# “Lupin Limited Q2 FY-19 Earnings Conference Call”

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## MR. ARVIND BOTHRA – HEAD (INVESTOR RELATIONS), LUPIN LIMITED

**Moderator:** Ladies and gentlemen, good day and welcome to the Lupin Limited Q2 FY19 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 presentation concludes. Should you need assistance during the conference call, please signal an operator by pressing '*' then '0' on your touchtone phone. Please note that this conference is being recorded. I now hand the conference over to Lupin Management. Thank you and over to you.

**Dr. Kamal Sharma:** Good afternoon, friends. It's my pleasure to connect with you once again for the quarter's performance.

Before I give you a brief outline, let me introduce my colleagues who are around the table. We have Vinita, Nilesh, Ramesh, and Alok Sonig - who recently joined us as the CEO of US Generics. We also have Sunil, Rajeev Sibal, Naresh, Rajiv Pillai and Arvind. So, we are all here to answer your questions.

You would have already seen the results for the quarter. We have been speaking over last few quarters that there have been very challenging times especially in the US. However, it appears like semblance of stability is now slowly coming in. It is slow but steady and we do hope to see further improvement in the coming quarters.

As regards the performance, you would have noticed that the sales have grown on a sequential basis and are flat on corresponding YoY basis. Our EBITDA margin stayed around 20% this quarter at 20.1%. We have been guiding to 18% to 20% EBITDA margin for the year and I think the team is confident that we would maintain that during the year. Also, I think some of the pressure that we saw in the Glumetza and Fortamet franchise is slowly getting addressed now with stability coming in the market on prices and the growth in business.

To take you through some of the details of the financials, I will hand over to Ramesh who will share with you the financial analysis of the results.

**Ramesh Swaminathan:** Thank you Dr. Sharma. As Dr. Sharma was saying, results were in line with our expectations. We have been saying that this particular year could be a difficult year. It was a difficult year last year as well, but the turbulence still continues in some ways, though there are green shoots visible. The good thing about this particular quarter was that there was sequential growth visible across all our major markets. We saw growth in America, Japan, Philippines, South Africa and India for sure. In the larger picture, it was also aided by very favorable forex tailwinds that contributed tremendously and that's one good reason why we saw improvement on the gross margin front. This cascaded to the EBITDA front also, however there was an impact of forex on the expenses front as well. To that extent the gross margin increase was pared down as it came down to the EBITDA level.

On another front, we continue to spend on Solosec because these are still early days. We spent about US$12 - $13 million this quarter, in addition to the US $12-$13 million that we spent in the first quarter. This obviously impacts the EBITDA, and you would notice that the EBITDA improvement is despite the fact that we have had this increase on that score. We do expect the second half of the year to be better. It's going to be aided by the fact that we could have the gRanexa launch, potential ramp up on Solosec and the onset of the flu season. It's also pertinent to talk about the EBITDA improvement measures that we have been undertaking. A lot of emphasis today is on cost cutting, because that's something which is in our hands. We on the previous occasions, spoke about the fact that we are working with world-class consultants to bring a lot of improvements on that score. A lot of progress has been made on that front in the last 5 months, but the results are yet to unfold. It's still early days, but we do expect that it will come through over time. We are working on procurement excellence - on the manufacturing front and various components out there, and on R&D productivity. We are very confident that there will be results coming in over the next several quarters.

One last word on the effective tax rate, because after the results people have been calling me and asking me why the effective tax rate for the first half is very high. It's because that there are losses in some of our subsidiaries. Whilst we pay a normal 26% tax in India, we have losses in other subsidiaries which should compress the overall PBT and that's why you will find the tax rate to be shooting up.

With that I would hand it over to Vinita to say a few words about the American market.

**Vinita Gupta:** Sure. As Ramesh and Dr. Sharma have already covered the overall revenue and profit performance, I would add on the US front. We saw 5% QoQ growth this quarter aided by forex of course, but also the base business grew 3% in local currency terms led by the generic business. The brand business witnessed some pressure, as you would recall in the last quarter we had a generic to Methergine that fully played out in Q2. So, the brand business was rather down QoQ, while the generic business was up primarily led by existing products, as we really didn't have any material new product launch during the quarter. It was primarily based on additional business that we picked up as a result of some supply-chain issues of peers and we are seeing more and more of these situations. It's actually a healthy sign as far as we are concerned. The US market is gone through a lot of pressure over the last couple of years, but we are starting to see some level of stabilization and moderation in price erosion setting in. In the last year or so, we have seen companies like Mylan, Teva get out of multiple products in their portfolio presumably because they had reached a threshold below which it was not feasible for them to continue to manufacture the product. So, we are seeing this supply disruption more and more which is a very healthy sign for the industry. We benefited from some of that in Q2 and we expect to continue to see this trend in the next couple of quarters. So, that plus the price moderation on the generic front, the upcoming flu season coupled with key launches in Q4 should help us grow our US business in the coming quarters. With the flu season coming up, we expect the Tamiflu franchise as well as the cephalosporin franchise to contribute more in Q3 and Q4. And with Ranexa as well as Levothyroxine, we would expect good contribution in Q4.

On the brand side of the business while Q1 and Q2 have been significant investments, we have seen a good ramp up in Solosec both in terms of prescriptions as well as managed care access, up now to 68% of unrestricted access and 90% plus overall access with some restrictions. This has been really positive, very encouraging for us to see this kind of access for the product this early in ramp up, early in the evolution. So we expect Solosec also to contribute more to our revenues in Q3 and Q4 as well as see the full-year impact in the next fiscal year.

With that I would like to open it up to questions.

**Moderator:** Thank you very much. Ladies and gentleman, we will now begin the question and answer session. The first question is from the line of Prakash Agarwal from Axis Capital. Please go ahead.

**Prakash Agarwal:** First question on the US FDA update on the facilities and do we continue to expect resolution by end of this financial year?

**Nilesh Gupta:** Yes, we've guided to the end of the financial year. The overall status remains the same, we've responded to all the updates that we wanted to provide. We have now requested FDA for a meeting, and the hope is that we get a meeting pretty shortly followed by a re-inspection if they need one. We are still hoping for the end of the fiscal at this point of time. We are starting to get a little bit toward that holiday period, but we have been trying hard to engage with the FDA. With the formal request for a meeting things should move ahead now.

**Prakash Agarwal:** But from your side you are fully ready and cost wise also the large part is already done, would that be fair?

**Nilesh Gupta:** Yes, we have addressed all the commitments that we made to the FDA. As I shared last time, we have also come up with an enhanced compliance sustainability plan and we have made a lot of progress on that plan. In fact, some of the strategic hires that we wanted are done - the head of compliance in the US, head of investigations in India. So there are also structural changes that we have made, a lot of improvement on lot of procedures and practices as well. So, a lot of great progress is made. We believe that we are ready.

**Prakash Agarwal:** And secondly on comment by Vinita, two things, one is the flu season already started. So, we have already seen early onset of winter and do you expect the market to be of similar size given the number of players have come in? And secondly, you also mentioned Levothyroxine, Ranexa now, so is it from Q4? The earlier thought was Levothyroxine should start coming in Q3?

**Vinita Gupta:** We are just starting to see the early flu season. I can't say that it's in full swing as of yet and I can't predict that. But we would expect that in Q3 and Q4, we should see the impact of the flu season on the flu season products. Yes, there are some additional competitors on Tamiflu, but they're still only a handful of competitors in the marketplace, so we expect the product to be a decent contributor to Q3 and Q4. On Ranexa, we have said it is a Q4 opportunity for us. On Levothyroxine we had a question from the FDA, and we have responded to the CRL fully and expect to get approved in Q4. We are working on the product supply launch quantities, and will be ready to launch the product in Q4.

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

**Anubhav Agarwal:** Vinita one question on US sales, in this September quarter did we benefit from supply of Tamiflu sales as well?

**Vinita Gupta:** We got very little in September. It was marginal.

**Anubhav Agarwal:** Just based on what IMS shows, it shows that even if at discount rate we could have benefit like mid to high single-digit, would that be a very high number for this quarter?

**Vinita Gupta:** Yeah that would be a very high number, but it's definitely not the case.

**Anubhav Agarwal:** And this Solosec incremental spend that you talk about, US$ 12-$13 million, you mentioned that we have built the team already. So, this is all captured in other expenses basically all marketing expense that we are talking US$ 12-$13 million?

**Vinita Gupta:** Actually it's the total spend on Solosec. If you look at the brand business now, with Methergine having gone generic, Antara and Suprax are also very small part of the franchise. So, if you look at our P&L, we are bearing a full investment of the women's health commercial infrastructure which is roughly around US $12-$13 million a quarter. So, it's not incremental US$ 12-$13 million, it is the woman's health spend per quarter that our P&L is bearing as an investment.

**Ramesh Swaminathan:** Because the revenue is just about US$ 3 million or thereabout.

**Anubhav Agarwal:** I understand it. So this is basically coming from one product to other product. But then what explains a very sharp increase in other expense and personnel cost for us in this quarter versus say Q1?

**Ramesh Swaminathan:** It's basically because of two things, firstly the increments that have been given to people. The second part is the forex itself.

**Nilesh Gupta:** It is the increments and incentives in India and forex.

**Anubhav Agarwal:** I just want one clarity on the material cost, for us material costs sequentially has gone down, in absolute term - I'm talking about by 3% to 4% whereas our revenues have increased. So, is there a region where we have benefited from forex gain in the cost of goods sold?

**Ramesh Swaminathan:** There are two parts to that. There is the element that we are buying from outside, and what is actually being made within the company itself, that's more for the India region. The second part is the impact from the forex conversion of the closing stock at the closing rate in Japan. So, the forex would certainly impact the movement of closing stock in Japan and other places where we actually have production.

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

**Neha Manpuria:** If I were to remove the increment and the FX impact on the quarter, have we seen benefit from the cost focus that you indicated in the opening remarks in the quarter? Would other expenses and employee costs have gone down quarter-on-quarter?

**Ramesh Swaminathan:** That's difficult to say but there is an element, as I said, and Nilesh also pointed out, of increments in India and that’s taken into the P&L.

**Vinita Gupta:** Lot of cost optimization efforts that are well underway, and you did not really see material impact of it as of yet. You're going to see it really at the end of the fiscal year and next fiscal year for certain.

**Neha Manpuria:** On the R&D expense, we seem to be running below the guidance of flat number year-on-year, should we expect this to pick up in the second half or because of the R&D productivity focus this is the run rate that we should be expecting?

**Nilesh Gupta:** Last quarter we talked about keeping it flat at more or less to that number. So, it’s exactly flat to that number this quarter and this is broadly the run rate. We would expect between INR 1,500 to 1,600 crores for the year now.

**Vinita Gupta:** And it’s down because of the sharp focus on the pipeline, the pipeline rationalization as well as productivity improvement.

**Neha Manpuria:** The second question is on Japan. It seems like Japan is having another tough quarter. What's the outlook there and how are we looking at growing that business from a two year perspective?

**Nilesh Gupta:** Japan is going through a very challenging period. In fact, Q2 was easier than Q1 because we didn't have the price cut that happened in Q1. However, they are already guiding to another price cut next year. So it’s really a fairly anti-generic environment. But in the broader picture, we are No. 6, and we have a very strong CNS focus. I think increasingly this is the market that's going to work for vertically integrated players, some of the stuff that we have already done - R&D in

India, manufacturing in India, vertical integration. I think those are the things that are going to work. We had the long-listed products that used to not see price cuts, now we see deep price cuts on the long-listed side as well. So, these are all things that are impacting the market. So, the market was not really perfect from that perspective. It's becoming more a generic oriented market, it is becoming a more substitution-oriented market where you don't need that much of promotion to doctors as well. So, it's starting to switch into a more generic-generic kind of market. I think that is the outlook for the market, I don't think the market itself is going to change. So we have two parts – One part is the portfolio that we bring, primarily out of India including some of the complex generic products for Japan as well. The second part was the specialty play as we launched Bipresso. A good part of the sales force is really working on Bipresso at this point of time. Its early days, the numbers are still small but we hope to pick it up to be a meaningful number. We also have the biosimilar strategy playing out, so we have filed Etanercept. We had queries, we have responded to the queries as well and we are on track for launching it in the middle of next year and we are preparing for the launch.

**Neha Manpuria:** On the working capital days, that seems to be increasing even if I look quarter-on-quarter, any color there? Is this because of the market share that we have been able to capture due to supply disruption?

**Ramesh Swaminathan:** No, I think it's a combination. Forex is the most important reason there.

**Nilesh Gupta:** Forex and stocking for the season.

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

**Surya Patra:** What is the net forex impact in the quarter that we are seeing?

**Ramesh Swaminathan:** Overall, it should be in the vicinity of INR 200 odd crores.

**Surya Patra:** And the large part of that is there in the other income. Is it fair to understand?

**Ramesh Swaminathan:** It's for sure, it's across various lines.

**Surya Patra:** Just on the domestic business front, so it is muted growth. Obviously there was possibly some—on the base of last year possibly this is muted—but just wanted to know is there any impact of this FDC ban thing that is there in the existing business? If not do you see any impact of that in the number of products that could have been launched in the domestic business and hence the impact on the growth number for the domestic business?

**Rajeev Sibal:** You said it right that this quarter was depressed because of the last year base, which was unusually high because of the post-GST channel re-filling, following a depressed Q1 of last year. Having said that if you look at our H1, we are growing at a very strong rate. Our growth is 15%

versus market growth of close to 12% as far as IMS is concerned, and as far as **AIOCD** is concerned the market growth is 8.5%. We are now the 5th ranked organization. Our market share has also improved. All our major therapy areas which are cardiac, anti-diabetics as well as respiratory we have been growing better than the market. We have introduced new products in this particular quarter, particularly our in-licensed product in diabetes therapeutic area which is Dulaglutide (Aplevant) - once weekly therapy as well as the combination of Empagliflozin + Metformin (Gibtulio Met) as well as Empagliflozin + Linagliptin (Ajaduo). So, I'm sure that, particularly in the diabetes therapy area we have gained significant ranks in the last 2-3 years. We are now the 3rd ranked organization on net basis. We are growing at a pretty good CAGR of 24% and we expect that CAGR to be continued. So, I am sure if you look at H1 performance we have grown at close to 15% and as I said in the last quarter call also that we will be ending the year at 14% - 15% growth. If you look at FDC ban, we have a minimal impact. We had an impact of just ~INR 26 crores for the year and I am sure that we will be able to compensate this particular impact from other products that we have.

**Surya Patra:** So, will this impact the number of new product launches in India?

**Rajeev Sibal:** Obviously, because of the regulation that all the FDCs have to now be approved by DCGI; the new product pipeline is shrinking. But we as an organization, are on a very strong footing as we have lot of in-licensed products and we are also working with our R&D to develop some innovative combination, which we can go through DCGI and we can launch in the market.

**Surya Patra:** So, one more on the gross margin front. So sequentially though there is an improvement and possibly there is element of forex gain that is there, excluding the forex impact and considering the price rise situation what we are witnessing from the fact of China impact, so sequentially what is the kind of a real changes in the gross margin front on a like-to-like basis?

**Ramesh Swaminathan:** It went up to 64.2% from 61.7%, that's a 2.5% increase sequentially. A large chunk of it was actually forex

**Nilesh Gupta:** About 60% to 70% was forex and 30% to 40% was other reasons basically a better business mix.

**Surya Patra:** Did you find any impact of this China related…

**Nilesh Gupta:** There is a little bit, but there will be some more which will come. In markets like India, for a large part, we are actually able to pass it on especially for the API business. But I think there is some that will kick in.

**Surya Patra:** Just last one question on the margin front so like as you said that because of per quarter specialty spend in US is around US$ 12 million like that. So, what is the kind of remediation spend that would be there for quarter currently because of the facilities?

**Nilesh Gupta:** It's very small. Like we shared earlier, Q1 was pretty much the last quarter where we had a meaningful spend and it has come down significantly.

**Surya Patra:** Any sense on the margin that you can provide because we have been seeing the most depressed margin scenario currently for our consol business why because three major markets obviously US, India and Japan, Japan is going through a kind of a significant negative phase. And there are challenges obviously in the US and we are in the spending mode, and possibly the only one market reliable currently is domestic. So, given the scenario any outlook on the margins?

**Ramesh Swaminathan:** Assuming that the tailwinds on the forex front are where they are, it's not going to continue. One would anyway be also coming out with newer products, in terms of products which will likely get you higher realization. We alluded to the fact it could include ramping up of Solosec, we could potentially have Ranexa and the flu season products itself. So, those would likely be better yielding products. The second part is on the cost front - while a lot of endeavors have been going on, these are not going to pay off in the short run, but certainly in the long run. The third part is the R&D itself and we have always said that we will reign this at current levels. So, the run rate is going to be potentially around INR 400 crores. So, I would think that the margins would hover around 18% to 20% mark.

**Surya Patra:** Including other income because forex is there in that?

**Nilesh Gupta:** What we are saying is net of that also. Not only at the gross margin line but also in the EBITDA line, as the business picks up. We talked about 18%-20%, we are now pretty much at 20% and that's really the number that we would love to keep it at irrespective of Forex.

**Moderator:** The next question is from the line of Girish Bakhru from Bank of America. Please go ahead.

**Girish Bakhru:** Vinita on Solosec you had given some color on the coverage, just if you could also give some color on how much is the preferred access right now?

**Vinita Gupta:** Around 68%.

**Girish Bakhru:** No, so 68% you said is unrestricted access, right. I am basically keen to ask how many formularies are like say putting it on a preferred coverage vis-à-vis other treatments that there in the market?

**Vinita Gupta:** Girish, we did not target Tier II coverage because what you pay for that is quite a bit. You have to discount a product quite a bit. We just wanted access. We wanted to make sure that the product is not blocked as long as we had access. We also have coupon that offsets the cost for the patient. So, our goal was really to get access and we have unrestricted access of 68%. That's what I meant.

**Girish Bakhru:** And this can continue to increase further as we go forward?

**Vinita Gupta:** Yeah, I mean as a product as its getting acceptance, you would expect some of the restricted access also to convert and there are still some where the product is blocked. So, we continue to work with them.

**Girish Bakhru:** On Levo there are some times certain articles mentioning that the product is actually under shortage even though FDA doesn't list it under shortage. What is your sense on that?

**Alok Sonig:** Our sense is that there is clearly a volume uptick possible on the product. To the extent it's in shortage, we only know through the FDA website and you are right, it's not all there. But yeah, there is an uptick possible as more entrants come in and the market is looking forward to few more entrants versus the historic peak that we saw on Levo. So there is that potential, so you are right.

**Nilesh Gupta:** I think as we shared earlier on Levothyroxine, post approval we will be submitting for the other bio-studies as well. We will have a very compelling product at the end of this period, but we have to go through that loop post-approval as well which is why we guided to a slow ramp up. But it's really in the next fiscal that you will actually see we getting approved for the entire line and that's when we will have a very meaningful proposition.

**Girish Bakhru:** Any color on Mesalamine?

**Nilesh Gupta:** So we're back to reformulation and we are in pivotal studies at this point.

**Moderator:** The next question is from the line of Chirag Dagli from HDFC. Please go ahead.

**Chirag Dagli:** How has the Metformin franchise moved quarter over quarter or year-over-year, if you could give us some color for the US, both Fortamet and Glumetza put together?

**Alok Sonig:** We have seen some improved trends this quarter versus the previous quarter for both products. So, overall as you see the most recent IMS data shows a pickup of about 10% for Fortamet and about 5% for Glumetza. As Vinita said earlier, that was largely driven by a couple of key players having supply issues, and that trend is likely to continue in the short term. So we are seeing stabilization there and we have seen earlier as well there has been a volume pick up, so those are good trends.

**Vinita Gupta:** Pricing seems to have stabilized as well. When we look at it month-on-month, it seems like the erosion has come down to a single digit in Fortamet and it is pretty much flat on Glumetza.

**Chirag Dagli:** So, Q2 Glumetza and Fortamet put together would be higher than Q1 sir?

**Nilesh Gupta:** A little bit.

**Chirag Dagli:** In your earlier comment on the US branded business, the sense I got was that there is a fixed cost of US$ 12 million a quarter on the business as a whole, this is not obviously incremental that is on Solosec. Is understanding correct?

**Vinita Gupta:** It is primarily on Solosec, the commercial structure for the women's health sales force that is roughly US$ 12 - $ 13 million a quarter.

**Chirag Dagli:** But this is not incremental for this year or …?

**Vinita Gupta:** It was actually not there last year.

**Nilesh Gupta:** It is incremental over last year. What we did not clarify was obviously that we ramped up the sales force last year, we started focusing on women's health, we repurposed as well and that is the investment that is going into Solosec at this point of time without the commensurate return.

**Chirag Dagli:** So, for the first half your investment in Solosec is US$ 25 million and this is incremental which is over and above what was there in the first half of FY18, is that understanding right?

**Ramesh Swaminathan:** We also had revenues there because we had Methergine and so on which is not there this time around. Gross margins and EBITDA margins flow through could have been better with the high revenue base.

**Vinita Gupta:** For the most part, the investment for Solosec was in Q1 of this year, it was not there last year.

**Chirag Dagli:** On the India business, how has profitability moved over the last say two, three years?

**Ramesh Swaminathan:** We don't go into segmental wise profitability, but suffice to say it is obviously one of the more profitable parts of our business.

**Nilesh Gupta:** Basically we have been getting good operational leverage over the last few years as we have been able to build the business without a commensurate increase in the sales force. So, we had a big ramp up 2.5 years ago, when we increased our sales force by 1,000 people and we have not added thereafter. So, obviously we have been getting that operational leverage in the course of the last couple of years.

**Ramesh Swaminathan:** But if we want to give any directions, it is higher than our corporate average.

**Moderator:** Thank you. We will take the next question from the line of Sameer Baisiwala from Morgan Stanley. Please go ahead.

**Sameer Baisiwala:** Vinita, a quick question on Solosec. Now that you have good formulary coverage, what would it take to ramp up the prescriptions, what are the key milestones and the actions required?

**Vinita Gupta:** So, it is really, Sameer, a matter of working on the pull-through of the product in the physician's office as well as pharmacies. Our team is working hard on both; the field force has been working on the top tier doctors and they have to get to the point where there is a good product awareness and willingness to utilize the product. We have started to see it but we need to see more and more of it. The pharmacies are also right now a significant effort for the sales force because once the initial stocking was done, we have not pushed more products to the pharmacies, so it really needs to be pulled through by the prescriptions. So, it is primarily the execution effort on the sales force front both with physicians as well as pharmacies. So, on top of that, we have also started the direct to patient campaign which was just implemented in the last couple of weeks through our digital strategy. So, that should expand the reach of the product as well. Plus we have plans pursue additional efforts with physicians that have not started writing the product as of yet. So it is really a matter of getting more physicians to adopt the product through the sales force effort or otherwise to be able to gain momentum on the scrips… it is hardcore execution.

**Sameer Baisiwala:** Vinita, how many cycle of doctor visits your field force had, how many does it take to really convince them and how many physicians are you targeting and if you could tell what the field force strength at the moment with you?

**Vinita Gupta:** So, the field force strength is 125 for women's health, OB/GYN sales force and the primary care sales force that has a few products as well as Antara also details Solosec in the third position. What our team tells me it takes roughly four to six months for the physicians to start listening to the reps and start to adopt the product and start writing the product and then once they see benefit to the patients, you will see the repeat writers. What we are finding is that we already have a good percentage of repeat physicians. So, the feedback that we have got is that the physicians that are utilizing the product is seeing benefit to the patient, that is why they are willing to write more of it. We just need to do more of it. We will get you the exact number of physicians and the details offline, Sameer, but I expect that in the next couple of months we should start seeing a larger prescribing base as well as repeat prescribers.

**Sameer Baisiwala:** Is this once a week visit by the field force to a doctor or once a month just a cycle?

**Vinita Gupta:** The high writers is once a week and then it comes down to once in two weeks depending on desire of the writers.

**Sameer Baisiwala:** The second question maybe Alok is on the discussions with the US customers on a generic side. Do they look at your rupee depreciation? Do they look at specific 15% drop? Do they ask for their pound of flesh in this?

**Alok Sonig**: I would not really comment on customer-specific conversation, Sameer, but those are secondary kind of details peripheral to the core conversation on, obviously, the products and the new launches, supply sustainability is a key question they have which we have been able to leverage demonstrably as you saw. So, that is really where the conversations are, they are obviously more focused on supply, pricing, new pipeline and then some of the ins and outs.

**Sameer Baisiwala:** Vinita, have you guys responded to Proair CRL? And second is for Enbrel, when do you expect Japanese and European authorities to do site inspection?

**Vinita Gupta:** We have responded to the Proair CRL and expect to get approval next year. We have shared that we expect to launch the product in the second half.

**Nilesh Gupta:** I think on the inspection somewhere before the end of the fiscal.

**Moderator:** Thank you. We will take the next question from the line of Saion Mukherjee from Nomura. Please go ahead.

**Saion Mukherjee:** Ramesh, you talked about this cost control measures. Can you quantify what is the quantum we are talking about here, if you can give some more color, how do you want to do it? On similar lines on R&D, you mentioned controlling the cost. So, how you are rebalancing your priorities there, which area you are focusing on more where you are cutting down if you can give some color?

**Ramesh Swaminathan:** It's pretty early days to speak about this, so we are still working with them and we have identified lots of opportunities. We've looking at various buckets and moving ahead in a structured way to actually implement it. So, it would be too early to speak about it and we will do it when the implementation program starts.

**Nilesh Gupta:** If I can add, we used to always realize a couple of hundred crores efficiencies every year based on procurement efficiencies, operational efficiencies and the like. The idea here was to go and materially look at the entire cost base, to look at every cost center and then define it. So, we are still in the midst of that program. It will be a couple of quarters before we get to final kind of plan, and then we have to execute, there is a lot of droppage in this plan, then there will be additions over time as well. The intent is to meaningfully resize the organization, resize investments in line with the strategy going forward and that of course takes a little bit of time. On the R&D also, I do not think we are giving up on any of the opportunities that we have and again that is market reality, instead of chasing 25, 30 oral solids, we are now chasing 18, 20 oral solids. So, you are certainly getting away from the numbers more to the quality, focusing more on the complex investments, whether it's inhalation, or injectables or biosimilars. So, it is repurposing some of that. Over a period of time we love to add more into the specialty. So, we do not know right now whether that will be an increase in the R&D spend or whether we will be able to carve it out enough of the existing itself. But in the near-term, it stays at this level without losing out any meaningful opportunity.

**Saion Mukherjee:** My second question would be on the impact of new launches. We had a fair bit of launches/approvals of 30+ over the last one year. Of course, we have the erosion in Fortamet and Glumetza but still these new launches seem to have very limited impact. So, it seems that when you look forward your pipeline of 150 ANDAs pending, is that the meaningful launches are limited few, how should we think about it because last one year the impact of new launches seem to be very limited because of competition and the nature of the market?

**Vinita Gupta:** That is correct, the new product approvals that we have had in the last 12-months have been smaller, more competitive products, not the products that we have been first-to-file have exclusive or semi-exclusive, mean, other than Tamiflu and maybe one or two other products it's been limited. So, that has been a challenge for the last 12-months but as we look at the next 12-months with products like Ranexa that we will launch in Q4, Levothyroxine, products like Proair and thereon. We obviously have evolved the pipeline that is more attractive than an oral solid only pipeline. As Nilesh mentioned, we will also have Etanercept in the second half of next year and Biosimilars kicking in. So we finally have the impact on the complex generics pipeline that you will start seeing in the next year and thereon which obviously gives us the confidence that we should be able to grow our generic business on a consistent basis over the next couple of years.

**Saion Mukherjee:** On Spiriva, you mentioned there is an inspection which happened and received some observations, can you give some comment on that and have you received any formal response from the FDA on the file and if not then by when you expect?

**Vinita Gupta:** We were very pleased actually that there was a PAI for Spiriva this early in the process. We just filed the product in May with the FDA. We were confirmed first to file, we're very pleased to be first to file for this product for our first DPI, did not really expect the FDA to come back quickly to come and inspect but very-very happy that we have got their feedback early on. We believe that all the questions they have raised, we can answer effectively and should be able to get the approval of the product in time. Fortunately, we have the first-to-file tariff, but unfortunately we have 30-months stay, so we have to go through the litigation but we look forward to an early approval and potentially an early launch subject to litigation with the product.

**Moderator:** Thank you. We will take the next question from the line of Nitin Agarwal from IDFC Securities. Please go ahead.

**Nitin Agarwal:** On the API business we have seen substantial growth over the last couple of quarters. Has there been any sort of rethinking in the way how we are looking at a business given the opportunities to there in the API space globally?

**Naresh Gupta**: You need to look into consideration the China factor. The big thing is in China because of the environmental there has been lot of supply issues. So, that is one of the major reasons. And API's as well as the intermediate they have been now shifted to the Indian business. So, at least, we as a company, have a very strong position in seven, eight molecules where we have been a global leader. So, that gave us an opportunity and we foresee that for the next four, five years, API growth story for the country as a whole will be much better. And if you look at the growth rate, even the exports of the API from India has grown up by 12% compared to last year. So, the API story both in terms of the manufacturing base in India as well as reduction in the supplies in China, and another area which will come very strongly from India will be the fermentation-based products. So, I feel this story will continue and Lupin is a committed player in the API business for a long time.

**Nitin Agarwal:** Nilesh, are we looking to commit more capital to this business incrementally going forward?

**Nilesh Gupta**: Marginal, as you see, even now we are down to INR.750 crores on an annualized basis kind of capex, so it is down from when we were probably at INR 1,500 crores at one point of time, right. The capex spend in general is down, we are pretty well-up on facilities, there are some marginal, so for example, Naresh talked about the fermentation base, there is an opportunity that we see and there are some smaller investments that would happen, so little bit, but for the most part we have the pots and pans for whatever plans that we have.

**Nitin Agarwal:** Secondly, Vinita on the US business, clearly our focus going forward is on the value added and high margin products. So, how does the strategy sort of reconcile with the opportunities that high volume, low value opportunities that the market will keep throwing up now with the trend towards some of the larger guys sort of walking out of below value products?

**Vinita Gupta:** We try to really build flexibility, agility around products that we already have a position in. Of course, we do backfill products if we see a real large shortage in the market and we see a real opportunity in the market, but for the most part the ability to take on additional volume would be in products that we have already established a position in. Otherwise investments are only driven around products that we believe in for the future. It is fair also to say that our portfolio is still well-diversified while we have a good number of these complex generics, different platforms, but there is an elation to complex injectables and the like, but we also have a good number of oral solids. We see a good opportunity in oral solids in the next five years and intend to leverage the opportunity and have already got a number of filings and plan to over the next few years.

**Moderator:** Thank you. The next question is from the line of Krishnan Dusaha from Quantum Mutual Fund. Please go ahead.

**Krishnan Dusaha**: Just a couple of understanding, suppose in Japan, the price cuts, do we get commensurate increase in volume like 69% penetration in generic volumes in Japan, so do we see an increase in volume for us and is Japan very profitable compared to US and India?

**Nilesh Gupta:** We do see a volume increase, but it is not commensurate and net-net on value terms it is a very marginal increase in the top line. In terms of profitability, Japan is at the lower end of the spectrum, so the markets like the US or India would be significantly higher than Japan.

**Krishnan Dusaha**: On your question on the US, if I remember correctly, I might be wrong also, we had sort of given guidance of US$ 850 million for the full year run rate for FY19, do we think that we will be able to get close to that?

**Vinita Gupta:** We have given a guidance of US$ 800 - 850 million and since we expect Levothyroxine to be more Q4 than Q3, we should be closer to that US$ 800 million level is what we mentioned.

**Krishnan Dusaha**: On Fortamet and Glumetza, there are supply issues. So, has the supply issue only kicked in this quarter or latter part of this quarter?

**Alok Sonig:** I would say, supply issues for the competitors actually crept in somewhere in the middle of the quarter

**Krishnan Dusaha**: This US$ 12 million which we spend every quarter, we expect that to see next year also right?

**Vinita Gupta:** That is right.

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

**Shyam Srinivasan:** Just a couple of data checks. What is the absolute revenue in the branded business in the US this quarter?

**Ramesh Swaminathan:** It is about US$ 8 million.

**Shyam Srinivasan:** I think you also said US$ 3 million is Solosec in that, just clarifying?

**Ramesh Swaminathan:** Yes.

**Shyam Srinivasan:** Second question is on the tax side, I think Ramesh talked about it. I know this quarter had whatever the losses bumping it up, but how should we look at the full year?

**Ramesh Swaminathan:** If we look at our standalone, it is about 26-27%, but if we look at the consolidated because of the impact of winding down of the previously established DTA and the losses in America; because of all of these, I would think it is between 32% - 35%.

**Nilesh Gupta:** I think it is going to be more like 35% full year.

**Shyam Srinivasan:** Last question on the specialty, I think we got a positive CHMP on Namuscla (for myotonia), can you just walk us through what do you think the market sizes and when do you think this can be kind of reach commercialization?

**Vinita Gupta:** We should get approved this quarter based on the positive CHMP opinion and expect to launch in Q4. We plan to launch in the two markets that we have a direct presence - UK and Germany ourselves, and the rest of the countries we are talking to partners that can potentially distribute the product for us. I mean it's an orphan disease, so it is a small number of patients, but as we look at the market potential over the years, once we get to the entire market, we think it is a US$ 100 million plus opportunity, that is going to be billed.

**Shyam Srinivasan:** This is just Europe you are talking about?

**Vinita Gupta:** This is Europe.

**Shyam Srinivasan:** Lastly on Etanercept, have you shared what the profit share with Mylan is?

**Vinita Gupta:** No, we have not shared the deal term.

**Ramesh Swaminathan:** But it is important to clarify that no part of that revenue milestones, etc., came in this particular quarter, because as you would recognize this is an IFRS issue and it is to be spread over the agreement period.

**Moderator:** Thank you. The next question is from the line of Chirag Talati from Kotak Securities. Please go ahead.

**Chirag Talati:** Sorry to labor on this point again, but US$ 12 million quarterly run rate for spend for Solosec, what was the quarterly spend last year for the Methergine and the other franchise?

**Nilesh Gupta:** We will have to take this offline, we need to put it together and share it.

**Chirag Talati**: Secondly, the Myotonia drug I would have assumed that it is 7,500 patients. I mean given this is pretty much a 30-year-old drug given the pricing that you would get, it should be $15 to 20 million drug, is there a disconnect with what I am talking about?

**Vinita Gupta:** It depends on what kind of pricing you assume for an orphan drug.

**Chirag Talati**: But then it is a 30-year-old product, there should be off-label?

**Vinita Gupta:** Yes, we did new studies on the product to get it through the CHMP and EMA obviously and have plans to really bring this drug to the market make it accessible, at a reasonable price at the same time so that it makes sense for us to really put promotion effort behind it.

**Chirag Talati**: In the current pricing environment, do you think that the kind of pricing that is employed really works?

**Vinita Gupta:** We have looked at the pricing for orphan drugs and believe that we have pretty reasonable plans from a pricing perspective.

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

**Rahul Sharma:** Just wanted to know how much is the branded business overall for the quarter vis-à-vis last year and Q1?

**Ramesh Swaminathan:** Last year it was about US$ 20 million, but this quarter it is about US$ 8 million.

**Rahul Sharma:** Out of that US$ 3 million is Solosec?

**Ramesh Swaminathan:** That is right.

**Rahul Sharma:** The entire erosion has come in Methergine?

**Nilesh Gupta:** Yes, Methergine and Suprax.

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

**Surajit Pal**: Could you tell me what is the total number of headcounts in your US sales team currently and what is the prospect of growing overall?

**Vinita Gupta:** Sales team is around 166 people on the brand side of the business.

**Surajit Pal**: Any addition in next one year?

**Vinita Gupta:** No, right now, we think we are well sized for Solosec which is the primary product.

**Moderator:** We have a follow-up question from the line of Prakash Agarwal from Axis Capital. Please go ahead.

**Prakash Agarwal:** Just a clarification on that Solosec spend that we are talking about in Q1 and Q2. Would it be fair to say that it is a recurring expense for couple of more quarters and then it comes down or how should we think about this?

**Vinita Gupta:** I think we should look at it as a spend that we are going to have going forward, Prakash, because we expect to invest in the product, the commercial infrastructure is very much going to stay, the marketing plans at least in the next couple of years will continue, we also have started working on life cycle management of the product and to other indications which we think can expand the use of the drug. So, we would expect this to continue, and the point of really calling out spend was really to give an idea, that we are bearing spends and still have that 20% EBITDA, that was the point.

**Ramesh Swaminathan:** Just to highlight that, we do not have any revenues against it, so obviously at this point loss.

**Prakash Agarwal:** Any expectations for a couple of years that we are sharing, what is the target that we are looking at for Solosec?

**Vinita Gupta:** We do not give out guidance for the product and there has been share expectation that market has had of 15% - 20% of the BV market. We continue to be confident of getting to that kind of share.

**Prakash Agarwal:** Secondly, on the EBITDA margin guidance, Nilesh mentioned even without other income, you could get to that 18% to 20% for the next couple of quarters is what mentioned, I missed that actually?

**Nilesh Gupta:** That is what I mentioned, especially for Q4 for sure as we see it, but we also see the uptick in Q3, we might be off by 1% here or there, but certainly we see the Q4 numbers picking up nicely in the US and for the rest of the business as well. So you will see it in that irrespective of the any additional forex income as such, Q3 also probably in all likelihood we see. In any case we are already seeing some forex gains at this point of time for Q3.

**Prakash Agarwal:** Lastly on Gavis, I think the US market has seen a structural change and you already took one round of haircut. Just trying to understand, would it be possible like you would evaluate again given the headwinds are here to stay for a second round, is that in your mind, may be this year or next year?

**Ramesh Swaminathan:** The fact of the matter is we have already integrated Gavis operations to our main business in America. So, calling it out separately, I think is not fair to us at all. The second part, even on the previous occasion I did come across and tell you that there are a lot of up sides that have not been covered when we took that impairment. So overall, I do not think there is a further impairment call for at this stage.

**Moderator:** We take the last question from the line of Srikant Krishnaprasad from Franklin Templeton. Please go ahead.

**Srikant Krishnaprasad**: Have you mentioned what is the forex gain as part of the other income in the current quarter?

**Ramesh Swaminathan:** Overall, the figure is about INR.200 odd crores spread across several lines.

**Nilesh Gupta:** A good part of that was in the other income.

**Srikant Krishnaprasad**: Can you also explain why do you have such large forex gain say over the last two quarters, is there anything specific that leads to this number?

**Ramesh Swaminathan:** The fact of the matter is realization, US$ 1 gets realized at 63, then at 70 and 75, so obviously that part of the gains. We also realize fair gains coming in from the hedging policies that we have got and lastly the very fact that our accounts receivable, all of those will get revalued, we need to take those gains as well.

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

**Dr. Kamal Sharma:** Thank you very much, friends for your questions. I hope you had good answers to your questions and look forward to seeing you again next quarter. Thank you and bye for now.

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