“Lupin Limited Quarter 3 FY18 Earnings Conference Call”

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MANAGEMENT: **DR. KAMAL SHARMA – VICE CHAIRMAN, LUPIN LIMITED**
MS. VINITA GUPTA – CHIEF EXECUTIVE OFFICER, LUPIN LIMITED
MR. NILESH GUPTA – MANAGING DIRECTOR, LUPIN LIMITED
MR. RAMESH SWAMINATHAN – CHIEF FINANCIAL OFFICER & EXECUTIVE DIRECTOR, LUPIN LIMITED
MR SUNIL MAKHARIA, PRESIDENT – FINANCE, LUPIN LIMITED
MR. RAJEEV SIBAL – HEAD (INDIA REGION FORMULATIONS), LUPIN LIMITED
MR. RAJIV PILLAI – HEAD (BFG), LUPIN LIMITED
MR. ARVIND BOTHRA – HEAD (INVESTOR RELATIONS), LUPIN LIMITED

Moderator: Ladies and gentlemen, good day and welcome to Lupin Limited quarter 3, FY18 Earnings Conference Call. As a reminder, all participant lines will be in the listen-only mode and there will be an opportunity for you to ask questions. In case 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 Dr. Kamal Sharma, Vice Chairman, Lupin Management. Thank you and over to you, sir.

Kamal Sharma: Hello friends, it is a pleasure for me to welcome you to this Earnings Call. I have with me Vinita, Nilesh, Ramesh Swaminathan, Sunil Makharia, Rajeev Sibal who is heading our India business. I have Rajiv Pillai, Head of our BFG and Arvind Bothra who is the head of M&A and Investor Relations.

As you would have seen by now that the performance this quarter has been muted. There are reasons that we have been discussing in the past. Added to that, some more negatives on account of forex, on account of deferred tax liability write-down because of US corporate tax coming down. So all in all, it has been a performance which has borne a lot of pressure from all sides. Having said that, we do believe that our investments are in the right direction. We are investing in good projects in R&D. Our operational efficiencies are being relooked at, at every level and we do hope to turn the corner soon.

In order to walk you through the financial details, I will request Ramesh to do the needful, please.

Ramesh Swaminathan: Thank you, Dr. Sharma. As Dr. Sharma was indicating, this is perhaps the worst quarter in several years, but this is not something that we did not anticipate.

Even at the start of the year, we did indicate the fact that this year could indeed be a challenging year. But if you look at our results closely now, the fact is that it is not as bad as it comes out only because in reality it has a lot of one-offs.

In the first instance, we have a forex volatility which has costed us Rs.82 crores this particular quarter. The second point was, essentially, as Dr. Sharma was indicating, whilst the tax base coming down in America is a good thing for us in the long term, in this particular quarter, it does cost us a bit. This has been particularly because the deferred tax asset that we created on unrealized profits on inventories lying in America had to be wound down and that cost us about Rs 38 crores this particular quarter.

If you look at, the growth, **on a sequential basis,** in America, we grew by about 4%. We reached $213 million. If you look at the other markets, APAC grew by about 6%, Latin America also grew 6.2%.

India of course, it is still muted only because we also had the impact of IFRS on GST, IndAS on GST; because of GST, the topline did not include excise duties and to that extent, it did not perhaps reflect the growth we saw versus the previous year.

Overall, things are the way we anticipated. In terms of EBITDA margins, this quarter is about 18.4%, but you recognize if we do correct for the forex, it will be normalized to 20.8%. This is in line with the full year figure of about 21% and if that were to be adjusted again, it will come to close to 22%. ETR this particular quarter was particularly high only because, t as I said, the wind down of the DTA has costed us a bit out there.

R&D expenses were on leash at 12.2% whilst the other initiatives on the operational excellence front still continue and that is one of the reasons why we are still able to show the kind of EBITDA that we are indicating.

For the real story on the various markets, I would request Vinita to take over.

Vinita Gupta: Well, we can certainly talk more about our performance across different markets in the Q&A.

I just like to add that while it has been a challenging quarter, it has been a challenging year, we stay very committed to evolve our developed markets business, in particularly US, into complex generics and specialty, while growing our business across all of the other regions within India, Japan, Latin America or EMEA. We have made significant progress on the pipeline front that again we can talk about further in the Q&A.

We have certainly made progress on biosimilars as well as on the inhalation front, but we are very pleased with the steps we have taken on the specialty front this year so far and 2018 is going to be a significant year for us to grow the specialty assets that we have invested into whether it is in the US, into women's health, with Solosec or Europe with Mexiletine or Japan with Bipresso**.**

So with that, I would like to really open it to Q&A.

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 Prakash Agarwal from Axis Capital. Please go ahead.

Prakash Agarwal: Since the last call we had one warning letter, could we please have some update where we had last mentioned that the remediation could take anywhere from 6 months and resolution could be anywhere from 12 to 18 months and you also mentioned that there is some, you need to go more granular in understanding. So what is our understanding today and we have any from you now?

Nilesh Gupta: Perfect. Thanks, Prakash. So we have made significant progress as far as the warning letter is concerned. As I had said before, first of all, we were extremely disappointed that we got this warning letter. This is not what Lupin stands for. But we have done a lot of work in the last 4 months on the warning letter, - obviously to understand in granular details, to engage consultants, to start working on the baseline. As you all know, there were basically two big buckets of work. One was around invalidated OS's and the other was on Hold Time exceeding a certain amount of time. We have engaged consultants, we have engaged consultants like Lachman, PAREXEL, others as well and obviously the independent assessment is well under way. We are pretty much close to completing that piece of the work on the invalidated OS's. There is other work that was to be done on hold times, hold time risk assessment. Again, that is deep underway. We have been sending monthly updates to the FDA, so we sent two updates after the initial to the FDA. As it stands right now, we expect to finish on work between April-May and then go back to the FDA. So, we are quite on track with what we said about completing work in the first 6 months and then going back to the FDA and there were trade-off between trying to rush versus doing things comprehensively. Obviously, we are erring on the side of being comprehensive in our approach. So, there is a lot of focus on enhancement. There is a lot of time being spent on this obviously and there are lot of good steps going on. Obviously, our intention is to go from where we are to be best in class and the next few months will be critical in terms of getting to that finished line.

Prakash Agarwal: And do we have clarity, last time we spoke that of the past work done, the hold time would be difficult to find out. So that was a little ambiguity area. We have more clarity there?

Ramesh Swaminathan: Yes, all of that stuff was done. So we scoped it out completely. We needed to share with the FDA tally of the number of batches that exceeded hold times of 20 days as well. All of that stuff comes from batch process records. We did not have that information when we did the call because that was the day of the warning letter. But thereafter obviously we kind of culled out that information. It has been validated by independent consultants as well. So we got a really good handle**.** I would say that on these two things, we got a very good handle and another key area that we are focusing on is improving the quality of investigation that we do. Fourth area that we are focusing on is training and we have engaged separate independent consultants for that and we want to be very heavy on training in QC and on the manufacturing front.

Prakash Agarwal: And second question on the US side, I see your comment on US business is now starting to stabilize at current levels. We also started to see the Q-on-Q growth, sure this is driven by Fosrenol and Vigamox, so I just wanted some color on how the US generics have performed on the price erosion front and as well as Vinita, on the specialty how has that ramped up Q-on-Q. Thank you.

Vinita Gupta: As far as the price erosion goes, we have started to see level out, means obviously in the last couple of years there has been tremendous pressure on the industry and we started seeing a number of the larger players really getting to their pain threshold. Teva went public with a

statement that a percentage of the portfolio where they lose money, or they have low margin, they are going to either get out of or increase price. Likewise, Sandoz have gotten out of number of products where they didn't make margin or they had low margin. So we are starting to see companies and the larger companies getting to their pain threshold which suggest that things have started to bottom out, means we can't say for certain that they have bottomed out, so the next few quarters will tell. At the same time, we are finding that on our baseline products, we are starting to see single digit price erosion what we used to see prior to this customer consolidation starting. So as we look at the last couple of quarters where we have had some price erosion but then we have had new product launches that have made up for it and brand business has made up for the loss in revenues due to price erosion. So if I look at Q3, we have had a growth in our brand business, nearly 25% growth on our brand business driven by Methergine and we have had contribution of new products like in Q3 we had hydro/APAP, Bupropion and Doxycycline, it is small number of products, but they more than offset the price erosion that we saw in our baseline products. When we look at the business going forward, the next couple of quarters, we are hopeful that in the current quarter we will have a number of decent product launches. We have 10 plus product launches that we expect this quarter. So it will be one of the largest launch quarters for us. Some interesting opportunities like Tamiflu that we have one of a few, but just given the strong flu season it is a really nice opportunity for us likewise. Axiron, again has limited number of players and similarly for few other products. So as I look at the business going forward over the next couple of quarters, we hope to be able to offset any price erosion that we see in the baseline generic business with the new product launches that we had planned while we have a few products that are held up because of the warning letter. There are number of products that are already approved by the FDA, that hope will more than offset the price erosion that we expect to see in the generic side of the business. On the brand side of the business, our focus is very much on Solosec that we expect to launch next quarter. We are gearing up salesforce to be able to launch this product hopefully by next quarter and are working towards redirecting our entire salesforce towards Solosec, given the opportunity and the longevity of the product and they have built a very nice base with Methergine. In December, we had Methergine at its peak revenues for the month and we will continue to promote Methergine for the next couple of quarters. But we believe there is no IP protection, no patent protection on Methergine. So whenever generic enters into the market, majority of our resources on the brand front are going to be deployed towards Solosec in the US.

Prakash Agarwal: Thanks. So on Metformin franchise, how have they shaping up given that competition, the current competition is stabilized now and we are yet to see Sun Pharma impact, so just your comments there.

Vinita Gupta: It is pretty much stabilized and if you look at the shares, they are fairly stable on Fortamet as well as Glumetza. But we haven't seen Nostrum launch in Fortamet as of yet. And we don't know when we can expect Sun to launch their version on the market. But so far the market shares have settled out.

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

Neha Manpuria: Just one question first on Solosec, is it fair to assume that the salesforce build-up for the launch has already happened and that's what is reflected in our other expense increase?

Vinita Gupta: It has already started, Neha. In Q3 we have had some impact of the additional SG&A spent but it has already started, we have started building capabilities on the women's health front with the acquisition of Symbiomix. We took over the team, that small but experienced team that Symbiomix had with very good experience on the women's health front and we have started building the infrastructure. So we have started some expenditure already.

Neha Manpuria: And Ramesh sir, is there any remediation cost in the other expense and if you could please quantify that?

Nilesh Gupta: No, it is a small expense, so far.

Ramesh Swaminathan : In the overall scheme of things, it doesn't really matter too much.

Neha Manpuria: Okay. So then it is fair to assume that the quarter-on-quarter increase in other expense is primary due to the SG&A related to…

Nilesh Gupta: It is actually forex loss that has contributed to it.

Neha Manpuria: Okay. Fair enough. And sir when we look at balancing our R&D spend given the spending on our complex generic like inhalation of biosimilars will probably go up and margins for the next year, how do we look at both of that, in the tough US operating environment. How would you look at R&D versus margins for FY19?

Vinita Gupta: So, we will continue to work to maintain R&D spend within 12 or so percentage points, maybe bring it down a little bit. Just given the structural change in the US market, it no longer makes sense to invest a good amount of money behind products where you are going to be fifth, sixth or seventh player to enter the market. So we have the potential, the opportunity to really prune down our pipeline further, to focus on products where we can be in the first 2-3 players in the market and can get a return on our investment and ideally sustainable revenue margin potential. So we will definitely maintain the current level of spend, if not reduce it.

Ramesh Swaminathan: Just to add color to what Vinita has been saying, it is actually a function of impact, the kind of products that we bring to market, the price erosion that there is on those products, on the overall portfolio itself, the forex and of course the R&D spends and the operational excellence measures that we actually undertake. On the operational excellence measures, it has not run its full course and there is lot more to squeeze out. So we would be working on that. So having said that, of

course, pressure on the pricing still continues and because of the warning letter, though there is of course only a marginal impact on that, the number of products that we actually bring to market next year would be and we have Levothyroxine in the fuel of good products, but indeed, we do expect next year also to be a little challenging.

Neha Manpuria: And my last question on, any update on Levothyroxine? Have we heard anything from the FDA?

Nilesh Gupta: The review is going well. Hopefully by the middle of this year we should be able to launch the product.

Neha Manpuria: Is there anything pending from our end?

Nilesh Gupta: There was some IR that we responded to.

Neha Manpuria: Okay. So we have already responded to them?

Nilesh Gupta: Yes.

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

Anubhav Agarwal: Ramesh sir, question on the FX loss. Is entirely FX loss of 82 crores in other expenses or it is in COGS as well?

Ramesh Swaminathan: So, it is across the couple of lines. So we have impact on the gross margins which is one portion. There is of course better realization because of hedges that we have taken and there is of course the loss on the expense front as well which we have taken in manufacturing and other expenses there.

Anubhav Agarwal: gross margin in this quarter is significantly lower on a sequential basis. So how much is the FX component on the raw material cost?

Ramesh Swaminathan: So, there is a portion of it about Rs.10 crores. It is actually captured because of inventory valuation which is on the gross margin line.

Anubhav Agarwal: But still even adjusted for 10 crores, why has gross margin declined sharply, sequentially?

Ramesh Swaminathan: It is a function of host of other things right essentially because of the forex drifting lower due to appreciation of the rupee itself.

Anubhav Agarwal: No, sequentially it is better only Ramesh sir.

Nilesh Gupta: So, I think part of it is the business mix where we have lesser sales from India, more sales from the US. So that has led to part of the margin decline and the balance would be due to forex.

Anubhav Agarwal: What do you say that the sales mix within US itself was inferior in this quarter with your higher margin products?

Nilesh Gupta: Yes, of course. We lost exclusivity on Mibelas**,** so that went out. Obviously, that was a big change. Also, there was a small decline further on Glumetza as well which was made up by some of the other products. There is increase in the Cephs into the flu season. There was pick up on products like Azithromycin. So there is a marginal change.

Anubhav Agarwal: And Vinita, just two questions on Hydrocodone/APAP, now on your quota on this product that safely has about 10% market share. What is the quota allows you? Have we reached a stable market share now or can we increase it further with the quota that we already have?

Vinita Gupta: We are continuing to increase our supplies, we have made a commitment to one major customer and are working both with the DEA as well as the customer to be able to meet the demand which just started last quarter. So in Q3, you will see not much of an impact of Hydrocodone/APAP. You will see more in Q4 and beyond.

Anubhav Agarwal: So IMS currently shows us about 10% market share, do you think it is reflective right now or we will see much more of it from here?

Vinita Gupta: IMS, so we should have a little bit more than that. IMS is probably not tracking completely because as I said we just started supply last quarter. So we are still building it up right now, but we expect to be around 15% or so.

Anubhav Agarwal: And around Fortamet, I just wanted to check if you look at market as a whole while your market share has been largely stable, but if you look at market as a whole, it continues to lose volume like even for us the volumes in Fortamet according to IMS decline, 15% sequentially. What is happening here because I remember your comment from the analyst meet, you were talking about that you have expected from April or June onwards the volume decline for Fortamet is stabilized, but it has not happened. What is happening in the market?

Vinita Gupta: So, I do not know because when we look at it between Q2 and Q3, it is really flat.

Nilesh Gupta: May be IMS reflects that, but not our internal numbers.

Anubhav Agarwal: So saying that the IMS impacts, so you are not seeing your volumes declining on Fortamet?

Vinita Gupta: No.

Anubhav Agarwal: And just one clarity on Methergine, your comment, so effectively you are expecting a generic competition Methergine in 2 or 3 quarters from now?

Vinita Gupta: We do not know exactly when, but we believe that a company has filed the product and we do not know when we could expect the generic.

Anubhav Agarwal: And last time you mentioned on the call that you know that 2 companies have filed the ANDA on Methergine right?

Vinita Gupta: I think we know one company. We do not know the additional one.

Moderator: Thank you. The next question is from the line of Rakesh Jhunjhunwala from Rare Enterprises. Please go ahead.

Rakesh Jhunjhunwala: My question is to Vinita, when you say that on one side Sandoz and Teva are withdrawing some products and increasing prices on those products. So what does it mean, are you saying that the process of bottoming out of pricing has started, but the actual prices are still declining?

Vinita Gupta: So we think that it is really starting to bottom out when you start seeing large players like Teva and Sandoz getting out of large portfolio of products, it really sends a signal that they are at the pain point from our perspective. Also, the number of product discontinuations that we have seen in the last 6 months has been more than what I have seen in the last couple of years. Again to me that is a signal that companies have got to the pain point. When I sit down with a number of our peers both here as well as in the US, what I am hearing from the companies CEOs is that all of them have been challenged over the last couple of years and we believe that for us to be able to maintain a healthy generic market, we have to be able to get a reasonable return on our products that we supply. So all of those suggest to me that we are starting to see a bottoming out. We have seen a few products where we have been able to pick up volume at a margin higher than what we have seen in the past, but I wish I could say that for 30%-40% of our portfolio. I would hope that within this year, we start to see the bottom. I think yes, we are close to it.

Rakesh Jhunjhunwala: Right. So, therefore, as of now you are still seeing erosion, but the erosion in number of products is coming down.

Vinita Gupta: Yes.

Rakesh Jhunjhunwala: Second thing Ramesh mentioned that you are visioning the portfolio / the R&D towards the new realities of the American market. So what is it you are doing, you are reducing number of products in which the competition will be huge or products which are not complex enough?

Vinita Gupta: Yes, Rakesh ji, it's basically optimizing our pipeline. When we look at the changes that have taken place in the US market which are structural, we have three major players that demand their

pound of flesh. When you look at product launches where you are one of 5, one of 6, the kind of return one can afford to make is not certain. So when we look at our pipeline with that lens and prioritize it we have the potential of pruning our pipeline down to products where we can be one of three, four and have certainty on both the return as well as sustainable margin revenue potential. That's what we are doing, not losing any material opportunities, but looking at the pipeline now with the changed market dynamics to determine what investments we should definitely make and what we can do without.

Rakesh Jhunjhunwala: That will be a very difficult task because you are seeing the market is going to undertake a change and lot of people are going to estimate, estimate today which products, how many people will come could be a very challenging task. Isn't it?

Nilesh Gupta: I think you go after complexity. That is your point how many people will eventually make it. We still end up doing 15-20 oral solids products. We will do probably 8-10 injectable products a year and we will do at least a couple of inhalation products, we will do one biosimilar every year as well. So it is obviously going to be a meaningful number of products, but the idea is to focus on that select list and make sure that the 15-20 that you want are the ones that we delivered.

Rakesh Jhunjhunwala: And when do you expect approval of your new injectable plant?

Nilesh Gupta: So we filed four last quarter. So in the next financial year, we hope to actually launch a couple of them because the FDA is actually very quick in the review process and our injectable plant is ready. So in the next month or two, we will start taking exhibit batches from that.

Rakesh Jhunjhunwala: Next year you will have products from the injectables?

Nilesh Gupta: Yes, that is correct.

Rakesh Jhunjhunwala: And you will have some complex products also in the injectables?

Nilesh Gupta: Yes. So we are focusing on, I would say medium range of complexity at this point. The more complex products will come out of Nanomi which will get filed from FY20.

Moderator: Thank you. The next question is from the line of Ashi Anand from Allegro Capital Advisors. Please go ahead.

Ashi Anand: First question is on Eternacept. Just wanted to understand the status of the filing in EU and US?

Nilesh Gupta: We are just about finishing our clinical trials and we hope to file at the end of this quarter in Japan and shortly after in Europe. There is a study that we need to do for the US. So that will go into the next financial year.

Ashi Anand: Excellent. And just passing the Eternacept, just wanted to understand what do still we have in the pipeline in terms of biosimilars, what are the other assets we could be working on?

Nilesh Gupta: So as you know we were late in the biosimilar scene. So - we have started with the select few targets and - we are really going to be able to hit the second wave of biosimilars in a big way. So there is a lot early stage projects which are going on. These are probably for the FY 23 to FY 25 horizon in terms of commercializing. We have already commercialized few products like Pegfilgrastim/Filgrastim in markets like India and we are looking at opportunities for them in developed markets as well. There are products like Ranibizumab in development as well. So - we are looking at the first wave of biosimilars and cherry picking the ones where we feel competition would be limited and there still be high value and then the pipeline is on what is today early stage products.

Ashi Anand: Just a quick follow-up on that. When we are speaking of the FY23-25 launches, are these biosimilars that are going off patent around that point in time. Or are we looking at being the second wave of launches?

Nilesh Gupta: No, these are biosimilars going off at that point.

Moderator: Thank you. The next question is from the line of Ritika Jalan from Narnolia Securities. Please go ahead.

Ritika Jalan: Most of my questions have been answered. Can you tell me what is the kind of opportunities you are seeing for the next 12 to 18 months and you have mentioned that there are 3 FTFs in FY19. Could it be possible to share that launches?

Vinita Gupta: We have products like Ranexa in the next fiscal year. We have large products like Levothyroxine which is not FTF, but there will be limited competition and a few products that we are launching in this quarter like Axiron and Tamiflu, that all are good size opportunities for us.

Ritika Jalan: And on the Indian business how do you see it shaping up in the balance part of the year in the next fiscal year?

Rajeev Sibal: Yes. So after the first quarter, it was good pickup in the second quarter which was July to September. Our India business grew at 16%. Even in this quarter also which is October-November-December, our prescription business has grown at 14%, so we are very sure that this type of growth will continue as far as India business is concerned.

Ritika Jalan: Okay. And can you guide me on the margin, will it sustain or will it improve or dip?

Ramesh Swaminathan: No, I said this before. It is really going to be a function of, there are several moving parts here and it is going to be a function of several things. It is difficult to conjecture, but I would think it is try to keep it within the range that we are seeing today.

Ritika Jalan: And debt equity ratio, if you can give me any idea about debt to equity ratio?

Sunil Makharia: Debt to equity ratio is at the level of 0.4 and we feel that this would remain more or less at the same level or should come down further.

Moderator: Thank you. The next question is from the line of Ranveer Singh from Systametix. Please go ahead.

Ranveer Singh: Sir, just on US business, with the part of base business, ex Metformin, what would have been growth or degrowth in this quarter. Is it possible to split this?

Vinita Gupta: I mean, not for the quarter, but year-to-date ex Metformin business has grown. In terms of inline products, we have had a price erosion that has been offset by volume increase and new products have contributed to the overall 6% growth for ex Metformin.

Ranveer Singh: Okay. And what has been contribution of branded business in US?

Vinita Gupta: It is 13% of sales.

Ranveer Singh: Primarily Methergine?

Vinita Gupta: Methergine as well as Suprax.

Ranveer Singh: Can you give CAPEX guidance for FY19?

Ramesh Swaminathan: Between Rs.800 to Rs.1000 crores is what we estimate at this stage.

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

Nitin Agarwal: Vinita, on the specialty business, since you mentioned about the likely competition that may emerge for Methergine, so how do you see, in specialty business going forward for us is going to be largely around how Solosec plays out or how do you see it going forward?

Vinita Gupta: So certainly in the near term is going to be very focused on Solosec, Nitin. But we are also actively working on bringing other opportunities, other products into the portfolio that complement Solosec as well as would help us leverage our commercial infrastructure better. We certainly have aspirations to bring in more products into our specialty portfolio. In the Solosec itself has got pretty longrun rate in 10 plus years and we see it as material opportunity in terms

of revenue potential over the next couple of years. So in the near term the next 5 to 6 months, the big part of our focus is to launch Solosec effectively.

Nitin Agarwal: And in terms of the field force, what is the size of field force that you would potentially be looking to deploy for that versus what you have right now?

Vinita Gupta: So right now we have 70 people and we are gearing up to 125 to launch the product.

Nitin Agarwal: Okay. One thing on Methergine, we really worked very hard to sort of build up the franchise, right? And I think probably we are doing about $4 million-$5 million a month on the run rate. Probably that is what we discussed last time. But this onset of generic competition was it envisaged or sort of took it with you by surprise in the way, was a little bit of surprise for us in terms of the timing of the potential competition?

Vinita Gupta: So, we knew that companies were working on generic version and timing of it was never you can tell for certain, but from our perspective, we have been able to relegate a good return on our sales force investment that we made on Methergine, that enabled us to really get into the OBGYN market to establish a relationship with both the clinical as well as other organizations that serve women's health. So we could never be certain about the timing and we are not certain about the timing of the generic launch, but we are cognizant of the fact that some point in time the generic would launch and therefore majority of our effort is going to be focused around Solosec. We will continue to promote Methergine until the generic enters, but really direct majority of our resources towards Solosec.

Nitin Agarwal: Lastly, can you provide an update on the inhalation portfolio, in terms of where we are in the different filings?

Vinita Gupta: Yes, so we filed Albuterol last year, January of 2017, our first inhalation device product. The review is on track with the FDA. We hope that within this calendar year or early next, we should get product approval and launch next calendar year. Tobramycin, we had already got approval and we are in the midst of launching right now this quarter. We filed Pulmicort to the FDA. We have been working on the DPI front, both on Advair as well as Tiotropium. We are further along on Tiotropium, we are in the process of completing Phase-III study right now. Subject to successful completion, we hope to be able to file it in the next two quarters. On Advair, we have had challenges with the product and continue to work on the formulation to be able to get the PK with the FDA has made fairly clear to the last few applicants that they would like to see a PK match with the brand. So we are really pleased that we have made progress on Tiotropium where hopefully we can be first-to-file and continue to work on Advair as well as other opportunities. We have pretty rich pipeline of inhalation products that we are pursuing.

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

Anmol Ganjoo: Just looking for a couple of numbers. For India, what was the like-to-like growth number for the quarter?

Ramesh Swaminathan: So I would say it is 11% we got a knock-off the impact of the accounting.

Anmol Ganjoo: And can we have the Somerset growth number for the quarter?

Ramesh Swaminathan: We don't give product wise portfolio numbers, Anmol.

Anmol Ganjoo: Yes. Vinita spoke about it the quarter before last, so that is why I thought you might make it a....

Nilesh Gupta: Yes. It has grown 31%.

Anmol Ganjoo: Thank you. And lastly on the US exit annualized run rate, $213 million is where we end the quarter at, sequential growth after a long time, so that is good news. But is $850 million the annualized run rate that we should be looking at in to grow this base, is this how we should be thinking about the US business from FY19 base perspective?

Vinita Gupta: I think that is fair to assume just given that we have some products that are held up in the warning letter and we will see some price erosion in single digits, but the new product launches should be able to more than offset them.

Anmol Ganjoo: And lastly I was just trying to understand that we have a warning letter situation at a couple of plants, but when you do FY19 risk assessment, what growth drivers are constrained by the situation we have at these two plants and what are the various scenarios we are working out in terms of the FY19 growth number contains and then obviously the resolution which no one would have great visibility on, but just trying to understand the impact from an FY19 growth outlook standpoint?

Vinita Gupta: So number of products for FY19 at are deep certain or otherwise good-size opportunities are not impacted. For example, Ranexa we already have final approval from the FDA. Levothyroxine is from a different plant. Look at maybe up side opportunities Memantine XR that we may have the potential of launching pending litigation outcome mean we again have final approval. So while the good number of the larger opportunities, we have better level of certainty in terms of launch as well as revenue potential next year, but there are handful of products that are held up.

Anmol Ganjoo: Thanks and my last question before I get back between 2Q and 3Q, we see a reduction in the number of first-to-file opportunities that we talk about and the number in 2Q is 49 versus 33 in the latest and 25 exclusive FTF opportunities in 2Q versus what is now in the press release which is 16, any particular reason?

Arvind Bothra: Anmol, this is just that earlier we used to report the total FTF including the past ones. We have now disclosed only the pending ones just for clarity perspective.

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

Surya Patra: In fact in the opening remarks if I heard correct, you have indicated about challenging FY19. So just a clarification whether it was about the US business that you are talking about or it was for the entire operation you are saying considering the kind of warning letter situation what you are currently having? Can you please clarify?

Dr. Kamal Sharma: No, I think it was primarily to do with the continuous pricing pressure as Vinita said that is bottoming out, but we still have to see it stabilize. Otherwise, nothing in particular. We know that major launches are actually going to come up somewhere in the end of FY19 and that is when the material effect will come, that is why we keep saying that there would be a pressure, but I am saying in the same breath that everything has been done in terms of business mix as well as operational efficiency makes sure that we turnaround.

Surya Patra: Thank you for that. And so seeing that here, how challenging business scenario in US, so are you now considering any other alternate market to really focus more on and which can to some extent deliver better growth than the current consolidated business. Anything on that front that you have thought or?

Dr. Kamal Sharma: I think Lupin's portfolio is very well diversified portfolio. So I do not see any other market mix which will be more optimized than what we are in terms of our mix of US, India, Japan, EMEA, Latin America. I think we are present in all the growth markets of future, so I think any necessity to further tinker.

Surya Patra: I actually wanted to know something like whether the growth trend in Japan could be better than the historical trend or something like that because for better focus or something?

Dr. Kamal Sharma: For the short term you would have seen even this quarter year-on-year, every market has grown well. Every market for your information grew 20.4%. EMEA grew about 6.5%, LATAM has grown 26.7%. So all of them are growing. So I do not see a situation why there should be any change in our market mix.

Surya Patra: So my question was also coming from the same point that okay LATAM and Asia Pacific and all that has grown much better number, so that is why.

Dr. Kamal Sharma: The fact remains that our salience of US business is very high in our business mix and US is of course the largest pharma market. So it will always have a dominant place.

Vinita Gupta: But suffice to say that we are continuing to get the best out of all of our key markets.

Surya Patra: And just one last question. On the tax incidence front, so currently whatever that is because of the kind of whether it is a one-off kind of impact and that is why the tax incidence is there or for few quarters that we will find similar kind of a higher incidence because of the tax rate changes in US?

Ramesh Swaminathan: As I said in opening remarks, the way it is coming down in US is certainly a good thing for the long-term, but in this particular quarter, there is of course this winding down of the DTA that has been created on the transfers from India and on which there is unrealized profits. That winding up will perhaps continue in next quarter also to some extent. Now we should be better off in America. I would think that the overall ETR for the company should be in the range of 28-30% because it also recognizes that the weighted deduction on clinical trials are going down.

Moderator: Thank you. We have the next question from the line of Aditya Ahluwalia from Invesco. Please go ahead.

Aditya Ahluwalia: You have mentioned that you are seeing an unprecedented number of products where Sandoz and Teva and large companies are withdrawing and that should help bottom out the US business. How about the new approvals that the US FDA is giving. Is that also at an unprecedentedly high level or is that stable?

Vinita Gupta: There have been a number of new entrants, last year there were 47 new entrants in, approved by the FDA. At the same time, you see product approvals, but their ability to really garner share is yet to be proven. So we have seen the faster pace of approvals given the current efforts that the FDA to facilitate additional generic approvals. So I would say that you are seeing a number of new approvals as well, but not as many new entrants.

Aditya Ahluwalia: So from the last quarter to this quarter, has there been any change in our outlook as far as the US business is concerned on the revenue front?

Vinita Gupta: There is no change in outlook.

Ramesh Swaminathan: There is no change in outlook except that as Vinita was mentioning price erosion is coming to an end, we believe that this actually being it is kind of bottoming out. So we think things will be steady from a price erosion front at least.

Aditya Ahluwalia: And just one last thing. The current quarter gross margin is what the new base is now?

Ramesh Swaminathan: I would think it is a new normal so to speak.

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

Saion Mukherjee: Sir one question on the margins which are around 21% EBITDA margin, generally we understand that domestic business carries a lot higher margin, sometimes like 25%-30% and correct me if I am wrong there. Does it mean that your rest of the business is lower than 20% including the US once you load all your expenses particularly R&D there?

Ramesh Swaminathan: We depend on various markets. So we talk about Japan, again there are pieces which are contributing better and is of course the KCC business which has been a laggard for some time. Certain businesses are still evolving. Look at, for example, Latin American business in Brazil, these are smaller in overall scheme of things, but you are right in saying that India is certainly one of those better markets which we are present in. But I think the EBITDA margin is really a function of several things, including the R&D spend and so to that extent it always, it is sum of various parts.

Saion Mukherjee: But sir can you confirm India EBITDA margin at 25%-30%, would that be a fair estimate?

Ramesh Swaminathan: Well, I would urge you to think in that direction for sure.

Saion Mukherjee: Okay. And sir on R&D, I understand you are controlling that, but don't you think it is still on a much higher side compared to peers. You mentioned about rationalizing your development programs, any assessment on that front?

Vinita Gupta: It is on the higher side for certain compared to a number of our peers, we believe that we are making investment not just for the next couple of years, but for the next 5-6-7 years, means number of our peers not investing in biosimilars while we as a company are investing into all solid first-to-files plus inhalation products, plus biosimilars, plus complex injectables. So we are obviously investing more than other companies, other peers do. At the same time, we are trying to really revisit our pipeline to see what part of it really makes sense for us to pursue just given the new market dynamics as well as looking at it from a lens of where we have the opportunity of being the first 3 to 4 to market.

Saion Mukherjee: Great. And just one last question on this on complex generics, particularly on inhalation and biosimilars. First on inhalation, did you have any interaction with the FDA on Albuterol, what that makes you feel, you could get an approval because we haven't seen other companies getting approval and similarly for Tiotropium, being the first player does carry risk. I mean, the interaction with the FDA does it give you more confidence that the path you are taking is okay and the product would be approvable?

Vinita Gupta: Yes. So we have had the interaction with the FDA on both the products and the other products that we are pursuing and feel pretty good about both our approach as well as our current standing with the FDA. The proof is in the pudding at the end of the day we get a product approval that will of course give us the certainty and give the certainty that we have the ability to deliver these products, but the FDA is really engaged with our team quite a bit on face-to-face meeting as well

as correspondence to clarify any questions that we have, to really help get inhalation product approval to market.

Saion Mukherjee: Okay. And just last one, Etanercept in Europe, when you think is the launch and assuming you file over the next few months and how do you see the market given there are two players already in the market there?

Nilesh Gupta: Like I said we hope to file in the next quarter and in the next 15-18 months we will be basically in the market. Vinita, you want to talk about this?

Vinita Gupta: Yes, so the market is still, it is a good sized opportunity, means given that the product would need salesforce effort in Rheumatology as well as Psoriasis, we are currently working with handful of partners that would like to partner with us in the major markets to distribute the products for us.

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

Shyam Srinivasan: Just on Solosec, can you just walk us through the commercialization, the next steps. If you remember, in October I think you said validating the product is the first step and that will make in larger quantities. Can you just walk us through that please?

Vinita Gupta: Yes. So we have validated the product in the last couple of months and had manufactured launch quantities and are in a position to start building up the trade in the next quarter. Basically, end of this quarter, early next quarter, we will be in a position to put the produccts into distribution. So right now we have an effort ongoing on their side, for market access. Our market access team is working with all of the major accounts to be able to get active for the product as we start promoting it. Simultaneously, we are building a commercial infrastructure where we have 70 people and the OBGYN salesforce already, but expanding the OBGYN salesforce. So on the commercial front, we are in the phase of recruitment, both the management team, sales management team as well as the reps and expect to have them on board also in April. So managed care would be taken care of and the commercial build. The messaging has been fairly clear based on the work that Symbiomix did. So we are in the process of really working with our marketing group to be able to churn out all of the materials to promote the product and lastly, we have a significant effort ongoing with on the KOL front with a medical group. They have been working both on publication as well as speaker programs to be able to disseminate the product information to the thought leaders and the broader OBGYN. So all of those efforts are ongoing right now. We in early stages talking about lifecycle management but we have a long runway with the products, so are taking our time to really determine what would make sense on the lifecycle management.

Shyam Srinivasan: So we are on track for the mid 2018 calendar year launch, right?

Vinita Gupta: Yes, we are.

Shyam Srinivasan: Okay, it is safe to assume that the cost that you are talking about for the front end is not yet in the numbers, you can see a ramp up in cost going ahead because of these recruitments?

Vinita Gupta: Yes. So we have small amount of expense in the last quarter, in Q3, but it will ramp up in this quarter and will have good amount of investment in Q1 of next fiscal year.

Shyam Srinivasan: Okay. My second question is on Minocycline FTF, we are not sure whether you have FTF on all strengths, we see about 5 strengths, but is it for all the 5 strengths that we have in FTF or is there….

Vinita Gupta: We have on one strength and we have final approval on the product.

Moderator: Thank you. The next question is from the line of Alok Dalal from CLSA. Please go ahead.

Alok Dalal: Just one clarification on Ranexa, are you guys pursuing site transfer still?

Vinita Gupta: We have final approval on the product.

Alok Dalal: Yes. But Vinita this approval would have come after the warning letters. So can you launch the product from the plant?

Vinita Gupta: So what we are doing with the product that have final approvals is they are proactively going to the FDA with a full assessment on the product along the lines that we have committed on all other products that are subject to the warning letter just to be abundantly cautious and informing the FDA beforehand about the work that we have completed and therefore our plans to launch the product.

Alok Dalal: So, this is your understanding that FDA will allow you to launch the product from an affected plant?

Vinita Gupta: That is our understanding. They are allowing us also to currently supply product from the affected plants.

Alok Dalal: Yes, but those products are already in the market whereas this is a product which is to be launched.

Nilesh Gupta: Our understanding right now Alok is that, yes we would be able to launch the products.

Vinita Gupta: And again we are working right now on this approach that I mentioned. If we learn anything different, we will accelerate.

Nilesh Gupta: Our bigger goal of course is to try and resolve the warning letter within the calendar year as well. We will see how that goes.

Moderator: Thank you. Ladies and gentlemen, that was the last question. I now hand the conference back to Dr. Kamal Sharma – Vice Chairman for closing comments. Thank you and over to you, doctor.

Dr. Kamal Sharma: Thank you, ladies and gentlemen I hope you had answers to all your questions and we now look forward to interacting with you in the next quarter. Thank you very much.

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