“Lupin Limited Q3 FY'17 Earnings Conference Call”

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Moderator: Ladies and gentlemen, good day and welcome to the Lupin Limited Q3 FY'17 Earnings Conference Call. As a reminder, all participant lines will be in the listen-only mode. There will be an opportunity for you to ask questions after the management's commentary concludes. Should you need assistance during this 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. D. B. Gupta – Chairman, Lupin Limited. Thank you, and over to you, sir.

Dr. D. B. Gupta: Friends, I welcome you all to Lupin's Q3 Earnings Call. People who are present here are, Kamal, Nilesh, Sunil, Vinita, Ramesh, Arvind, Rajiv Pillai, Naresh and Rajeev Sibal.

I am happy to inform you that sales in this quarter crossed 4,400 crores, higher by 31.5% against corresponding quarter. Sales growth in nine month is 34.3%. Profit in Q3 is 633 crores, higher by 21% over corresponding quarter.

Profits for nine months, that is 2,177 crores, is almost equal to the last full-year's profit. R&D spend of the Company continues in the range of about 13%. During this quarter, we completed acquisition of 21 products from Shionogi in Japan.

I welcome you, all the best, and we're open to start talking now. Thank you.

Ramesh Swaminathan: Thank you Chairman, may I take over from you.

So in terms of our sales, as the Chairman was saying, our sales were up about 32%, in terms of EBITDA, we grew by 45%, so indeed a very good set of numbers. But what is particularly pleasing was that this growth is reflected across all our geographies. So it's been secular growth across geographies. US leading all the way with 58% growth year-on-year, Japan was 19%, LATAM, a small geography from our perspective, still going at 33%, India despite the demonetization, is growing by 12% and EMEA by 17%.

Overall, gross margins were about the same as previous quarter, but what is more pleasing is the fact that the EBITDA margins went up and people have been asking me this question as to how we were able to manage that. That's

obviously because of having a tight leash on cost, some beneficial impact coming in from FOREX and of course R&D down by about 0.7%.

The other thing that has been asked about is essentially how much of FOREX impact is there in the overall results itself, and to tell you that it's just about Rs.27 crores, while the swing between quarters is about Rs.72 crores.

In terms of effective tax rate – that's been another question that has been asked, that's essentially because of unwinding of the deferred tax asset, it is particularly low in the previous two quarters, the overall rate, and of course the subsidy losses across geographies. But we do expect the overall ETR for the year to be around 28%. Now we'd be very happy to take on questions from here on.

Moderator: Thank you very much sir. Ladies and gentlemen, we will now begin the question and answer session. We have the first question from the line of Prakash Agarwal of Axis Capital. Please go ahead.

Prakash Agarwal: Thanks for the opportunity sir, and congrats on good set of numbers. I'm just trying to understand the US business quarter-on-quarter growth of 8%. So this is despite some competition seen in Fortamet. If you could help us which are the key launches which has held or would it be due to some price hikes, if you could just help us understand Q-on-Q growth?

Vinita Gupta: Prakash, it was growth in products like Glumetza, Fortamet obviously had additional competition of Mylan through the quarter. Glumetza did better because we took more share from the brand during the quarter, and other smaller products as well did well during the quarter. So the combination of Glumetza plus other products.

Prakash Agarwal: This clarification has smaller products from the new launches side, madam, or you know the existing products in the base business did also some…?

Vinita Gupta: No, primarily new launches.

Nilesh Gupta: And also more of the Somerset pipeline, Somerset business kicking in.

Vinita Gupta: Well, from the Somerset front, it was more Methergine, so the brand side of the business also contributed to the growth in the quarter, in sequential quarters, the brand business has gone up 25% or so.

Prakash Agarwal: Sequentially 25% up?

Vinita Gupta: Yes.

Prakash Agarwal: Okay. And second question on India business, despite demonetization issues, 12% growth is a very good growth, I would say. Is there any one-off or we see this moderating in the coming quarter or we expect the growth to be much better and this is being lower due to de-mon?

Rajeev Sibal: Yes, absolutely right. If you look at our Q2 growth, our branded business has grown by 14%-15%. Because of demonetization we have been impacted in this quarter by 2%-3% but we are very sure once the demonetization impact lessens, obviously we will be back to the track of 15%+ growth.

Prakash Agarwal: So what you're seeing in January month, is it behind us, we are back on track or we are still seeing some effects still left?

Rajeev Sibal: I think some effect is still there, we are very sure that it will take more two-three months, but I think April onwards we will be back on 15% plus growth.

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

Manoj Garg: Vinita, just like to understand your take on this recent AG launch of Glumetza, how do you see the competitive landscape evolving and when do you see maybe other competition getting into the market?

Vinita Gupta: So Valeant has already launched their authorized generic. I mean, we had AG-free launch for 12 months. So there was always the potential of Valeant launching in 12 months. We expect the generic market to expand a little bit given the Valeant launch. So far, we had 75% of the market that we converted to generic and 25% remained with the brand. So we're looking forward to that market expansion. We would expect Sun and Teva to launch at some point over the next 12 months, we have heard that Sun potentially will launch in the second half of this calendar year, third quarter, and Teva,

in one of the recent presentations had put Glumetza in the risk adjusted bucket, to launch in Q2. So it's hard to predict, but we would expect some point over the next 12 months for Teva and Sun to launch.

Manoj Garg: Fair enough. And if you look at in this quarter, like since you have got around 11 approvals and particularly I think post Goa clearance, we have seen the definite ramp-up in the new approvals and we have launched four products so far in this quarter. So if we have to take into consideration the next 12 months, how do you see the launch calendar and do you think that we have enough in our pipeline to offset any incremental competition which is going to come in Fortamet or Glumetza?

Vinita Gupta: So we have 25+ products that we have the potential of launching in the next 12 months, and some larger ones, a number of small ones as well, but just looking at the next 12 months beginning – for the start of the next fiscal year, we have Minastrin that we intend to launch, - Epzicom, which should be a limited competition product, Bupropion XL, which is a challenging product, plus a number of products that we have ramped-up production at Somerset, number of control substances plus KCL, a challenging product. This is what we expect on the generic side of the business. And then on the brand side of the business, we are still ramping up Methergine. In the last 9 months, we have brought the brand up to $4 million a month kind of level, and it continues to grow. So we hope to build it up further into the next year. We expect a number of these product launches will help us offset the erosion in Glumetza, but it's hard to predict how much and we're looking forward to get through the next couple of months with some of these major launches to determine what we can expect in terms of run rate with some of these new products.

Manoj Garg: Sure. That's very helpful. And Ramesh, just one question, while, you alluded the reason for the higher tax rate for the quarter, is there some inventory build-up during the quarter, which probably had also resulted this higher tax rate in the US?

Ramesh Swaminathan: Actually it's lowering of inventory, products just transferred from our Swiss operations and so on.

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

Neha Manpuria: In the US business, Vinita, if you could just explain to us, how you're seeing pricing, particularly with the upcoming McKesson Walmart negotiations? Do you see it being higher than the high single-digit, double-digit that peers are talking about and even you have alluded to in the past?

Vinita Gupta: No, we see price erosion at the high single-digit level, Neha. And I think this will vary from company to company depending on the exposure they have to McKesson Walmart. We have taken that into account and believe that will be at the high single-digit.

Neha Manpuria: Okay, noted. And second on Japan, Japan constant currency growth seemed muted in this quarter, was there any particular reason for that, particularly given that in the first half, we have been doing 10% - 11%?

Nilesh Gupta: Yes. So the main pushback was on the reform that the government got on generic substitutions, basically taking away some of the benefits that pharmacies get on substituting generic product. I think in some of their dispensing benefits taken away as well and that was the kind of a one-time impact in the quarter. Obviously on the positive side, we have the Shionogi portfolio kicking in, we only had a few days of that coming into Q3 so Q4 will be the full effect. Obviously as we fold the Shionogi business into ours, we basically expect strong double-digit growth in the next year.

Neha Manpuria: Got it. And my last question is on the other expense. What would be the foreign exchange impact, if at all in the other expense? Because if I strip out the R&D spend from the other expenditure, there seems to be a good decline quarter-on-quarter?

Ramesh Swaminathan: As I said, the overall FOREX impact for this particular quarter is about Rs.27 crores in terms of positive impact, and this is spread across various lines. We have something on the sales line and we have got something else in other lines as well. So overall Rs.27 crores.

Nilesh Gupta: So there is some FOREX line in that as well.

Sunil Makharia: No, in the sequential quarter, there was a FOREX loss of Rs.56 crores, which was there in the expense line in the sequential quarter, which is not the case now in this quarter.

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

Anubhav Aggarwal: One question on Methergine. Vinita, if I just see the IMS prescriptions, they still show that the brand is only one-third of the total prescription, let's say we just add up Lupin and Gavis volumes, whereas you seem to suggest that the brand size already about $50 million. So is IMS, let's say, reporting the prescription on the brands?

Vinita Gupta: No. So, our data suggests, Anubhav that it's 50%, the brand in terms of unit dispensed from retail. Maybe it's a prescription versus dispensing that where we have the difference. We are looking at 50% of the prescriptions are dispensed with the brand, 50% still with the generic because the retail still had the generic bottle on the shelf.

Anubhav Aggarwal: And I was just seeing that just year-on-year on the prescriptions, if I look at the total market of Lupin plus Gavis here, prescriptions are down about 20%, so which is the other product that we are losing this prescriptions to?

Vinita Gupta: So you're right. The prescriptions are down, the units are down overall 20% and the product, when we took it over was declining at that level already over the last few years. And our hope was that we will, one, start stabilizing the decline that we saw for a few months, in the last couple of months and then hopefully with our promotional effort, be able to grow the volumes as well.

Anubhav Aggarwal: If you can just help, which is the alternative for this product, so if the prescriptions were declining, who was gaining, which other product?

Vinita Gupta: So actually there is no alternative for the product, the only alternative is injectable Methergine in the hospital as opposed to having the patient use oral out of the hospital. If the physicians require the patient to stay longer in the hospital and get injectable, that would be the one that you can substitute it for the oral.

Anubhav Aggarwal: And on Renvela can you provide some update, some of the Indian peers seem to have hinted towards significant amount of delays with the recent queries they got from FDA. What's the status for us?

Nilesh Gupta: I think everybody is in the same bucket on that one. And this is what we had shared last quarter also. We had queries back from the FDA and we believe that the rest of the portfolio, they would ask the same kind of questions as well, which is why we're trying to address all of them comprehensively. We now have CRLs spending on pretty much all of them and the intent would be in the next quarter to respond to those CRLs. We had earlier guided to a late FY'18 approval, I would still hope to do that if the FDA accepts the priority review, which they were willing to consider in the past, but hopefully this is still late FY'18 or otherwise early FY'19, then. But I do think that everybody's in the same bucket and the FDA is also evolving its position on this.

Anubhav Aggarwal: So just to understand, the same will be the fate for Welchol as well?

Nilesh Gupta: Yes. Absolutely.

Anubhav Aggarwal: And what are the FDA queries, in general, I'm not asking a specific query here, so they have a guidance you guys have worked as per the guidance or is it that the FDA is trying to ask more than the guidance what they have done?

Nilesh Gupta: Yes, they're moving well beyond the guidance.

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

Surya Patra: Just wanted to check, excluding the Methergine performance, what is the kind of a performance that you're seeing for the Gavis business excluding the branded business?

Ramesh Swaminathan: It's shaping up very well, Surya. Obviously there are some teething problems because we took some time in setting up the capacities and the like. But overall, we are fairly happy with that acquisition and you would see better results coming up in the next several quarters.

Vinita Gupta: So you had a number of product approval that you got over the last six months that we have just prepared now in the last quarter after the facility expansion was in place, it's gone through the validation batches to roll out these launches. So far we have launched four products and we're going to be launching another three before the end of this fiscal year. So on the

generic front, Somerset launches have not contributed as much as we had hoped to, in this fiscal year, we are going to start seeing a contribution starting this quarter itself to help set the tone for next year.

Surya Patra: And the sequential improvement in the US business is led by new launches, or it is because of the flu season contribution? What really has contributed to the sequential improvement?

Vinita Gupta: So as I mentioned earlier, it was a combination of Glumetza, we were able to take a higher share of the Glumetza molecule that was one. Second, we launched four new products, two out of India, two out of Somerset, so they contributed. Third, Methergine ramp-up, sequentially the brand business went up 25%, a large part due to Methergine. And fourth, you're right, seasonality on the Cephalosporin certainly contributed.

Surya Patra: Okay. Regards the plant inspection schedule, can you just give some light, any of your plant that is scheduled for FDA inspection in the next six months or so?

Nilesh Gupta: I think we had a whole set of inspections last year for pretty much all our meaningful facilities. And as you know, we have come out very well through that. And I think for the most part, the FDA still thinks to open that two-year cycle, but obviously, products get supplied much more, product get inspected more often as well. So hard to say at this point of time, but I'm sure we will have a few inspections in FY'18.

Surya Patra: Just one last question. On the tax front, whether we are guiding for a higher tax incidence for current financial year at 28%, which was earlier something at 25%, what we are indicating and that would be the same case even for the next year?

Ramesh Swaminathan: Next year is too early days to say anything because the overall weighted deduction is coming down. I would imagine there would be some impact. For the current year, I think we already said this is within 26% to 28%. It will actually come down from the previous year.

Moderator: Thank you. Our next question is from the line of Aditya Gupta of Narnolia Securities Ltd. Please go ahead.

Aditya Gupta: Sir, what is the CapEx guidance for FY'17 and FY'18?

Ramesh Swaminathan: So last year we had new facilities being commissioned in Japan, so that obviously was a fair bit and we have a new R&D facility coming up at Pune and all of that. So we do expect, in fact this year would be closer to the 1,900 crores overall capital expenditure. Next year it will come down quite a bit, perhaps around 1,300 crores - 1,400 crores.

Aditya Gupta: Okay, sir. And what is your guidance on your filings in the fourth quarter?

Nilesh Gupta: So we typically have a higher number of filings in the fourth quarter. I think overall between Somerset and Lupin India, we should be filing well over 30 ANDAs, cumulatively for the year.

Aditya Gupta: Okay. And is there any plan for reducing the debt?

Ramesh Swaminathan: Our EBITDAs are obviously growing and all of these results in cash accruals. Debt, in net terms it will - be coming down. So there is of course we have committed to the syndicated loan till such time but we would also have other accruals coming in. It's already come down.

Sunil Makharia: At the beginning of the period it was in the range of over 6,400 crores, which is now already at the level of 5,400 crores. So this has already come down by almost 1,000 crores, despite our acquisition of the Shionogi portfolio.

Aditya Gupta: And is there any plan to reduce the debt further?

Ramesh Swaminathan: The fact of the matter is, we are a Company which believes in growing by acquisitions also, and we're pretty fairly acquisitive there. We are still looking at assets on the specialty front. So we are pretty opportunistic on that score. So it's really a function of how successful we are in our pursuits.

Aditya Gupta: So my last question is for you. First to file, is there any data you have guided because we have got 13 new ANDAs. So how many of them are for first-to-file?

Nilesh Gupta: We will find out right, so obviously some of them we are targeting at potential first to file, but only on filing will we have a proper tally. I think when we

connect to you guys in May we will be able to give you a complete picture of what we were able to do in FY'17.

Vinita Gupta: One thing we'd like to add is, on the pipeline front, we made significant progress on our complex generic pipeline in the last 12 months as our R&D investment has gone up, we have evolved our inhalation pipeline, our biosimilars pipeline, we have filed our first major inhalation product, we filed Albuterol MDI last quarter and have multiple DPIs in various stages of development. And on the biosimilar front, we have continued to make progress on Etanercept with a Phase III trial.

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

Rakesh Jhunjhunwala: I'm asking a very general question. All these speculation about what Trump is going to do and pricing for today's earnings report, now pricing is stabilizing, it's going up from there, at some places. So what's your take on all these speculation on the American part of the business? General, I mean, not specific to Lupin, but general to the business?

Vinita Gupta: Generally, Rakeshji, there is a lot of concern around drug pricing over all, even before the Trump administration started and that doesn't go away. There has been a public outcry to price increases and lot of scrutiny on drug prices, more on the brand front than on the generic front. From our perspective, the generic business, the generic industry is a solution to the problem to really be able to bring drug prices down you have to bring more affordable medicines to market. So I expect the market for the generic industry to continue to grow and just given the Trump administrations move to also try to deregulate perhaps will accelerate the pace of approvals from the FDA. We have already seen a good level of acceleration over the last couple of months, but hopefully that will improve further with the de-regulation moves from the administration, plus hopefully they come up with better regulatory pathways for more complex dosage forms like inhalation products, like biologics to again be able to bring more affordable products to market. So I think overall it should be good for the generic industry.

Rakesh Jhunjhunwala: And what about current pricing pattern in 3Q reported, as you know, pricing is stabilizing and even going up at certain places?

Vinita Gupta: Well, sir, pricing is stabilizing from the standpoint of price erosion, I would say. I mean the generic industry has been under so much price pressure in the last few years, I mean every year we have seen double-digit price erosion because of customer consolidation pressure, competitive pressures, government pressures, it's only so much that you can afford to erode pricing, I mean at the same time, the cost of staying in business has gone up from a regulatory perspective, compliance standpoint and the investment in R&D has gone up because of the need to really go after more of a complex generic pipeline. So I'd say that that is what is really driving the pricing pressure to go down to maybe still saying that we would likely have price erosion, but more in the single-digit level given all of the pressures that we have already seen over the last many years.

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

Girish Bakhru: Couple of questions on US side. Vinita you said, some of the small products have done well in the US in this quarter, but if I actually look at some of the recent launches like Nuvigil and Vfend® our market share has been very low despite six weeks, seven weeks of launch. Is there any capacity issue that has been constraining that?

Vinita Gupta: No, we have just started with some of those launches. So relatively speaking, it's a small number, but it certainly has added to our revenues over the Q2.

Girish Bakhru: And on Fortamet, I mean, how do you read the new filing by one of the peer companies, if you could throw some color on when, according to your best case, can be a competition incremental?

Vinita Gupta: I would think that because the patent is outstanding, a good number of years, I would think that they would have the 30-month stay, so they will go through litigation and we think this brand has the incentive to litigate with them because the brand had, before Mylan launched, 50% of the market, we were sharing the market with the brand through the AG. So we would expect that they would litigate on the Para IV and we would expect a potential Aurobindo launch in 30 months or thereafter.

Girish Bakhru: And one question on the controlled substance you launched morphine recently, hydrocodone is still not launched and just on overall guidance perspective, if you could throw some color where do you see this piece evolving say in 2-3 years of time, can it be say 10% of the US business overall?

Vinita Gupta: Yes, certainly will be a big part of our growth into next year. I mean, hydrocodone had not been launched but it's actually just been manufactured and released. So our team is in the process of launching it right now. And as we look at next year, a good portion of the Somerset launches are going to be the controlled substances. And if I look at the total controlled substances market in the US, it's a $30 billion market. And what we have in terms of the covered market with our portfolio and pipeline out of Somerset is roughly around $12 billion. And then the C3 and C4 is out of India is another $7 plus billion. So we have covered $20 billion, both our products through our pipeline in Somerset as well as India. So we would expect the next year, a good number of controlled substances to be launched out of Somerset and so a significant contribution maybe year after will be more meaningful than next year because on the controlled substances, it still takes time to build up share. The DEA will allot quota only after you have proven to them that you can gain shares. So it's a little bit of a chicken and egg story there. So because of the ramp up, we expect more of a meaningful contribution in the year after, but we will see a significant number of launches in the next 12 months.

Girish Bakhru: So currently does Somerset has a sizable quota or the quota is very small?

Vinita Gupta: It's small right now.

Girish Bakhru: Okay. So as you launch more products, you basically gain on the quota?

Vinita Gupta: Yes. And as we are launching products, we are demonstrating to them, you gain market share, all you have to demonstrate confirmed purchase orders to them to get the quarters allotted. So we're in the process of doing that right now.

Girish Bakhru: Okay. But would you still say that in FY'19 perspective, this could be $150 million plus controlled substances put together?

Vinita Gupta: It certainly has the potential. In the next year we expect all of the areas that we have been investing in controlled substances together and dermatology products in India as well as Somerset, we would expect to launch a good number of derma products next year as well.

Girish Bakhru: Okay. And just last final question on the ADHD film products, I mean, there are, I think two, three more partners with MonoSol, are they exclusive on each product like suppose if you're filing Suboxone or something like products, would you be exclusive on them with partnership with MonoSol?

Vinita Gupta: Yes. So the ADHD product concepts are our concepts that we developed with our medical and clinical and marketing group and we are developing it with on their platform, so they are exclusive with us on those products.

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

Nimesh Mehta: Can you quantify the total branded sales this quarter, and also if you can help us know what is the sales of Suprax, that will be helpful.

Ramesh Swaminathan: $22 million is the total brand sales in US for this quarter.

Nimesh Mehta: And it would be largely Suprax or it will be kind of equally divided with…?

Vinita Gupta: It was actually Methergine is a big part of it and followed by Antara is our second largest brand and Suprax is third.

Nimesh Mehta: Okay. So I was asking this because we recently saw a generic approval of Suprax just yesterday on the oral suspension. So this should not be a meaningful impact on our numbers?

Vinita Gupta: No it will not. I mean actually the Suprax suspension is the smallest part of our Suprax franchise, it was $1 million in the quarter.

Nimesh Mehta: Okay. Thanks And on the Albuterol MDI that you mentioned that you filed an ANDA, so just wanted to know whether it's an ANDA or NDA under the 505(b)(2) route, so basically is it interchangeable?

Vinita Gupta: It's ANDA to ProAir.

Nimesh Mehta: Okay, understood. And if you can give some guidance on some of the important launches that we feel, you can correct me if they are not important, Prevacid SoluTab and Travatan Z that will be helpful.

Vinita Gupta: Sorry? What products you mentioned?

Nimesh Mehta: Prevacid SoluTab.

Vinita Gupta: Yes, that would be a decent product. The more meaningful products I mentioned earlier, I mean we will have Minastrin, which will be a large one for us where we are first-to-file, that will be next month. Epzicom, end of next month where we have multiple competitors, but still limited number of competitors we expect in the market. And then products out of Somerset, products that KCL, hydrocodone APAP and oxycodone APAP, Vigamox would be a major one. And we have multiple, it's hard to predict all the launches, we have multiple litigation products that could potentially be opportunities for next year, we're looking at products like Namenda that are in active litigation right now, that could be an opportunity in the year. Products like Restasis, there's again pending litigation outcome that could be an opportunity during the year. So a number of opportunities subject to litigation outcomes.

Nimesh Mehta: Namenda would be Namenda XR, right?

Vinita Gupta: That's right.

Nimesh Mehta: Okay. And just last one, sometime back you received an approval on the generic Norco tablets, which hydrocodone bitartrate and acetaminophen, I was surprised, I mean there was an AA rating written on that. So is this an interchangeable product for my benefit, if you can tell me.

Vinita Gupta: Yes, it's definitely an AB rating from what I believe, because we're in the process of launching it right now.

Nimesh Mehta: Okay. It was mentioned as AA rated. So I was not sure what does it mean, so that was the reason and…?

Arvind Bothra: Nimish, if I may add, all the generics in the market currently are AA rated. And the difference between AA and BB is that the bio study requirement is

much lower in AA. So in a sense, they are far more substitutable from FDA's standpoint.

Nimesh Mehta: Okay, thank you. So if this is true, cannot this be an important launch for you, because I guess there is very little competition on the sales of these…

Vinita Gupta: It is a very important launch for us.

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

Prakash Agarwal: Just more color on the respiratory front, if you could help us where we are, in terms of development and approval for generic Advair? I mean, last we spoke about was entering clinical trials, I think fiscal 2018 and getting approval by 2019 and something like that. I mean, is that what we're still looking at?

Vinita Gupta: Yes, Prakash. So we're making significant progress on Advair. It's at the point of exhibit batches right now. We have gone through a pilot study successfully and have planned the clinical trials. So if everything goes well, it will be a fiscal year 2018 filing.

Nilesh Gupta: So we're on track with what we had said before.

Prakash Agarwal: And questions for Ramesh on SG&A. If I understood that correctly, so it was the last quarter, which was impacted by Forex loss and that's the bump.

Ramesh Swaminathan: That's right.

Prakash Agarwal: And Y-o-Y, but still also Y-o-Y, if I see this is just 4% growth, so?

Ramesh Swaminathan: There is the operating leverage kicking in.

Prakash Agarwal: So such a large business and, because of operating leverage, you're seeing is 4%?

Ramesh Swaminathan: That's right. So there is considerable operating leverage kicking in.

Prakash Agarwal: And if you could also share, last quarter if we normalize with Forex, how would it look like?

Nilesh Gupta: I think we will have to get back to you on that.

Ramesh Swaminathan: Yes, we will get back to you on this, sir.

Prakash Agarwal: Okay, thanks. And Japan, if I heard the comment correct that the Shionogi asset is consolidated, but we have not seen the numbers, so it would be the fag end or maybe a couple of days of consolidation, is it?

Nilesh Gupta: That's correct. It was sometime in December and we will obviously get full Q4.

Prakash Agarwal: Okay. And lastly on the other income, so if you could just break it up because there's been a little jump there?

Ramesh Swaminathan: So other income is principally because of the fact that we had this Forex coming in. As I said, we had it last time which came into the manufacturing other expenses, while this time it is a profit, we take it under different head.

Prakash Agarwal: What would be the quantum of gain?

Ramesh Swaminathan: About Rs.74 crores.

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

Surjit Pal: When you were talking about domestic sales 15% growth post de-mon, even including two months of impact in Q4, are you also considering that GST rollout in FY'18? I mean, as of now, it is supposed to come in June, July. So even if you consider the destocking condition in say Q1 one quarter before and after this say two months after that, even if you consider that, do you believe that 15% growth is achievable in FY'18?

Ramesh Swaminathan: I will answer this question. I think the fact of the matter is GST is certainly going to be disruptive because whenever there is a change, any structural change of this kind, obviously the trade will kind of destock because they're a little uncertain about the way the impact would pan out for them. So one would expect in fact destocking to happen in that particular quarter. It's over quarter that actually gets rolled out. But then things will come back to normal.

So if we had talked about secular growth rate for India over the next couple of years, you could at least say it's going to be 15% to 20%.

Surjit Pal: I'm still not clear. When you were estimating something else, you still believe that 15% if it's GST or no GST is achievable?

Ramesh Swaminathan: Yes, between quarters, there could be some volatility, but over a period of time this will at least pan out to be okay.

Surjit Pal: Ramesh, another thing is that the kind of gain you have made in leading margins or headline margins, do you believe that it is sustainable going forward in all the quarters?

Ramesh Swaminathan: As you are aware of the fact that we are kind of investing ahead of the curve, but for those bumps here and there in terms of R&D and the like, you generally see the EBITDA to be hovering around at 26% or 28%.

Surjit Pal: Okay. My last question is on the recent changes in US political scenario and which could come into your business like say border tax or possibility of something like forcing companies over there to put a plant over there. Do you think that could put a pressure on the operating margin benefits, which we have producing product in India? Even if you consider that, that could be a possibility given that make in USA kind of scenario could come up. What will be the likely possible impact at operating margin even if those case comes in?

Vinita Gupta: So we think the border tax overall, not only in pharmaceuticals, overall will have the impact of raising the cost of products for Americans and including drugs. So the solution is you could manufacture locally, where your cost of manufacturing is going to go up, but the whole industry is not going to switch to that. Even if you look at the generic business, 40% of generics are supplied out of India and good 50% plus ex-US. So if there is a border tax on generic products, it would automatically have to be passed on to the consumers and patients and the healthcare system. So you would have a price increase, in fact, either through importation of the product or because you manufacture locally and therefore your cost of manufacturing goes up.

Surjit Pal: I mean when you were saying this, you also consider that for a single older generic where 7 to 10 guys are present, do you think this could be overall

scenario that all the guys will push up the price because of the passing on of the increase in manufacturing cost or this kind of over competition intensity may not be reflecting into that kind of increase in push up the price because of the cost?

Ramesh Swaminathan: Yes, there are quite a few other things also. So the fact of the matter is, if the overall costs go up then the interest rates will go up and that would actually mean that the dollar would strengthen and that itself could be a self-defeating move from the US perspective, because that would make imports cheaper. He's also talking about for example, making all of these imports not tax deductible from a US company perspective, that again, would been a very different thing. So all of this is, and it actually test the very fundamentals of free trade and the like worldwide. So there is a lot of uncertainty around all of this, and it's very difficult to conjecture on the way it's going to pan out. So we will take it one step at a time, it actually manifests as a law, then we will certainly cross the bridge when we actually come to it.

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

Nitin Agarwal: Vinita, on Methergine, in the new GDUFA environment where approvals are expected to be fairly accelerated, I mean, is it not a risky strategy to pursue in terms of trying to build a brand around off-patent product, are there some specific manufacturing complexities associated with this product also?

Vinita Gupta: Well, there certainly are manufacturing complexities around the active ingredients and the finished dosage. So that was the one level of barrier that we liked. Second, we knew the product was really small before we took it over. So from that perspective, we would expect as we ramp it up, people are going to take a look at it and certainly will start developing generic. Third, we started workaround lifecycle management of Methergine even before we closed the acquisition. So we are pretty far along the way to develop a lifecycle management products as well for Methergine.

Nitin Agarwal: And secondly on Fortamet, have you seen any change in the price competition dynamics in the market over the last quarter or so?

Vinita Gupta: We certainly had lost some share to Mylan as well as we had erosion in price.

Nitin Agarwal: But is it sort of stable situation where the three-play market being it is, isn't it in a stable state right now?

Vinita Gupta: Yes. Now, I mean they would still and in the last quarter, you did not see the buildup of the Mylan shares, so they have made certain commitments in the market. They have got a certain segment of the market and we know what share of market they have at this point and it will certainly have an impact on our share as well as our pricing.

Nitin Agarwal: And that should reflect in this quarter?

Vinita Gupta: That's right.

Nitin Agarwal: And lastly, this Vigamox you mentioned, it should be more like a June quarter opportunity for us or it will be second half of the year?

Vinita Gupta: In July this year.

Nitin Agarwal: And that should be a limited competition opportunity for us?

Vinita Gupta: That should be as well, yes.

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

Anubhav Aggarwal: Just one question on Vigamox itself. My understanding was this will be at least 10-20 products where generics lost the case so and there were like five or six companies who are pursuing this opportunity. So you think you will have lower competition from five or six guys or all those guys will enter next year?

Vinita Gupta: So, it's very hard to predict who all will enter.

Anubhav Aggarwal: No, if we assume everyone gets FDA approval, is there any litigation or settlement which blocks others from entry?

Vinita Gupta: Yes, so, I mean a number of companies are still litigating. So depending on where they are, we believe that it could be a limited number of players that make it to market.

Anubhav Aggarwal: And we are not FTF, I think Actavis was the FTF on this one.

Vinita Gupta: That's right.

Anubhav Aggarwal: They will come, only then we can end up with that?

Vinita Gupta: No, I think there's a forfeiture also, yes.

Anubhav Aggarwal: Okay. And just one thing on Minastrin, now Amneal and Mylan both have settled on that. Do you think how extended exclusivity can it be because we have certainly six months, but looks like with the Amneal launch, can it be like more than 10 months of exclusivity for us?

Vinita Gupta: No, I would count on the six months, Amneal we would expect to get to market on Day 181.

Anubhav Aggarwal: Okay. And will it be fair to assume this the other player enters in FY'19 itself?

Vinita Gupta: Yes, they are more players later.

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

Rahul Sharma: Just had one question was on the interest part, on Q-on-Q, we have certainly gone up quite a bit. Just wanted your take, is there anything to look beyond other than Forex part or what is the reason for this?

Sunil Makharia: You're talking about the increase in the interest amount?

Rahul Sharma: Yes

Sunil Makharia: So as you will see that, it's again obviously, again the sequential quarter. So in the sequential quarter, we have taken the loan for the Shionogi portfolio. Also there is an interest rate increase you can see how the interest rates in it, because most of our loans are in dollar terms, so the interest rate has been increasing on that. And also we do some of the borrowings to take the advantage of arbitrage opportunities. So it has to be seen, the net of the interest income with the interest income which we have on the surplus funds. So we see the net of interest income then the amount is lower.

Rahul Sharma: Okay. But just wanted your take, how do we look at this number going ahead, it will be much lower than Q3 or similar?

Sunil Makharia: No, it would be more or less at same level, we feel that. It should come down little bit, because the overall debt should come down with the increased earnings. So it should come down little bit. But in any case, the interest in the overall P&L interest is not a large number.

Rahul Sharma: Okay. Is there any substantial increase in the borrowing or it's not. It's just a function of your…?

Sunil Makharia: If we compare from the beginning of the year, as I said earlier, the loans have come down, it has come down by almost 1,000 crores, but in the sequential quarter it has increased

Ramesh Swaminathan: Because of Shionogi.

Rahul Sharma: Okay. How much is it come up because of Shionogi in this quarter? Any…?

Nilesh Sharma: I don't think we disclosed that in the past.

Moderator: Thank you. Our next question is from the line of Krishna Prasad of Franklin Templeton. Please go ahead.

Krishna Prasad: If you could talk about your view on how the M&A market, and specialty pharma in the US is shaping up, what are your views around that at this point in time?

Vinita Gupta: The whole specialty market in the US is down quite a bit, the sector has been down. At the same time, one is not seeing too many transactions happen. So people are not really transacting at the current level of valuation. I think when you look at specialty assets there are not too many companies now that commercial stage companies, mid-size $1 billion organizations that are out there, that one can look at. So we expect to see a lot more on the pipeline front when you already see number of mid and large size specialty companies transact on the pipeline. And we expect to see smaller companies as well as ourselves really looking at pipeline to build the specialty business.

Krishna Prasad: Just to follow-up, I mean would you be willing to take up higher risk on the pipeline or would you increase your size to buy a larger commercial company, which one would be more favorable for you?

Vinita Gupta: We will look at both, but like I said, there are not too many commercial stage assets or already commercialized assets that are available, that have everything that one looks for in a growth asset. So it would have to be a combination of pipeline plus and to try to build the business on a sustainable basis.

Moderator: Thank you. We will take the next question from the line of Ashish Thavkar of Motilal Oswal Securities. Please go ahead?

Ashish Thavkar: Could we have an update on Albuterol filing?

Vinita Gupta: We just filed the product.

Ashish Thavkar: Okay. And you believe there could be couple of guys who might be on schedule along with us?

Vinita Gupta: Yes. I think the first one is Perrigo, and we think there is going to be three to four players based on all of the activity that we have seen so far.

Ashish Thavkar: But it's a $2 billion brand, right?

Vinita Gupta: It's a $3 billion market.

Ashish Thavkar: Again ma'am, last question would be on, if you could give us an update on how Advair trials are progressing? Have they started?

Vinita Gupta: As I mentioned earlier, we have developed the product, we have done pilot study. We are in the process of manufacturing exhibit batches and we have planned the clinical trial.

Ashish Thavkar: And that should take around 18 months, the trial?

Vinita Gupta: No, we expect to go through the clinical trial in the next fiscal year and file within fiscal year 2018.

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

Shyam Srinivasan: Just on the earlier point that was dwelled a bit on delayed in key approvals. I think several of the companies now have actually mentioned this, so is there something that's structurally changing with respect to key large opportunities, is the US FDA kind of prioritizing the easier ones so that that they can get through the backlog, is that something that's a valid argument?

Vinita Gupta: Well, we're certainly seeing the simpler products getting approved fast. We have seen a number of our simpler products get approved within 14 months to 15 months in the last six months, which is promising. At the same time, I think the delays are on products, where you don't have clear FDA guidance or where FDA is still evolving their thoughts. So I think it is a lot to do with the FDA guidance itself.

Shyam Srinivasan: You think that this is going to last for some time before the FDA kind of gets its head around how to get through some of these drugs?

Vinita Gupta: They're trying, the FDA is working at it, they came up with guidance on inhalation products, Advair in particular, they have had good dialog with us on majority of the inhalation products. On the biosimilar front, I know that they're still working on an easier pathway to get biosimilars approved. And if the Trump administration efforts to try to deregulate the industry, they're going to try to get the FDA to get products approved quicker, so we would expect that overall where we are right now and the current market sentiment, current dynamics, the approval rate should improve.

Shyam Srinivasan: My last question is just a clarification on the branded numbers. I thought our last quarter US branded number was $22 million and you said sequentially they have improved by 28%. So I'm just trying to reconcile those two numbers.

Ramesh Swaminathan: It's $18mn last quarter, $22mn this quarter.

Moderator: Thank you. We have one last question. It is from Nitin Agarwal of IDFC Securities. Please go ahead.

Nitin Agarwal: Vinita, we have had a pretty large base this year on account of, for the upside we had in both Glumetza and Fortamet. When we look out over the next two to three years, do you still see the possibility of growing at a 15% compounded rate on this higher base you have created for the business?

Vinita Gupta: No, so the higher base that we have enjoyed obviously pose a challenge in the near term, but in the mid to long term, we expect to continue our double-digit growth momentum.

Nitin Agarwal: And when you say our near term, it's like in FY'18, I mean how would classify FY'18?

Vinita Gupta: I think the next few quarters.

Kamal K. Gupta: Yes. I think as a policy we don't give guidance, but we will strive hard to produce as good a performance as we can and that's what we have been saying.

Moderator: Thank you. As there are no further questions from the participants, I now hand the floor back to the management for closing comments.

Kamal Sharma: Hello friends, Dr. Gupta just stepped out. Thank you very much for your questions and I hope all of you found requisite answers from the team. As you know, we have done well this quarter and as a team, we will continue to strive harder to put up better performances even in future. But all of you alluded to the fact that there is a lot of uncertainty, a lot of challenges with pharmaceutical business whether it is in India or it is in America. Therefore, some of it would get resolved as the problems come and we face them and find meaningful solutions, but look forward to getting back to you again next quarter and thank you very much for all your questions. In the meantime, if you have anything specific to ask, you could write to Arvind Bothra or our finance department and get your queries answered. Thank you very much.

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