“Lupin Limited Q2 FY17 Earnings Conference Call”

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Moderator: Good day, ladies and gentlemen and welcome to Lupin Limited Q2 FY17 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 after the opening statements. Please note that this conference is being recorded. I would now like to hand the conference over to Dr. Kamal Sharma - Vice Chairman, Lupin Limited. Thank you and over to you sir.

Kamal Sharma: Hello friends, welcome to this conference call, rather I should say Earnings Call for the second quarter of our performance.

Again, I think I like to say that this quarter has been a good quarter for the company when we compare it with the corresponding quarter of last year where you would see a growth in sales of about 32% and a growth in net profit of about 58%.

However, in the sequential quarter from the Q1, we have seen a minor dip in sales over 3% and there is also a reduction in the profit and there are very requisite reasons for it, and your concerns, if any, we would like to address them on this call.

For the details, I like to hand you over to Ramesh who will give you the numbers and thereafter we will open the floor for question and answers. Thank you.

The team supporting me here – I have Nilesh, the Managing Director of the Company; Naresh Gupta, who is heading API; Mr. Makharia, President of Finance; Mr. Arvind Bothra, who has joined us, just yesterday for Investor Relations and M&A. So, he is as fresh as two days ago

Ramesh Swaminathan: But he is very well known to the investing community.

Kamal Sharma: We have Rajiv Pillai; Ramesh you know; Vinita is here with us from US, our CEO; and Rajeev Sibal, who is heading the India Region business. He was till yesterday supporting Shakti and now he is taking independent charge of India Business and Shakti has moved on to other important responsibilities in the Group. So, that is the group supporting me and over to you, Ramesh.

Ramesh Swaminathan: Thank you, Dr. Sharma.

As Dr. Sharma was saying, we do have a good set of numbers. The growth for the quarter was 32%. If you look at the geographical growth also, it has been pretty secular. America grew at 73% in rupee terms, in dollar terms it was about 70%.

India after a lacklustre first quarter and that is true for the industry itself, second quarter was up by 12%. Japan back to the 10% growth rate whilst in INR terms, it is much higher because of the yen depreciation itself. Amongst the emerging markets, we found South Africa did extremely well year-on-year growth being 27%.

Other markets like Philippines also grew. We had some problems with Latin America, which we think we will sort out.

While just speaking to the investing community immediately after announcing our results, people have been asking me three specific things. Why is there a quarter on quarter decline on the top-line in the US? And we would certainly speak about that.

To take this upfront, it is seasonality coming in, cephalosporin sales are the lowest in the second quarter, and there is a small price decline as well which has come into the results.

If you look at the EBITDA margin, it has dropped more because there are two factors coming in. It is because the presence of a larger quantum of FOREX loss, the swing is much larger than the last time around, between quarters it is about 170 crores and total quantum of FOREX loss built into this quarter's result is about 45 crores and there is a huge rise on the R&D front. So that is the reason why the EBITDA margins went down from 32% to about 25%.

And if you were to normalize for that, we would still expect the EBITDA to be about 26% to 28% as we said in the previous quarter. And, the tax rates we do expect to be normalized at around 25% for the full year.

Ramesh Swaminathan: So, I open the floor for discussions.

Moderator: Thank you very much, Sir. Ladies and gentlemen, we will now begin the question and answer session. The first question is from the line of Neha Manpuria from JP Morgan. Please go ahead.

Neha Manpuria: My first question is on the US business. The quarter-on-quarter decline has been partly being the Glumetza impact is factored in. Just wanted to know how much of the Fortamet competition is there in the numbers? And also, Vinita, if you could give any commentary on generic pricing particularly after the weak commentary that is come from our peers yesterday?

Vinita Gupta: So, Glumetza actually did not have any additional competition so it is pretty much flat quarter-on-quarter. Fortamet, as you know, we had additional competition. Mylan came into the market in September so we had given up small share, 6% actually, and had an impact on pricing as well. Again, very reasonable, but since we had the impact in September, there was a material impact on Fortamet within September. But on an annual basis, we expect Fortamet to still continue to contribute very nicely to our revenues as well as profitability. The rest of the portfolio especially the inline products, we saw single-digit price erosion and expect it to continue to be at that kind of level.

Neha Manpuria: And would this be on the higher end, would this be high single-digit or less than 5%? Is the high single-digit number going forward the normal run rate for our base business erosion?

Vinita Gupta: I would expect 8% to 9% especially given also the news that we have heard from McKesson in the last couple of weeks that they expect to have pricing pressure themselves and at the end of the day it will all come back to us as manufacturers. We also expect the McKesson and Wal-Mart business coming together to have some impact on pricing. So, I would expect it to be in the high single-digit.

Neha Manpuria: And just wanted to confirm, we have not received any subpoena from the DoJ on any price hikes that we have taken in our portfolio in the past, is that correct?

Vinita Gupta: No, we have not.

Neha Manpuria: And do we see a risk of this investigation potentially broadening and including more generic companies and remaining sort of a regulatory overhang?

Vinita Gupta: It is hard to predict. What I can say about ourselves is we have had very responsible pricing policies in place and have ensured that our pricing is competitive to make sure that people have access to our medicines. So, we think the risk to us is limited.

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

Anubhav Agarwal: Vinita, one clarity on the expression that you have given right off for the US sales decline sequentially. So Glumetza is flat, Fortamet had a sequential decline, but the single-digit price revision you mentioned for the base products; how would base product would have done sequentially? Would this be down as well sequentially also?

Vinita Gupta: Yes, little bit.

Anubhav Agarwal: And can you also update on this DPI inhaler trial, have you started and also on the R&D guidance accordingly, when you plan to start? At the start of the year you guided for 12% to 15%, you have done 12% so far.

Nilesh Gupta: Maybe I can just start it off and Vinita can add. On the inhalation, we are well on track. With Albuterol, the clinical trial is going strong and we expect filing in Q3 so we are on track. The biosimilars, Etanercept trial is proceeding ahead of schedule.

So, again as you know, that is the trial across Europe, Japan, and India and that is going strong as well. Overall on the R&D side, I think these are two of the big deltas that have happened and the other part has been the higher pace of filings of DMFs and ANDAs. We are tracking close to 30 filings again for this year as far as the ANDAs is concerned. We expect to stay within that 12%-14% that we talked about as far as R&D spend is concerned.

Anubhav Agarwal: And Nilesh, can you also update about the DPI inhaler? When do you plan to start the trial?

Vinita Gupta: We are scaling up the two products right now, so we expect to start the trials later this year in summer, maybe in the Q4.

Anubhav Agarwal: And Vinita, just some clarity on Fortamet. Post Mylan's entry, you mentioned there is some pricing impact. Would it be fair to assume let's say one incremental player cutting prices in normal scenario in the US that will be applied to this product as well?

Vinita Gupta: Yes.

Anubhav Agarwal: And just one last question. Ramesh, you mentioned about 45 crores FOREX loss, is that captured in other income or which line item will that be captured in?

Ramesh Swaminathan: It is in the manufacturing and other expenses line.

Anubhav Agarwal: It will be other expenses. Okay. Thank you.

Moderator: Thank you. Next question is from the line of Girish Bakhru from HSBC Securities & Capital Markets. Please go ahead.

Girish Bakhru: Again on the US front, just need bit clarity. When you say single-digit price erosion, would that be applicable to Gavis portfolio as well?

Vinita Gupta: Yes, it was I think across the whole portfolio.

Girish Bakhru: But just on the data, again I am going back to IMS which may not be fully representative or the fact, we see large decline in the GAVIS. Why would that be the case?

Vinita Gupta: I think probably because of the switch of the product from GAVIS to Lupin portfolio. If I look at the GAVIS business, it is up a little bit, marginally up, but it is up and a big part of what we expect out of GAVIS in the near term is going to be growth out of Methergine which is now reflected in our brand business. So, I do not know. I have not looked at IMS because especially for generic products, we typically do not rely on IMS revenues in any case. But the GAVIS business is fairly stable as far as the generic portfolio goes and then the brand was Methergine, which was in the generic portfolio, is now part of our brand portfolio and that so far has been stable, but we expect to see a ramp up from this month onwards in fact. So, really you should not really see any decline.

Girish Bakhru: We were waiting for say capacity to come on board in September, has it happened? And I was expecting that capacity led volume bump up should probably see US moving up from last?

Vinita Gupta: Yes. So, that just completed last month and we have got all the approvals in place actually in the last couple of weeks and have started doing validation batches of the material products.

Potassium chloride is one major one that required additional capacity so we are scaling that up as we speak, would expect to launch that over the next couple of months.

Girish Bakhru: And just two product clarification, Vinita, on US side. One on Tamiflu, are you set for launch post February when the patent expires?

Vinita Gupta: We expect it to launch next fiscal year. It is not supposed to be this fiscal year, it is really fiscal year 2018.

Girish Bakhru: And just on Prezista, I see you have settled that case, if you could just comment whether you have that launch somewhere in next two years and if you have STF on that product?

Vinita Gupta: It is not in the next two years, we do not expect it. I think it is out.

Nilesh Gupta: But we have approval.

Girish Bakhru: And are you first to file on Prezista?

Nilesh Gupta: On certain strengths.

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

Aditya Gupta: Ma'am, what are the new products that you are going to launch in FY17?

Vinita Gupta: We have a number of new products out of India as well as Somerset that we expect to launch.

Aditya Gupta: CAPEX guidance for FY17?

Ramesh Swaminathan: So, I would put it around $250 million to $300 million if you are talking about FY16-FY17, next year it will come down a bit. This year is particularly high because we actually have expenditure at Japan, we are building up a new facility out there and we have put up a new R&D facility in Florida, we have a R&D building at Pune, and we are putting up injectables plant and others. But all of this will taper down over time. So, next year we expect it to be lower than that past the 1,500 crores.

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

Ranjit Kapadia: My question relates to the domestic market, have you seen the pricing pressure and how the NPPA has impacted to us in the current year as well as what is the product portfolio, which is under price control?

Rajiv Sibal: If you look at NPPA recent guidelines about para 19 if you are asking about that. Para 19 actually if you look at, there were only 43 products at the time when para 19 was announced. But after that, NLEM 2015 came and most of the products price was reduced as far as 2015 NLEM is concerned. We had only five products after the Supreme Court judgment, only five products where we had a price which was more than notified price which also we have implemented.

Ranjit Kapadia: And what is percentage of product portfolio under price control?

Rajiv Sibal: We have approximately 23% of our overall portfolio under NLEM.

Ranjit Kapadia: On the price control of that 23%, how much is under price control, domestic portfolio?

Rajiv Sibal: 23% of the total portfolio is under price control.

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

Surya Patra: Ma'am, can you just update on both sevelamer as well as Welchol, what is the update then? Is it possible that okay after the plant clearance, the opportunity to launch that is visible in the near term?

Nilesh Gupta: So, I think both of these we were tracking for late FY18 so the next financial year and they remain on track for that. There are CRLs that are pending for the sevelamer products, which we are on track for answering this financial year and then will be approved in the second half of next financial year for launch and the same applies for Colesevelam both products as well. So, I think all four products we are tracking for second half of next financial year.

Surya Patra: And by the time it would be like we have to do second, third, or something like that or there is no clarity about it?

Nilesh Gupta: No, I am hoping that we will still be first wave in these products and we will see.

Vinita Gupta: There are no other approvals on these products right now.

Surya Patra: And any change in the guidance for the US business front so far as launches, growth outlook, after getting the final clearance for all of your plants now with the Goa plant clearance? So, any outlook that you are going to provide for the near term as well as two years down the line what is the kind of outlook that you would be having for the US business considering your progress in the R&D pipeline?

Vinita Gupta: So, we expect a larger number of approvals, now that we are through with the Goa 483. So, in the near term we should have at least four to five products out of India between Goa as well as Indore and four to five products out of Somerset in the next couple of quarters. And then in the

next two years, we would expect that the FDA is working well through the backlog. As we have seen in the last couple of months, they have had the largest number of approvals that they have granted. So, we would expect that a good part of our backlog will also clear in the next two years in fiscal year 2018 and 2019. So, we would expect this year with the launches that we have had so far, five products that we have launched and 10 plus that we expect; we will have 15-16 launches next year. We will hope that would double and can stay that 30 plus level over the next couple of years.

Surya Patra: And just one more question on the GAVIS front where seeing the kind of a continued pricing pressure on the base portfolio and all that so the kind of outlook what we had given earlier so whether we are sticking to that or there is a revision on that trend?

Vinita Gupta: Actually the GAVIS base business has been fairly stable as I mentioned. And while we are a little bit delayed in our plan to ramp up GAVIS, we have all of the growth initiatives well on the way; Methergine should start contributing to growth in this quarter, next quarter. Now that the capacity expansion is in place, we will start seeing material launches in the next couple of months and we also expecting new product approvals out of GAVIS over the next couple of months, in particular the controlled substances front.

So, we think we are six months behind from where we were when we started and so we think this year **I would** really go back to the two-year guidance that we had given. We had said that we should be able to take the business to 3x, we think we will be at the $250 million level based on where we are right now.

Surya Patra: With the change of the powers in the US so what is the kind of business environment that you are anticipating so far as pricing trend and all that?

Vinita Gupta: We do not expect much of a change. We have enough pressures from multiple stakeholders in the industry whether it is our customers with the consolidation of the customer end and the pressures that they are facing that ultimately gets to us and then the public focus around pricing. So, we did not expect. Of course I think maybe the Republicans are a little bit better than the Democrats. But at the end of the day, really the market conditions around our industry are tough enough to keep us grounded.

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

Shyam Srinivasan: Just on the branded business, can we quantify what the number is? I remember it was 22 million last quarter.

Ramesh Swaminathan: It is around the same around about 20 is what it is.

Shyam Srinivasan: And the bulk of the sales have come from Methergine, right, a large part of it?

Ramesh Swaminathan: So we have Antara, we have Suprax, and we have Methergine, in all three. So, as you would recognize the Cephalosporin business would take a beating this quarter principally because it is not actually the flu season.

Vinita Gupta: Methergine is the largest product followed by Antara actually. Antara has grown very nicely for us.

Shyam Srinivasan: My second question is on the Japan business, I think we have had a deal with Shionogi. So, any update on the strategy there and how we are progressing there with local distributors? Have we now managed to start working with all of them?

Nilesh Gupta: As you know, we have been growing Japan at 10% to 15% yen terms over the years and we have been pretty much on track with that similar kind of story for this year as well. We are very happy with the Shionogi deal. Again that is on track for closing, it should close in Q3. It is not closed as of now, but in the next two months we would expect to close that.

The Shionogi deal adds very meaningful scale to what we are doing. It adds a lot of products in the CNS portfolio, it adds the brand equity with the doctors as well, and it really helps us in starting to hybridize the model from a generic to a long listed branded generic kind of mode and then over a period of time we would love to get into more specialty into Japan as well. Size is also very important in Japan and the Shionogi deal takes us significantly up, we are around Number 10, we will get to Number 6 with the Shionogi deal. The aspiration would be with our own means and with looking at other acquisitions to get into the Top 5 and I think that would be a strong position to be in Japan.

Shyam Srinivasan: So with the biennial price cuts, what do you think is a decent trend? Do you think the 10% to 15% local currency would be the right number to look at?

Nilesh Gupta: We would expect to keep growing at a 10% to 15% I think more based on the products and the alliances that we are doing.

Ramesh Swaminathan: And you would also appreciate that the penetration rate is also going up in Japan, it is currently about 56%-57% and they expect to reach the 80% level over the next three years and for that reason, we would expect the generic market to expand. We would partake in that growth.

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

Nitin Agarwal: Vinita, on the US business, how should we look at this business in terms of Fortamet? Is it right to assume some more pricing pressure is yet to reflect, we have seen only partial pressure for the quarter?

Vinita Gupta: No. So whenever we have new competition, you see a good adjustment based on the share loss as well as pricing impact in the rest of the business. So, you would see a more reasonable impact going forward is the best I can say.

In terms of filings, we are aware of one other that we track very closely, Nostrum that we know is a smaller player and smaller capacity. But we do not know if and when they are going to be launching their product. But in the current situation, additional competition from Mylan, it is had a pretty reasonable modest impact on our business both from a share as well as pricing standpoint. As I mentioned earlier, we lost or we gave up 6% share and the pricing impact was modest as well.

Nitin Agarwal: So it is fair to say that this quarter would probably reflect some of the pricing adjustments you would have taken on the inventory, which would have led to a higher sort of an impact more than 6% impact that would have reflected on the share loss?

Vinita Gupta: Absolutely, yes.

Nitin Agarwal: And secondly when we go forward, some of our bigger launches are scheduled only for March. From now to March, how do we see the US business?

Vinita Gupta: So, we see obviously there is some pressure on Fortamet although it is modest but there is the pressure. Glumetza fortunately we have not seen additional competition so has been pretty stable and we hope that will continue. We do not know when our competition is going to get in. It looks like it might be out another couple of months. We will hope to get through this quarter as well, which will be a nice upside in the current quarter.

We expect Methergine to pick up starting this quarter to help both the breadth of the business as well as contribution out of GAVIS. We expect to start launching other products out of GAVIS like potassium chloride I mentioned earlier with the capacity expansion. We are now scaling up the product and will hope to launch in the next couple of months. And we also hope to launch a couple of material controlled substances; hydrocodone APAP, oxycodone APAP; that we are expecting to receive approval in the next couple of months. So, we will hope to launch at least by Q4 if not Q3.

And out of India, we have of course Minastrin which you mentioned. It is at the end of the fiscal year, but still a material product $350 million product where we are first to file so are looking forward to that launch. And expect now that Goa is cleared, we could potentially get approval for Bupropion XL, which will be a nice addition to our portfolio. And then out of Indore, we

have couple of products; we Paxil CR, Paroxetine CR that we expect to launch that we already have approval for, and then we have of course Minastrin out of Indore as well as Activella, another oral contraceptive out of Indore.

So good number of product launches, ramp-up of the GAVIS existing portfolio through Methergine, plus new product launches out of GAVIS after this expansion should help us offset the erosion that we see out of Fortamet and Glumetza and hopefully there is some upside on Glumetza if the competition is delayed any further.

Nitin Agarwal: And lastly if I can squeeze one in. On Sevelamer, you mentioned that we are looking for a second half FY18 launch. One of our peers mentioned about supplying APIs right away for some of the competitors. How should one look at that? That seems to suggest like an earlier launch or planning for earlier launch for some of the players.

Nilesh Gupta: Hard to say, be prepared for launch for Colesevelum done last year as some of the other players. I think the FDA is still making up their mind on these products. These are very important products from our perspective. We are working very hard to try to get that to market. We have a reasonable set of outside experts helping us with these products as well. But I think the only visibility that I see right now is for late next year.

Moderator: Thank you. Next question is from the line of Manoj Garg from Bank of America Merrill Lynch. Please go ahead.

Manoj Garg: Vinita, taking the question on price deflation. Most of the price deflation which we are seeing today is largely on account of customer consolidations and as you have indicated that obviously you see a pickup in approvals from the FDA, do you think that this price deflation which is today trading in a high single-digit kind of range can be easily moving to double-digit kind of range?

Vinita Gupta: I hope not. It is very hard to predict this, but right now we are really looking at a single-digit price erosion. Again it is very hard to predict. It could go into double digit if we have a major event in the marketplace, which as of now the only one that I foresee is this Wal-Mart McKesson coming together. Additional competition on existing portfolio, yes, as the FDA clears the backlog, maybe there is more competition on the existing baseline products, but we should also start seeing a good contribution of new products that we have filed to the FDA. As I mentioned earlier, we are expecting to have double the number of launches next year and the year next from what we will see this year. So, we would expect that our product launches will offset any erosion in our existing baseline business. Also as I look at the next two years, we will see an increasing contribution out of areas like dermatology given the GAVIS pipeline as well as our own pipeline, we will see increased contribution of controlled substances. So, areas that we currently do not participate in will start contributing to our revenue line as well. So from our perspective, we continue to invest in our growth drivers. We foresee a single-digit price erosion, but again it is hard to predict these things.

Manoj Garg: And on Methergine, if one has to take an outlook for the two, three years down the line; how big this product or opportunity could be with us and is there any IP strategy around this product?

Vinita Gupta: It could be a material product just if I look at the current units. What we have done in the first half of the year is really stabilize the units, stabilize the erosion decline of the product. We would expect this quarter onwards for us to book the prescriptions and units at the brand pricing. We could get to a $70 plus million run rate on an annualized basis with the product once we get to the level where we are getting a full brand price for all of the units that we sell. In terms of IP protection, there is none on the product. There is no patent protection on the product, but there are limited number of competitors from an API perspective that one can track so that is a natural barrier. And then we have started working on lifecycle management, already we have been working on it for the last six months and had started working on the concept even before we closed the transaction on an extended release product that is well into development at this point.

Manoj Garg: And the last question from my side on the M&A side, I think Lupin name is there in terms of acquiring some of the derma assets of a European company. So just would like to understand again the thought process out here because in the past we were indicating that our focus would be now to add more specialty portfolio rather than established or strong brand portfolio per se?

Vinita Gupta: So, our focus is very much on specialty assets and the derma portfolio would have been specialty asset that we looked at. So, we will continue to look at assets that can help us build our specialty franchise

Manoj Garg: Sorry for my limited understanding, but most of the assets which we are in kind of derma portfolio, they are I think in late stage of expiry. So, how will it help you to build that specialty portfolio per se?

Ramesh Swaminathan: We can take this offline, Manoj. But in simple terms, it actually gives us legitimacy in that space. But as I said, let's take it offline.

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

Surajit Pal: I have 3 questions. One is the very recent change in US political system. While we know that Democrats were creating lot of hue and cry on the prices front, but there is also a big fear of like Make in India, Make in US. So, do you think like Russia that after some years some guy has to put up their plant? Do you see a similar kind of situation could arise in terms of fear of putting plant otherwise putting higher tax in US possibility?

Vinita Gupta: Today 40% of the US generic industry is supplied by India. And I think more than Make in the US, I think pricing as one has seen over the last couple of quarters, last year-and-a-half has been a huge issue in the US that there has been a public outcry on pricing of drugs and now pricing

of generic drugs. So, I cannot imagine that they ignore pricing and affordable medicines and just turn close the doors in the US to just US manufactured product. It will not serve their overall cause of reducing healthcare expenditure.

Surajit Pal: Another thing is sir, very recently that news of Indian regulated disbanding by the government. So, my question is two. One thing is that there is confusion whether that band on FDC will continue? Second is that do you think going forward the kind of hangover on the pricing front will be subsided going forward given that government is planning to come out with a new policy which may not be that restricted?

Rajeev Sibal: So FDC, which we have talked about, FDC ban obviously there had been lot of products which had come under ban. But as an organization, we had taken stay on certain products. Now the matter is being referred to Supreme Court from High Court so we are awaiting for the judgment and that is how right now the status is.

Surajit Pal: No, that is true. But do you think that fear of slowing down growth will be to a great extent will be subsided so the domestic growth will come back again on the track?

Rajeev Sibal: No. See, the only thing is FDC is one. Another list also government is looking at that so obviously hangover will be there. But at the same time, companies are looking at launching new products which are not FDC so that any pressure which comes from FDC ban can be negated by bringing up the volumes of new products as well as other existing products.

Nilesh Gupta: If I can add from our perspective, we probably have one of the best portfolios to offer for the Indian market between what we are developing internally, between the kind of analysis that we have with multinationals, I think we have a very strong portfolio for the Indian market.

Surajit Pal: In Glumetza, definitely you were quite lucky that the other two guys has not yet launched. But given their preparation and your understanding of their preparation to come in the market, do you think there will be quite a big price disruption or do you think they will also participate in the current price and slowly and gradually trying to push the volume? What kind of competition intensity we are looking at?

Vinita Gupta: Just by the fact that it is taking them longer to launch the product, it tells us that there are a good amount of barriers on the product and one would expect when you participate in markets like that you would be more rational. So, we do expect more rational competition from the additional launches. And after the two, we do not foresee any additional competition in the near term so the product could potentially contribute very nicely to us and our competitors.

Surajit Pal: So, what is the basic USP in terms of complexity? Is it the compound molecule or what do you think that is the biggest barrier for any guys not to enter into the counter?

Nilesh Gupta: I do not think it is the API itself. I think this is difficult for us to formulate, it is a difficult bio study, and it is a difficult product to scale up and commercialize. So, I think the challenges are there on an ongoing basis. We have got it very well set in our own plants and I think that has come after a significant number of batches as well. So, those are the inherent challenges with the products.

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

Sameer Baisiwala: Vinita, when you look at your US business, structurally speaking next two, three years, how do you expect this to grow from what you have right now maybe $1.2 billion base?

Vinita Gupta: Just, Sameer, by the sheer number of launches and the kind of products that we are going to launch over the next two years. As I mentioned, this year 15, 16 launches; next year 30 plus launches and the year after well beyond that; and then also the kind of launches we have next year we should have good contribution from Derm product, good contribution from controlled substances; likewise, the year after that should only be larger; plus a couple of exclusives whether there is Minastrin this year or products out of Somerset as well like Suprax and Diastat that we have in our pipeline there. So, it is a combination of the number of launches and entry into areas like Derm, controlled substances, plus couple of exclusives and large products.

Sameer Baisiwala: So, what does it all mean in number terms? Just some rough ballpark and if you adjust this for the price erosion, maybe you said high single-digits so maybe $100 million get knocked off. So do you think that every year you are knocking out $100 million and then adding new products? So where can this portfolio go, net-net what can be your growth?

Vinita Gupta: The long term and I would not say quarter-after-quarter, but in the two to three year timeframe we should be looking at a 20% plus growth.

Ramesh Swaminathan: We got the entire respiratory portfolio clicking in at some stage, we got complex injectables, we got the biosimilars coming up and we are building up a portfolio for that we got the derma assets. So, a lot of this actually is coming up and we are getting into specialty also. So, all of this will make it over the next two to three years.

Sameer Baisiwala: Ramesh, you have not filed for any of those products so let just keep them out for a second. Vinita, when you said 20%, you are saying it per annum or you are saying point to point?

Vinita Gupta: I am saying per annum not point to point.

Sameer Baisiwala: And this net of price erosion, this is the gross?

Vinita Gupta: Net of price erosion.

Sameer Baisiwala: So, that means you are going to add roughly about $250 million per annum roughly about?

Vinita Gupta: We hope to.

Sameer Baisiwala: But Vinita, very frankly those two, three products that we have some visibility, Nilesh mentioned that they all push out to second half of next year. So, I am not quite sure for $250 million sort of net addition and that means 350 gross addition, these should be very visible products and you are saying per annum so that means for next three years and we hardly know these product identities. Is this wishful thinking or this is bottom up calculation by you?

Vinita Gupta: No. So, maybe we are a little more optimistic than others on our portfolio. But the material products when I just look at where we stand right now, for next year per se, you should have a good contribution from Methergine. We hope to build it to a very good level by the end of this fiscal year so that should be a good contributor next year.

Then you have other products that we expect to launch this year like Bupropion XL, Minastrin should be a good contributor next year, you have Epzicom, potassium chloride so, these are not $50 million products each but if you take 30 products where you have $10 million plus, it really adds up.

Now can there be a shift here or there? Yes, for sure. But do we have a good enough size pipeline in place where if we execute in the pipeline, we launch the products that we have on hand right now, and we can get to a good number of $10 million plus products? Yes, we have the potential.

Sameer Baisiwala: Just second question, Ramesh, for you. You mentioned that on EBITDA margin where you ended this quarter of Q2 at roughly about 25%. I think in your outlook you said you will keep it at 25% to 28% and this is when almost no impact of Fortamet and Glumetza really being felt and that would be felt as we go along. So, do you think what is going to help you maintain these margins, actually take it up 200-300 basis points?

Ramesh Swaminathan: Firstly, we do not think that the fall is going to be precipitous. There is going to be the competition coming in for Glumetza as well Fortamet, but it is going to be over time. The second part of it is, as Vinita was mentioning Methergine is certainly going to go up and there will be at least about four products from Goa being launched, four products from the GAVIS table, and a few products from the Indore's table and you have got Minastrin coming up. So, all of this will total up. And there is the R&D expenditure and that is the incremental bet, so we take that in totality, we would still end up between 26% to 28%.

Sameer Baisiwala: I would have thought, Ramesh, that the margins for these products that you cited and versus those two are quite different so really making up on the margin basis could be difficult.

Ramesh Swaminathan: Well, it is your view, Sameer. We could take it offline for sure. But the way we have seen our math working, we do believe that it should be possible for this to be maintained over the next couple of quarters.

Sameer Baisiwala: With your permission just one final question from my side. Vinita, you had mentioned that the aspiration of guidance for GAVIS for fiscal 2018 was $300 million and on this call you mentioned something about $250 million. So, what exactly is the guidance now for which year?

Vinita Gupta: We are delayed, Sameer, as I mentioned given the late expansion of the capacity, the GAVIS and also buildup of the controlled substances. There is a lead time to build up share and to get a DEA quota to be able to really get what we need to for our target share. So, we believe we are six months off and should be able to get to $250 million in fiscal year 2018.

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

Prakash Agarwal: Just trying to understand the comment you made four to five approvals from Goa and four to five from Somerset. Given the fact that we just got the facility cleared, would not you expect Goa to see all the blocked approvals coming up faster or are we facing difficulty which was cited by media sometime back on the CRO front, similar issues?

Nilesh Gupta: So, there is a bunch of issues. So, I think there were basically one or two products that were technically held up on the account of compliance so those are the ones that we would expect to come through. Some of the others we had a CRL in one or two products we had the similar issue out of the Goa list as well. So, it is a blend of first half. For example on the similar issue, we have very aggressively been addressing those bio-studies and I think more than half of them have already been addressed and the rest of it will follow shortly. So, I think near term we basically see a couple of products coming approval and about five to six between this and next quarter as far as Goa is concerned.

Prakash Agarwal: And just correct me if I am wrong, were we not exclusive on Seroquel, Quetiapine? We settled for a November launch, is that correct?

Vinita Gupta: No.

Nilesh Gupta: No, I do not think we were exclusive on that but there is a settlement date, but not exclusive.

Prakash Agarwal: But this settlement date goes to couple of years further or would we expect in like next few months or quarters?

Nilesh Gupta: It is not in this financial year for sure maybe we can get back to you on Seroquel**??**

Prakash Agarwal: And on the FOREX loss which Ramesh mentioned, I am just trying to understand the nature of it because if you are doing business in Japan and other markets where the currencies have been pretty volatile so, what is the nature of these and are these like recurring subject to movement in the currencies or can you explain the nature of this please?

Ramesh Swaminathan: As you said, it is essentially because of Dollar the Rupee at this stage is also a bit which is impacted negatively. There is the volatility on the Yen front, which bulk of it is actually captured in the balance sheet, but there is a stock movement which is captured in the P&L and equally there is something that is happening on South Africa, for example a bit of depreciation. You have Brazil which has appreciated, you have Mexico which has depreciated so, all of this put together you actually found a large swing which has been captured in the manufacturing and other expenses line.

Prakash Agarwal: And the benefit of which also comes as a revenue if the currencies are depreciating?

Ramesh Swaminathan: For sure, absolutely. It really depends on the cross movement we have with the rupee.

Prakash Agarwal: So it is more of a recurring item, right?

Ramesh Swaminathan: It is volatile, right. It is very difficult to say that it cannot be recurring. There is a mean reversal which is always possible, but it really depends on the global economy and all of that.

Prakash Agarwal: And the staff expense we spoke this last quarter, you mentioned half of it is related to the GAVIS scale up and the other half should normalize. We have seen the similar level like last quarter. So, what is the outlook there? Is this the base which we can expect?

Ramesh Swaminathan: That is what it is. There is a percentage in this model is the same as the previous quarter.

Nilesh Gupta: And so, outlook is pretty flat from Q1.

Prakash Agarwal: The entire scale up which you had done on the R&D front and all this is largely done, right? From this base, we do not expected to go further from here?

Ramesh Swaminathan: Not from the employee expenses.

Prakash Agarwal: And lastly if I may, just adding or what Sameer asked on the profit profile of the products, clearly Glumetza, Fortamet, when we see Sun and the other players coming on Glumetza and the products that we just described, the profit profile of these products seem to be very different and we tend to maintained or improve the margins. So, little help or little more color would really help us.

Ramesh Swaminathan: It really depends on how you characterize this fall itself. So, we have never said that there is going to be a rapid fall. It is going to be a slow gradient. So, we do recognize that there is going

to be competition for Glumetza clicking in towards the end of the year. We do know that Mylan aspect, it is not as though we have lost too much of market share as Vinita was explaining. So, I think it is basically around you expect it to come down very rapidly whilst we do not and we do expect a ramp up on other products to happen. So, the gradient of the slope perhaps in the normal course would not be rapid as we feel it is.

Moderator: Thank you. The next question is from the line of Kartik Mehta from Deutsche Bank. Please go ahead.

Kartik Mehta: So just looking at your top-line thing for FY18 and beyond, would it be fair to assume that we stand by $3.5 billion US number and if not, can you help us with your assumption in that for organic as well as inorganic?

Ramesh Swaminathan: Yes, so, there is this ramp-up which has happened on several fronts. So there is pipeline in America, there is as I said it is not as though Fortamet and Glumetza are going to come down very rapidly. We do expect GAVIS to ramp up over time and there is Shionogi which is coming up and there is this ramp up on the newer acquisitions that we bought into, essentially Medquimica and Grin and others, so, all of that and then the pipeline in other parts also including Europe. So, we do believe that there is going to be good growth as we see it. The aspirational figure of 3.5 is slow there but we are working towards making that happen.

Kartik Mehta: Would it be fair to assume that of the 3.5, at least 10% to 15% from now that we know how much we make for GAVIS let's say in FY18, at least 10% to 15% there would still be inorganic assuming that in that $3 billion number you are adding the $250 million for GAVIS? Just a ballpark will help, Ramesh.

Ramesh Swaminathan: Yes, that is true. That is always there. That is correct.

Kartik Mehta: And it will also help if you could just share the Dollar rate that we should assume on this number?

Ramesh Swaminathan: There is a current Dollar rate about Rs.67.

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

Saion Mukherjee: Nilesh, on the respiratory front, you mentioned about Albuterol filing this quarter. How should we think about this opportunity how large it is in the US? And secondly on DPI, you mentioned about scaling up that. So it seems like it is taking longer, right? The trials were supposed to have started by now. So, is there any specific reason for the delay there?

Vinita Gupta: So in terms of market size, Saion, it is a $2 billion market when you look at Pro Air plus Ventolin and I forget the name of the third brand. The overall Albuterol market is $2 billion and right now we know that Perrigo has filed and they are still waiting for their approval. They are delayed. So

we were expecting we expect to file this fiscal year and hope to launch as soon as we get approved but I am very excited about the potential of that market. Your question on the DPIs on Advair as well as Tiotropium, we have been making progress but have been cautious because Advair in particular has got a number of challenges from a stability perspective. We had to make sure that all of the strengths we feel confident that are stable and we can manufacture on a consistent basis. So, we decided to take a little bit longer to scale up the products and then start the clinical trial, which as you likely know is a substantial investment, one of the largest clinical investments on the inhalation front for us. Tiotropium, we are very much on track per our timeline. We have made progress on the development, have done pilot PKs. Again we have following maybe a more conservative approach because these are new areas for the Company and the investment is significant. So, we have been going through pilot bios and pilot studies and scale-up before we can go to the pivotal PD study. So, we are happy with the progress that we are making on the pipeline.

Saion Mukherjee: And on Albuterol once you file it, there would be litigation and 30 months stay, so all of that would be there, right?

Vinita Gupta: We don't know.

Saion Mukherjee: And on Etanercept, you mentioned you are ahead of schedule. You are developing it for Japan and Europe and any plans for the US market there and why not and are there any other biologics that you plan to take to clinics for the developed market over the next one year?

Nilesh Gupta: So on the Etanercept, we are ahead of schedule on enrolling patients. The trial itself will continue till next year of course. And right now this is a Japan and importantly a Europe opportunity. We are evaluating our options for the US. We are actually going to be meeting with the FDA to be discussing our strategy for Etanercept as well. We do have a select few products that we have finalized for the US that we are working on and if things go well, then you should expect a couple of filings in the next two years.

Saion Mukherjee: And how large is the market in Japan for Etanercept?

Nilesh Gupta: It is small. We expected it to be bigger. The switch rates just did not happen and the market rate smaller, then I do not have the specific number right now, but it is smaller. To me, the European opportunity is more interesting than the Japan one.

Ramesh Swaminathan: But that said, there is a recent report which I have been reading also that the authorities are contemplating impact for additional incentives and that is what they expected that to be the next wave of action in Japan.

Vinita Gupta: Like Nilesh said, the European opportunity is significant. In the near term other than the US, Europe would be our largest market for Etanercept and if the FDA accepts our proposed pathway

for the US filing, the US also has got a patent hurdle, but we should know the outcome of that in the next two years certainly before we get our product approval. So, that could be a potential upside as well.

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

Nimish Mehta: Just a few questions on the potential launches. Do we expect Prevacid SoluTab and Fosrenol launch this year or what is the outlook there?

Vinita Gupta: What are the products again?

Nimish Mehta: Lansoprazole SoluTab and lanthanum carbonate?

Nilesh Gupta: Both of these are for next year.

Nimish Mehta: For next year and Fosrenol being the phosphate binder will be more or less in line with the Sevelamer launch?

Nilesh Gupta: No, I hope that it will be sooner actually.

Nimish Mehta: The other question is actually a broader question on the India market. There were some news that the uniform marketing code was to be made mandatory first I mean, I do not have an update if it was made mandatory, what do you think would be the impact on Lupin?

Nilesh Gupta: So, I think basically the status quo continues as far as UCPNP is concerned. Basically it is voluntary at this point of time, but I do think that things are tightening around that front and we just have to deal with it when it comes up.

Nimish Mehta: But do you see any shift in the market trends because of that or that is just a normal change that would just come and not change much in the market?

Nilesh Gupta: In many ways the India market is a very dynamic market. For example with the in-licensed portfolio, the on-patent portfolio that we are promoting; these are products that doctors would write any which way and there are not alternatives to them, if you bring an FDC to market, there are not many options that a doctor has when he is writing this product. So, I think prescription behavior will change over time in any case. MCI itself is looking to tighten the practices that they have that they would expect doctors to follow. So, there is a little bit of fluidity in this that I think in the next year we will have more clarity. But I am a strong believer as far as the Indian market is concerned and I believe that we will continue to grow at that 15%, 20%.

Nimish Mehta: And on the India market itself like what would drive the growth, will it be in-licensed products or new first to market launches kind of products or so addition to therapy areas? What would be it?

Nilesh Gupta: Maybe I will start and Rajeev can add. I think it is prescriptions for doctors first of all. So, we have added a whole bunch of representatives, we have created five new divisions and we have a lot more product that we are bringing to market. A lot more in-license on-patent product that we are bringing to market, which are becoming very meaningful in size as individual products. Rajiv, would you like to add?

Rajiv Sibal: Absolutely, And apart from that in-licensing product, there are other new products which we are launching in Indian market and there is a lot of scope in existing products per se. So we are working on lot of brand building, which will also drive the volume growth. So, I think that is how we are looking at India market.

Nimish Mehta: When you say a lot of opportunity, you mean to say geographical expansion in the same brand? Is that what you are hinting at or just Lupin overall?

Rajiv Sibal: So if you look at, you can increase the sales either by increasing prescriber base or productivity per doctor. So what Nilesh has talked about expansion, we are increasing the productivity per doctor as well as at the same time we are increasing reach through other means also so that we can increase the prescriber base also. So, we have good portfolio of new products as well as existing and we are launching in-licensed product portfolio, which is going to really contribute to a great extent.

Nimish Mehta: Finally if you just can just tell me the number of new launches that you are expecting in the Indian market this year and maybe the next year as well? Please do not include the line extensions area.

Rajiv Sibal: So, we have launched in H1 almost eight or nine products and those are very substantial product what we have launched as far as in-licensing is concerned. So I am not talking about the line extension, I am talking about the whole set of new products which are in-licensing or otherwise first-to-launch product. So, I think these products only are going to contribute in a major way.

Nimish Mehta: Can you expect the same run rate to follow next half and --?

Rajiv Sibal: Absolutely. We have other products also in pipeline, which obviously will see the light of the day in the next six months.

Kamal Sharma: Can we suggest last two questions, please?

Moderator: Certainly sir. It is on the line of Anmol Ganjoo from JM Financial. Please go ahead.

Anmol Ganjoo: Most of my questions have been answered, but just one question to Vinita. Vinita, you yourself conceded that for GAVIS you have had to recalibrate expectations. Now that we have had chance to look at the asset in great detail, would you kind of concede with some degree of confidence that the downward adjustment as far as expectations is concerned is broadly done this $250 million number for FY18, do we feel fairly confident of that number?

Vinita Gupta: Yes. The best we see based on all of the areas that we expect to build out of GAVIS, we think that we can do it.

Anmol Ganjoo: And the second question is around the M&A strategy. Without going into specific assets and what is being appearing in the press, would you like to help us understand that what is the balance sheet headroom that we are working with?

Ramesh Swaminathan: Our EBITDA to debt ratio is hovering around the 1 mark of today and most banks are comfortable with three times that level whilst the rating agencies would look at something around 2 they are comfortable with that. So, it gives us at least one more turn of our EBITDA if you would look at another 4,500 crores odd and we could also leverage the cash flows of the target balance sheet as well. So, I think about $1 billion is what we can muster but it does not necessarily mean that we are going to expend that kind of amount in one tranche. Our sweet spot still remains fairly lower than that.

Anmol Ganjoo: And in terms of valuation benchmarks, what are the ceilings we would be working on?

Ramesh Swaminathan: We always looked at a payback period of about five to six years so it automatically puts a ceiling around what we can actually buy.

Anmol Ganjoo: One last question from my side, Ramesh. We have been working with fairly volatile revenue streams and while I concede that it is not going to be precipitous fall in Fortamet and Glumetza, but from an R&D perspective if you could help us at least indicatively have a sense of what the guidance could be absolute numbers and not in percentage terms of sales for 2017 and 2018 that would be helpful?

Ramesh Swaminathan: So, if we look at, firstly, I do not fully follow this argument about volatility on the cash flow front because I think that year-on-year it is been pretty consistent, we have been growing at and I think that is the way we would see it. On the R&D front, this year I think we will close around 2,500 odd crores and next year perhaps by another 10%, 15% more possibly. But we are also looking at how do we make the R&D dollar run up a longer mile so, productivity and other issues being considered. So, I think we would try to extract a lot more out of our spends.

Kamal Sharma: Can we have the last person to ask the question, please?

Moderator: It is on the line of Nitin Agarwal from IDFC Securities. Please go ahead.

Nitin Agarwal: On Methergine just finally, Vinita, the way we scaled up Suprax; in the current political environment as things are in US, do you see any challenges to replicating the strategy that we had in Suprax and Methergine?

Vinita Gupta: No. So, the big question is really when can generic competition comes in which in Suprax we had a good run of 10 years. We are not expecting that. But in terms of the strategy to brand the product, we have really met the material need of the market where the product was being ignored and not promoted and people actually dying of postpartum hemorrhage. There were a lot of folks that really did not know that the product existed. So, we really have been able to help from a market standpoint by investing into commercial infrastructure that helps us stabilize as well as grow the brand, which obviously supports the strategy.

Nitin Agarwal: And what is the overall thought process on the specialty brand business now going forward and how do we see it is growing beyond Methergine and the current set of products?

Vinita Gupta: So, we have three areas of focus right now. On the specialty front, really women's health and pediatric and then we have the PCP products where we are really focused on the high-volume writers on products like Antara and Suprax caps. But the biggest driver in the near term is women's health with Methergine and then we have the life cycle management of Methergine underway.

We are looking at other product opportunities in women's health that have the potential that we can potentially launch in the next couple of years.

On the pediatric front, we have Suprax and InspiraChamber right now, but we are subscale in terms of the portfolio on the pediatric front. We have started developing ADHD products. We have two ADHD films in development that will come to market not in the next two to three years, but in a three to four-year timeframe and then we are looking at additional pediatric products that can add to the portfolio. So as much as the near term, we will be able to grow the brand business with Methergine franchise and existing portfolio. The long-term growth will still come out of additional pipeline investments like films as well as acquisitions and in-licensing.

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

Kamal Sharma: So friends, thank you for all your questions. I hope they have been meaningfully replied and if you have any questions which you still feel not fully addressed, please feel free to take them offline with Ramesh and his team.

In closing, I just want to say that most of us know about it and I am sure you know it very well that the pharma industry has been going through kind of a paradigm change in the sense that there is a new rigor of regulatory bodies right from pricing to compliance, there is increase in

competition, there is also a change in business complexion from small generics to complex generics and specialty.

So, I think in this scene there is definitely enhanced unpredictability in the business. But the way we have built our Lupin organization in terms of its capabilities and research and creation of capacities and also in terms of building the organization, we believe that notwithstanding the unpredictability, the Company will continue to churn out good performance in the future quarters as well.

So with that, thank you very much once again and we will meet again in the next quarter.

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