



“Lupin Limited Q1 FY18 Results Conference Call”

August 3, 2017



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Moderator: Ladies and gentlemen, good day and Welcome to Lupin Limited Q1 FY'18 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 presentation concludes. Should you need assistance during the conference call, please signal for an operator by pressing '*' then '0' on your touchtone phone. Please note that this conference is being recorded. I now hand the conference over to Lupin management. Thank you and over to you.

Dr. Kamal K. Sharma: Hello, good afternoon, friends. My name is Kamal Sharma. It is my pleasure to connect with you for the quarter's performance.

With me, I have Nilesh Gupta, Vinita Gupta, Sunil Makharia, Ramesh, Arvind and Rajeev.

As you have all seen, I think the results for the quarter have not been to our satisfaction, we have been rather unhappy about it, but some of it I think was expected and we admit similar kind of indication even in our early meetings, but should things would have happened little worse than what we had expected is now a reality, and the broad reasons, as you all know by now, that it has been the pressure on Glumetza in US, GST in India and also certain decline in Japan on account of change in the copay policy in Japan, and some element of seasonality especially in South Africa business. But I would like to say is that while we are not happy with this but I think the team is working hard and is very confident that we are going to make up for all this in due course.

I would now hand it over to Ramesh for sharing the details of the financial performance." Over to you, Ramesh.

Ramesh Swaminathan: Thank you Dr. Sharma. As Dr. Sharma was saying, at the end of Q4 when we met during our Investor Meet, we did speak about the fact that this particular year could be a pretty difficult year for us and you would expect lackluster performance and that is exactly the way it actually turned out to be, and as for the reasons Dr. Sharma actually started out saying it is because of what is happening in America relating to Glumetza, because of GST and so on.

North America:

So let me give a little more color to it. If you look at America performance, the year-on-year decline has been about 27%, the quarter-on-quarter is about 16%, a large chunk of it is only because of Glumetza itself. Brand business, has done better than our previous quarter. If we speak about India, despite GST, we actually grew 6.1% quarter-on-quarter. If we normalize for impact of GST, sales would been higher by at least Rs.150 crores.

APAC

Dr. Sharma also spoke about the fact that there was a decline in Japan. If we take the last year's performance, we actually had the Shionogi portfolio in and that is the reason why we actually



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show growth over previous year, but we had some headwinds in the first month of the year principally because of higher copay and that is the reason why you find the APAC performance to be low by 2.1%. It is also accentuated by Philippines, a large chunk of which was tender business which did not come through this particular quarter, and that exasperated the decline itself.

EMEA:

South Africa registered a very high sales in the fourth quarter. That is principally because of the fact that we expected a price hike and the price hike was about 7.5%, and for that reason Q4 was very good last year and there was a slight decline in the Q1 of the current year. That is why you find EMEA to be a little lower.

ROW:

Topline is higher vis-à-vis the previous year by 12.9% but it is lower vis-à-vis the previous year because of tender business in certain parts.

FOREX has declined vis-à-vis the previous year. If FOREX had not declined, you would have seen the gross margin level, at least about Rs.72 crores of profit. On quarter-on-quarter basis, this is actually about Rs.62 crores.

In terms of EBITDA margins, we saw only about 21%, but if we normalize that with GST impact, it would have been close to about 23%.

R&D has been lower than the previous quarter, because Q4 is generally lumpy and it is stacked up in favor of Q4. Q1 declined but that is still 13.1% of our sales and we shall do what it takes to maintain it at the same level.

With that I would like to open the floor for discussion.

Moderator:

Ladies and gentlemen, we will now begin with the Question-and-Answer Session. The first question is from Aniket Nikumb from Amansa Capital. Please go ahead.

Aniket Nikumb:

I have two questions; first question is on the North American Formulations business. So as you mentioned that has degrown for us 26% Y-o-Y and 16% Q-o-Q, and when I look at Glumetza, we have seen Teva launch in May and maybe Sun launch it sometime later this year, and you and your peers have also talked about high single digit type pricing erosion happening due to consolidation. So just considering all of this, could you just help us understand what is the sort of growth number that you are underwriting in the US for FY'18 and beyond just in terms of some sort of degrowth are we talking kind of mid-teens degrowth just to get some triangulation, that will be useful?



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Vinita Gupta:

As we had mentioned earlier in our May meeting, we are seeing potentially a single digit price erosion in the US for baseline business. Having said that when we look at Q1 performance versus Q4, while majority of the decline in the US business was due to Glumetza, our baseline business actually grew and our in-line products actually grew 9% without Glumetza and 11% without Glumetza and Fortamet. So having said that just given the contribution from Glumetza last year as you know we had a major upside in fiscal year '17 grew 38%, we did not expect Glumetza to be exclusive for one year, really enjoyed that exclusivity by 12-months as opposed to six, and we are going against that high base. We expect this year we are going to see a decline. It is going to be difficult to get to the levels of the last year. But based on the product approvals that we foresee in the next 12-months and beyond, we expect to be back in strong growth in fiscal year '19.

Aniket Nikumb:

The 11% numbers that you have mentioned, could you just help us understand how much of that is from kind of the new products that you have launched versus kind of your base business, basically, if you looked at it like-for-like, what would the erosion be like, just we get a sense of what is...?

Vinita Gupta:

Really getting more out of our existing products as well as getting more out of Somerset. There was very little contribution from new products... just couple of million dollars. The biggest new product launch was Bupropion XL that will grow into the rest of the year, but the first quarter contribution was very low. The majority of the upside was our baseline business that we grew even all the products that we grew in Q1 as well as the Somerset products. The Somerset products that we had launched in Q4 have contributed very nicely into Q1. Generic business out of Somerset grew over 23% and the Brand business growth was primarily due to Methergine out of Somerset, Methergine itself grew 48% Q-o-Q. So was really the current in-line products that contributed to the growth.

Ramesh Swaminathan:

Price decline for the first quarter was flat. So most of it is essentially new products in the volume increase.

Vinita Gupta:

No new products, it is just a couple of million dollars in new products. It's baseline products that we have.

Aniket Nikumb:

My other question was on your Japanese business. So when I look at your annual report, I have seen kind of the margins for Kyowa and Kyowa CritiCare compressed by something like 500 and 1,200 bps and this is before the new yearly price cuts that you mentioned in your last conference call. Could you just help us understand what is kind of going on in that business and how do you see this Japanese business going forward?

Ramesh Swaminathan:

I think you should not actually merely rely on annual report because it does not capture the full picture into Japan the products that you are supplying from India also, so to that extent, it does not necessarily reflect overall profits that you could generate out of the Japanese business itself.



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But having said that there are changes in the offering in Japan, firstly on the price regime front itself, we were looking at the price changes being affected every two years. They are at this stage looking at an annual price cut. So potentially what used to be about 11-12% price cut for every two years could potentially become 6% price cut on an annual basis, and that is the normal course is being handled by passing part of it to the trade itself and pushing back the vendors and absorbing some portion of it ourselves. There are some changes the overall copay regime out there, restricted at just about \$600 per annum per patient, that is off the table and a little higher, and that is the reason why you found the first month to be impacted. The changes are still being unfolded, but we do think that we have seen the worst of it in Japan. If you look at the performance since then, particularly May, June and July itself, we are pretty optimistic about our overall chances in Japan.

Moderator: Thank you. The next question is from the line of Nitin Gosar from Invesco Mutual Fund. Please go ahead.

Nitin Gosar: Hi, Ramesh. You mentioned about gross profit impact of roughly Rs.70-72 crores because of the FOREX element, but when I look at the press release, there is the dollar number and INR number which is given out for US business. There we continue to do booking at the rate of Rs.67. How should I look at these two different data points?

Ramesh Swaminathan: So essentially what I meant was there is actually a decline in terms of realization itself. There is an element of profits that you make on hedges that we already concluded, so we obviously booked well in the past. So the rates that we got on those forward contracts would be certainly higher and that all put together was about Rs.14 crores to this particular quarter.

Nitin Gosar: So ongoing basis, what should we look at it... the realizations that we are seeing at 67 as of now, that should drop down?

Ramesh Swaminathan: I would say that we would hold on to the current level of FOREX. It is around 64, much of the first quarter, it has been declining a bit. So I think the current level should hold, I would imagine.

Nitin Gosar: So we have seen the worst part of the INR impact right now in our numbers?

Ramesh Swaminathan: You can never say that because essentially it really depends on so many part of these outside India... Trump's policies and the way the other market currencies also behave. But I would imagine it is going to be range bound between 63.50 and 64.50.

Nitin Gosar: No sir, my question is not related to the policy, my question is more pertaining to the different data points which are visible right now. You have hedges which is what we are running down right now. So idea is more to understand at which point of time the hedges will run down and your realization will drop down to 64-65?



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- Ramesh Swaminathan:** The point is we obviously, have taken hedges for 18-month position. So there would be some portion of it coming in every quarter. So that portion is the unhedged portion which obviously would be at current levels.
- Moderator** Thank you. The next question is from the line of Ashish Rathi from Infina Finance. Please go ahead.
- Ashish Rathi:** Could you first indicate the split of the Branded and the Generics business for the quarter?
- Ramesh Swaminathan:** The branded business is about \$23 million and the balance is Generics, total is 238.
- Ashish Rathi:** What was this number for the fourth quarter?
- Ramesh Swaminathan:** Brand was \$19 million in the previous quarter.
- Ashish Rathi:** In Levothyroxine, how is this molecule shaping up for us and when does the company expect the launch?
- Nilesh Gupta:** We are very optimistic about Levothyroxine. I think that is a great product for us to bring to market and we hope that we will be able to launch it this financial year, we had a PAI for that product as well, so I think things are in line for an end of the year launch.
- Vinita Gupta:** We are also very encouraged by the fact that it is in the FDA list product that they want to prioritize approvals for. We are hoping that we get an expedited approval.
- Ashish Rathi:** The PAI was also for Tamiflu, am I correct?
- Nilesh Gupta:** So there were two different PAI -- there was one in Indore for Levothyroxine and the Tamiflu one was in Aurangabad.
- Ashish Rathi:** Secondly, on the India business, how do you see it shaping up for the balance part of the year... do you expect channel filling in coming quarters at least talking to make up for the lost sales in 1Q?
- Nilesh Gupta:** First of all, we are very bullish in India and we have always talked about 15% growth. I think we are sticking with that number at this point. Obviously, the first quarter has not been the way we like it to be... Ramesh already talked that we lost about Rs.150 crores worth of sales in the first quarter. We are certainly seeing much more optimistic numbers from July, but I will let Rajeev add.
- Rajeev Sibal:** As Nilesh spoke about, the first quarter was impacted on account of GST. July has been very promising month for us as far as the first month numbers have come. But if you look at overall, the market growth in the Q1 as per IMS has come down and the market has grown at 4.5% only,



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and if you look at even MAT numbers for the market is growing at 8%. We surely expect that the market to pick up in the next three quarters, but we expect the market to be at the same current level of 8%, and India business has always grown much-much better than the market. So that is where our expectation is in the overall one-year basis, we will be growing at least 20-30% more than the market levels.

Ashish Rathi: Lastly, on the gross margins, the dip ex of GST, is it fair to assume that this will be the new base or do you think with Minastrin exclusivity kind of going away, there could be further dip for the balance part of the year?

Ramesh Swaminathan: Gross margins is also depending on the FOREX. So if it is going to be in the same range that you are seeing today, I would imagine the gross margins will be at the same level.

Ashish Rathi: So like 70% kind of a gross margin should one expect for the balance part of the year?

Ramesh Swaminathan: Current level would be, I think, good indication.

Nilesh Gupta: 67.6% was the number for the quarter.

Moderator: Thank you. Next question is from Prakash Agarwal from Axis Capital. Please go ahead.

Prakash Agarwal: Just trying to understand your guidance which you had alluded in your May Analyst Meet. So you did mention about some headwinds on the US growth piece, but on the margin front, if I remember correct, it was still 26%. Now how do we see this going forward given the fact that you just mentioned gross profit margin of around similar levels. So what is the new level that we are looking at?

Ramesh Swaminathan: When we spoke about 26% is more in the light of rupee we did not expect it to kind of remain at the levels that it does right now because there were too many people who are also saying, analysts, who talk about rupee could depreciate over time. But given the new reality seems to be that it will be range-bound between 63 and 64.50, I would think that guidance does not hold. We also had not reckoned the impact of GST and more than normal decline that we saw on Glumetza. For those reasons, we are now giving a range between 21% and 23% as the EBITDA range so to speak. Also, the other fact was R&D. But as you would see, we have kind of contained at about Rs.500 crores levels and I think going forward you will see the same kind of same outlets over the next three quarters as well. So I think 21%-23% is where we are at this stage.

Prakash Agarwal: If you could just update on the recent US FDA status for your Indore Pithampur plant Unit #2, 3, one is cleared I think, and the Goa plant status please?

Nilesh Gupta: Unit #2 was a GMP inspection, Unit #3 was a PAI inspection and we had certain observations out of Unit #2. We believe we have addressed them to the FDA satisfaction and hopefully in the next two months, we should get clarity. Same story for Goa. Again three observations. We



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believe we have addressed them satisfactorily and there hopefully in the next one month, we should get clarity. There unfortunately is period of uncertainty post an inspection and that set to 3-month period that goes on.

Prakash Agarwal:

Any approvals that we have received on these facilities post the inspections?

Nilesh Gupta:

No, not since the inspections, one we did not have many products which were anyway coming at this point of time, but I think it would be fair to say that in the next 1, 2 months, we would also need clarity on the GMP status as we get these approvals because that is a typical thing that FDA relies on at this point.

Prakash Agarwal:

Lastly, just trying to understand the next 12-18-months kind of opportunities. I did see some comments by Vinita on the known products like Fosrenol and Tamiflu, just trying to understand about some of the exclusive products that she spoke about, if Vinita could expand?

Vinita Gupta:

I think the material products that I talked about were Tamiflu which now out after the successful Aurangabad inspection, we expect approval hopefully soon, we look forward to launching it soon. The other material product in the near-term Lanthanum Carbonate that we have partnered with Natco, that looks like will come to market soon. As Nilesh mentioned Levothyroxine, that potentially is going to be a nice upside opportunity. We can work with the FDA to get that approval within this fiscal year. Apart from these products, from Somerset, we have some of the Controlled Substances, Hydrocodone APAP that we have made significant progress on, we have got commitments from the customers, we have got commitments from the DEA and have our in-process manufacturing launch quantities, we will start booking sales this quarter. Likewise, Potassium Chloride, we made significant progress in the last couple of months and manufacturing launch quantities again with the expectation that we would launch this quarter. These are going to be the material products for the current fiscal year.

Nilesh Gupta:

In the next 12-18-months, there is obviously a much bigger pipeline that kicks in; we have other products like Toprol XL, lot more controlled released products, some Derm products that still seem pretty interesting. So all of these will start kicking in that 12-18-months horizon.

Moderator:

Thank you. Next question is from the line of Neha Manpuria from JP Morgan. Please go ahead.

Neha Manpuria:

Sir, since you mentioned that our R&D would be more contained in Rs.500 crores per quarter range. Have we in any way changed our focus in terms of what we are looking at R&D for this year versus next because the initial expectation was slightly higher percentage of sales given we do not know the sales even Rs.500 seems like a decline year-on-year?

Vinita Gupta:

Neha, we have not changed any of our focus on the R&D front, we are very actively pursuing the Complex Generic pipeline that we mentioned that we are working upon areas like Inhalation products, Complex Injectables, Biologics. What we have done is for some of the risky projects,



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we have opted to get a financing partner, the Biologics in particular, we felt given the current market evolution and the clinical risk, it would make sense to share some of the risk, so we have brought in some external financing in the biologics, but have maintained all of our material projects.

Neha Manpuria: This external financing partner would be for the US market, it is other than the JV that we have already for Japan, correct?

Vinita Gupta: Yes, it is not for the US market only, the first product that we got financing partner is Etanercept and that is global.

Neha Manpuria: My second question, ma'am, if you could also update us on the Respiratory pipeline, how we are progressing there, when we should see filings coming in?

Vinita Gupta: The filing started last year of course. We had ProAir filed in January that we announced. We are making really good progress on Spiriva well. We have started the PD study on Spiriva, completed the PK study and should be in a position subject to successful PD study to file at the end of this fiscal year. On Advair, we have had some developmental delays and decided to do some additional work before we start the PD study. So that is delayed by a couple of months. But Spiriva is the next one that you are going to see filed, followed by Advair and then we have host of other products that we are pursuing like Symbicort, Qvar and others.

Neha Manpuria: On the US business, since you mentioned that there was no pricing impact quarter-on-quarter, is it fair to assume that McKesson, Walmart impacted pretty much there whatever had to be for our portfolio, we will not see anything incremental because the commentary that we are hearing from peers, the flat pricing is pretty good, so just wanted to understand if you expect more from that in the second quarter or all of that is already incorporated?

Vinita Gupta: I would still say that we would expect single digit price erosion because apart from McKesson and Walmart, you have now WBAD and Express Scripts that is coming together. We do not know the exact timing of their deal, but we expect that they are going to try to get procurement efficiencies sooner rather than later. So I will maintain a single digit price erosion.

Moderator: The next question is from the line of Aditya Khemka from DSP BlackRock. Please go ahead.

Aditya Khemka: Vinita, couple of questions; firstly, on the Metformin franchise, Fortamet and Glumetza put together, so if I were to look at the erosion that we have seen in Glumetza and the pressure is obviously on pricing as well, can you bifurcate the pressure between the competitive pressure and the channel consolidation pressure? I know this cannot be exact numbers but just a ballpark as to how much of the Glumetza decline? Is it majorly competitive or is it majorly channel consolidation?



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- Vinita Gupta:** It is majorly competitive, we had a real wild card as the second entrant in Glumetza, the authorized generic was a pretty tough competitor for us to have and that brought the pricing down for the entire market. Like I mentioned, the rest of the portfolio including Fortamet was pretty much from a pricing standpoint flat.
- Aditya Khemka:** The pricing on Fortamet was also flat. So there was no impact of the channel consolidation on the Fortamet pricing?
- Vinita Gupta:** We have already seen pressure on Fortamet pricing in previous quarters.
- Aditya Khemka:** So there was no incremental between sequential quarters?
- Nilesh Gupta:** Marginal.
- Aditya Khemka:** Just on the Mesalamine franchise of Gavis, I remember Apriso is one asset,- that you guys divested when you acquired Gavis and Lialda I think Nilesh mentioned that your filing is little away from approval. So Nilesh, now that we have one generic competitor there could you update us on our standing on the Lialda filing?
- Nilesh Gupta:** I think both of these are from the India pipeline actually and I think both of these are planned for launch next year.
- Aditya Khemka:** So Apriso you expect in FY'19 or...?
- Nilesh Gupta:** We have a date but we also had a query that we are addressing. Based on that query response we believe one year later we will be able to launch. So we expect to answer the query later this year based on which we expect to launch next year.
- Aditya Khemka:** Can you also give me some similar color on Lialda please, Nilesh?
- Nilesh Gupta:** Same story, we actually have a query on Lialda as well which we are addressing and we expect to launch it next year.
- Aditya Khemka:** Could you also confirm that since we have the mesalamine products these two from the India basket, have we filed for the other mesalamine products as well Asacol HD, Pentasa, Canasa what have you?
- Nilesh Gupta:** Those are in our pipeline.
- Aditya Khemka:** So none of those other products have been filed including Asacol HD?
- Nilesh Gupta:** Yes.



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- Moderator:** Thank you. The next question is from the line of Anubhav Agarwal from Credit Suisse. Please go ahead.
- Anubhav Agarwal:** One clarity on the R&D spend. We have done about Rs.2,300 crores last year. As a whole for this year fiscal '18 do we plan to do lesser than that or same level?
- Nilesh Gupta:** I think like Ramesh said, Rs.500 crores per quarter is roughly the number that we are looking at. We are seeing some decline in areas like Drug Discovery. Vinita already talked about the funding partner as far as Biosimilars is concerned. On the Generic side, we really see spend as flat versus last year and that is why we will more or less be in line within what we did this quarter.
- Anubhav Agarwal:** So we should expect about Rs.2,000 crores number this year, right?
- Nilesh Gupta:** Yes, and last year was Rs.2,300 crores as you said.
- Anubhav Agarwal:** Just one clarity on Minastrin as well. Out of six months exclusivity, how many months of sales we have already done if we put together fourth quarter and this quarter sales?
- Vinita Gupta:** I think the six months ends in September.
- Anubhav Agarwal:** That is clear, but we never book like that, right, in terms of bookings what we have seen in the P&L?
- Nilesh Gupta:** How many months of sales did we do? So typically, in Q4 we would have done higher than the average for the quarter because it is good in quantities and stuff as well.
- Vinita Gupta:** Typically, we sell two months at the beginning of the quarter. It was normalized sales in Q2.
- Anubhav Agarwal:** So, would you mean that out of six months we would have already booked for about five months roughly?
- Vinita Gupta:** Yes.
- Anubhav Agarwal:** On Glumetza, just checking very roughly, for us annualized level of Glumetza right now will be about \$60 million to \$80 million range now or higher?
- Vinita Gupta:** Not going to give product-wise sales.
- Moderator:** Thank you. The next question is from the line of Surya Patra from PhillipCapital. Please go ahead.
- Surya Patra:** Just one clarification on the Gavis number that we gathered from the annual report which says that revenue of around \$86 million wherein we are also seeing that the branded products are of



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around \$42 million for last year. So does that mean the Gavis portfolio as a whole has witnessed a significant price erosion or something like that?

Arvind Bothra: Surya, I think there is some communication gap here. In the annual report we have mentioned about the Brand business sales being \$86 million and it is not the Gavis sales that we are referring to, we have not mentioned Gavis sales in the annual report while we are talking about Gavis numbers as we speak, over time we would be fusing - it as part of our US business. So I think that is what your assessment should be, right.

Surya Patra: No, I was just referring to the subsidiaries numbers that what we separately give for different subsidiaries, so there from I collected that number that says it is around \$86 million.

Ramesh Swaminathan: But that is a transfer price, so obviously it does not disclose the full detail, but we have actually gone and told analysts that we did about \$110-odd million last year and we expect it to be north of \$200 million. In overall sense, we are behind our own schedule by one year. So we are very well on the Gavis front and would do better in the days to come.

Surya Patra: So \$200 million by FY'19 that we mean to say?

Nilesh Gupta: FY'18.

Surya Patra: On the R&D front, sir, R&D productivity if you see how should one look at it because on the filing front though now we have moved to a qualitative productive portfolio, that is a possibility that gestation period or the filing period has enhanced so the number of a product filing also declined a bit whereas the R&D cost from a couple of period base if you see then it has obviously witnessed a kind of up-move? So how should one look at the R&D productivity front for Lupin?

Nilesh Gupta: This year we expect to do more filings than last year... we expect to file 35-40 ANDAs this financial year and that is a similar number to what we did last year combined with Somerset, that was a similar number as well last year. So I think more or less it remains the same. Sometimes it maybe more from India and lesser from Somerset or the other way around. So overall 35-40 ANDAs per year.

Surya Patra: So this quarter what one number that we have said on just one ANDA filing, it is from the India base that we talked about?

Nilesh Gupta: Given all this lumpiness, I think you should look at that aggregate number because we are now increasingly just work backwards from times and work the optimal time to file the ANDA and we are always heavier on Q4 versus the rest of the quarters.

Surya Patra: Just one more question on the Domestic Formulations business. We have already seen some impact of the destocking in the first quarter, possibly in the next two quarters we will be seeing a gradual recovery. But whether the inventory holding at the channel levels which earlier used



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to be like whatever like 1.5-months or something like that, so whether that is getting corrected and so possibly FY'19 on a low base so FY19 may not see a kind of an enhanced growth in the domestic business, is that correct?

Rajeev Sibal: If you look at the inventory levels as you are talking about, in the market normally the inventory levels have been at 45-days, but because of this GST destocking, the inventory levels have come down to 25-days. If you look at next few quarters, obviously, there will be some recovery as far as inventory levels are concerned but we have to see that how much recovery happens. I do not think exactly 45-days we will go back to those inventory levels but obviously there will be some recovery as far as next few quarters are concerned.

Surya Patra: So that means FY'19 should not look a stronger year considering the low base of the current year?

Rajeev Sibal: No, FY'19 is going to be a good year because even if you look at this year, even if you normalize, it is not going to be much different. Even FY'18 also for India business as Nilesh spoke earlier also, the next three quarters we expect to grow the business at 15%. So our overall growth of this year also is going to be at least 20-30% more than the market.

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

Manushi Shah: I wanted a clarity on Lialda. Sir, you said you are going to launch it next year but as I understand Lialda is under patent litigation. So is it that you are targeting non-infringement like all the other companies or how are you expecting a launch?

Nilesh Gupta: Zydus already launched as you know. We believe that we believe everybody will be able to launch it next year.

Manushi Shah: So you believe that you will get an outcome or will it be a launch at risk?

Nilesh Gupta: We will see what the circumstances are, but we believe that we will launch next year.

Manushi Shah: In past two quarters, Lupin launched a couple of Controlled Substance products like Roxicodone, Narco which has significant sales and Lupin was at 10th, 11th player to enter but still the products have significant sales. So how are these products doing?

Vinita Gupta: They are doing pretty well. We have been able to garner a pretty good share in these products with the relationship that we have with the customers. As I mentioned in our May meeting also, we had a lag because we had to get quotas from the DEA. We are very pleased now that we have established a good line of communications with the DEA and have got commercial quota for all our material products.



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- Manushi Shah:** How much would the market share be for Lupin for these products?
- Vinita Gupta:** I do not have the individual product market share but for these products we have 20% plus. The Hydrocodone product that we launched we were at 20%.
- Moderator:** Thank you. The next question is from the line of Ashi Anand from Allegro Capital Advisors. Please go ahead.
- Ashi Anand:** First question is with regards to Etanercept. You mentioned the financial partner. Just wanted to understand is this a strategic partner or is this a marketing partner as well or is fully financial?
- Vinita Gupta:** It is fully financial.
- Ashi Anand:** Any kind of timelines with relation to when we are expecting Europe and US filing?
- Vinita Gupta:** Right now, we are on track for a filing this year in Europe and Japan. We will have to do a supplemental study for the US and then also patent hurdle in the US, but expect next fiscal year to file for the US.
- Ashi Anand:** Second question is you had mentioned in the previous concall that you are expecting three first-to-file launches in FY'19. Would it be possible to share that launches expected to be?
- Vinita Gupta:** Yes, we shared in the past, I know Ranexa is probably the largest one, I know that Minocycline, and Moxeza is the third.
- Moderator:** Thank you. The next question is from the line of Cindrela Carvalo from Dolat Capital. Please go ahead.
- Cindrela Carvalo:** Just wanted to understand, Vinita, last year we almost launched 18 products and we have approvals for more than 30-odd products. So why there is a disconnect in terms of number of launches?
- Vinita Gupta:** There is always depending on anticipated approval time and preparation for launch. There can be a lag between approval as well as launch. We have a number of products that were approved in Q4 last year that we have launched in Q4 but have built up in Q1. So, we try to launch our products as soon as possible, but sometimes there could be a lag, Derm products for example that we have got approvals for recently in Somerset, we were doing tech transfer to our facility in India, we did not want to duplicate manufacturing, so the tech transfer takes a little bit of time before we can launch. The other lag that one sees is like I just mentioned on controlled substances where you need to get quota from the DEA before you can launch and that would be the other reason for a lag.



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- Cindrela Carvalo:** Any kind of number of products which are still pending for which we already have approval, can you indicate?
- Vinita Gupta:** There are a number of products that we already have approval for that. We are planning to launch for the next 8 to 12-months. In Somerset, we have products like Potassium Chloride, we have Hydrocodone APAP, we have Oxycodone APAP, we have a number of these Derm products that they are doing tech transfer on right now.
- Cindrela Carvalo:** In terms of our margin guidance, we have now given a range of 21-23%. But what sense do we have on FY'19 given the kind of exclusivities that we are talking about... any range that we can share?
- Ramesh Swaminathan:** Actually, it is dependent on several factors including the way the FX would actually pan out. Currently it is in an appreciating mode but next year we really do not know. If it gets back to the depreciating mode, obviously, it will contribute to increasing our margins also. Safe to state that we in the past have generally been increasing our margins by about 75 or 100 basis points on an annual basis that is abatement about for at least good 7-8-years. I would think there would be an increase from the current levels, but it is very difficult to conjecture at this stage.
- Cindrela Carvalo:** Can you say how much would be your gross margin impact due to GST this quarter?
- Ramesh Swaminathan:** I said that before; it is close to about 2-2.5%.
- Cindrela Carvalo:** Coming back to Controlled Substance, Vinita, just to clarify, you said that we will start booking the sales from this month onwards for two of the products, right?
- Vinita Gupta:** We have already started booking sales.
- Cindrela Carvalo:** When do you think that we have now (45.00) contracts from DEA. When do we see a sizeable contribution coming from this portfolio?
- Vinita Gupta:** It will be in Q3 and Q4 we will have the full impact, in Q2 also we are launching a couple of major products like Hydrocodone APAP hydrant. So you will see the full impact in Q3 and Q4.
- Moderator:** Thank you. The next question is from the line of Samir Baisiwala from Morgan Stanley. Please go ahead.
- Samir Baisiwala:** Vinita, just curious when you say that ex-Metformin the base business growth sequentially was 11%, my guess is almost all of it was driven by Minastrin?
- Vinita Gupta:** Actually not. Minastrin actually came down a little bit from the first quarter marginally and it was really the rest of the products - our inline products, our Somerset products are the ones that drove growth.



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- Samir Baisiwala:** So you are saying that it was not Minastrin at all?
- Vinita Gupta:** No, you can consider Minastrin was almost flat.
- Samir Baisiwala:** Which is surprising because you had a few days in Q4 and you had full three months in Q1.
- Vinita Gupta:** We had two months for that launch.
- Samir Baisiwala:** So once now Minastrin gets normalized in this quarter, would you say that your \$238 million run rate that you had in Q1, is it going to dip before it rises or do you think this is a bottom?
- Vinita Gupta:** I would say that you will see majority of the Glumetza impact, we saw in Q1, but there is a little bit also in Q2, so you will see a little bit marginal dip in Q2, but that is the bottom.
- Nilesh Gupta:** And then it will hopefully start picking it up in Q3 and Q4.
- Samir Baisiwala:** You are citing only Glumetza, not Minastrin for a dip in September quarter?
- Vinita Gupta:** Yeah.
- Samir Baisiwala:** Just on Gavis, how do you make a bridge between \$110 million in previous year to \$200 million this year. Is it because of the Somerset capacity expansion or is it about the new launches that you talked about? Second, where were you in Q1 on Gavis?
- Vinita Gupta:** It is a combination of the capacity expansion as well as the product launches building share on the products that we launched in Q4 last year, building on the brand business and the confidence that we have the optimism is really based on the run rate that we have on commitments that we have got from customers so far.
- Samir Baisiwala:** Q1 was reflective of \$200 million or was it more like one-tenth?
- Nilesh Gupta:** Definitely more than one-tenth, but I think we are still in ramp-up mode.
- Samir Baisiwala:** Nilesh, I was surprised by your commentary on Lialda because as the previous speaker was saying, I check your court case is still on in discovery stage I think it started on 59, the patent expires in June 20. So how do you expect to be in the market next fiscal year?
- Nilesh Gupta:** Maybe I will just get back separately to you on that.
- Samir Baisiwala:** If I go back 10-years, 40-50 quarters, this is for the first time that I am seeing YoY decline in the top line. So what is the outlook for the full year fiscal '18...just a directional guidance would be helpful?



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- Ramesh Swaminathan:** I would think at this stage if we see rupee being at the same range at very best it will be at a same level as last year and that was perhaps a percentage or two lower as compared to the previous year, that is about it.
- Nilesh Gupta:** Low single-digit decline is what we are seeing unless we get some upsides from where we are right now.
- Moderator:** Thank you. The next question is from the line of Anmol Ganjoo from JM Financial. Please go ahead.
- Anmol Ganjoo:** One directional question; given the adverse pressures in most of our segments do not seem to have bottomed. How do you reconcile your yesterday statement in the press that seems to be behind us and when you do some of the numbers and look at the outlook and try to capture the commentary during the course of this call just does not seem to add up, what is the driver of the confidence that the worst seems to be behind us?
- Ramesh Swaminathan:** If you look at our growth prospects for each region, India obviously, you would appreciate the Q2, Q3 and Q4 would be certainly better than Q1 with normalcy being restored. If you look at EMEA and as I said it was particularly bad only because of South Africa. If you look at APAC, the first month was lackluster, was bad, but the growth after that has been on a ramp-up. If you go back to Americas itself, there is Glumetza, but we are looking at quite a few launches. So for those reasons I believe that the sales can only ramp up from now and as I said before if we normalize for GST, you would find the EBITDA margins to be higher and that is the reason I said there is a lot of reason for optimism when we speak about the next few quarters being better than the current quarter.
- Nilesh Gupta:** If I can clarify Ramesh's statement, we have obviously expected the next few quarters to be better than Q1 but I think the real growth starts from FY'19.
- Anmol Ganjoo:** My second question is on the margins. Gross margin settling at around 67-67.5. We are not taking obviously a call on the rupee here plus whatever we see in terms of pressures, so R&D run rate quarter of Rs.500 crores stays. So don't you think there is downside risk even on the lower end of our revised guidance of 21-23% on the margin side?
- Ramesh Swaminathan:** Not at this stage, I think we are pretty cautious at 21-23%.
- Moderator:** Thank you. The next question is from the line of Nitin Agarwal from IDFC Securities. Please go ahead.
- Nitin Agarwal:** Vinita, on the US branded business, any rethink on how we are looking at doing this business now incrementally?



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Vinita Gupta:

Last year there was a change from a therapeutic area standpoint, we got into women's health and have been able to build up Methergine over the last couple of quarters and have started to create relationships with the OB-GYN. So very focused on building on the start with Methergine and looking at bringing other women's health products into the portfolio. Simultaneously, we are also looking to build Neurology as a company not only in the US but in other markets, the US we have the ADHD products with MonoSol that fit with neurology focus and in Japan and Europe we have got into CNS from Neurology, meaning Japan we have the Shionogi portfolio that bolster our CNS franchise and then the Quetiapine XR product that we license from Astellas that we will launch later this year is really going to be the first IP protected brand that we promote and build in Japan. In Europe, we filed Mexiletine, a Myotonia product in June and there is no product approved for Myotonia. So it is a major unmet market need. We are going to be working over the next few quarters to get this product approved and launch next fiscal year hopefully in the big five countries in Europe and then beyond the big five as well.

Nitin Agarwal:

Secondly, on the US Generic business, we mentioned we did 238 for this quarter and we talked about a slightly softer Q2 Vs that we did last year. Given this run rate, we will be materially short of what we did last year, right, instead of our probably earlier expectation or around being like a flat on US on YoY basis?

Vinita Gupta:

That is right, we are going to be down from last year.

Nitin Agarwal:

But '19, would you see like a pretty sharpish sort of return recovery on whatever base we end up hitting in FY'18?

Vinita Gupta:

Yes, we are and thankfully we have some really good products that we already approved for have exclusivity and now potentially add to that with the products that we talked about today like levothyroxine, other products that we are hoping that we can expedite given the FDA's new guidance with the GDUFA authorization, they are prioritizing products with limited competition. So we have a number of products and our current file products that we are hoping to expedite as well. So we should definitely see a strong growth into fiscal year '19.

Nitin Agarwal:

Just to get some sense, because there is so much of uncertainty around it for the current year, US decline will be what ...single digit or could be even a double digit decline from where you see right now?

Vinita Gupta:

We see a double-digit decline.

Nitin Agarwal:

If we just go beyond '19, we have made major R&D investments over the last two to three years, the situation which is there in the industry where you and your peers have probably ramped up R&D spend materially over the last three years and output has been pretty slow to come by. How do you see for yourself playing out in terms of the output of this R&D that you have done for the last two to three years?



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Vinita Gupta:

We expect the recent investments that we have made in the last three or so years have been in Inhalation, in Complex Injectables, Depot Injectables that is and Biologics. In Inhalation front, as I mentioned, we have started filing products. We expect ProAir potentially to be our first product in market and then Spiriva following that and then the rest of the pipeline that we are pursuing. So we expect the Inhalation pipeline to start kicking in fiscal year '20 and '21 onwards we would expect it to make significant contribution to our Generic business. The Complex Injectables pipeline has been slower than the Inhalation products, but we expect our first product Risperdal Consta to be filed fiscal year '19. So that should kick in really in fiscal year '21 onwards. The Biologics with our first product Etanercept we expect to file in Japan and Europe this year but the US is going to be subject to patent, we are going to file next year and then subject to patent litigation. So in these Complex products, there have been a lag because we first had to build capabilities, then build the pipeline and then wait for the products to get approved. But we look at fiscal year '20 onwards a significant contribution from these Complex Generics that we have been investing in for the last few years.

Nitin Agarwal:

Nilesh, on Sevelamer, is there still a relevant opportunity now given the generic launch from one of the competitors?

Nilesh Gupta:

We are very disappointed with our own performance on Sevelamer. I think this is still going to be a good opportunity. Long-term there will clearly be another two-three competitors that will come in as well. We are still seeing this as an opportunity for next year. But we will still look forward to bring it to market.

Moderator:

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

Arpit Kapoor:

My question is with regards to your M&A strategy with what is happening in US currently with generic price erosion and channel consolidation and our experience with Gavis for the last two years, has there been a rethink or what would be our M&A strategy specifically for the US market going forward?

Vinita Gupta:

M&A strategy for the US as we mentioned for the past few quarters is primarily focused on the Specialty brand side of the business. On the Generic side of the business, we are very well positioned and majority of the areas that we want to pursue, whether it is Inhalation products, Complex Injectables, Controlled Substances, Derm, we have a pretty comprehensive coverage and then Biologics on top of that. Our strategy has been to really build from simple generics to complex generics and brand. We think that on the Complex Generics front we have majority of the investments in place and it is going to be more execution over the next few years. On the Specialty front, we will need to build through product acquisition, pipeline acquisition over the next couple of years. So that is where the focus is.



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- Arpit Kapoor:** So then in that context, our R&D can inch up let us say if we go ahead and acquire some of the Specialty assets and the lead pipeline and then invest behind them for the few patients so that we can launch them in the market?
- Vinita Gupta:** We will manage R&D spend like we are managing it this year as well. We have rationalized it, we have cut down where we felt our returns were lower, we have partnered in areas where we felt the risk was higher and we will continue to adopt that approach as we evolve our pipeline.
- Arpit Kapoor:** Is there any specific absolute target of R&D that we are targeting for the next few quarters that will not breach that mark or it is a moving thing and we may change it as things progress?
- Nilesh Gupta:** Right now, like Nilesh said, it is going to be Rs.500 crores per quarter and we will manage it, we are in a tough year and we are managing all our expenditure lines very carefully without compromising, without foregoing any of the material opportunities, we will continue to manage it effectively.
- Arpit Kapoor:** That will hold true, Ramesh, for the staff cost as well because again over the last five quarters, the staff cost has been pretty sticky at Rs.700-odd crores, so the number would remain here given the fact that we will have some top line pressure in this year?
- Ramesh Swaminathan:** In terms of sheer magnitude, yes, it will remain around that same level.
- Moderator:** Thank you. The next question is from the line of Aditya Iyer from Pico Capital. Please go ahead.
- Aditya Iyer:** My question is largely regarding your working capital. There have been a sharp sequential increases. So if you could just bifurcate how much of it is because of the GST disruption versus how much is because of structural consolidation in the US?
- Ramesh Swaminathan:** I was saying, the major portion of it is because of inventory increase and that you could contribute attribute to GST, but the portion coming from accounts receivable increase across that, there is an increase in government business in the API business. So all of them put together we saw working capital increase but you could be sure that you are working towards reducing in the days to come, there is tremendous focus on reducing the capital employed across business. So you would see fruits bearing in the next few quarters.
- Moderator:** Thank you. Ladies and gentlemen, we will take our last question now from the line of Kartik Mehta from Deutsche Bank. Please go ahead.
- Kartik Mehta:** Just trying to understand the EBITDA margin. I know there has been a fair amount of discussion. So in Q1, we had exclusivity for Minastrin, Q2 will be the same and on average we are at the lower end of the EBITDA guidance in a quarter like Q1 where we had an exclusivity advantage. So is there anything or any other part of the business where you would be doing well in this



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second half of FY'18 or is it fair to assume that our margin is more at the lower end of the guidance?

Nilesh Gupta:

Like we talked, there is a lot of the business that is going to pick up over time; we already talked about the India business, we talked about Japan, we talked about markets like South Africa as well, like we said in the US maybe we will see a little bit more decline in Q2, you will see the number picking up thereafter in Q3 and Q4 as well. So that is the reason why we talked about 21-23% and we think it will be somewhere in that range. Ramesh gives the caveat of FOREX. Of course, that is not in our hand, but otherwise what we see is 21-23%.

Kartik Mehta:

So the question was more from the perspective that H1 FY'18 would have been relatively stronger and as you had earlier also mentioned that you were expecting another competitor in Glumetza probably in H2, so if you mention there are other than non-US parts of the business which will be able to drive the EBITDA margin. Is that what you are saying?

Nilesh Gupta:

That is correct, in Minastrin obviously a smaller opportunity in the overall scheme of things.

Vinita Gupta:

Not so Glumetza, we have already taken a bigger hit than we had anticipated. From there we are off a little bit in Q2 and bottom out there, because of full impact of the India region business, obviously, you can imagine it is going to get us to higher than the current EBITDA level.

Kartik Mehta:

Are we assuming any competition in Fortamet in FY'18 and this EBITDA guidance or is that not?

Vinita Gupta:

No, we are assuming that the current competitive mix stays.

Moderator:

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

Kamal Sharma:

Thank you very much, friends for your questions and I hope you had all the answers that you are looking for. We all will value your questions because that helps us to improve our own performance and own analysis. Look forward to seeing you again next quarter. Thank you very much.

Moderator:

Thank you very much members of management. Ladies and gentlemen, on behalf of Lupin Limited, that concludes today's conference call. Thank you all for joining us and you may now disconnect your lines.