"Lupin Ltd Q1 FY19 Results Conference Call"

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Moderator: Ladies and gentlemen, good day and welcome to the Lupin Limited Q1 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 the Lupin management. Thank you and over to you, sir.

Dr. Kamal Sharma: Hello, good afternoon, friends. This is Kamal Sharma. I have with me the entire top management team; I have Vinita Gupta, Nilesh Gupta, Ramesh Swaminathan, Rajeev Sibal, Naresh Gupta, Sunil Makharia, Rajiv Pillai and Arvind Bothra – Head of Investor Relations.

You already have seen the results for the quarter. I think it is a very unhappy situation for us, we are not happy at all with the results, but the real-life situation is such. While we had been contemplating that things are not going well with the generic business in US, there have been some surprises which were beyond us.

Aside from that, Japan has not turned out well because the volumes have gone up but the biennial pricing cuts has depressed value performance in that place. Having said that, there has been good performance in India across both formulations and API. Germany has done well. South Africa has done very well but obviously the salience which the US and Japan have in our overall business tells on the results as you would have seen.

Going forward, it looks like the situation is going to be similar for a few more quarters. We have some green shoots in the second half of this year but see much better performance from the second half of next year. This is what we see today and hopefully some of the other efficiency improvement measures will also add to value creation.

With that, I will hand it over to our CFO, Mr. Swaminathan, to take you through the details. Thank you

Ramesh Swaminathan: Thank you, Dr. Sharma. Friends, whilst we are disappointed with the results, we do believe that better days are ahead of us at least in the second quarter. I have spoken to a lot of investors since yesterday afternoon and the questions hovered around our run rate in the US and our overall margins itself.

I just want to clarify that at the outset, when it comes to the US, there has been a decline in our overall turnover and some people did comment about the fact that it was less than US$200 million for the first time in the last couple of years. This is for three reasons: Firstly, the overall Metformin franchise itself has eroded a bit. Secondly, the flu season is over and accordingly Tamiflu and other anti-infective sales were lower. Finally, Methergine went generic, for which we enjoyed brand status for some time. But having said all that, we do believe that the second quarter to come would certainly be much better.

The second half would be much better because the launches that we are bringing to the market include Levothyroxine, Ranexa, and we do believe that Solosec would certainly ramp up. So, for these reasons I think, as Dr. Sharma was saying that there are green shoots in the offering.

In terms of the EBITDA margins, you must be aware of the fact that we are working with top consultants to actually ramp it up over time. We are working on several initiatives and we do believe our business will certainly improve over the next several quarters.

With that, I would like to open the floor for discussions.

Moderator: Sure. Thank you very much. We will now begin the question-and-answer session. We will take the first question from the line of Saion Mukherjee from Nomura Securities. Please go ahead.

Saion Mukherjee: Sir, regarding the QoQ fall in the US, you mentioned about three – four products which have come down. But what is the largest contributor to this fall this quarter?

Vinita Gupta: Saion, the largest contributor was really Tamiflu. We had an opportunity in the previous quarter to get some upside on Tamiflu because we got approval just in the nick of time before the flu season closed. Additionally there was a shortage in the marketplace. We leveraged that on one-time good price buy, and the business had picked up significantly between Q3 and Q4 last year. So, the biggest part of it is really Tamiflu, followed by the Metformin volume decline that we have seen in the last two quarters after Metformin lost its preferred formulary status on PBMs. The third, as Ramesh mentioned was Methergine going generic. So, we had the confluence of both in the generic side of the business as well as the brand side of the business - the impact of the decline in the Metformin franchise in terms of the market volume, few products drop off and Methergine going generic.

Saion Mukherjee: Now since the competitive pressure on Methergine and Metformin are likely to continue, this base will therefore go down further before we get the impact of new launches, is that a right statement to make?

Vinita Gupta: I would expect it to be at a very similar level in Q2 actually. While the volumes of Metformin products have come down quite a bit, we expect marginal decline going forward. With the products that we have in our portfolio now, for example, we did not have any revenue on Tamiflu in Q1 but we expect the product to ramp up particularly in Q3, Q4. Among other product approvals, Axiron got approved in this quarter but we were able to get commitment only at the end of the quarter, so we expect that to contribute in Q2. We expect Q2 to be at a similar level with further pick up in Q3 and Q4.

Saion Mukherjee: Vinita, would you like to give any guidance for the US business this year given all the volatility we are seeing currently?

Vinita Gupta: As we have shared even at the investor meet in the last quarter, our endeavor is to try to really maintain it as closely as possible at the last year's level, but we see challenges in achieving it.

Saion Mukherjee: Any specific decline numbers that you would like to highlight?

Ramesh Swaminathan: I think it is going to be around US$ 800-850 million mark at this stage, Saion.

Moderator: Thank you. We will take the next question from the line of Neha M from JP Morgan. Please go ahead.

Neha M: Ma'am, if you could throw some color on the Solosec launch and how we expect that to ramp up?

Vinita Gupta: Yes, Neha, it has been an excellent launch, very-very encouraging response from the marketplace. We have data now for the last six weeks and week after week the scrips have ramped up nicely, ahead of our expectations in fact. While it is still early days, but we have had a very promising start to the product. We have also seen very little resistance or reluctance on the part of physicians and the practitioners to write the product, so the introduction to the product has been very strong and the formulary coverage that our team has been able to get us, has also been very promising. When we launched the product, we had 50% coverage on commercial plants, at this point it is at 68% and our target is to be at (+80%) by the end of this year. So, I would say that given the momentum right now, we believe that we should be able to exceed our internal expectations of the product, but again early days.

Neha M: What could be the peak sales ramp-up that we can expect from this product? You did mention that this could be larger than Methergine, but what is the peak sale that Solosec could see?

Vinita Gupta: I think we have said that it has the potential of taking 25% of the market in peak sales in a couple of years. If you look at the market from the perspective of our net price for Solosec which is around US$170, it is over a billion dollar market overall. So, there is significant potential, we are trying to get there as soon as we can, but making sure that we build it in the right way into the market.

Neha M: Second related to Solosec. Is some amount of expense related to Solosec in the quarter or should we expect a large part of it to start flowing through from the second quarter?

Vinita Gupta: No, we have a good part of the expense already in the quarter. We had a lot of marketing expenses in these past two quarters and then the sales force expense ramped up within Q1. We will now have the marketing expense fall a little bit because a lot of it was front loaded before launch. The field force expense, however will continue quarter-after-quarter.

Neha M: Given that this quarter had a large part of the Solosec expense, we have seen a good improvement quarter-on-quarter or even if I compare the last two quarters in terms of maintaining other expenses, is it fair to assume that in the cost saving initiatives that we were talking about, etc., is reflected to some extent or there is more scope for improvement in the expense run rate?

Ramesh Swaminathan: When it comes to cost, there has been some impact with procurement of inputs from China going up but that has been marginal. When it comes to the initiatives that we spoke about, these are ongoing but it would be some time before the fruits really are visible, likely in the third or fourth quarter and thereafter.

Moderator: Thank you. We will take the next question from the line of Anubhav Agarwal from Credit Suisse. Please go ahead.

Anubhav Agarwal: Vinita, what was the brand sales this quarter?

Vinita Gupta: US$12 million, with Methergine gone generic, it came down to roughly half of previous quarterly run rate.

Anubhav Agarwal: Yesterday Apotex got approval under FDA's new CGT initiative. Just wanted to check for us, do we have any of our pipeline products among the almost 30+ products FDA has in the CGT right now, do any of our products qualify under that?

Vinita Gupta: Yes, we have a few products that we expect could qualify for the same. The big question is going to be if there is anyone ahead of us in the race, but there are a number of products where we have priority right now.

Anubhav Agarwal: So, among those 33 ANDAs that FDA has classified under this initiative, you have some of them right now or in future you can have?

Vinita Gupta: We have some of them right now, which we have filed.

Moderator: Thank you. We will take the next question from the line of Rakesh Jhunjhunwala from Rare Enterprises. Please go ahead.

Rakesh Jhunjhunwala: What is the non-recurring Solosec expense of this quarter?

Ramesh Swaminathan: It is about Rs.10-12 crores.

Rakesh Jhunjhunwala: How is the pricing pressure in America now?

Vinita Gupta: Rakesh-ji, pricing pressure on the base line products has come down to a high single digit as we have witnessed. It is the newer products where you have material additional entrant or exclusivity launch where one sees a higher pricing erosion, but otherwise it is high single digit.

Rakesh Jhunjhunwala: What happened to Advair and all those respiratory products?

Vinita Gupta: Advair is still in the development, Rakesh-ji. We have made significant progress on Spiriva which was the second DPI that we were pursuing. Post our filing, we have also got the confirmation that we are first-to-file on that product. So, we are pursuing that one with the FDA right now. On ProAir, we have questions that the FDA has raised that we believe we can respond effectively. We are in the process of responding to them and we believe we will be on track to launch the product next fiscal year as planned. So, among the two products that we have already filed, ProAir should come to market next year. We have seven other products in various stages of development.

Rakesh Jhunjhunwala: So, will you be able to launch Advair next year?

Vinita Gupta: Not Advair, ProAir.

Rakesh Jhunjhunwala: How big is that a product?

Vinita Gupta: It is a US$3 billion market for Albuterol.

Rakesh Jhunjhunwala: Lot of competition?

Vinita Gupta: There are a few competitors.

Moderator: Thank you. We will take the next question from the line of Anik Mitra from SMIFS. Please go ahead.

Anik Mitra: Ma'am, my question is regarding Enbrel. I just wanted to know the revenue for Enbrel in Japan and what is the status of launch of Enbrel in Europe?

Vinita Gupta: As you know, we have partnered with Nichi-Iko in Japan and Mylan for Europe and certain other markets. We expect both our partners to potentially launch in the next fiscal year. We expect Nichi-Iko to perhaps launch in the first quarter and Mylan in the second or third quarter. So, we expect at least half year of our revenues next fiscal year both in Japan as well as Europe.

Anik Mitra: What is the profit margin in your domestic business as well as the international?

Ramesh Swaminathan: We do not share that figure. But in a general sense, we would say that the margin in India is slightly above the corporate average, while the highest contributing region historically has been the US.

Anik Mitra: What is the tentative date of approval for Neulasta and Lucentis?

Nilesh Gupta: We have not filed either of them at this point of time. We are hoping to file Neulasta in FY20 and hopefully we should get approval in late FY21. On Lucentis, we are still reviewing what to do with the product.

Moderator: Thank you. We will take the next question from the line of P Rangamai, who is an individual investor. Please go ahead.

P Rangamai: I think the EBITDA margin for Q1 is about 13% and I believe the management has guided for 18-20% for FY19. So, how is this going to come from?

Ramesh Swaminathan: From our perspective, we consider other income as part of EBITDA margin. Knocking that off is not fair, because a chunk of it is essentially coming in from forex which is part of the business itself. The other part is settlement income and other IP-related stuff which is again a part of the pharmaceuticals business. So, knocking it off from EBITDA margin is not a fair at all from our perspective.

Moderator: Thank you. We will take the next question from the line of Chirag Dagli from HDFC Asset Management. Please go ahead.

Chirag Dagli: Sir, what volume share does Q1 reflect for Methergine?

Vinita Gupta: Roughly about 50%.

Chirag Dagli: The US$225 million Gavis write-off that we have done last year, was this largely for the dermatology pipeline or for the controlled substances pipeline?

Ramesh Swaminathan: It was for a host of products; it was for the entire pipeline that we have bought.

Vinita Gupta: We undertook a realistic assessment and based on the current potential, we decided to take a one-time write-off.

Chirag Dagli: It is not more towards dermatology or controlled substances either?

Ramesh Swaminathan: No.

Moderator: Thank you. We will take the next question from the line of Surya Patra from PhillipCapital. Please go ahead.

Surya Patra: Can you repeat, what was the brand revenue in 1Q?

Ramesh Swaminathan: US$12 million.

Surya Patra: On the US business front, it looks like there will be a sequential decline this year, so that means we will witness two years of decline. Though we have already indicated about few products which will be driving sales, what is the general outlook we are having for the US business this year and next year?

Vinita Gupta: As I mentioned, while the first half of the year is challenging, we expect to see a pick up in the second half due to both the flu products like Tamiflu and other flu products that we have in our portfolio coupled with new product launches like Ranexa, Levothyroxine. Additionally, on the brand side - Solosec pick up should have a material impact at least in the second half of this fiscal. In terms of the outlook for the next year, we expect Solosec to ramp up favorably this year, so that would be a significant contributor next year on the brand side of the business. On the generic side of the business, we would continue to see upside from Ranexa at least for the initial part of the year and then later half of the year we should see upside from the complex generic business - primarily from ProAir in the US as well as Etanercept in ex-US markets

Surya Patra: Is it possible to share what is the commercial agreement for Etanercept and how influential this revenue could be next year, any sense?

Vinita Gupta: We have very good terms given that we invested in developing the product all the way through clinical trials. Obviously, we took majority of the risk and therefore the commercial terms reflect that. We have a good percentage of the upside. In terms of revenue contribution, we have half year or maybe three-fourth of the next fiscal year for Japan and half fiscal year for Europe. But for FY21 we expect the product to be a significant contributor to the company.

Surya Patra: Just one last question on the overall margins. Out of the three markets that we have - US, Japan and domestic Indian formulations market, US and Japan are seeing a sequential decline for some time, what margin levers do you have for the subsequent periods?

Ramesh Swaminathan: The margin itself is a function of three things, the kind of products that we bring to the market and the resultant realizations, the second is the R&D spend and third is on the cost front and the kind of initiatives we take on that. On the realization front, we have got quite a few good products lined up for approval, this particular year we will get at least a couple of products, but next year onwards for example, we are looking at ProAir and then Spiriva, a host of complex injectables coming up and there is Solosec which is obviously going to be a good contributor to the margins. When it comes to the R&D spends, we have been trying to keep it as low as possible and this particular quarter you would appreciate that it is just about 10% of sales. This is a function of two things: we are increasing the productivity of the people associated with R&D and the second part is that we are also tied up with the financial investors who take away the risk from us whilst we share in the upside when we get to launch the product itself and that lowers the overall R&D spends in our books. When it comes to the cost initiatives, it is something that has been going on for quite some time. We have implemented it in a number of ways - there have been initiatives on the procurement front, there have been initiatives on labor rationalization using MOST

techniques and the like, pursuing excellence on the operational front and so on. All of these have contributed in the past and will continue to do so. There is also a fresh leash of initiatives that we will be bringing in due course with the help of top tier consultants and all of this will also bear fruit. So, we do believe that there is scope for improvement on that front and this is a continuous endeavor.

Surya Patra: Sir, what is the higher amount that is there in the other income this quarter?

Ramesh Swaminathan: So, there are two parts to that: First, which is relating to FOREX, the other is settlement income and both we believe are parts of the overall business itself.

Surya Patra: Can you please quantify FOREX gain at least?

Ramesh Swaminathan: It is around Rs.152 crores in this particular quarter.

Moderator: Thank you. We will take the next question from the line of Ashi Anand from Allegro. Please go ahead.

Ashi Anand: The first question was on Etanercept. You indicated launch in the second half of FY19. Mylan yesterday on their webcast kind of guided for approval in the second half of CY18. Just trying to understand any reason why the launch would not happen earlier?

Vinita Gupta: We filed the product in Europe only in April of this year. So, we expect the approval to take at least one year. We will be happy to see the product in the market in the current calendar year, but it probably will be only in the markets that do not require longer lead time. Major markets will really open next fiscal year.

Ashi Anand: Secondly on Spiriva. Just trying to understand your outlook on potential litigation and outlook on when we could potentially launch this product?

Vinita Gupta: We have it latest for FY22 launch right now, but we are taking a look at our patent position to see if we can accelerate it.

Ashi Anand: There have been questions around the margins. So, I am just trying to understand is it possible to give some kind of an outlook on what margins could look like in the second half, once we actually get the benefit of Levothyroxine and Ranexa in our numbers?

Ramesh Swaminathan: For the full year we are still looking at a range in between 18% and 20% on EBITDA margin.

Ashi Anand: In FY20 could we see a boost on that or is 18-20% EBITDA including other income kind of the new normal we should look at?

Ramesh Swaminathan: Next year we do have ProAir coming in for us and that would certainly contribute significantly. The other part is essentially the newer initiatives that we are speaking about, some of those we are carrying it through fruition. So, to the extent there would be benefit of that coming through next year as well

Nilesh Gupta: Especially in the second half.

Ashi Anand: Just wanted your outlook on the competitive scenario in Ranexa and Levothyroxine as we go into FY20 and as Ranexa gets out of the exclusivity?

Vinita Gupta: After the exclusivity period, we expect a few other competitors at least based on the competitive landscape we see right now. On Levothyroxine as well we would expect a couple of additional competitors by FY20. So, I would think that there will be six, seven players in the market for Levothyroxine.

Moderator: Thank you. The next question is from Sameer Baisiwala from Morgan Stanley. Please go ahead.

Sameer Baisiwala: Vinita, did I hear you correctly, you mentioned net price on Solosec is US$170?

Vinita Gupta: That is right.

Sameer Baisiwala: I think the WAC price or list price is about US$270?

Vinita Gupta: That is right. The net price is after all of our rebates to managed care as well as other factors.

Sameer Baisiwala: But is it not out of ordinary to have a branded product at such a steep rebating?

Vinita Gupta: No, especially in the launch time period when you are trying to build access to the product. We have a good level of couponing as well that is built into that number. So, it is a combination of rebating as well as coupons.

Sameer Baisiwala: Given that Vinita you are almost close to 70% formulary listing, what are the key milestones or key challenges that will take you up to 25% market share?

Vinita Gupta: So, the biggest one that we expected even pre-launch was pricing and that is why we spent a lot of time trying to determine what the WAC price as well as the discounts and coupon strategy ought to be. We are seeing good level of uptick right now. We have not seen any disconnect so far. So, at this point it is all about execution and our managed care team has really put us in a very strong position from access perspective and we will continue to build on that. It is really how much of share we can switch from Flagyl at this point, which we have started on a very strong note.

Sameer Baisiwala: So, now it is all about moving to doctors' chamber and getting more and more prescription filled, is that where it moves to?

Vinita Gupta: Yes.

Sameer Baisiwala: The IMS is reflecting about 700 to 800 prescriptions a week now. How do you see this trend up by the end of this year and next year?

Vinita Gupta: Yes, we expect it to go up week-after-week over the next couple of quarters. We hope to end up this fiscal year with an exit market share of between 4% - 5%

Sameer Baisiwala: The second question is on ProAir. You said FDA has given you some query. So, is this a CRL or is this a post TAD which was expected sometime now?

Vinita Gupta: No, it is a CRL.

Sameer Baisiwala: Is it a major one or a minor one?

Vinita Gupta: No, we are in the process of getting a response together and expect to file our response in the next month.

Sameer Baisiwala: On Levothyroxine, I remember the TAD was somewhere around this time. Have we passed that?

Nilesh Gupta: I think they moved it out by a couple of months.

Sameer Baisiwala: On Enbrel, Nilesh, my understanding is that a couple of things have to happen for you to get into European market - one is CHMP approval and the other is site inspection which I presume should be a Pune facility. So, can you just share some thoughts on that?

Nilesh Gupta: That is correct, because it is a clinical trial they will probably inspect some of the clinical sites in the light as well, some of which are actually beginning already. So, two of the big milestones that we need to hit before we bring the product to market are inspection of our Pune facility as well as the approval itself.

Sameer Baisiwala: When do you expect EMA to visit Pune and has that facility ever been inspected by any regulated market regulator?

Nilesh Gupta: We would expect Japanese authorities to come in sooner and then we would probably expect European authorities to come in. But a regulated market regulator has not come in so far. We have had a bunch of others and they were very successful. So, obviously we are preparing for these audits, we have regulatory expertise from both Japan and Europe helping us in this process as well. It is a small, but a very good facility. So, we are very hopeful that things should be good.

Vinita Gupta: We also had the advantage of number of our partners and potential partners that looked at the product and the facility, which really helped give us the confidence that we are in a very good position.

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

Prakash Agarwal: First question on the facility clearance, what is our thought and where are we at, especially once we have cleared the European inspections for both Indore and Goa?

Nilesh Gupta: As you know, we got the warning letter in November and then we submitted monthly updates to the FDA thereafter. In July, we submitted the last update to the FDA. We have taken care of all the specific observations that FDA had to address in the warning letter. Parallel to that we also developed an overall enhancement plan which we have shared with the FDA as well, that really is the multi-year plan in any case. Next step now is to connect with the FDA, likely meet with them, share with them what we have done to-date and following that would be a re-inspection. Earlier, we had talked about resolution by the end of the year, so we should hopefully be able to clear both facilities before the end of the fiscal.

Prakash Agarwal: Secondly, if you could give some color on the outlook of gross margins?

Ramesh Swaminathan: For the next few quarters, it is going to be kind of this rate only Prakash, it will hover around the 60% to 62% mark and go up in the second half of this fiscal.

Prakash Agarwal: Sir, on the FOREX, you said, it is an integral part. So, we saw very big jump in FOREX this quarter. How do we foresee this given rupee-dollar remaining constant here for the next couple of quarters?

Ramesh Swaminathan: Next quarter you might not have the upside that you have seen in this quarter, but we will have newer products coming in towards the second half of the fiscal

Nilesh Gupta: And it will translate into the revenues itself, so obviously we have been booking revenue at lower rate till this point of time, so that will translate into some business gains

Prakash Agarwal: On Enbrel, just trying to understand the milestone payment that we received US$15 million, I understand it has not been recognized. First question is what is the market opportunity that we are looking given the milestone is relatively smaller at US$15 million?

Vinita Gupta: The upfront milestone with Mylan was US$15 million, Nichi-Iko was about US$6 million and we have other milestones as well for regulatory approvals and launch. So, the additional milestone add up to a pretty good size number, but our focus was really to try to get a good percentage of the upside. We expect long-term revenues from our product and that is how we decided to go after this kind of deal structure.

Prakash Agarwal: Do we model in 50:50 or your share would be higher?

Vinita Gupta: I think 50:50 is a good assumption.

Prakash Agarwal: On Levothyroxine, is the approval subject to facility clearance or we have a de-risked facility on this?

Nilesh Gupta: We have a de-risked facility on this, so it is not subject to the Indore facility clearance.

Moderator: We move to the next question. The next question is from Manoj Agarwal from BMI. Please go ahead.

Manoj Agarwal: Ma'am, you mentioned about gSpiriva that you are the first to file company. So, has FDA given any TAD or when do you think you can get approval and launch the product?

Vinita Gupta: As I mentioned, at present we think it is FY22, but we have just started the litigation process, so we will see if we can accelerate it.

Manoj Agarwal: Has the FDA mentioned any TAD?

Vinita Gupta: I do not recall the date, but right now litigation itself is longer than TAD.

Nilesh Gupta: So, we have a TAD, but we are not in a position to disclose right now.

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

Nitin Agarwal: Vinita, on Solosec, what is the competitive situation from your perspective on the product over the next couple of years?

Vinita Gupta: There are couple of smaller products that have got the promotional effort recently like Nuvessa that Exeltis bought from Allergen, and there are a couple of products in development, but nothing that really has the kind of dosage profile that Solosec does. So, from a competitive standpoint, we were pretty confident even through diligence that there is nothing else that comes close to the profile of Solosec.

Nitin Agarwal: In terms of the brand USP versus the current alternatives including generics which are there, what are the milestones to watch out for which can give us the market shares that we are aspiring/aiming for?

Vinita Gupta: It is really consistent ramp up of share, the new physicians that our team is able to convert to Solosec. So those are the milestones that we are tracking on a weekly and monthly basis.

Nitin Agarwal: You believe over the next two years we should be able to hit the 25% sort of market share levels?

Vinita Gupta: 20 to 25% is really the peak share that we have planned for and we should see it in three to four years.

Nitin Agarwal: On the R&D spends, we have done a fair job of calibrating R&D spends and that is probably a challenge that the whole industry is probably facing at this point of time with the challenges on the top line growth. But from your perspective how much of a hindrance does this create at the time when you guys need to really ramp up spends on specialty?

Vinita Gupta: Yes, we have rationalized a lot of the R&D spends on the generic front with all of the changes in the generic industry and competitive landscape. We determined that it does not make sense to really pursue new products if you are going to see six, seven, eight players going forward. So we rationalized spend on the generic front in favor of products that have limited competition like inhalation products, complex injectables and others. So, this really helped us to start creating room for specialty R&D spends and we started building a pipeline. On the Specialty front, we are right now looking at other opportunities to add to our portfolio and our focus still is on late stage products that have gone through phase-3 trials. There are some other interesting opportunities that we are also looking at right now that need to complete phase-3 studies. So, we certainly will not overlook opportunities that can really build our specialty business.

Moderator: Thank you. The next question is from Damayanti Kerai from HSBC Securities. Please go ahead.

Damayanti Kerai: Coming back to FDA remediation. Are we done with most of the cost involved there or something more can come in the next few quarters?

Nilesh Gupta: The consultant fee and the like, for the most part is done. Some of it would come in to July as well, but with that we are done. There are certain investments we are making for the future, but that is much lesser than what we have incurred in the past.

Damayanti Kerai: So, majority of cost has already been incurred, and quantum should be lesser going ahead?

Nilesh Gupta: Correct.

Damayanti Kerai: Another question on Japan, like how should we look at that market and are we profitable in Japan?

Nilesh Gupta: Japan is going through quite a transition at this point of time, especially with the price cut and the room for future price cuts as well, the world has to start looking at Japan as more of a substitution oriented market. You have to question, why you need a sales force, you need to see how you can bring R&D cost down, manufacturing cost down, etc. So this is valid for us, but also for the rest of the industry. These are the same challenges that people are seeing right now in Japan. For our part, obviously, the move was how much more research we can do in India, how much more manufacturing we can do in India, what do we do with the sales force, and also

the move to specialty. So, we started with long listed, but even long listed products are not protected anymore. We have Bipresso on the Specialty side, but the intention would be to do more of complex generics and specialty in Japan as well. So, while Japan makes money, it is going through quite a bit of transition. We will have to go through the pains of Japan for the next two years as it emerges into a more substitution-oriented market.

Damayanti Kerai: How much manufacturing we do in India for Japan market right now or is it entirely done there?

Nilesh Gupta: We do a significant part in Japan. We have three facilities in Japan to manufacture, and about 10% of what we sell is manufactured in India.

Moderator: Thank you. The next question is from Abhishek Sharma from IIFL. Please go ahead.

Abhishek Sharma: I was just going through my 1Q FY18 notes which is one year back and at that point in time you were talking about Levothyroxine launch by the end of 2017 and from there the timeline has shifted by about 9 to 12 months. Broadly wanted to understand what has led to this delay?

Nilesh Gupta: It is only the TAD moved out from FDA's perspective.

Abhishek Sharma: So, we have been ready all this while, but FDA has sort of delayed acting on the file?

Nilesh Gupta: Readiness has no meaning right, in the sense that if FDA moves out the date, then they move out their entire review process as well, whatever questions that they are asking to us as well, so you really do not have control on that process. Parallel to that we were also ramping up facilities for that, we have actually been able to complete that ramp up. So, I think if we had got approval three or four months ago, we would have had a challenge to be able to cater to the volumes, but now we have the whole capacity to be able to take care of it also.

Abhishek Sharma: So as TAD has continued to shift from FDA side, have they continued to raise fresh queries on the file?

Nilesh Gupta: The TAD can move irrespective of being asked questions. We do not have any questions pending on Levothyroxine at this point.

Abhishek Sharma: The other question was around capital deployment. I understand that you have several long-ended R&D initiatives going on for the US market. But just from an incremental capital deployment perspective, what would be your preference in terms of geography, what would be the hierarchy, is it the US, is it India, is it opportunistic, just some color there?

Ramesh Swaminathan: So, money should grow where the yield is the highest and as you all recognize the US is the highest paying market, but for sure India is also equally important and so essentially if the proposition is compelling enough, we would deploy money in India also.

Abhishek Sharma: But the priority remains US?

Ramesh Swaminathan: Specialty in the US certainly is going to be the priority.

Moderator: Thank you. The next question is from Arpit Kapoor from IDFC Mutual Fund. Please go ahead.

Arpit Kapoor: I just wanted to understand how the ramp up would be for Levothyroxine once we get an approval. So is it going to be like a normal generic where we get target market share or is it going to be slightly slower ramp up?

Nilesh Gupta: It is going to be a slower ramp up because there are multiple RLDs that you need to be approved against as you sell the product. Anybody who files cannot file against three different RLDs at the same time, so we have to file against one, get an approval for that, put supplements for follow on RLDs as well and then eventually be approved for the entire line, so I think the ramp up will be slower.

Arpit Kapoor: In that context, given the guidance that we are sticking to in terms of US with $800 million of revenue or thereabout and with Vinita suggesting in the call that the second quarter is also going to be somewhat flat on QoQ basis, so what kind of ramp up are we expecting in second half for us to get to an $800 million US sales for the full year?

Nilesh Gupta: The seasonality element will play out in Q3 and Q4 where you have products like Tamiflu coming back, you have the Cephalosporin business picking up more as well, even products like Azithromycin which we will sell more. Obviously Solosec is ramping up at this point. Levothyroxine hopefully and then obviously Ranexa will also drive sales. In order, Ranexa, Solosec and then probably Levothyroxine will be the growth drivers in the second half.

Arpit Kapoor: How much of our EBITDA guidance of 18% to 20% is contingent on the fact that we get $800 million sales for the full year?

Ramesh Swaminathan: It is dependent on that, right, so our confidence levels for getting that figure is fairly high and hence also for the margin guidance of 18% to 20%.

Moderator: The next question is from Shyam Srinivasan from Goldman Sachs. Please go ahead.

Shyam Srinivasan: Just a conceptual question on biosimilar Enbrel. So, when we look at it next year, how would you look at the market opportunity? It is very large clearly, but do you think given the chronic conditions will we be targeting new patients, any color generally on commercialization strategy will be useful?

Nilesh Gupta: It is a little premature to share some of the deeper commercialization strategies, but as far as Japan is concerned, as you know, there is one product that is already approved, we expect the next product coming into the market, so we will be one of two or three players in Japan. There

are already approvals in Europe so we will be one of three or four approvals in Europe, and in many ways the commercialization strategy would be similar to what people have already started in Europe or going to start in Japan.

Shyam Srinivasan: Which is to target new patients. Would that be the first target population?

Nilesh Gupta: I do not quite want to comment on that right now, but typically it starts with that.

Shyam Srinivasan: My second question is on the India business. So, we have like-for-like it is at 31%. How should we look at this business for FY19 and also the partnership with Boehringer, can you just shed some light on that?

Rajeev Sibal: India business, as we have mentioned earlier also that we will grow at 14% to 15% level for the year and we are pretty much there as far as that particular growth is concerned. Because of the GST impact in the first quarter of the last year, the growth is more, but going forward I think we will stabilize, but on yearly basis 14% to 15% growth is what we are looking for and we are pretty much sure that we are there as far as that growth is concerned. As far as partnership is concerned, I think we have done very good partnership as far as our oral antidiabetic drugs are concerned because diabetes therapy area is one of the most progressive therapy area in Indian pharmaceutical market and we get almost 20% of our India business from diabetes therapy area. So, in that sense it is a significant partnership further getting strengthened and we are very sure that since diabetes is very progressive, it will add to our overall growth as far as our India business growth is concerned. So, that gives us more confidence because our chronic presence is higher and chronic is the key driver of the market and that gives us more confidence that we will be at 14% to 15% growth as far as FY19 is concerned.

Shyam Srinivasan: Last question to Ramesh. Just on tax guidance is it still the 27% or 28%?

Ramesh Swaminathan: This quarter has been an aberration because of the fact that we had losses in a couple of subsidiaries and because of the DTA wind down which also happened. For the full year, I would imagine that the tax guidance to be about 30%.

Moderator: Thank you. The next question is from Nimish Mehta from Resource Delta Advisors. Please go ahead.

Nimish Mehta: Vinita, on Levothyroxine, are we likely to launch a branded product or a generic product?

Vinita Gupta: We are targeting a generic product.

Nimish Mehta: So, there are other generics also in the market and they still have not been able to gain any market share. Do you think that generic market share will increase which is what will help us also have a better penetration or how does it go?

Vinita Gupta: We are trying to ensure that we are substitutable to all of the three RLDs and that is why it has taken us longer to get this product to market. But once the FDA accepts that and approves us to be bioequivalent to all three RLDs, we would expect good level of switch.

Nimish Mehta: So, what is holding back the current generic companies in the market to gain market share?

Vinita Gupta: Not every company has got bioequivalent study against all three RLDs.

Nimish Mehta: I am sorry, you said no company has bioequivalent study against all the three RLDs?

Vinita Gupta: Not all the companies in the market have approval.

Nimish Mehta: But if I read well, you can correct me if I am wrong, none of the company who have launched generic version have any meaningful market share, and that would also include companies who have done bio studies against all the three RLDs?

Vinita Gupta: No, there are companies that have reasonable market share, maybe you are comparing with one particular RLD, but for example Mylan has a decent market share with the product.

Nimish Mehta: They have done bio studies against all the three RLDs?

Vinita Gupta: I believe so. We can maybe confirm that offline to you with more detail from our pipeline group.

Nimish Mehta: The other thing I just wanted to know is the impact of raw material price increase from China. What do you think is likely to be the impact to us in coming quarters?

Ramesh Swaminathan: It has been pretty marginal in the first quarter, but we do believe that for the full year it is certainly going to be a significant amount. We are also hearing of more environmental restrictions coming in from China. So, I would think in the days to come, there is going to be some significant impact because of that.

Nimish Mehta: So, what is our exposure as of now to Chinese raw material as a percentage of sales or as a percentage of total materials cost?

Nilesh Gupta: Typically we buy early starting materials, but we buy products like Pen-G from China, so there is definitely an impact, but the impact is certainly relatively nominal at this point and we have small impact in the coming quarters based on the total cost of goods.

Nimish Mehta: But if you can just let me know the exposure to Chinese raw material that would be helpful… some ballpark?

Ramesh Swaminathan: We will take this offline.

Moderator: Due to time constraints we will be able to take one last question. The last question is from the line of Vishal Manchanda from Nirmal Bang. Please go ahead.

Vishal Manchanda: On ProAir, just wanted to understand whether litigation is a hurdle to your launch or you could launch after 30 month exclusivity expires?

Vinita Gupta: No, we have already settled with the brand and the litigation will not be a hurdle.

Vishal Manchanda: It will be a full launch or there are restrictions like limited quantity as Teva has settled with other players?

Vinita Gupta: No, we cannot talk about the details on the settlement, but we expect to really be able to get a decent share.

Dr. Kamal K. Sharma: Okay friends, thank you very much for your questions. I hope you had all the answers and we look forward to meeting you again next quarter and share with you the performance status of the company. Thank you and bye for now.

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