidiaries generate profit over the years to come, these tax rates would naturally go down closer to the cash tax rate level of ~30%.

Moderator: Thank you. The next question is from the line of Anmol Ganjoo from JM Financial. Please go ahead.

Anmol Ganjoo: A couple of questions. Around the Rs.157 crores forex impact across line items, would you want to quantify it, because the swing is now across quarters becoming very too large in terms of how it is captured across various line items?

Arvind Bothra: We will take it offline, Anmol.

Anmol Ganjoo: Second question is around the US. Vinita, you alluded to most of the improvement in the US coming from greater share in top-10 products. What is the underlying trend here – what has changed with respect to pricing, competitive behavior, volume, if you can just help us understand that better because going forward are we at an inflection point where disruptive pricing has probably taken a back seat, is something really at an inflection point in the US that we should be understanding?

Vinita Gupta: The impression I have from what we are hearing from all of our peers as well as customers is that the pricing pressures have somewhat abated in the US. Companies have been far more rational over the last few quarters and have pushed back on demands to lower price. You have seen number of companies exit, Teva of course being the largest from a portfolio standpoint, Sandoz exiting the business, Mylan exiting portfolio and there have been other disruptions as well. These actions sends the right message to our customers that the manufacturers have really gotten to a point where you have to be reasonable to be able to have viable quality manufacturers. So what we are hearing from majority of our peers as they make statements, majority of them are also looking at the market the way we do that pricing pressure is back to the single digit level and we hope that stays for the year to come and going forward. So that stabilization from a pricing standpoint and then some exits from the marketplace that we were able to leverage to be able to grow our share in a number of our older products and believe that this is the turning point for our US generic business. Now that we have material new product launches like Ranexa, like Levothyroxine hopefully ProAir later this year, we have new growth drivers for our business along with stabilizing base business.

Anmol Ganjoo: A couple of follow-ups on that. One is as far as US is concerned, if we look at this quarter, that is US$ 800 – 830 mn annualized new base that we should be working with, is that the number which you have a comfort on?

Vinita Gupta: I would say at the lower end of that range right now just given the first half performance. Needless to say Q4 will be a strong close because of Ranexa.

Anmol Ganjoo: From FY20 perspective, given the kind of regulatory situation at some of our facilities, are there some of the key assets we are thinking in terms of de-risking and how much of our incremental growth is linked to a satisfactory resolution of these?

Vinita Gupta: We can launch 20 products or so with the current compliance status. We should have an upside to that once the warning letter in Goa and Pithampur clears.

Moderator: Thank you. The next question is from the line of Srijan Sinha from Future Generali. Please go ahead.

Srijan Sinha: Just wanted to check, is Ranexa filed from one of the warning letter affected facility and if so will it impact our launch?

Nilesh Gupta: We have final approval on Ranexa.

Srijan Sinha: Which means you can launch the product, right?

Vinita Gupta: That is right.

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

Ashish Thavkar: First question is on the licensing income. So on a net-to-net basis, at the EBITDA level, how much you would have realized? I guess you might have expensed out some of the R&D and then you would have realized the sale. Out of Rs.210 crores of sales this quarter, how much would be at EBITDA level if you could share?

Nilesh Gupta: This is not netted off any R&D expenses against that.

Rajiv Pillai: It has flowed through from the revenue line all the way to the EBITDA level. That is why when we talk about the normalized EBITDA, it was excluding this number.

Nilesh Gupta: I think the specific question is did we offset any R&D.

Management: No.

Ashish Thavkar: So, what would explain the dip in the gross margin if I strip off licensing income?

Nilesh Gupta: Like we said, it was forex and the business mix.

Ashish Thavkar: You are saying the net forex loss of Rs.157 crores is at the PBT level

Nilesh Gupta: We talked about 1.5% impact in the gross margin line, just on forex count.

Ashish Thavkar: Going forward into like FY20, FY21, how confident are you on the US business vis-à-vis the current financial year?

Vinita Gupta: We are on a good track at this point to close the year on a strong note and now that we have Levothyroxine as well as ProAir next year plus the base business and other launches, we believe that we are on the right track.

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

Shyam Srinivasan: Just the first one on the India business. It declined 1% sequentially this quarter maybe because of inventory last year. So can you just tell us how to look at this business now from fourth quarter

or an FY20 perspective, how should we look at this and in terms of new product launches you have done lots of in-licensing as well, so just trying to get some sense on the India business?

Nilesh Gupta: As you would know for India typically the first half is stronger, given the seasonality of the country, function of winter months versus monsoon. So typically we see that the first half will always be stronger than the second half. So we expected this sequentially, and one should see the year-on-year growth. Again the next quarter will be no different. So typically we would see more growth in the first half than in the second half. 12-14% YoY growth is what we always talk about, about few percentage points more than the market and that will continue. So we will see that into Q4 as well and certainly we see that for the forthcoming years. On the in-licensing, that is something that Lupin excels that, we have really done this well and there is no reason to not believe that it will continue more and more. Certainly, we have a pipeline of further products that we are chasing or have lined up as well and these will keep coming.

Rajiv Pillai: Our year-on-year numbers of growth are around 13.5-14% and that is what we should continue to grow at this.

Shyam Srinivasan: You are talking nine months here, right?

Rajiv Pillai: We should look at it annualized because there is seasonality between H1 and H2.

Shyam Srinivasan: Just a related question to this, given that maybe 4Q is also going to be softer from India source, the 63% gross margins that you talked about normalized, is that what we should be kind of keeping in mind for 4Q as well?

Nilesh Gupta: Yes in general, but we will have Ranolazine as an exclusive generic launch. So obviously that will skew it.

Shyam Srinivasan: My last question is on the effective tax rate. I know there are several moving parts here, but some of your peers have had US tax rate actually come off. So is there a sense that we could actually see the benefit of lower US tax rates on your bottom line as well?

Sunil Makharia: No, the way in which our transfer pricing works is that most of the profits are kept in India and in India our tax rate is in the range of about 27%. But yes going forward, we will see that how we can take the benefit of the lower tax rate in the US.

Vinita Gupta: In addition to that, improving performance of the US assets will help us to get there quicker.

Moderator: Thank you. The next question is from the line of Arpit Kapoor from IDFC Mutual Fund. Please go ahead.

Arpit Kapoor: The other operating income seems a little higher this quarter. So if you can just quantify how should we go about building the number?

Rajiv Pillai: I think that is driven by higher export sales. So we have got export benefit. There would be some other litigation kind of income but that is a normal run rate. …

Nilesh Gupta: It is higher export benefit and settlement income

Arpit Kapoor: The forex loss of Rs.150 crores, can you quantify what is the nature of the forex loss, we had hedges, why did we incur that bigger forex loss?

Rajiv Pillai: That is influenced by the closing rates.

Nilesh Gupta: It is translation and transaction losses that would happen on a QoQ basis. I think the rupee moved by almost Rs.3 in the course of the quarter.

Rajiv Pillai: Closed much lower than the previous quarter. So your receivables and payables would get adjusted appropriately and that is why you see what you call as a transaction gain /loss as the case would be. So that is the primary driver.

Moderator: Thank you. The next question is from the line of Saket Bansal from Stock Axis. Please go ahead.

Saket Bansal: I wanted some data points. What will be your total branded business for the quarter?

Vinita Gupta: It is US$ 8 mn.

Saket Bansal: That would be completely Solosec, right?

Vinita Gupta: No, it is a combination of the legacy products; Solosec was at the same level as Q2 around US$ 3 mn, the rest of it is Antara, Methergine, and Suprax.

Saket Bansal: I missed the initial commentary. If you have mentioned something about Levothyroxine, what kind of sales figure you are looking at for this year and going forward, can you throw some light on it?

Vinita Gupta: We just mentioned that we are going to be launching the product later this quarter in March, so very little in this year but it should contribute very well to FY20. We mentioned that it could be a ramp up because we are going to be strategic about how we build share in the market. It is important product for us for the next couple of years. So it should be a good contributor next year.

Saket Bansal: But nothing for this year?

Vinita Gupta: We will just launch it later this quarter, so just some launch quantities

Saket Bansal: Like Albuterol is there, there is ProAir, Spiriva are this in line for launching?

Vinita Gupta: Yes, we are hoping to get approval for Albuterol later this year and hope to launch it later this year. So both Levothyroxine as well as Albuterol should contribute well to FY20. We also have other smaller products, I mentioned 20-odd so launches. Once we clear the warning letter at Goa and Pithampur, we should have additional upside launches.

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

Ranjit Kapadia: My question relates to Capex. How much was the Capex guidance for FY19 and FY20? My second question relates to Perindopril litigation. We have already provided Rs 3.4 bn for the provision. So is there any further provision or this is full and final?

Nilesh Gupta: On the Capex about Rs. 600-700 crores is the run rate that we have, pretty much running at a quarterly run rate also, so Rs. 600-700 crores for this year and next year will be a similar number also. On Perindopril, we have provided for the entire amount.

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

Sameer Baisiwala: Vinita, what is your current revenue concentration for the US market like top-5 or top-10 products?

Vinita Gupta: It is well spread actually, Sameer, unlike in the past when we had big dependence on Fortamet Glumetza, we do not have that any more.

Sameer Baisiwala: That is now completely normalized?

Vinita Gupta: Yes, pretty much.

Sameer Baisiwala: I think on the news channel you said that you expect, just want to confirm, 23- 24% operating margins over next few years. Is that the direction?

Nilesh Gupta: On EBITDA, we said in the next few years we are going to bring it back to the 23 - 24%.

Vinita Gupta: We are talking about it as we look at our plan over the next 4-5 years as the complex generic pipeline unfolds, as well as the built-up on specialty business, we expect our margins to improve. In addition to that we talked about the fact that our margin optimization measures would also start delivering in the next fiscal year to a good extent but full extent the year after.

Sameer Baisiwala: Just on Solosec, given what you mentioned, Vinita on the pricing side, your net is US$ 170 or has it now moved a bit lower?

Vinita Gupta: It is a little bit below that, Sameer. Our focus right now has been to really drive scrip generation, scrip utilization. So when we brought the savings card down to US$ 25, we gave a little.

Sameer Baisiwala: For the US base business, when your competitor is vacating space and you get additional volumes, do you ask for better pricing, how does the volume pricing dynamics work for such products?

Vinita Gupta: Always ask for better pricing, Sameer. Fortunate situation is when you have these exists in the marketplace, you have folks that are forced out of the market sometimes due to compliance issues like we have seen in the last couple of months. We are then in a position to get share at a more reasonable price. So we always try to maximize on that front, while still keeping our customers competitive. Our goal is really to have a stable share. I think we took many quarters and couple of years of hit on pricing and are now trying to ensure that we optimize.

Sameer Baisiwala: On Enbrel, Nilesh, what is the update over here especially for the site inspection by EMA and CHMP timelines?

Nilesh Gupta: We had inspections by both Japanese and European authorities and they have gone well. On Japan, we are on track for approval probably in the next quarter and then launch probably in September or so. In Europe also, somewhere between September or the following quarter is when we would expect approval and launch.

Sameer Baisiwala: There were no observations from any of these agencies?

Nilesh Gupta: There were some small observations. I do not even think we have final report from them. It is only the point that we have noted down, which still has to go through that closure.

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

Nimish Mehta: Just wanted to understand better the situation of Solosec. Could you just explain the current pricing vis-à-vis your competition and what is the change from when we started?

Vinita Gupta: Our pricing is fairly competitive compared to the competition. We had done very good pricing research when we set both our WAC price as well as net price. The only change compared to when we launched was we brought in a savings cards to help offset some of the outer pocket cost for patients that were on high copay, as at least right now until the managed care gets caught up in all the individual territories.

Nimish Mehta: How much does that cut us in terms of percentage from when you started?

Nilesh Gupta: The goal at this point of time is to gain and get repeat prescriptions to get doctors to write frequently. Once you do that and I think these kinds of copays are part of regular product launches. You get a lot of time to be able to optimize them overtime.

Nimish Mehta: We are competing with the currently generic products, right?

Vinita Gupta: Yes, the market leader is a generic product but when we look at brand, we compete with products like Clindesse and Nuvessa.

Nimish Mehta: So, when we are benchmarking our pricing, we are benchmarking it with the generic product or with the brand product?

Vinita Gupta: No, we would not have been able to launch the products if we were comparing with the generic products. It was obviously priced as the brand product.

Nimish Mehta: What is the range of pricing among this competition if we are 100 then others would be what?

Vinita Gupta: All are in that same US$ 150-180 range.

Nilesh Gupta: It is similar. You would keep the pricing very similar as the cost of therapy.

Nimish Mehta: On Ranexa, I guess you have 180-days exclusivity.

Vinita Gupta: We have three months exclusivity, not 180-days.

Nimish Mehta: Do you expect competition post that or it will remain no competition in the market?

Vinita Gupta: We expect competitors after that, at least three to four.

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

Damyanti Kerai: Coming back to US, I just need clarity, you said current quarter numbers represent our new base, right. So we have seen stabilization in terms of pricing and whatever improvement we have seen frequently that all came from higher market share, is that understanding correct?

Vinita Gupta: That is right.

Damyanti Kerai: Big products like Methergine or your Metformin, now like we are able to protect our share or get some more share against the competition?

Vinita Gupta: Not Methergine, as Methergine was the brand and we actually lost share as the brand wend generic. So we launched an AG to Methergine but others like Metformin products for Glumetza have stabilized.

Damyanti Kerai: Stabilized in terms of market share you mean to say?

Vinita Gupta: That is right.

Damyanti Kerai: Coming back to Goa and Indore, now what kind of timeline you are looking for resolving the pending warning letter there?

Nilesh Gupta: As you know the Indore inspection got done, the Goa audit is ongoing. Earlier we had obviously guided towards the end of this fiscal as a likely timeline for resolution. Our hope at that point of time was FDA would have come in November or so timeframe for an inspection. That obviously did not happen, they actually came only in January. So the whole thing has moved out by a few months. I am hoping that if things go well, if we are able to satisfy things to the agencies' level, probably the first quarter or in the worst case the second quarter is when we would expect resolution.

Damyanti Kerai: So most likely by second half of next fiscal, right, we should be…?

Nilesh Gupta: I think before the second half of next fiscal.

Damyanti Kerai: Can you update us on the Advair generic development program, and how much cost you have earmarked for that?

Vinita Gupta: We continue to pursue the product. We are still not through the positive PK studies, which will be further along but we continue to pursue the product. In terms of the overall contribution of cost in R&D, our number is very small given that it is still not at the PD study level.

Damyanti Kerai: Right now you have allocated cost till PD studies and then going ahead as we move further in the program more cost will come in here, right?

Vinita Gupta: Yes, subject to a successful PK studies we will go into PD study and that will be at a higher cost.

Moderator: Thank you. The next question is from the line of Ankur Shah from Quasar Capital. Please go ahead.

Ankur Shah: Just going through the whole R&D spends which you have undertaken in the last three, four years and maybe the figure totals up to around Rs.7,000 crores, so I was just thinking about the efficiency of the R&D because from an incremental revenue perspective or margins we have not been able to monetize a lot of it at least in the last two years because of maybe some of the disruption in the market? If I think about the next three, four years, how would you think about the R&D efficiency because we have been very aggressive over it?

Vinita Gupta: I think we have been fairly disciplined in managing R&D as under 10% of sales, mainly obviously we have invested ahead of the curve into areas like inhalation, complex injectables,

and biosimilars. And to be honest we will start to see the benefits of it this year. So really we are round the corner from realizing returns from these investments with our first biosimilar, first inhalation product coming to market. As we look at the next 4-5 years, the products that we have invested in, in the last few years, in particular the complex generics, are a big part of our growth. So, we expect them to be a big part of our growth driver. So, parts of R&D that we have questioned from the efficiency standpoint in the past in particular NCE, with the MALT1 deal with AbbVie, we have started to get the return on that investment.

Nilesh Gupta: I would say about 70% of our R&D spend is on complex generics at this point of time, whether it is biosimilars or complex generics. That is the big bet, right. Obviously as we look at the generic market, a lot of the market is now moving towards opportunity in complex generics and that is where we are investing in.

Ankur Shah: Second question is on the margins. If I think about the Indian business, I know it does around in upwards of more than 25% margins. If I think about rest of the business and if I think about majority of the R&D spend allocated to the US pipeline, is it like the US business hardly makes single digit margin, is it right to conclude that in the current…?

Nilesh Gupta: First of all, I do not think we give segment wise profitability. India and the US are the two big profit generators of the company. There is always a base level cost but as the US picks up, it obviously churns out very meaningful profits.

Ankur Shah: I agree with the point that you do not give the segmental EBITDA margins but just from a business SKU perspective, it is a question that maybe India does not require that much R&D investment support which the US business might require and eventually India as a mix will do 25- 27% margins and still we are ending up with 16-16.5%?

Nilesh Gupta: I do not know where you are getting the India margin from because we never really compute or share that. If you are making the point on the ROC perspective, for sure, right, India obviously is the much higher return on capital compared to any other market for us, and also for everybody else in the market. It is the market that does not require lot of R&D spend. I think a meaningful generic business requires significant R&D spend, because the business is all based on new products. If we are going to do that, obviously you are going to invest significantly. But you are investing for the future, you are investing for the next, not just one, two years, sometimes you are investing for 10-years ahead, right. So, if you look at some of the big P4s that have happened in the last week even, it is for a product which is a 10-years out but people are looking at that.

Vinita Gupta: Setting aside the one-off quarters, overall our EBITDA margin out of both India and US, are above the company average.

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

Dheeresh Pathak: Just want to confirm the forex line item which you said was Rs.157 crores above EBITDA which is a gross line item?

Rajiv Pillai: That is right.

Dheeresh Pathak: You also said that gross margins were impacted by 1.5% because of forex?

Rajiv Pillai: That is right.

Dheeresh Pathak: Then about roughly 67 or 70-odd crores of that Rs.157 crores by that math is in the cost of goods sold?

Rajiv Pillai: Fair to assume. You can do the math.

Dheeresh Pathak: Can you explain this because I understand translation, transaction impact on current assets and all that but on the cost of goods sold, why is the forex impact such high?

Rajiv Pillai: This is also on account of translation of inventories the way accounting works. So last quarter the inventory was evaluated at a particular rate, that rate has come down, that is going to impact the gross margins, and the real impact that you are seeing.

Kamal Sharma: It will come down for the closing stock and therefore the cost of goods sold will go up.

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

Saion Mukherjee: Vinita, you talked about the US business turning the corner, it appeared as if you had this older products growing because people exiting from the market. I was wondering like there have been good number of launches, 20-25 launches you had. So how much of this let us say US$ 190 mn would have been contributed by these products which are launched over the last one year?

Vinita Gupta: Actually a very small part. When I look at our growth, majority of the growth has come from the older products. The new launches in the last one year have roughly contributed under US $15 mn on a quarterly run rate.

Saion Mukherjee: So the point is like when we look forward over the next couple of years besides the high value products you mentioned, is that something will change or you would expect US$60-70 mn from the rest of these 20-launhes that you would have, will anything change there or mostly in that range, it would be like US $3 mn kind of product right,?

Vinita Gupta: Apart from the ProAir as well as Levothyroxine, the others will be relatively smaller. But roughly around 20-products that we expect to launch.

Nilesh Gupta: For the 20 odd products, I would say about somewhere US$ 70-100 mn; that is usually the kind of new product number that comes out except for the one-off kind of products.

Saion Mukherjee: Have you launched - Budesonide Suspension already?

Vinita Gupta: We are in the process of launching it in this quarter.

Saion Mukherjee: Last question on the Bacterial Vaginosis market. There are some new products which are planned for launch. How do the dynamics change should we think of anyway?

Vinita Gupta: We have not seen any material new product that has caught the eye of the KOL. There was the Vivagel product out of Australia that was licensed by Italfarmaco; that seems like it is stuck with the FDA at this point. We have not heard of any material, new entrant that is positioned with the kind of positioning Solosec has. As we look at Solosec, when we have a 10-year runway, right now we are really focused on building share of the product. Apart from that, we also have significant potential of expanding the label and indication. Just started the pediatric study for the product. We are about to start a study on Trichomoniasis, that should expand the scope of the product and we have other life cycle management as well that we are working on. We would not invest in the product if we saw competition around the corner that can disrupt this market.

Moderator: Thank you. The next follow question is from the line of Anubhav Aggarwal from Credit Suisse. Please go ahead.

Anubhav Aggarwal: Just one question, Vinita, on Solosec is when we translate our EBITDA breakeven into weekly prescription, just as an idea, would you say that when we reach prescription about 9,000 - 10,000 per week, would be breakeven or could be breakeven even earlier?

Vinita Gupta: You are absolutely right, when it is around 9,000-10,000 scrips a week, that would be breakeven. Meanwhile I would like to say we can think even earlier, we really see a lot of potential in this product, the potential to get it to 15- 20% of the market and want to ensure that we invest into building it.

Anubhav Aggarwal: One more clarity on Levothyroxine. When do you expect to get approval against all remaining three RLDs – is it like first half or first quarter next year?

Vinita Gupta: We just filed against the other two RLDs as well. Hopefully soon, I mean, in the next few months.

Nilesh Gupta: They are prior approval supplements. Technically take longer but I think if we are lucky then hopefully in Q1 but otherwise probably Q2.

Moderator: Thank you. Ladies and gentlemen, that was the last question. I now hand the conference over to the management for their closing comments. Thank you and over to you.

Dr. Kamal K. Sharma: Thank you very much. I hope you had meaningful answers to your questions and look forward to connect with you next quarter. Thank you and good luck.

Moderator: Thank you very much. Ladies and gentlemen, on behalf of Lupin Limited, that concludes the conference call. Thank you for joining us and you may now disconnect your lines.